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Implementation of the Food Safety Modernization Act among fruit and vegetable processors in the North Central Region

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Implementation of the Food Safety Modernization Act among fruit and vegetable processors in the North Central Region

by

Jacques Ludwig Alexander Overdiep III

A thesis submitted to the graduate faculty
in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE

Major: Food Science and Technology

Program of Study Committee:
Angela Shaw, Major Professor
J. Gordon Arbuckle
Shannon M. Coleman

The student author, whose presentation of the scholarship herein was approved by the program of study committee, is solely responsible for the content of this thesis. The Graduate College will ensure this thesis is globally accessible and will not permit alterations after a degree is conferred.

Iowa State University
Ames, Iowa
2018

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DEDICATION

This thesis is dedicated to all of those who have supported and pushed me to do more.

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NOMENCLATURE

CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
FDA	United States Food and Drug Administration
FMI	Food Marketing Institute
FSMA	Food Safety Modernization Act
HACCP	Hazard Analysis and Critical Control Points
ISO	International Organization for Standardization
NCR	North Central Region
US	United States of America
USDA	United States Department of Agriculture

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ABSTRACT

The Food Safety Modernization Act (FSMA) is a food safety law that changed the way food companies are regulated to prevent foodborne illnesses. The FSMA Preventive Controls for Human Food rule was released September 2016 for facilities in manufacturing, processing, packing, and holding of human food. The North Central Region (NCR) Center for FSMA Training, Extension and Technical Assistance was founded by the Food and Drug Administration to assist with the education of processors around the Midwest. The NCR Center funded a project with three phases designed to help small fruit and vegetable processors in the Midwest understand their relationship with FSMA. Phase one was an audit checklist, phase two was extension fact sheets, and phase three was a needs assessment survey for processors. A prior needs assessment disseminated to growers in the NCR identified checklists and fact sheets as preferred methods of receiving educational materials about FSMA. The results from the grower needs assessment were translated into a checklist for processors. An audit checklist for processors to use in their facilities was designed in phase one. This checklist provided processors with a tool to determine their compliance with several parts of FSMA. Extension facts sheets were developed in phase two to help processors know their state food safety regulations. Topics in the fact sheets were post-harvest processing methods such as freezing, dehydrating, fermenting, pickling, and canning of jam and jelly products. The final phase was the design and dissemination of a needs assessment survey to processors in the NCR to determine what additional materials can be provided to help the population. Questions were asked about the processor's understanding of the FSMA. Food safety professionals representing each processor responded to the survey. The needs assessment identified Amendments to Registration of Food Facilities, validation of

the food safety plan, and the supply-chain programs as specific areas of FSMA processors would like assistance with. The needs assessment also verified the interest in the previously developed materials. Overall, the project increases the knowledge of FSMA among fruit and vegetable processors in the NCR.

CHAPTER 1. INTRODUCTION

An estimated 4.4 million illnesses are caused by consumption of produce each year in the US (Scharff, 2010). Many of the foodborne illnesses occur due to fruit and vegetable processing plants because of contaminated surfaces throughout the harvesting, packing, processing, and shipping of produce (Beuchat & Ryu, 1997). Frozen shredded coconut also has led to an outbreak of *Salmonella* in 9 states (CDC, 2018). 32 people in 12 states became ill after consuming SoyNut Butter (CDC, 2017). These are only a few of the many recalls among others demonstrate many of the possible outbreaks and products touched by food processing.

Signed into law in 2011, the Food and Drug Administration (FDA) created the Food Safety Modernization Act (FSMA), , to change the focus of food safety from reaction such as the Hazard Analysis Critical Control Points (HACCP) method to prevention (FDA, 2018). FSMA consists of several Rules which affect fruit and vegetable processing, three of the most notable being (1) Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Preventive Controls for Human Food), (2) the Sanitary Transportation of Human and Animal Food Rule (Sanitary Transportation Rule), and (3) Amendments to Registration of Food Facilities. The North Central Region (NCR) of the United States (US) consists of Illinois, Indiana, Iowa, Minnesota, Michigan, North Dakota, South Dakota, Kansas, Nebraska, Ohio, Wisconsin, and Missouri (Tables 2 and 3). The NCR Center for FSMA Training, Extension, and Technical Assistance is focused on improving the implementation of FSMA in these states.

This thesis outlines the development, evaluation, and usage of educational materials for fruit and vegetable processors in the NCR. Four fact sheets (Figures 2-5) as well as one scenario quiz for the state of Iowa (Figure 6) for home-processors who sell pickled

vegetables, dehydrated and frozen fruits and vegetables, jams and jellies, and fermented fruits and vegetables. A checklist (Figures 7-10) developed for food processors describes four pertinent aspects of FSMA, Hazard Analysis and Risk-Based Preventive Controls for Human Food, Current Good Manufacturing Practice, the Sanitary Transportation Rule for Human and Animal Food, and Amendments to the Registration of Food Facilities. A needs assessment (Figure 11) was conducted to survey fruit and vegetable processors in the NCR about FSMA-related educational needs for the implementation of the law in their facilities.

This research and these documents are important for the continued progress and development of food safety systems across the NCR. Many processors have shown a desire for additional resources they can use within their establishments. The information contained in this thesis describes the creation of these materials and the future opportunities it creates.

CHAPTER 2. LITERATURE REVIEW

North Central Region Information

The NCR Center for FSMA Training, Extension and Technical Assistance is an extension group selected by the Department of Health and Human Services' Food and Drug Administration. The organization is charged with dispensing information, education, and extension services to growers and manufacturers in Iowa, Illinois, Indiana, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, South Dakota, Ohio, and Wisconsin. Several states in the NCR belong to the Corn Belt ("Corn Belt," 2016) and this is evident by the breakdown of agriculture sales in the region. According to the United States Department of Agriculture (USDA) (2015) only 17 of the 1,054 counties in the NCR have more than 25% of their agricultural sales come from vegetables. It was also reported that nearly 75% (787/1054) counties in the NCR have less than 1% of their agricultural sales come from vegetables. Most of these counties are located in Wisconsin, Michigan, and Minnesota and their crop tends to go to processing. These three states are also in the top 10 states in harvested acres in the US while Michigan and Wisconsin are also in the top 10 states of sales of vegetables in the US (USDA - National Agricultural Statistics Service, 2015). Table 1 shows the breakdown of fruit and vegetable production in the NCR from 2012 (USDA - National Agricultural Statistics Service, 2018).

Food Safety Modernization Act

New regulations

FSMA contains seven rules (Table 2) that address modern concerns in food safety. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, or (Preventive Controls for Human Food), regulates most food processors that are under FDA's jurisdiction. Generally, these are food processing and manufacturing

facilities that do not exclusively process meat or meat products because these are under USDA jurisdiction. Title 21 CFR Part 117(b) explains rules for processors to comply with Current Good Manufacturing Practice. Documentation required for subpart B is limited to training documents for personnel. Subpart B describes methods to maintain a clean and sanitary facility. It covers personnel sanitation, the plant and grounds, equipment cleaning and purchasing, warehousing, and the requirements for processes.

The bulk of the Preventive Controls for Human Food rule is covered in Title 21 CFR Part 117(c) – Hazard Analysis and Risk-Based Preventive Controls. Subpart C gives the regulations that would be covered in a federal audit. The primary requirement for all processors is a food safety plan which includes hazard analysis that is the foundation of the plan. The hazard analysis determines if there are any preventive controls that need to be established for a process. Preventive controls are “those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis” (Title 21 CFR Part 117.3). In other words, preventive controls are the methods a company uses to ensure the safety of a food through proper hazard analysis. If these identified preventive controls are not performed, the resulting product would be considered adulterated or unsafe for human consumption. For a food that requires a preventive control, the processor must have a recall plan, a monitoring program, corrective actions, verification and validation of that preventive control. The food safety plan must be reevaluated at least every 3 years or whenever the process changes. Title 21 CFR Part

117.126(b) in Subpart C specifies that all of this information must be *written* and documented in the food safety plan.

The Sanitary Transportation of Human and Animal Food rule was developed to “advance FDA’s efforts to protect foods from farm to table by keeping them safe from contamination during transportation (FDA, 2016)”. This rule applies to shippers, receivers, loaders, and carriers of foods that are covered by FDA. This includes any food that is manufactured in the US or any food that is imported into the US for sale or consumption within the US. The key requirements in the Sanitary Transportation of Human and Animal Food rule are for vehicles and transportation equipment, transportation operations, training, and recordkeeping (Title 21 CFR Part 1 Subpart O). Vehicles and transportation equipment are required to be designed in a way that would minimize the possibility of contamination such as equipment and vehicles must be able to be cleaned and maintain the proper temperature for the food it is carrying. Transportation operations must prevent cross-contact and cross-contamination events from occurring and minimizing other food safety concerns, such as time-temperature abuse.

Each rule in FSMA has the potential to affect large and small fruit and vegetable processors in the NCR. The interconnectedness is evident upon consultation with a processor. Some companies import ingredients from overseas and sell their byproducts to animal feed companies. In this instance, a company would have to comply with at least the Preventive Controls for Human Food, Preventive Controls for Animal Food, Sanitary Transportation of Human and Animal Food, and Foreign Supplier Verification Programs rules. The majority of the food industry had until at least until 2016 to adjust and prepare for the new changes. There are rolling compliance dates required based on size of the company for each of the

rules other than the Third-Party Certification Rule, which came into effect January 26, 2016 (FDA, 2017).

Effect on Small Businesses

A survey of 13 industry and academic professionals from the Midwest region of the US described six main challenges for small food facilities (Grover, Chopra, & Mosher, 2016). The six challenges are understanding the FSMA law, the cost of implementation, timeline for implementation, employee preparedness, absence of quality culture, and employee willingness. Each of the themes encompassed several thoughts that describe why these are the most important themes. Identifying hazards and finding scientific justification for all verification procedures were the biggest concerns in the understanding of FSMA by processors. A company's lack of intricate and detailed knowledge of their processes as well as a lack of management focus were perceived issues in the understanding of FSMA (Grover et al., 2016).

The cost and timeline of the implementation of FSMA were concerns for processors. The concerns included budget planning, costs of training and consultations, long-term investments, and a relatively small timeframe to work with (Grover et al., 2016). While the larger companies only had one year to complete FSMA requirements, many of these companies already had a HACCP plan or customer's audit scheme to comply with. In many instances, these plans already included much of the FSMA requirements. FDA acknowledges the implementation of FSMA will be expensive, especially for very small facilities, due to a lack of prior extensive food safety regulations (Federal Register Document 2014-22446). HACCP forms a base for some of the requirements of FSMA, making it easier for companies with previous HACCP plans to comply with FSMA (Levin & Newslow, 2013).

An absence of food quality culture is another issue for small facilities in the Midwest (Grover et al., 2016). Many of these companies do not have pre-existing HACCP plans or ISO 9001 certification. An absence of quality culture in a facility refers to a “lack of systematic practices within the organization, which facilitates continuous improvement” (Grover et al., 2016). These small companies rarely deviate from their historical processes and modes of production. Companies that have standards, plans, or audits, such as HACCP and Good Manufacturing Practice, tend to be more efficient at integrating new procedures into the preexisting system (Levin & Newslow, 2013). According to the survey participants conducted by (Grover et al., 2016), the lack of quality culture in small companies would make it more difficult for implementation of FSMA due to cost and time concerns.

Fresh Cut Fruit and Vegetable Processing

FDA defines fresh-cut produce as “fruits and vegetables that have been minimally processed and altered by peeling, slicing, chopping, shredding, coring, or trimming (FDA, 2007).” Within this definition, washing and other treatments may be included. Fresh-cut produce generally does not need any additional preparation before consumption. Many processors use sanitizers to wash the produce to ensure the consumer can eat the product without washing in their home or retail environment (Zagory, 1999).

The fresh-cut produce industry has increased in sales in recent years with overall sales of fresh-cut fruits and vegetables of \$3.3 billion in 1999 to \$15.5 billion in 2007 in the United States (James, Ngarmsak, & Rolle, 2010). Weekly sales, in dollars per store, increased 12% and 10.9% for fresh-cut fruits and vegetables, respectively, from 2013 to 2014 (Cook, 2014). The growth in sales of produce has been attributed to increased demand for fresh, convenient, and nutritious foods. Convenience is a large contributor to a consumer’s

decision to purchase fresh-cut produce (Ragaert, Verbeke, Devlieghere, & Debevere, 2004). The beneficial effects of fresh fruits and vegetables on human health have also influenced the consumer's decision to purchase produce (Abadias, Usall, Anguera, Solsona, & Viñas, 2008). Fruits and vegetables have been inversely correlated with mortality in England (Oyebode, Gordon-Dseagu, Walker, & Mindell, 2014). MyPlate.gov describes nutrients associated with various fruits and vegetables, such as potassium in tomato products to maintain healthy blood pressure (USDA, 2016). The website states the benefits of a healthy diet on the human body, including information on the effects of specific nutrients. Reduced risk for heart disease, certain cancers, diabetes, and obesity have been linked to the consumption of fruits and vegetables in a balanced diet.

In 2016, 86% of shoppers stated they are “mostly or completely confident the food in their grocery store is safe” (FMI, 2016). The Food Marketing Institute (FMI) report also reviewed the perspectives of customers about health risks of foods purchased at the grocery store. In their finding they found that 79% of shoppers were concerned about contamination by bacteria or germs. Shoppers also expressed concerns about pesticide and herbicide residues on foods. Product tampering and terrorism in the food supply were two categories of concern in those shoppers surveyed that grew the most between 2015 and 2016. Product tampering was a concern for 65% of shoppers in 2015 and increased to 73% in 2016. Terrorism in the food supply increased from 58% to 68% in the same period. Contamination by bacteria or germs concerns are also addressed in FSMA regulations and is a major focus in the Preventive Controls for Human and Animal Food rules, the Produce Safety rule, and the Sanitary Transportation rule. The Foreign Supplier Verification Program and Prevention

against Intentional Adulteration rules in FSMA address tampering concerns from consumers (FDA, 2011a).

Fruit and vegetable processing may improve convenience for the consumer but may influence nutritional quality, appearance, shelf life, and overall microbial load. Research on the nutritional quality of fresh-cut fruits and vegetables shows The concentration of antioxidant compounds in lettuce leaf tissue increase after wounding (cutting) the vegetable (Kang & Saltveit, 2002); fresh-cut citrus (Piga, Agabbio, Gambella, & Nicoli, 2002) and fresh-cut spinach (Gil, Ferreres, & Tomás-Barberán, 1999) show decreases in antioxidant content after cutting and storage. Perishable foods, such as fruits and vegetables, tend to have a shelf life dictated by quality rather than safety. These foods tend to have a very short shelf life ranging from days to a few weeks (Newsome et al., 2014). The shelf life of fruits and vegetables is further reduced by processing techniques, such as slicing and peeling. This processing creates a perfect environment to allow for more available nutrients for bacteria growth. Other parameters such as low acid/neutral pH and the high water activity of many fruits and vegetables also provide a beneficial environment for bacteria (Beuchat, 1996; O'Beirne & Francis, 2003). Many forms of processing, such as shredding and slicing, affect the concentration of microorganisms on fresh-cut produce. With both methods, there can be an increase aerobic plate counts while many other techniques such as water baths and chlorinated ice water maintain bacteria at its original level, typically between 10^4 and 10^7 aerobic plate count per gram (Garg, Churey, & Splittstoesser, 1990).

Foodborne Illness

Hazards that contribute to foodborne illness include foreign objects (physical), pesticides and cleaning agents (chemicals), and pathogens (biological). Scallan et al. (2011a,

b) estimate 48 million people in the US become ill each year from foods. Of these 48 million illnesses, there are a reported 128,000 hospitalizations and 3,000 deaths. While there are many factors that can cause foodborne illness, microbiological pathogens, rather than chemicals and physical objects, are the major cause of foodborne illness in the US (Lynch, Painter, Woodruff, & Braden, 2006). Casadevall and Pirofski (1999) define a pathogen as a microbe capable of causing host damage. This host damage caused by pathogenic microorganisms is most often represented by gastrointestinal dysfunction in humans. It is important to note the reference to pathogens in this thesis refers to human pathogens, rather than animal or plant pathogens (Brackett, 1999).

Another form of foodborne illness in the US are food allergies. According to the USDA (2013), about 2% of adults and 4-8% of children in the US have some form of food allergy. Anaphylaxis causes 30,000 emergency room visits, 2,000 hospitalizations, and 150 deaths each year in the US (USDA - Food Safety Inspection Service, 2013). Anaphylaxis is defined as a serious allergic reaction requiring immediate attention that is sudden in onset and can cause death (Food Allergy and Reserch & Education, 2017). The eight major allergens in the US are wheat, soy, milk, peanuts, tree nuts, fish, crustacean shellfish, and eggs. Allergen contamination of foods is a growing concern. Gendel and Zhu (2013) report 78 recalls in the 2007 fiscal year due to allergen contamination or mislabeling. This number gradually increased each year to 189 recalls in 2012.

Contamination of fruit and vegetables can occur at many different points in the processing of fresh produce. Raw produce from the field may have pathogens on it. Packaging materials used in the field or in the processing facility can be contaminated with pathogens before their use for the fruit and vegetable. During the manual trimming and

preliminary washing steps, human hands and dirty wash water may transfer pathogens from a contaminated fruit to a clean one. The processing steps of for raw produce where similar contamination and growth events can occur during slicing, shredding, secondary washing and disinfection, packaging, or storage (Figure 1) (Francis, Thomas, & O'Beirne, 1999). Ceilings and overhead structures where employees walk can drop physical hazards such as debris onto processing equipment (FDA, 2007). Drains, standing water, condensate, and rubber seals around doors can harbor these microorganisms, allowing them to grow and proliferate before a series of unfortunate events lead to inadvertent contamination of the product (FDA, 2007). FSMA regulations increases the traceability and documentation of food within the processing facility and throughout the supply chain to better prevent and capture contamination events before they are sent to the consumer. If these events are not contained, they can lead to serious outbreaks of foodborne illness.

Raw fruits and vegetables have microorganisms from the field associated with them, however, not all of these microorganisms are pathogenic. (Nguyen-the & Carlin, 1994). These organisms typically come from the environments the produce originated from but also can come from various other places in the food chain as discussed in the Fresh Fruit and Vegetable Processing section of this chapter. The predominant pathogens of concern in fresh fruit and vegetables are *Listeria monocytogenes*, *Staphylococcus aureus*, *Escherichia coli*, *Shigella spp.*, *Bacillus cereus*, *Clostridium spp.*, Hepatitis A, Norovirus, *Cyclospora*, *Giardia*, and *Salmonella spp.* (Beuchat, 1996, 2002; Buck, Walcott, & Beuchat, 2003; Burnett & Beuchat, 2001; Nguyen-the & Carlin, 1994). These pathogenic organisms tend to cause gastrointestinal distress resulting in symptoms such as vomiting, diarrhea, abdominal pain, fever, and chills (US Department of Health and Human Services, 2014).

Fresh, fresh-cut, and frozen fruits and vegetables have been responsible for many foodborne illness outbreaks in recent years. Outbreaks occur “when two or more people get the same illness from the same contaminated food or drink” (FDA, 2011b).

- In 2006, fresh spinach caused 199 illnesses, 102 hospitalizations, and 3 deaths in 26 states due to contamination from *Escherichia coli* (CDC, 2006). All of the spinach in the outbreak came from one production lot in southern California. FDA estimated there could have been 4,000 cases of *E. coli* O157 from this outbreak if it was not contained quickly. *E. coli* is not the only microorganism to cause foodborne illness in leafy greens.
- An outbreak of listeriosis, due to *Listeria monocytogenes*, in 2016 caused one death and the other 18 illnesses resulting in hospitalizations. The outbreak was traced back to a single Dole processing facility in Ohio (CDC, 2016b). Fresh produce outbreaks also occur due to imported fruits and vegetables.
- Maradol papayas from Mexico were implicated in three different, yet simultaneous, 2017 outbreaks of at least seven different strains of *Salmonella*: Newport, Infantis, Urbana, Thompson, Kiambu, Agona, and Gaminara. The papayas caused 210 illnesses, 65 hospitalizations, and one death (CDC, 2017).
- Another outbreak caused by imported produce occurred in 9 states in 2016 with frozen strawberries imported from Egypt were linked to an outbreak of hepatitis A. The virus caused 143 illnesses and 56 hospitalizations (CDC, 2016a).
- Frozen vegetables have also been the cause of an outbreak of *Listeria monocytogenes* with all nine of the illnesses causing hospitalizations and 3

deaths. The vegetables processed by CRF Frozen Foods in 2014 led to the recall of over 350 products under 42 different brand names (CDC, 2016).

- Another outbreak of listeriosis occurred in prepackaged caramel apples in 2015. This outbreak resulted in 35 illnesses, 34 hospitalizations, and 7 deaths in 12 states. The contamination was found in the apple-packing facility. The apples were sent to at least three caramel apple producers who each had a voluntary recall of their products (CDC, 2015).

Food Safety Checklists

Gawande (2007) states the U.S. Army Air Corps began their use of checklists in 1935. A flight competition was held on October 30, 1935 at Wright Air Field in Dayton, Ohio to determine the Air Corps' next-generation long-range bomber. The Boeing Corporation submitted the Model 299, a bomber that "could carry five times as many bombs as the Army had requested; it could fly faster than previous bombers, and almost twice as far" (Gawande, 2007). The bomber was expected to outshine any and all other competitors that day. Once the plane took off, it almost immediately stalled and crashed, killing 2 of the 5 crew members on board. The aircraft was more complex than other aircraft of its time, requiring more of the pilot's attention to many different tasks. The pilot, veteran Major Ployer P. Hill, "had forgotten to release a new locking mechanism on the elevator and rudder controls" (Gawande, 2007). The plane lost the competition, but Boeing was able to supply a few planes to the Air Corps. The solution to the complexity of the Model 299 was a checklist for the pilot to go through before, during, and after operating the aircraft. The idea was planes had evolved and any one of the numerous tasks required by the pilot, no matter their expertise, could be easily forgotten (Gawande, 2007).

Checklists have been identified in the medical community as ways to minimize doctor and nurse errors (Ely, Graber, & Croskerry, 2011; Hales & Pronovost, 2006). There are many simple steps in the complicated methods of modern medicine that are overlooked by doctors and ultimately lead to further injury and death to patients (Gawande, 2007; Pronovost et al., 2006). Haynes et al. (2009) created a 19-item surgical safety checklist implemented in 8 hospitals in 8 different countries to improve the morbidity rates of surgeries. The outcomes of 3733 patients undergoing non-cardiac surgery were compared to the outcomes of 3955 patients after the introduction of the surgical safety checklist. The result was a decrease in death from 1.5% before the use of the checklist to 0.8% after the use of the checklist. Inpatient complications also decreased from 11.0% to 7.0% after the introduction of the checklist (Haynes et al., 2009). Checklists have been demonstrated to lead to a decrease in catheter-related infections. In the 103 intensive care units, the median infections decreased from 2.7 infections before the introduction of a checklist to 0 at 3 months after implementation of the checklist. The mean decreased from 7.7 infections to 1.4 at 16-18 months of follow-up (Pronovost et al., 2006).

A checklist has also been used for food handling in foodservice where researchers used a food safety audit form to evaluate the conditions in school foodservice environments. Giampaoli, Cluskey, & Sneed (2002) developed audit forms were checklists incorporating the answer choices “Yes”, “No”, and “Not Applied”. Checklists were used by observers of foodservice handlers in school cafeterias. “Yes” meant the item on the checklist was performed correctly all of the time by all employees. “No” meant the item on the checklist was incorrect or inconsistent throughout the observer’s visit. “Not Applied” described irrelevant and not observed items during the audit. The checklist “was considered easy to

complete and resulted in the identification of some areas of noncompliance with safe food-handling procedures in the study” (Giampaoli et al., 2002).

Curriculum Development

During World War II, the military developed systematic approaches to training to analyze the needs of military personnel (Rossett, 1987). This was termed ‘instructional systems development’ and it was the method used to identify ways to teach soldiers how to successfully perform their work. Robert Gagne, Leslie Briggs, Robert Morgan, and Robert Branson, all from Florida State University, developed the big box model of training development or the ‘Interservice Procedures for Instructional Systems Development”. This method was used to create targeted training curricula for employees. The big box model contains five boxes: Analysis, Design, Development, Implementation, and Evaluation (Rossett, 1987).

The analysis stage asks the target audience ‘who, what, when, and why’ to determine their needs. Design takes the answers to the needs assessment questions and selects the most important as the focus of the educators’ training program. Design highlights specific objectives of training identified from the needs assessment during the analysis stage of the big box model. Objectives are honed to achieve a very specific result during the development stage. Researchers during the development stage take the answers to ‘who, what, when, and why’ and decide how the training will be conducted. The curriculum and materials are created based on these identified objectives from analysis and design. The program materials or course is put into practice during Implementation. Training curricula are taught, and educational materials are distributed to the target audience. The developed training materials

are evaluated for effectiveness. The evaluation stage asks, “was this program successful?”, “will it have lasting effects?”, and “how can this course be improved?” (Rossett, 1987).

The big box model is a holistic approach to the development of training curricula. It encompasses the needs of the group to be trained, the targeted design and creation of educational materials based on the needs of the group, the implementation of the developed training, and the evaluation of the program’s success (Rossett, 1987).

Needs Assessment

Analysis, or assessment, have been used through extension programming to identify the problem at hand. A needs assessment is used to address a specific problem and useful part in developing educational materials. They are used to define the gaps by importance and select the most pertinent to be the focus of improving the group (Kaufman & English, 1979). A need is defined as the difference between the current knowledge of the population of interest and the knowledge the population of interest should have (Witkin & Altschuld, 1995). The term, need, has also been described as “the discrepancy between current and desired results or consequences” (Kaufman & English, 1979; Witkin & Altschuld, 1995).

Altschuld & Witkin (2000) explain the development of a needs assessment has three phases: (1) Pre-assessment; (2) Assessment; and (3) Post-assessment. The preassessment stage explores the purpose and focus areas of the needs assessment. During this phase, researchers should decide on the data to collect, how to collect the data as well as the sources and uses of that data. This stage also determines a plan of action for the development and analysis of the needs assessment. The assessment stage is the data collection phase of the needs assessment. Not only are data collected, but the data is analyzed and organized as to its potential usefulness. The data from a needs assessment can only be used in particular

contexts and scopes and within certain boundaries. By identifying these boundaries, information gathered from a needs assessment can be applied in the most efficient way. The outcome of the assessment phase is “criteria for action based on high-priority needs.” These are the needs identified by the respondents as the most necessary and impactful areas of improvement. During phase 3, or the post assessment stage, determines how the needs assessment data will be used. The results are discussed among researchers to convert the data into actionable results. Solutions to the identified needs are determined and a plan is developed to address the identified needs from phase 2 (Altschuld & Witkin, 2000).

Survey Distribution Methods

Creswell (1998) describes five philosophical assumptions that researchers must understand before undertaking research with human participants:

- Ontological assumptions describe the reality the participants are living in by directly taking their words and thoughts as evidence of different perspectives pertinent to the research;
- Epistemological assumptions are the relationships the researcher builds with their participants which are vital to the success of extension agents;
- Axiological assumptions combine the values of the researcher with that of the participants to create the research narrative;
- Rhetorical assumptions refer to the style and language of the research and researcher’s interactions with the research participants;
- Methodological assumptions describe the process of the research(Creswell, 1998).

The methodological assumptions utilized in surveying a population are key, particularly the survey method. Roster, Rogers, Hozier, Baker, & Albaum (2007) describe five methods typically used in survey research, two online methods and three offline. Online methods are conducted via the internet and e-mail while offline methods include personal interviews, telephone interviews, and mail surveys (Roster et al., 2007). There are many sources describing the success of various survey methods. Shih & Fan (2008) show that college students are more likely than professionals to respond to web surveys while professionals are more likely to respond to mail surveys. Barrios, Villarroya, Borrego, & Ollé (2011) found response rates of web surveys were higher than mail surveys among PhDs while controlling for number of contacts. The study goes on to state “web participants may have felt motivated to participate in the study on reading the subject heading and the content of the email”. Continuing on the subject, the authors describe topic salience has a pertinent effect on the respondent’s decision to respond to the survey or not.

The Delphi Technique

The Delphi technique comes from work by Dalkey and Helmer (1963) during the Cold War. The study concluded ten years before the confidential manuscript was released to the public. The researchers developed the Delphi technique to assess vulnerabilities in key industries within the US to bombings by the Soviet Union. The Delphi technique has been applied in fields such as business course curriculum development (Sitlington & Coetzer, 2015), agricultural education (Dyer, Breja, & Ball, 2003), and the tourism industry (Cunliffe, 2002).

The Delphi technique’s purpose is to establish consensus among a group. There are four crucial elements of Delphi that make it unique: anonymity, iteration, controlled

feedback, and statistics using group response (Rowe & Wright, 2001). Anonymity is key to the Delphi method because it removes “fears of potential repercussions and embarrassment” and “no single individual need commit himself publicly to a particular view until after the alternatives have been put on the table” (Linstone & Turoff, 1975). Individuals feel pressured into answering questions ‘correctly’ instead of answering with their true understanding of the topic. Online surveys can be used to assure anonymity when using the Delphi technique. Similarly, Delphi studies are beneficial by moving away from typical focus group style survey processes. There are times and situations where individuals participating at these focus groups dominate and drown out the voices of other participants. In doing so, dominant individuals can sway group consensus and result in an incorrect representation of that group (Norman Dalkey & Helmer, 1963; Reeves & Jauch, 1978).

Delphi works in a series of iterations that allow the researcher to evaluate the information received from the group. After each iteration, the group receives feedback from the researcher to reach some sort of consensus or stability. The goal of each round is to have the group converge or stabilize more than the previous round. Typically, Delphi studies have the most convergence between the first and second rounds. Some critics suggest this is one of the faults of the Delphi method when used quantitatively. Dalkey (1969) performed an experiment with very small groups to produce estimates to questions and found that between rounds one and two, subjects were more likely to keep the same estimate or become more accurate towards the correct answer. The study found the ratio between the smallest and largest initial answer was 1:10 and at the end was 2:1. In a review of Delphi method literature, Woudenberg (1991) found the Delphi technique to have several flaws, especially as a quantitative technique. Many of the studies he reviewed focused on making forecasts

which he dubbed as “a weaker term for prediction to indicate the tentative nature of their and related investigations”. In contrast, Coates (1975) tries to remind the scientific community of the Delphi technique’s usefulness. He mentions, “the value of the Delphi, is not in reporting high reliability consensus data, but rather in alerting the participants to the complexity of issues...by having them challenge their assumptions”. The Food Safety Modernization Act is one of these complex concerns which needs to be addressed in the best way possible.

Figures and Tables

Table 1. Fruit and vegetable production in the NCR of the United States(USDA - National Agricultural Statistics Service, 2018).

State	Fruit, tree nuts, and berries in \$1,000s (Rank in US)	Vegetables, melons, potatoes, and sweet potatoes in \$1,000s (Rank in US)
Illinois	19,535 (32)	127,592 (20)
Indiana	10,897 (36)	104,411 (22)
Iowa	3,669 (42)	19,699 (42)
Kansas	5,808 (40)	21,517 (40)
Michigan	257,133 (7)	462,726 (9)
Minnesota	17,974 (33)	405,597 (12)
Missouri	25,749 (25)	63,122 (31)
Nebraska	3,157 (44)	101,141 (23)
North Dakota	247 (49)	251,033 (15)
Ohio	27,215 (23)	133,796 (19)
South Dakota	887 (47)	2,186 (50)
Wisconsin	219,271 (9)	555,432 (6)

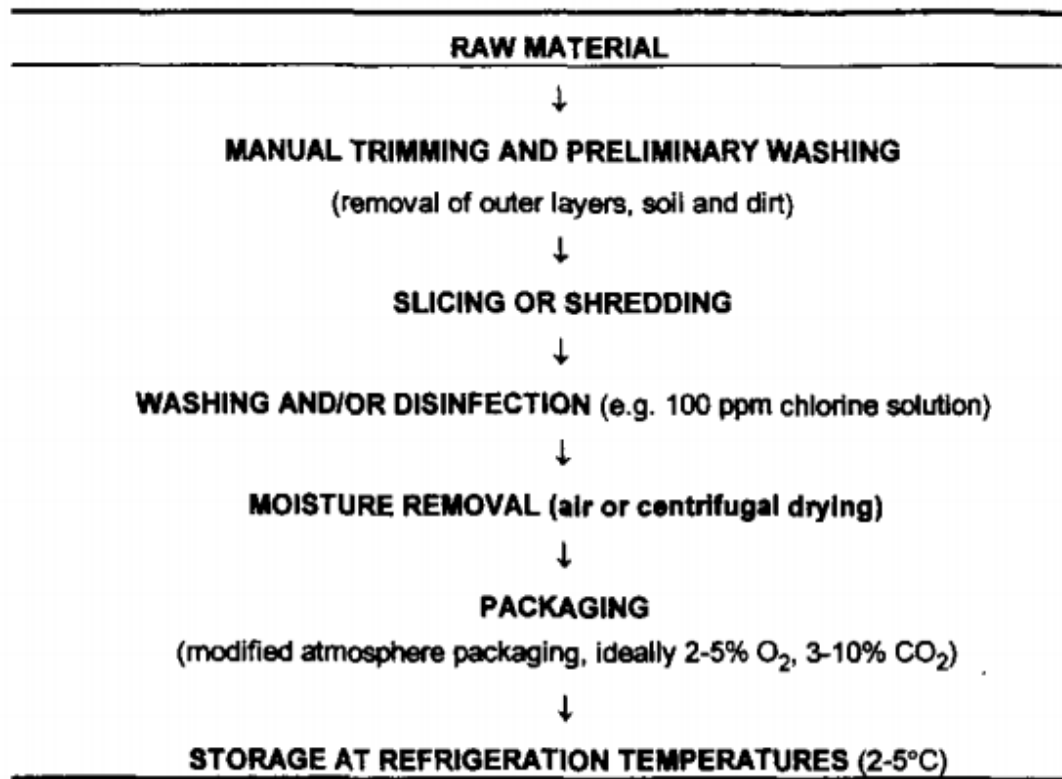


Figure 1. "A flow diagram for the production of minimally processed vegetables"
(Francis and others 1999)

CHAPTER 3. DEVELOPMENT OF FSMA FACT SHEETS AND SCENARIO QUIZZES

Introduction

Foods sold at farmers' markets are often viewed as "healthier and safer than foods produced and shipped long distances and sold in stores" by consumers (Harrison, 2017). In addition, many operators of businesses at farmers' markets (55-74%) believe their product is unlikely to cause illness (Harrison, 2017). However, very severe foodborne illnesses have been linked to improperly processed foods sold at farmers' markets (Burke et al., 2016). For example in 2014, improperly jarred pesto purchased from a farm stand in California led to two cases of botulism in Ohio (Burke et al., 2016). Farmers' market shoppers in Detroit were cautioned against consuming and told to dispose of relishes, syrups and jams produced by a small company in 2015 due to improper canning and risk of botulism (Abdel-Razzaq, 2015). And in California, consumers were warned against eating Taste of Roux, LLC jarred soups for the same reason in 2012 ("California warns of botulism risk in jarred soups," 2012).

Every state within the US has different state regulations on what type food products can be sold and where. Within the North Central Region (NCR), each state has different regulations on what they allow for home processing of food. The NCR consist of Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin. Home processing is defined as processing on the premises of a residence in which prepared foods are created for sale and the food is consumed off the premises (Huss & Haxton, 2010). These sales are exempt from Food Safety Modernization Act (FSMA) regulations; however, they are required to follow rules set forth by the state. Many home processors have difficulty locating the rules for their state. These rules are often buried deep within the state's Food Code, a resource that may prove difficult for home

processors to access. Furthermore, these rules are often vague and may not be clear to the home processor about their specific product. For example, home processors in Iowa may not sell pickled products without a licensed kitchen while home processors in Minnesota can sell these products if the product is below an equilibrium pH value of 4.6 and heat treated to kill vegetative cells who may live through the acidity (Iowa Department of Inspections & Appeals, 2017; Minnesota Department of Agriculture, 2017).

To alleviate the burden of finding the state and federal regulations, a series of regulation fact sheets for home processors was developed. Fact sheets are common methods of disseminating information to the public. Fujita & Miura Public Relations Inc. (2011) explain that fact sheets are effective because they are short, easy-to-read, to-the-point, cheap, and time saving. A fish fact sheet in the South to discuss the safety of fishing in contaminated rivers found that over 99% of the people they stopped to ask about their fact sheet were willing to spend up to 30 minutes interacting with it (Burger & Waishwell, 2001).

The four sheets, 'Pickles and Relishes', 'Fermented Foods', 'Jams and Jellies', and 'Frozen and Dehydrated Foods', cover the main home processes used in the NCR states as well as FSMA regulations for those processors required to comply and resources where processors can find more information. These subjects were identified as primary areas of concern in previous needs assessments and phone calls with extension agents. Home processors can access these documents and increase their knowledge of the regulations in their state. In addition to the fact sheets, a scenario quiz was developed to be provided on the ncrfsma.org website which includes questions based on the spreadsheets and specific situations based on state. Online interactive quizzes give immediate feedback to the test taker about the material being covered while simultaneously revealing areas of weakness with the

subject (Harter & Harter, 2004). The fact sheets (Figures 2, 3, 4, and 5) and the quiz (Figure 6) provide home processors the information needed to produce safe food for farmers' markets and minimizes confusion for those who may sell in multiple states or who sell multiple types of products.

Methods

Development of the Fact Sheets

Background Knowledge

Food preservation techniques, such as reducing water activity, temperature, and fermentation, are important aspects of maintaining high quality and safe food (Leistner, 2000). Water activity, the water available for microbial growth and enzymatic activity, is the primary mode of preservation in jams and jellies by binding the water using the sugars added to the food (Fontana, 1998). Fruit and vegetable dehydration removes water from the food system while minimally affecting flavor, texture, and color. The drying process reduces water activity, preventing growth of pathogenic organisms (Kendall, DiPersio, & Sofos, 2012). Another method of home-preservation is freezing which inhibits enzymatic action and preventing pathogens from growing during storage (Welch & Mitchell, 2000). Lactic acid bacteria ferment the food, increasing the acidity of the product and reducing counts of non-lactic acid bacteria. In some fermentations, ethanol is produced by the microflora which also preserves the food. This preservation technique improves the safety of the food by preventing the growth of pathogenic microorganisms (Mensah & Tomkins, 2003). The pickling process, due to the addition of vinegar as the acid rather than fermentation, prevents growth of pathogenic microorganisms via pH reduction (Ito, Chen, Lerke, Seeger, & Unverferth, 1976).

Rationale for Developing Facts Sheet

Virtual listening sessions with a group of extension agents took place between July and September of 2017 suggested that home processors needed more information on their own and neighboring states regulations for selling processed products. These agents were from Iowa State University, Kansas State University, Purdue University, Michigan State University, The Ohio State University, University of Minnesota, North Dakota State University, South Dakota State University, Lincoln University, University of Wisconsin, and University of Nebraska-Lincoln. The focus was on the questions processors were asking the agents about local, state, and federal regulations.

Prior to the aforementioned phone calls, a needs assessment was conducted within the NCR for produce growers. The two round needs assessment asked respondents about their perceived knowledge and information needs regarding key topic areas of the Produce Safety Rule (soil, water quality, animals, worker health, equipment and tools, and other information needs) using a five-point Likert rating scale. A similar scale was also used to assess preferred methods of information delivery. Comment boxes were available in all sections. Within the comment sections, growers provided comments on the need for information on value added produce items because they were taking leftover produce and using it for further processing. Many of these produce growers relayed that processing related fact sheets would be beneficial for their home-based processing businesses.

Format of Facts Sheets

As a result of the needs assessment and comments by extension agents, facts sheets were developed for ‘Pickles and Relishes’, ‘Fermented Foods’, ‘Jams and Jellies’, and ‘Frozen and Dehydrated Foods’. These topics were identified as common processing

methods used by home-based processors in the NCR. Each document has the same format: an introduction which includes the scientific principle of the safety of the product if done correctly (for example, pH of 4.6 is important for acidified foods), Standards of Identity and other definitions as written in the CFR, a section briefly describing federal regulations including FSMA and specialized regulations from the CFR for manufacturers who do not sell directly to consumers (they sell to grocery stores, wholesale markets, etc.), a section which includes state regulations from all 12 states for home-based manufacturers who sell directly to consumers at farmers' markets and roadside stands, recipes which have been verified by extension agents across the country, and the links to all information used in the development of the document.

The introduction section of these fact sheets explains the scientific basis for the process in that sheet and why it is crucial that specific measures are met each time in the process. Pickles, relishes, fermented foods, jams and jellies predominately rely on pH as the method of preservation and safety for the food. The introduction explains the importance in preventing *Clostridium botulinum* from producing its deadly toxin. This toxin is produced in anaerobic environments where the pH is above 4.6 (USDA - Food Safety Inspection Service, 2010). Jam and jelly production also uses water activity to reduce the possibility of spoilage or pathogenic contamination. These are the types of information relayed in the introduction of each fact sheet.

Standards of identity, definitions, recipes, and resources were all provided as a means to provide additional information to home processors about their own product. Definitions of sauerkraut and kimchi, jams and jellies, and other items from the CFR prevent processors from making unsafe and illegal products. Recipes from university extension websites across

the country are verified using standardized methods and were used in the facts sheets as templates for home processors to use to ensure the safety of their product. The links to the recipes as well as the links to any resource used to create the facts sheets were included as it provides processors with the ability to find more information on those government and extension websites. Resources, such as extension websites, federal documents, and state Department of Agriculture website, were cited throughout the document so sources of specific pieces of information could be easily identified and utilized.

A brief summary of Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food was included for processors who may acquire the document and need to be pointed in the correct direction for their facility. The majority of the document is specifically for home-based processors, who are not required to comply with FSMA due to their small size and gross revenue. This summary also included federal provisions for specialized processes such as acidifying and fermenting foods.

Validation of the Facts Sheets

The developed fact sheets were given to FDA for review. Abbot, Byrd-Bredbenner, & Grasso (2007) used a more comprehensive procedure for the development of their fact sheets. The group conducted baseline interviews and focus groups with food-service managers and, after the creation of the documents, used follow-up interviews with food-service managers to “assess the readability, relevance, usefulness, and completeness of the content” within the sheets. To maximize the effectiveness of these fact sheets, they should be reviewed with processors that should be using the sheets. This would also provide some information as to the effectiveness of the work and provide numbers to report. The development of my fact

sheets utilized baseline interviews with extension agents and asked processors about the usefulness of the sheets in a less formal manner.

Manufacturers who sell directly to consumers are typically those who are not required to comply with FSMA regulations. The regulations from each of the 12 states was provided for these small, home-based processors. States where the processes are not allowed are included as well to make clear which products are allowed in each state. The site from the Department of Agriculture website of each state was noted for quick and easy access for processors to find additional information.

Development of Scenario Quizzes

Scenario quizzes supplement the information presented in the facts sheets by testing the knowledge of home-based processors. Terminology related to value added products has been a concern for extension agents. These quizzes will be built in Qualtrics. There will be one quiz for each state which will include information from all four sheets, totaling 12 quizzes. At the current moment, a quiz for Iowa has been developed. The other states' quizzes will resemble the Iowa one with answers from their own states' laws. Questions on the Iowa quiz ask about the ability of a home processor to sell specific goods at farmers' markets, grocery stores, and other locations.

There are also questions about the safety of particular versions of processed foods. For example, "low/no sugar jams and jellies can be less safe than full sugar jams/jellies. True or false?" This question aids the home-based processor's thought process on the safety of their product. The correct answer to the low/no sugar jams and jellies question above is 'True'. However, just providing a right or wrong response is not enough. To truly increase food safety knowledge, correct and incorrect answers are supplemented with the reason why

the answer is right or wrong. If the respondent had responded with 'True' to the question above, the message provided would state "You are correct. Sugar is used to bind water in the jam/jelly and reduce the water activity. Water activity below 0.85 in jams and jellies prevents bacterial growth. If the water activity is too high, pathogens can grow and cause illness."

Water activity is a term which may not be understood by all home-based processors. To clarify any confusion, the program would have a textbox appear when the words 'water activity' are hovered over displaying the definition, "Water activity is a ratio that represents the water available for microorganisms to use for growth. It is different from moisture content which is the total water contained in a food." Additional information for home-based processors will be hyperlinked into the question or answer as necessary. 21 CFR 150 was referenced in some of the jams and jellies questions; a link to the eCFR website should be included for the processor to find additional information the actual law being described.

Conclusion

The fact sheets are designed for small, home processors rather than large, commercial processors. Home processors are those who sell at farmers' markets and roadside stands rather than grocery stores. The scenario quizzes were created to clarify differences between home and commercial processors. While the final product is not complete, the base is prepared for other states to have their own quiz. The hover over text is highly recommended as it will add clarification and further educate the population about unfamiliar terms. Many individuals have been confused about state and federal regulations and how they apply to their operation. This series of documents and quizzes will aid processors with the distinction between the two types of regulations.

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Fact Sheets

Federal and State Regulations on Selling Jams and Jellies

Introduction^{1,2,3}

Jams, jellies, fruit butters, and preserves are shelf-stable food products. They contain high amounts of sugar and acid which lower the water activity and pH, respectively, of the product to minimize the growth of microorganisms. Moisture migration, mold growth, and oxidation are reduced by hermetically sealing the jar. Important to the safety of jams and jellies is ensuring the pH of the product is below 4.6. Below this pH, *Clostridium botulinum*, a very serious human pathogen, cannot produce its deadly toxin.

Figure 2. Federal and state regulations on selling jams and jellies

Making low or no sugar jams, jellies, and preserves not only affects the type of pectin used to set the fruit but also can affect the microbiological safety and quality of the product. Sugar binds water in jams and jellies, reducing the water activity. Bacteria and molds grow well at high water activities and cause spoilage and illness. By reducing the sugar in a jam or jelly recipe, the water activity is increased and pathogenic organisms can grow. Be sure to accurately follow verified recipes and process the jams and jellies well to kill pathogenic bacteria that may be present. Water activity below 0.85 prevents bacterial growth. If the water activity is too high, pathogenic (harmful) bacteria can grow and cause illness. Water activity is a ratio that represents the water available for microorganisms to use for growth. It is different from moisture content which is the total water contained in a food. Pepper jellies and other vegetable jellies do not have as much acid naturally present as fruit jellies. Low acid foods, pepper and other vegetable jellies, have strict standards and regulations due to their enhanced safety risk. Be sure to check with your state on the production of low acid foods.

Standards of Identity⁴

Jellies - Jelled foods made from a mixture of one or a permitted combination of fruit juice ingredients described in 21 CFR 150.140(b). It may or may not include any combination of optional ingredients in 21 CFR 150.140(c). The jelly must have no less than 45 parts by weight of fruit juice ingredients measured in accordance with 21 CFR 150.140(d)(2) to each 55 parts by weight of saccharine ingredient as measured in accordance with 21 CFR 150.140(d)(4). The soluble solids content of the finished jelly must not be less than 65%.

Jams/preserves - Jams/preserves are viscous or semi-solid foods, each of which is made from a mixture composed of one or a permitted combination of the fruit ingredients in 21 CFR 150.160(b) and one or any combination of the optional ingredients in 21 CFR 150.160(c) that meets the specifications in 21 CFR 150.160(d). The mixture must be 45 [47 if using only group 1 fruits as defined in 21 CFR 150.160(b)] parts by weight of the fruit ingredients to each 55 parts by weight of the saccharine ingredient. The soluble solids content of the finished jam or preserve is not less than 65%.

Fruit butters - fruit butters are smooth semisolid foods made from a mixture of one or a permitted combination of the optional fruit ingredients in 21 CFR 150.110(b) and one or any combination of the optional ingredients in 21 CFR 150.110(c). The mixture must not be less than five parts by weight of the fruit ingredient to each two parts by weight of nutritive carbohydrate sweetener. The soluble solids content of the finished fruit butter must not be less than 43%.

Figure 2 (continued).

The information below pertains to specific types of manufacturers. Manufacturers that sell their product directly to consumers through farmers' markets, roadside stands, or other similar venues should direct their attention to the "For Manufacturers Selling Directly to Consumers" portion of this document. Manufacturers that do not sell directly to consumers (those that sell to restaurants, grocery stores, or other manufacturers) should view the "For Manufacturers Not Selling Directly to Consumers" portion of this document, directly below.

For Manufacturers Not Selling Directly to Consumers

Federal⁵

In general, jam and jelly manufacturers are subject to the Current Good Manufacturing Practice, Hazard Analysis and Risk-based Preventive Controls for Human Food rule [21 CFR Part 117], also known as CGMP & PC rule, unless an exemption applies [21 CFR 117.5 for exemptions]. Under the Current Good Manufacturing Practice provisions, processors are required to process food in a sanitary manner. Current Good Manufacturing Practices minimize the possibility for the physical, microbial, and chemical, including allergen, contamination of equipment, finished foods, and raw materials. Personnel require food safety and hygiene training as it pertains to their job duties in the plant (21 CFR 117.4).

Small or very small businesses that only perform on-farm production of jams and jellies from acid fruits and vegetables which must have a pH of 4.6 or below are recognized as exempt from PC rule. Very small businesses are also exempt from the qualified facility requirements [21 CFR 117.201]. If no exemptions apply, jam and jelly producers are required to develop a food safety plan consisting of written documentation of a hazard analysis, any identified preventive controls or an explanation of why preventive controls are not required, a supply-chain program, a recall plan, procedures for monitoring preventive controls, corrective action procedures, and verification procedures, including validation of process preventive controls, (e.g., that microbial hazards are controlled by the canning process).

For Manufacturers Selling Directly to Consumers

Illinois^{6,7,8}

Jams, Jellies, and Preserves - Only high acid jams, jellies, and preserves made from the following fruits are permitted: apple, apricot, grape, peach, plum, quince, orange, nectarine, tangerine, blackberry, raspberry, blueberry, boysenberry, cherry, cranberry, strawberry, red currants, or a combination of those fruits.

Any other jams, jellies, butters, or preserves not listed may be produced by a cottage food operation provided the recipe has been tested. The testing must be conducted by a commercial laboratory at the expense of the cottage food operation. The lab report must document that the product is not potentially hazardous, containing a pH equilibrium of less than 4.6 or has been specified and adopted as allowed in administrative rules by the Department.

Figure 2 (continued).

Low Sugar Jams and Jellies - The best practice for low sugar jams and jellies or those using sugar substitute is that they be processed only in a boiling water canner for a minimum of ten (10) minutes and not by any other methods unless water activity is determined by a commercial lab to be less than 0.85. Other flavors-any other jams, jellies, or preserves not listed may be produced by a cottage food operation provided their recipe has been tested and documented by a commercial laboratory as containing a pH level equilibrium of less than 4.6.

General Guidance - Name and residence of the person preparing and selling products as a cottage food operation must be registered with the county health department of a unit of local government where the cottage food operation resides. A fee may be charged for registration. The person preparing and selling products as a cottage food operation needs a current Department of Public Health approved Food Service Sanitation Management Certificate. Foods must be labelled as described by University of Illinois Extension.⁴

Indiana^{9,10}

Jams and Jellies - Traditionally prepared fruit-based jams and jellies, e.g., grape, strawberry, blueberry, raspberry, blackberry, etc. can be sold by a Home-Based Vendor.

Fruit butters (e.g., apple, pear, pumpkin) and “low sugar” or “no sugar added” jams and jellies - Not allowed to be sold by a Home-Based Vendor.

General Guidance - All Home-Based Vendors foods must have the following statement printed at a minimum type size of 10 points on product labels: “This product is home produced and processed and the production area has not been inspected by the State Department of Health.” The product must include a detailed label.

Iowa^{11,12}

Jams, jellies, and preserves – Must meet the standard of identity for jams and jellies specified in Title 21 of the Code of Federal Regulations, Part 150. If they do, they can be sold without a license.

General Guidelines - Home food operations in Iowa are allowed to produce such food products. Non-Temperature Control for Safety food products can only be sold direct to consumer (face-to-face only) from the operator’s home or at farmers markets. No licensing or inspection of kitchen is required. Should have a simple label on the product.

Kansas¹³

Home canned fruit jams and jellies – Home canned fruit jams and jellies as well as jams and jellies flavored with pepper-flavored vinegar or small amounts of pepper powder can be sold without a license, but must follow labeling requirements.

Pepper jams and jellies - Water activity must be tested. If product is determined to have a low water activity, product can be sold without a license. Otherwise, KDA license required.

Low-sugar fruit jams and jellies - Must be canned and shelf-stable. To determine shelf stability, the pH, water activity, and product formulation must be evaluated by an accredited lab. If the product is determined to be an acid food, formulated acid, or low water activity food, no license is required. Otherwise, KDA license required.

Figure 2 (continued).

General Guidelines- While not all food producers and processors are legally required to follow specific regulatory requirements due to the type of products they produce, all can and should utilize some basic Good Manufacturing Practices (GMPs), which are the basic sanitary and processing requirements necessary to ensure the production of safe food. GMPs are also essential to meeting current and future FDA and USDA food safety requirements, and are a key pre-requisite for Hazard Analysis and Critical Control Point (HACCP) programs, which are required for certain food products, including meat and poultry, juice, seafood, and some vacuum packed products, and by some food buyers.

Michigan¹⁴

Fruit jams and jellies– if sold in glass jars that can be stored at room temperature (except vegetable jams/jellies), they meet the requirements for cottage foods and can be prepared in a home kitchen and sold directly to consumers without a license. Vegetable jams/jellies and fruit/vegetable butters (e.g., hot pepper jelly) must be produced in a licensed kitchen.

General Guidelines– Must follow labeling requirements and include the following statement: "*Made in a home kitchen that has not been inspected by the Michigan Department of Agriculture & Rural Development*" in at least the equivalent of 11-point font (about 1/8" tall) and in a color that provides a clear contrast to the background (All capital letters or upper/lower case are both acceptable).

Minnesota¹⁵

Fruit butters, Jams, Jellies, Preserves - Exempt from licensing, except for non-tested recipes that add peppers, herbs, etc., will need to be tested and then submitted to MDA for approval consideration prior to production.

Adding alcohol, flowers, flavorings like lavender, or low acid ingredients is NOT allowed.

General Guidelines - Cottage food producers must do the following:

1. Register with the Minnesota Department of Agriculture (MDA) before selling exempt food regardless of the amount of food sold.
2. Take an approved food safety course once every three years while actively selling cottage food.
3. Register with the MDA each year food is sold under the Cottage Food Exemption.
4. Prepare and sell only NON-potentially hazardous food (such as baked goods, certain jams and jellies) and/or home canned pickles, vegetables, or fruits with a pH of 4.6 or lower.
5. Label food with your name and address, the date produced, and the ingredients, including potential allergens.
6. Display a sign that says "These products are homemade and not subject to state inspection." If you are selling on the Internet, post this statement on your webpage.
7. Deliver food directly to the ultimate consumer. The person who makes the food must be the same person who sells and delivers the food.
8. Sell from a private home, at farmer's markets, community events, or on the Internet.
9. Check with your local city, county, or township regarding business licensing or sales prohibitions due to zoning requirements.
10. Sell less than \$18,000 in a calendar year. If you sell between \$5,000 and \$18,000 per year, a \$50 fee applies to your registration.

Figure 2 (continued).

Missouri^{16,17}

Jams, Jellies, and Preserves - Generally jams and jellies may be produced in an uninspected kitchen; exceptions are sugar-free or no sugar added jams or jellies, ones made with fruit juices or jams or jellies made with non-standard ingredients (pepper jelly is an example).

General Guidelines - Products are exempt if the seller is the producer of the food or an immediate family member residing in the producer's household and familiar with the food, • foods are sold only to the end consumer, • packaged foods must be labeled according to the code including a statement that the food was made in a kitchen not subject to inspection, or • a sign is posted at the stand for unpackaged foods, that they were prepared in an uninspected kitchen.

Nebraska¹⁸

Jams and Jellies- You can sell traditional jams and jellies without a permit. You need a permit to sell jams and jellies that have jalapeno or other added ingredients. Rhubarb jelly made with pectin, not gelatin, is allowed to be sold without a permit.

General Guidelines- A clearly visible placard is required at the sale location stating the food was prepared in a kitchen that is not inspected or licensed by the regulatory authority.

North Dakota^{19,20}

The North Dakota Department of Health (NDDOH) is currently revising administrative rules after the 2017 legislature passed new laws around the cottage food industry. The new guidelines are expected to go into effect in 2018.

Jams and Jellies - Jams and jellies that are highly acidic in nature (pH less than or equal to 4.6) and do not require time and temperature control for food safety are allowed to be home-processed and sold. High risk jams and jellies (pH greater than 4.6), such as pepper jellies, are not considered approved cottage food products by definition.

General Guidelines- Each food container and/or food item sold must include the following statement in a front size that is prominent, conspicuous, and easy to read, "This product is made in a home kitchen that is not inspected by the state or local health department."

Ohio²¹

Jams and Jellies– May be sold as a cottage food and do not require a license. Home processing of low acid jams/jellies (those with pH greater than 4.6 and a water activity greater than 0.85) are not all to be sold or distributed.

General Guidance– Products must be labelled with the Statement of Identity (the name of the food product), the net quantity of contents (the net weight, in both U.S. Customary System and International System units), ingredient list (listed in descending order of predominance by weight), statement of responsibility (the name and address of the business), and must contain the following statement ten-point type: "This Product is Home Produced".

Figure 2 (continued).

South Dakota^{22,23}

Jams, Jellies, Fruit Syrups, and most fruits – May be sold without a license at farmers' markets and roadside stands. Jams and jellies with a pH greater than 4.6 may not be sold without a license.

General Guidance – All products must have official verification from a third party processing authority in writing. Products must be clearly labeled and include the disclaimer that states “This product was not produced in a commercial kitchen. It has been home processed in a kitchen that may also process common food allergens such as tree nuts, peanuts, egg, soy, wheat, milk, fish, and crustacean shellfish.”

Wisconsin^{24,25}

Jams and Jellies - Fruit and vegetable jams are allowed to be sold without a license if they have an equilibrium pH of 4.6 or lower.

General Guidance - To sell without license, no more than \$5,000 in sales per year, direct from producer to consumer, only at community or social events, such as bazaars, or at farmers' markets.

Verified Recipes**National Center for Home Food Preservation**

- <http://nchfp.uga.edu/>
- http://nchfp.uga.edu/how/can7_jam_jelly.html
- http://nchfp.uga.edu/publications/publications_usda.html
- https://nchfp.uga.edu/publications/usda/GUIDE07_HomeCan_rev0715.pdf

Wyoming Extension

- <http://www.wyomingextension.org/agpubs/pubs/B1210-3.pdf>

Ball™

- <http://www.freshpreserving.com/canning-101-getting-started.html>
- <http://www.freshpreserving.com/recipes-all/>

Figure 2 (continued)..

Resources

¹<https://ag.tennessee.edu/foodscience/Documents/Low%20or%20no%20sugar%20in%20jams,%20jellies%20and%20preserves.pdf>

² <http://ucanr.edu/sites/cottagefoods/files/199766.pdf>

³ <http://blog.extension.uconn.edu/2015/08/19/home-canning-food-safety-and-botulism/>

⁴ 21 CFR 117(b) <https://www.ecfr.gov/cgi-bin/text-idx?SID=01afb009a9de6f6797d02757e59ef157&mc=true&node=pt21.2.117&rgn=div5#sp21.2.117.b>

⁵ <http://web.extension.illinois.edu/cottage/foods.cfm>

⁶ <http://web.extension.illinois.edu/cottage/business.cfm>

⁷ <http://web.extension.illinois.edu/cottage/labeling.cfm>

⁸ <https://ag.purdue.edu/foodsci/pages/in-hea-1309-info.aspx>

⁹ <https://www.extension.purdue.edu/extmedia/FS/FS-18-W.pdf>

¹⁰ <https://store.extension.iastate.edu/Product/15225>

¹¹ https://dia.iowa.gov/sites/default/files/documents/2016/07/basic_requirements_for_farmers_markets.pdf

¹² <https://www.bookstore.ksre.ksu.edu/pubs/MF3138.pdf>

¹³ http://www.michigan.gov/mdard/0,4610,7-125-50772_45851-240577--,00.html

¹⁴ <https://www.mda.state.mn.us/licensing/licensetypes/cottagefood.aspx>

¹⁵ <http://health.mo.gov/safety/foodsafety/pdf/FarmersMarketsBrochure.pdf>

¹⁶ <http://health.mo.gov/safety/foodsafety/pdf/JamsJelliesBakedGoodsBrochure.pdf>

¹⁷

http://www.nda.nebraska.gov/publications/foods/food_safety_farmers_markets_craft_shows.pdf

¹⁸ <http://www.ndhealth.gov/FoodLodging/CottageFood.asp>

¹⁹

http://www.ndhealth.gov/FoodLodging/PDF/Cottage%20Food/Cottage_Foods_Memo_8.1.17_Final.pdf

²⁰ <http://www.agri.ohio.gov/foodsafety/food-cottageindex.htm>

²¹ <https://doh.sd.gov/food/farmers-markets.aspx?>

²² igrow.org/up/resources/04-2004-2013.pdf

²³ https://datcp.wi.gov/Pages/Programs_Services/FSHomeCannedFoods.aspx

²⁴ <https://datcp.wi.gov/Documents/HomeCannedFood%20FD-PUB-61-web.pdf>

²⁵ 21 CFR 150 https://www.ecfr.gov/cgi-bin/text-idx?SID=1c8978d7d9015c56c6fed1063ed6a916&mc=true&tpl=/ecfrbrowse/Title21/21cfr150_main_02.tpl

Figure 2 (continued).

Federal and State Regulations on Selling Fermented Foods

Introduction¹

Fermented foods are low-acids foods (typically fruits and vegetables) subjected to the action of acid-producing microorganisms to reduce the pH of the food to 4.6 or below. Examples of fermented foods are sauerkraut, some pickles, kimchi, and kombucha. The concern about fermented foods is *Clostridium botulinum*. *Clostridium botulinum* is a microorganism that produces a fatal toxin in anaerobic environments with a pH above 4.6. The toxin causes botulism, a serious paralytic illness that can be fatal and is considered a medical emergency. As you may notice below, the differences between state regulations are rather large. Take time to ensure you are following the correct laws. Be sure to also look at additional resources for more information.

Standards of Identity/Definitions

Sauerkraut²—The product of characteristic acid flavor, obtained by the full fermentation, chiefly lactic, of properly prepared and shredded cabbage in the presence of not less than 2 percent nor more than 3 percent of salt. It contains, upon completion of the fermentation, not less than 1.5 percent of acid, expressed as lactic acid. Sauerkraut which has been rebrined in the process of canning or repacking, contains not less than 1 percent of acid, expressed as lactic acid.

Kombucha³—While there is variation among kombucha products, the term “kombucha” generally refers to a fermented beverage produced from a mixture of steeped tea and sugar, combined with a culture of yeast strains and bacteria. The combination of sugar and yeast triggers fermentation, which may produce a kombucha with an alcohol content of 0.5% or more alcohol by volume. When this happens, the kombucha is regulated as an alcoholic beverage under federal law and TTB regulations.

Kimchi⁴—Kimchi is a Korean spicy fermented combination of pickled vegetables. The vegetables most commonly used in its preparation are celery, cabbage, Chinese turnip, and cucumber. The vegetables are sliced, seasoned, and fermented in brine in large earthenware jars. During fermentation, which takes approximately one month depending on weather conditions, the kimchi jars are stored totally or partially underground in cellars or sheds built expressly for this purpose.

Fermented foods⁵ are low-acids foods (typically fruits and vegetables) subjected to the action of acid-producing microorganisms to reduce the pH of the food to 4.6 or below. Examples of fermented foods are sauerkraut, some pickles, kimchi, and kombucha.

The information below pertains to specific types of manufacturers. Manufacturers that sell their product directly to consumers through farmers’ markets, roadside stands, or other similar venues should direct their attention to the “For Manufacturers Selling Directly to Consumers” portion of this document. Manufacturers that do not sell directly to consumers (those that sell to restaurants, grocery stores, or other manufacturers) should view the “For Manufacturers Not Selling Directly to Consumers” portion of this document, directly below.

Figure 3. Federal and state regulations on selling fermented foods

For Manufacturers Not Selling Directly to Consumers

Federal⁶

All fermented foods producers are required to follow current Good Manufacturing Practices [21 CFR Part 117, Subpart B]. Most fermented foods producers are required to comply with Hazard Analysis and Risk-based Preventive Controls [21 CFR Part 117, Subpart C]. Businesses which average sales in human food of less than \$1,000,000 annually (adjusted for inflation) during the 3-year period before that current year sales and the market value of any food produced that was held without sale are considered “very small”. Fermented foods are exempt from the hazard analysis and preventive controls requirements components in 21 CFR Part 117, Subparts C and G (and are subject to modified requirements in 21 CFR 117.201). Current Good Manufacturing Practices are practices that minimize the chance of chemical (including allergens), microbial, and physical contamination of foods. Personnel must be trained in food safety as it relates to their job duties. The plant, grounds, equipment, utensils, and processing lines must be kept in good sanitary condition. The fermentation process must be adequate to create a safe fermented product.

Fermented foods with acid added are considered acidified foods under 21 CFR Part 114. Operators must have a supervisor who has attended an FDA recognized training course specifically designed for canning acidified foods. The most widely available approved course is the Better Process Control School. Anyone working on the processing and packaging side of an acidified foods operation must be under supervision by the trained individual during all operating hours.

The food safety plan required by 21 CFR Part 117, Subpart C must include a written hazard analysis. This hazard analysis identifies reasonably foreseeable hazards and whether any of those hazards require preventive controls, or must justify why a hazard does not require a preventive control. If a preventive control is identified, written documentation of monitoring procedures, verification procedures, corrective actions, a recall plan, and validation information are required for each process control.^{7,8,9}

For Manufacturers Selling Directly to Consumers

Illinois¹⁰

Fermented foods - All fermented foods, including kombucha and kimchi, must be produced in a licensed kitchen. They are not able to be produced or sold as home-processed foods.

Indiana¹¹

Fermented vegetables- vegetables placed in a brine (saltwater) solution in which bacteria produce lactic acid to acidify the product and do not require refrigeration may be sold by a Home-Based Vendor. Note: Vegetables that require the addition of any acid (e.g., vinegar) are NOT considered fermented.

General Guidance-All Home Based Vendors foods must have the following statement printed at a minimum type size of 10 points on product labels: “This product is home produced and processed and the production area has not been inspected by the State Department of Health.” The product must include a detailed label.

Figure 3 (continued).

Iowa¹²

Fermented Products– Home canned fruits and vegetables as well as foods prepared using a specialized process are not allowed to be sold at a farmers’ market unless they are produced in a licensed kitchen.

Kansas¹³

Fermented Food- Naturally fermented canned foods– sauerkraut, kimchi, and kombucha-require a license to be sold.

Michigan¹⁴

Fermented food – No beverages, including fruit/vegetable juices and kombucha tea, are allowed to be made in a home kitchen. Canned fruits and vegetables or pickled products like corn relish, pickles, or sauerkraut are not allowed to be made in a home kitchen.

Minnesota^{15,16}

Fermented food– Fermented fruit, vegetables, pickles, sauerkraut, and kimchi that have an equilibrium pH value of 4.6 or lower and heat treated to kill vegetative cells are allowed. Fermented products needing refrigeration and kombucha are not allowed to be home-processed and sold.

General Guidance- Cottage food producers must do the following:

1. Register with the Minnesota Department of Agriculture (MDA) before selling exempt food regardless of the amount of food sold.
2. Take an approved food safety course once every three years while actively selling cottage food.
3. Register with the MDA each year food is sold under the Cottage Food Exemption.
4. Prepare and sell only NON-potentially hazardous food (such as baked goods, certain jams and jellies) and/or home canned pickles, vegetables, or fruits with a pH of 4.6 or lower.
5. Label food with your name and address, the date produced, and the ingredients, including potential allergens.
6. Display a sign that says “These products are homemade and not subject to state inspection.” If you are selling on the Internet, post this statement on your webpage.
7. Deliver food directly to the ultimate consumer. The person who makes the food must be the same person who sells and delivers the food.
8. Sell from a private home, at farmer’s markets, community events, or on the Internet.
9. Check with your local city, county, or township regarding business licensing or sales prohibitions due to zoning requirements.
10. Sell less than \$18,000 in a calendar year. If you sell between \$5,000 and \$18,000 per year, a \$50 fee applies to your registration.

Missouri¹⁷

Fermented foods—Sauerkraut, kimchi and kombucha tea are fermented foods and must be made in an inspected facility.

Figure 3 (continued).

Nebraska¹⁸

Fermented food—fermented foods may not be sold at farmers’ markets without a permit.

North Dakota^{19,20}

The North Dakota Department of Health (NDDOH) is currently revising administrative rules after the 2017 legislature passed new laws around the cottage food industry. The new guidelines are expected to go into effect in 2018.

Fermented food - Naturally fermented foods such as sauerkraut and kimchi where the equilibrium pH level has been reduced to 4.6 or less and verified using a calibrated pH meter can be sold under the cottage food laws. Guidance does not mention kombucha.

General Guidance- Each food container and/or food item sold must include the following statement in a front size that is prominent, conspicuous, and easy to read, “These food products were produced in an uninspected home kitchen where major food allergens may also have been handled and prepared, such as tree nuts, peanuts, eggs, soy, wheat, milk, fish, and crustacean shellfish.”

The seller must display a sign or placard at the point of sale which states “These canned goods/baked goods are homemade and not subject to state inspection.”

Ohio²¹

Fermented food– All fermented foods, including kombucha and kimchi, must be manufactured in an inspected facility.

South Dakota^{22,23}

Fermented food – Fermented foods may be sold at a farmers’ market, roadside stand, or similar venue. Fermented foods must have an equilibrium pH value below 4.6 and meet standards that destroy bacteria, yeast, and molds to a required level. All fermented foods must have official verification from a third-party processing authority in writing. All products must be labeled properly.

Figure 3 (continued).

Wisconsin^{24,25}

A person is not required to obtain a license to sell retail food products that the person prepares and cans at home in Wisconsin if all of the following apply:

- The food products are pickles or other processed vegetables or fruits with an equilibrium pH of 4.6 or lower
- The person sells the food products at a community or social event or a farmers' market in Wisconsin
- The person receives less than \$5,000 per year from the sale of the food products
- The person displays a sign at the place of sale stating: "These canned goods are homemade and not subject to state inspection"
- Each container of food product that is sold is labeled with the name and address of the person who prepared and canned the food product, the date on which the food product was canned, the statement "This product was made in a private home not subject to state licensing or inspection.", and a list of ingredients in descending order of prominence. If any ingredient originates from milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, or soybeans, the list of ingredients shall include the common name of the ingredient.

Recipes**Kimchi**

farmtotable.colostate.edu/prepare-ferment/kimchi.php#.WaXo3fqGOM8

Sauerkraut

extension.psu.edu/food/preservation/news/2012/sauerkraut

Kombucha

farmtotable.colostate.edu/prepare-ferment/kombucha.php#.WaXpXPqGOM8

Pickles

<https://onionline.osu.edu/factsheet/HYG-5342>

Figure 3 (continued).

Resources

- ¹<https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm228244.htm>
- ²<https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074636.htm>
- ³<https://ttb.gov/kombucha/kombucha-general.shtml#general>
- ⁴<https://www.britannica.com/topic/kimchi>
- ⁵<https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm228244.htm>
- ⁶<https://www.ecfr.gov/cgi-bin/text-idx?SID=c7ab64fd267b222cdeb875f6ab2ccd98&mc=true&node=pt21.2.117&rgn=div5>
- ⁷<https://www.ecfr.gov/cgi-bin/text-idx?SID=5adb4042d1b92be50b44b5e3653cd3c8&node=pt21.2.114&rgn=div5>
- ⁸http://ucfoodsafety.ucdavis.edu/Better_Process_Control_Schools/
- ⁹<https://foodsafety.ncsu.edu/acidified-foods-manufacturing-school/>
- ¹⁰<http://web.extension.illinois.edu/cottage/>
- ¹¹<https://ag.purdue.edu/foodsci/pages/in-hea-1309-info.aspx>
- ¹²<https://dia.iowa.gov/sites/default/files/documents/2016/10/homebasedfoodoperations.pdf>
- ¹³<https://www.bookstore.ksre.ksu.edu/pubs/MF3138.pdf>
- ¹⁴http://www.michigan.gov/mdard/0,4610,7-125-50772_45851-240577--,00.html
- ¹⁵<https://www.mda.state.mn.us/licensing/licensetypes/cottagefood.aspx>
- ¹⁶mfma.org/resources/Documents/MFMA%20Fact%20Sheet%20NPH%20Foods%20List%202016-03-15.pdf
- ¹⁷<http://health.mo.gov/safety/foodsafety/pdf/FarmersMarketsBrochure.pdf>
- ¹⁸http://www.nda.nebraska.gov/publications/foods/food_safety_farmers_markets_craft_shows.pdf
- ¹⁹<https://www.ndhealth.gov/FoodLodging/CottageFood.asp>
- ²⁰www.ndhealth.gov/FoodLodging/PDF/Cottage%20Food/Cottage_Foods_Frequently_Asked_Questions_9.01.17_Final.pdf
- ²¹<http://www.agri.ohio.gov/foodsafety/food-cottageindex.htm>
- ²²<https://doh.sd.gov/food/farmers-markets.aspx?>
- ²³igrow.org/up/resources/04-2004-2013.pdf
- ²⁴https://datcp.wi.gov/Pages/Licenses_Permits/FoodLicenses.aspx
- ²⁵docs.legis.wisconsin.gov/statutes/statutes/97.pdf

Figure 3 (continued).

Federal and State Regulations on Selling Frozen and Dried Produce

Introduction^{1,2}

Freezing and dehydrating produce commodities, including fruits, vegetables, and nuts, are ways to increase the shelf life of the produce.

Freezing can preserve freshness and quality. Freezing does not kill bacteria on the product but it does prevent microbes from growing. Once a food is thawed, bacteria begin to grow and can spoil the produce, or if pathogenic (harmful), can cause foodborne illness. Be sure to store the fruit or vegetable at 0°F or below for the duration of its frozen life.

Drying is one of the oldest methods of food preservation. Water allows growth of bacteria on food. When a food is dried, it removes water that was available for microorganisms to use and prevents their growth. Water activity below 0.85 prevents bacterial growth. If the water activity is too high, pathogenic (harmful) bacteria can grow and cause illness. Water activity is a ratio that represents the water available for microorganisms to use for growth. It is different from moisture content which is the total water contained in a food. It is important to check dried foods for moisture as the introduction of water to a dehydrated food can reduce quality and increase the chance of microbial growth.

Standards of Identity/Definitions³

Frozen—Frozen foods should be prominently labeled as “frozen”.

Frozen fresh—Foods which were quickly frozen while still fresh may be labeled “frozen fresh” or “fresh frozen”.

Dried or dehydrated—a food which is dried or dehydrated should be labeled with a designation which includes one of these words, unless the name is one like “raisins” which consumers recognize as indicating a dried product.

The information below pertains to specific types of manufacturers (those who identify as a facility). Manufacturers that sell their product directly to consumers through farmers’ markets, roadside stands, or other similar venues should direct their attention to the “For Manufacturers Selling Directly to Consumers” portion of this document. Manufacturers that do not sell directly to consumers (those that sell to restaurants, grocery stores, or other manufacturers) should view the “For Manufacturers Not Selling Directly to Consumers” portion of this document, directly below.

Figure 4. Federal and state regulations on selling frozen and dried produce

For Manufacturers Not Selling Directly to Consumers

Federal⁴

The Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food rule apply to facilities that freeze and dehydrate produce for human consumption in the United States and are required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, unless otherwise exempt. Current Good Manufacturing Practices (CGMP) must be followed [21 CFR Part 117, Subpart B] by facilities that manufacture, process, pack, or hold frozen and dehydrated food. Subpart B does not apply to establishments solely engaged in hulling, shelling, **drying**, packing, and/or holding nuts (without additional manufacturing/ processing, such as roasting nuts). For example, farms that dry/dehydrate raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins) without additional manufacturing/processing are not subject to the preventive control requirements of part 117, but subpart B (CGMPs) applies to the packaging, packing, and holding of the dried commodities. CGMPs include personnel, plant and grounds, sanitary operation, sanitary facilities and controls, equipment and utensils, processes and controls, warehousing and distribution, and holding and distribution of human food by-products for use as animal food. Employees must be trained on how to maintain a sanitary environment and how to produce safe frozen and dehydrated fruits and vegetables.

When freezing and dehydrating, it is imperative to monitor the operating temperatures and humidity of the equipment and produce. Be sure to keep instruments calibrated and record temperatures, humidity, and times throughout processing. Facilities that freeze and dehydrate produce may be required to develop a food safety plan based on their Hazard Analysis and identification of Risk-based Preventive Controls [21 CFR 117, Subpart C]. A food safety plan must include written documentation of a hazard analysis, preventive controls, (or reasons as to why a hazard does not need a preventive control), supply-chain program, if applicable, a recall plan, monitoring procedures verification procedures, and corrective actions, and validation documents for process preventive controls [21 CFR 117.126(b)(1) through (7)]. Conducting a complete and accurate hazard analysis is one of the most important steps in developing an effective, risk-based, and prevention-oriented food safety system.

For Manufacturers Selling Directly to Consumers

Illinois^{5,6}

Dried herbs— Sales of dried herbs are permitted by an Illinois Cottage Food Operation.

Frozen and dehydrated vegetables—Dehydrated and frozen fruits and melons are allowed to be sold without a license. However, dehydrated tomato and melon as well as frozen cut melon require a license.

General Guidance- The name and residence of the person preparing and selling products as a cottage food operation must be registered with the county health department of a unit of local government where the cottage food operation resides. A fee may be charged for registration. The person preparing and selling products as a cottage food operation needs a current Department of Public Health approved Food Service Sanitation Management Certificate.

Figure 4 (continued).

Indiana^{7,8}

Frozen and dehydrated produce, except for dehydrated tomato and frozen cut or dehydrated melon, are allowed to be sold by a home-based vendor. Check local government bodies (i.e. county and state level) for labeling and other requirements.

Iowa⁹

Foods prepared using a specialized process are not allowed to be sold at a farmers' market unless they are produced in a licensed kitchen.

Kansas¹⁰

Fresh (or dried) uncut fruits, vegetables, or herbs (tomatoes, melons, okra, apples, basil)- may be home-grown. Any pesticide use must comply with label directions. May be sold without a license.

Certain cut produce and cut herbs (other than cut tomatoes, melons, or leafy greens), cut berries, cut herbs, cut carrots, etc,- can be frozen, fresh, or dried. If produce is blanched before freezing, licensing is required. If not blanched first, no licensing required.

Fruit leathers (apricot leather, other fruits)- No license is required.

Cut leafy greens (fresh or dried), cut or torn lettuce- requires KDA food establishment license at production facility and point of sale. Must be sold at or below 41 degrees F.

Certain cut produce (fresh or dried) (melons, tomatoes)- requires KDA food establishment license at production facility and point of sale

General Guidelines- While not all food producers and processors are legally required to follow specific regulatory requirements due to the type of products they produce, all can and should utilize some basic Good Manufacturing Practices (GMPs), which are the basic sanitary and processing requirements necessary to ensure the production of safe food. GMPs are also essential to meeting current and future FDA and USDA food safety requirements, and are a key pre-requisite for Hazard Analysis and Critical Control Point (HACCP) programs, which are required for certain food products, including meat and poultry, juice, seafood, and some vacuum packed products, and by some food buyers. Standard hygiene and sanitation requirements must be followed.

Michigan¹¹

Dried Products- Dry herbs, dry herb mixtures, and dehydrated vegetables or fruits may all be made in a home kitchen.

Frozen products - Ice and ice products are not allowed to be sold by a home kitchen.

General Guidelines- Must follow labeling requirements and include the following statement: "*Made in a home kitchen that has not been inspected by the Michigan Department of Agriculture & Rural Development*" in at least the equivalent of 11-point font (about 1/8" tall) and in a color that provides a clear contrast to the background (All capital letters or upper/lower case are both acceptable).

Figure 4 (continued).

Minnesota¹²

Dried, Dehydrated, Roasted Products- fruits, fruit leather, herbs, vegetables, vegetable leathers, and chips are exempt from licensing.

Frozen—no mention of frozen produce

General Guidelines-

1. Register with the Minnesota Department of Agriculture (MDA) before selling exempt food regardless of the amount of food sold.
2. Take an approved food safety course once every three years while actively selling cottage food.
3. Register with the MDA each year food is sold under the Cottage Food Exemption.
4. Prepare and sell only NON-potentially hazardous food (such as baked goods, certain jams and jellies) and/or home canned pickles, vegetables, or fruits with a pH of 4.6 or lower.
5. Label food with your name and address, the date produced, and the ingredients, including potential allergens.
6. Display a sign that says “These products are homemade and not subject to state inspection.” If you are selling on the Internet, post this statement on your webpage.
7. Deliver food directly to the ultimate consumer. The person who makes the food must be the same person who sells and delivers the food.
8. Sell from a private home, at farmer’s markets, community events, or on the Internet.
9. Check with your local city, county, or township regarding business licensing or sales prohibitions due to zoning requirements.
10. Sell less than \$18,000 in a calendar year. If you sell between \$5,000 and \$18,000 per year, a \$50 fee applies to your registration.

Missouri¹³

Dry pasta, coffee, and dried fruits- examples of foods that vendors are allowed to sell because they are Non Potentially Hazardous Food.

Frozen—no mention of frozen foods.

General Guidelines- Products are exempt if the seller is the producer of the food or an immediate family member residing in the producer’s household and familiar with the food, • foods are sold only to the end consumer, • packaged foods must be labeled according to the code including a statement that the food was made in a kitchen not subject to inspection, or • a sign is posted at the stand for unpackaged foods, that they were prepared in an uninspected kitchen.

Nebraska¹⁴

Fresh or dried herbs- can be sold without a permit.

No mention of other dried or frozen fruits and vegetables.

General Guidelines- A clearly visible placard is required at the sale location stating the food was prepared in a kitchen that is not inspected or licensed by the regulatory authority. You may need a current Food Handlers Permit or a special farmers’ market permit.

Figure 4 (continued).

North Dakota^{15,16}

The North Dakota Department of Health (NDDOH) is currently revising administrative rules after the 2017 legislature passed new laws around the cottage food industry. The new guidelines are expected to go into effect in 2018.

Dehydrated fruits and vegetables may be sold without a permit as well as dry herbs, seasonings, and herb mixes.

No mention of frozen fruits and vegetables but ice and ice products are not allowed.

General Guidance- Each food container and/or food item sold must include the following statement in a front size that is prominent, conspicuous, and easy to read, “These food products were produced in an uninspected home kitchen where major food allergens may also have been handled and prepared, such as tree nuts, peanuts, eggs, soy, wheat, milk, fish, and crustacean shellfish.”

The seller must display a sign or placard at the point of sale which states “These canned goods/baked goods are homemade and not subject to state inspection.”

Ohio¹⁷

Dried herbs, dry herb blends, dry seasoning blends, and dry tea blends– may be sold as a cottage food and do not require a license.

General Guidance– Products must be properly labeled. The label must contain the statement: “This Product is Home Produced.”

South Dakota¹⁸

Vegetables packed and frozen for preservation– cannot be sold under the home-processed food law. (Some exceptions apply.)

Dried herbs, fruits, and some vegetables– Are allowed for sale under the home-processed food law. They do not require approval from a third party processor. Contact an SDSU Extension Food Safety Specialist for recommendation on safely dehydrating foods.

General Guidance- All products must have official verification from a third-party processing authority in writing. Products must be clearly labeled and include the disclaimer that states the following: “This product was not produced in a commercial kitchen. It has been home-processed in a kitchen that may also process common food allergens such as tree nuts, peanuts, eggs, soy, wheat, milk, fish, and crustacean shellfish.”

Figure 4 (continued).

Wisconsin¹⁹

A retail food license or food processing plant license is required to make and sell food items to the public. A person is not required to obtain a license to sell retail food products that the person prepares and cans at home in Wisconsin if all of the following apply:

- The food products are pickles or other processed vegetables or fruits with an equilibrium pH of 4.6 or lower
- The person sells the food products at a community or social event or a farmers' market in Wisconsin
- The person receives less than \$5,000 per year from the sale of the food products
- The person displays a sign at the place of sale stating: "These canned goods are homemade and not subject to state inspection"
- Each container of food product that is sold is labeled with the name and address of the person who prepared and canned the food product, the date on which the food product was canned, the statement "This product was made in a private home not subject to state licensing or inspection.", and a list of ingredients in descending order of prominence. If any ingredient originates from milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, or soybeans, the list of ingredients shall include the common name of the ingredient.

Recipes**Freezing**

food.unl.edu/freezing

extension.missouri.edu/p/gh1503

extension.oregonstate.edu/fch/sites/default/files/documents/pnw_296_freezingconveniencefoodsthatyouvepreparedathome.pdf

Drying

<http://food.unl.edu/drying>

http://nchfp.uga.edu/how/dry/csu_dry_vegetables.pdf

<http://nchfp.uga.edu/how/dry/herbs.html>

http://nchfp.uga.edu/how/dry/csu_dry_fruits.pdf

<https://extension.psu.edu/drying-fruits-and-vegetables>

<https://www.extension.umn.edu/food/food-safety/preserving/drying/drying-food/>

Figure 4 (continued).

Resources

- ¹https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/safe-food-handling/freezing-and-food-safety/CT_Index
- ²https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/safe-food-handling/shelf-stable-food-safety/ct_index
- ³<https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074581.htm>
- ⁴<https://www.ecfr.gov/cgi-bin/text-idx?SID=c7ab64fd267b222cdeb875f6ab2ccd98&mc=true&node=pt21.2.117&rgn=div5>
- ⁵<http://web.extension.illinois.edu/cottage/foods.cfm>
- ⁶www.ilga.gov/legislation/ilcs/fulltext.asp?DocName=041006250K4
- ⁷<https://ag.purdue.edu/foodsci/pages/in-hea-1309-info.aspx>
- ⁸https://www.in.gov/isdh/files/HEA_1309_guidance_final_6_11_09.pdf
- ⁹https://dia.iowa.gov/sites/default/files/documents/2016/07/basic_requirements_for_farmers_markets.pdf
- ¹⁰<https://www.bookstore.ksre.ksu.edu/pubs/MF3138.pdf>
- ¹¹http://www.michigan.gov/mdard/0,4610,7-125-50772_45851-240577--,00.html
- ¹²<https://www.mda.state.mn.us/licensing/licensetypes/cottagefood.aspx>
- ¹³<http://health.mo.gov/safety/foodsafety/pdf/FarmersMarketsBrochure.pdf>
- ¹⁴http://www.nda.nebraska.gov/publications/foods/food_safety_farmers_markets_craft_shows.pdf
- ¹⁵<https://www.ndhealth.gov/FoodLodging/CottageFood.asp>
- ¹⁶http://www.ndhealth.gov/FoodLodging/PDF/Cottage%20Food/Cottage_Foods_Memo_8.1.17_Final.pdf
- ¹⁷<http://www.agri.ohio.gov/foodsafety/food-cottageindex.htm>
- ¹⁸<https://doh.sd.gov/food/farmers-markets.aspx?>
- ¹⁹https://datcp.wi.gov/Pages/Licenses_Permits/FoodLicenses.aspx

Figure 4 (continued).

Federal and State Regulations on Selling Pickled Vegetables

Introduction^{1,2}

Pickling is an ancient method of food preservation dating back to 3rd century BC China. Unfermented pickles are typically put into an airtight jar with acid and flavorings and heated to kill any potential bacteria on the fruit or vegetable that may cause illness or spoilage. After a few days, the pickles are ready for consumption. The biggest concern about pickled foods is *Clostridium botulinum*. *Clostridium botulinum* is a microorganism that produces a fatal toxin in anaerobic environments with a pH above 4.6. The toxin causes botulism, a serious paralytic illness that can be fatal and is considered a medical emergency. Be sure to follow recipe directions and try to use recipes from reputable sources such as universities.

Figure 5. Federal and state regulations on selling pickles and relishes

Standards of Identity/Definitions

Acidified foods³—low-acid foods to which acid(s) or acid food(s) are added; these foods include but are not limited to, beans, cucumbers, cabbage, artichokes, cauliflower, puddings, peppers, tropical fruits, and fish. They have a water activity greater than 0.85 and have a finished equilibrium pH of 4.6 or below. These foods may be called “pickles” or “pickled _____”.

Low-acid foods⁴ - any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (a_w) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods.

Pickles³—pickles are considered an acidified food as they have a water activity (a_w) greater than 0.85 and have a finished equilibrium pH of 4.6 or below

The information below pertains to specific types of manufacturers. Manufacturers that sell their product directly to consumers through farmers’ markets, roadside stands, or other similar venues should direct their attention to the “For Manufacturers Selling Directly to Consumers” portion of this document. Manufacturers that do not sell directly to consumers (those that sell to restaurants, grocery stores, or other manufacturers) should view the “For Manufacturers Not Selling Directly to Consumers” portion of this document, directly below.

For Manufacturers Not Selling Directly to Consumers

Federal⁵

All pickle and relish producers are required to follow current Good Manufacturing Practices [21 CFR Part 117, Subpart B, and 21 CFR 117.4 (Qualifications of individuals who manufacture, process, pack, or hold food.)]. If the manufacturer sells less than \$500,000 in the preceding 3 years, that business is exempt from Hazard Analysis and Risk-based Preventive Controls [21 CFR Part 117, Subparts C and G]. If the manufacturer sells more than 50% of their food directly to consumers within 275 miles of the production facility, that business is exempt from Hazard Analysis and Risk-based Preventive Controls [21 CFR Part 117, Subparts C and G]. Current Good Manufacturing Practices are practices that minimize the likelihood of allergen/chemical, microbial, and physical contamination of foods.

Personnel must be trained on food safety as it relates to their job duties. The plant, grounds, equipment, utensils, and processing lines must be kept in good sanitary condition. The canning process must be adequate to create a safe pickled product.

In addition to 21 CFR Part 117, acidified foods operations must also follow 21 CFR Part 114. These operations must have a supervisor who has attended an FDA recognized training course specifically designed for canning acidified foods (21 CFR 114.10). The most widely available approved course is the Better Process Control School. Anyone working on the processing and packaging side of an acidified foods operation must be under supervision by the trained individual during all operating hours.^{3,6,7}

Figure 5 (continued).

The food safety plan required by 21 CFR Part 117, Subpart C, must contain a written hazard analysis. This hazard analysis identifies hazards requiring preventive controls or must give a justification as to why a hazard does not require a preventive control. If a hazard requiring a preventive control is identified, written documentation of the preventive control, monitoring procedures, corrective actions, verification procedures, including validation information for process preventive controls, and a recall plan are required.

For Manufacturers Selling Directly to Consumers

Illinois⁸

Pickles– Pickled products are not allowed to be sold in accordance with an Illinois Cottage Food Operation.

Indiana⁹

Non-fermented, pickled vegetables– For example pickles, beets, etc. that are acidified (i.e., vinegar added) and do not require refrigeration may not be sold by a Home-Based Vendor. Note: Vegetables that require the addition of any acid (e.g., vinegar) are NOT considered fermented.

Iowa¹⁰

Home canned fruits and vegetables (i.e. pickles)- are not allowed to be sold at a farmers' market unless they are produced in a licensed kitchen.

Kansas¹¹

Home canned pickles meats, vegetables, and sauerkraut- are not allowed to be sold without proper licensing.

Michigan¹²

Canned pickled products– items like corn relish, pickles or sauerkraut must be produced in a licensed kitchen.

Figure 5 (continued).

Minnesota¹³

Pickled products– products with an equilibrium pH value of 4.6 or lower and heat treated to kill vegetative cells are exempt from licensing. Examples, including but not limited to: Pickled asparagus, Pickled beets, Pickled cantaloupe, Pickled carrots, Pickled chow chow, Pickled corn relish, Pickled cucumber, Pickled green beans (Dilly Beans), Pickled green tomatoes, Pickled okra, Pickled relish, Pickled summer yellow squash, Pickled three-bean salad, Pickled watermelon rinds, Pickled zucchini, and Pickles, sweet or dill.

General Guidance- Cottage food producers must do the following:

1. Register with the Minnesota Department of Agriculture (MDA) before selling exempt food regardless of the amount of food sold.
2. Take an approved food safety course once every three years while actively selling cottage food.
3. Register with the MDA each year food is sold under the Cottage Food Exemption.
4. Prepare and sell only NON-potentially hazardous food (such as baked goods, certain jams and jellies) and/or home canned pickles, vegetables, or fruits with a pH of 4.6 or lower.
5. Label food with your name and address, the date produced, and the ingredients, including potential allergens.
6. Display a sign that says “These products are homemade and not subject to state inspection.” If you are selling on the Internet, post this statement on your webpage.
7. Deliver food directly to the ultimate consumer. The person who makes the food must be the same person who sells and delivers the food.
8. Sell from a private home, at farmer’s markets, community events, or on the Internet.
9. Check with your local city, county, or township regarding business licensing or sales prohibitions due to zoning requirements.
10. Sell less than \$18,000 in a calendar year. If you sell between \$5,000 and \$18,000 per year, a \$50 fee applies to your registration.

Missouri¹⁴

Salsa, pickles, and BBQ sauce- These foods are common examples of acidified or low acid canned foods that require a license and must be produced in an inspected facility. A producer must attend a Better Process Control School and have their process reviewed by a process authority.

Nebraska¹⁵

Meat, fruits, vegetables (green beans, tomatoes), pickles (all low acid canned foods)- You must have a permit to sell these home canned products.

General Guidelines- A clearly visible placard is required at the sale location stating the food was prepared in a kitchen that is not inspected or licensed by the regulatory authority.

Figure 5 (continued).

North Dakota^{16,17}

The North Dakota Department of Health (NDDOH) is currently revising administrative rules after the 2017 legislature passed new laws around the cottage food industry. The new guidelines are expected to go into effect in 2018.

Pickled foods- You may sell foods, such as dill or sweet pickles, salsa, tomato products, barbecue sauces, taco sauce, ketchups, mustards, and other acidified foods, where the equilibrium pH level has been reduced to 4.6 or less and verified using a calibrated pH meter.

General Guidance- Each food container and/or food item sold must include the following statement in a front size that is prominent, conspicuous, and easy to read, “These food products were produced in an uninspected home kitchen where major food allergens may also have been handled and prepared, such as tree nuts, peanuts, eggs, soy, wheat, milk, fish, and crustacean shellfish.”

The seller must display a sign or placard at the point of sale which states “These canned goods/baked goods are homemade and not subject to state inspection.”

Ohio¹⁸

Pickles and pickled products- must be produced in a licensed facility.

South Dakota¹⁹

Home-canned foods- having an equilibrium pH value below 4.6 and meeting standards that destroy bacteria, yeast, and molds to a required level. All products must have official verification from a third-party processing authority in writing. All products must be properly labeled.

Wisconsin^{20,21}

A person is not required to obtain a license to sell at retail food products that the person prepares and cans at home in Wisconsin if all of the following apply:

- The food products are pickles or other processed vegetables or fruits with an equilibrium pH of 4.6 or lower
- The person sells the food products at a community or social event or a farmers’ market in Wisconsin
- The person receives less than \$5,000 per year from the sale of the food products
- The person displays a sign at the place of sale stating: “These canned goods are homemade and not subject to state inspection”
- Each container of food product that is sold is labeled with the name and address of the person who prepared and canned the food product, the date on which the food product was canned, the statement “This product was made in a private home not subject to state licensing or inspection.”, and a list of ingredients in descending order of prominence. If any ingredient originates from milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, or soybeans, the list of ingredients shall include the common name of the ingredient.

Figure 5 (continued).

Recipes

Recipe 1:

extension.oregonstate.edu/fch/sites/default/files/documents/pnw_355_picklingvegetables.pdf

Recipe 2: www.clemson.edu/extension/hgic/food/food_safety/preservation/hgic3420.html

Recipe 3: extension.colostate.edu/topic-areas/nutrition-food-safety-health/making-pickles-9-304/

Resources

¹extension.oregonstate.edu/fch/sites/default/files/documents/pnw_355_picklingvegetables.pdf

²<https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm228244.htm>

³21 CFR 114 <https://www.ecfr.gov/cgi-bin/text-idix?SID=5adb4042d1b92be50b44b5e3653cd3c8&node=pt21.2.114&rgn=div5>

⁴21 CFR 113 https://www.ecfr.gov/cgi-bin/text-idix?SID=3d037581cdbeef69950d3a18e049bf94&mc=true&node=se21.2.113_13&rgn=div8

⁵21 CFR 117 <https://www.ecfr.gov/cgi-bin/text-idix?SID=01afb009a9de6f6797d02757e59ef157&mc=true&node=pt21.2.117&rgn=div5#sp21.2.117.b>

⁶http://ucfoodsafety.ucdavis.edu/Better_Process_Control_Schools/

⁷<https://foodsafety.ncsu.edu/acidified-foods-manufacturing-school/>

⁸<http://web.extension.illinois.edu/cottage/foods.cfm>

⁹<https://ag.purdue.edu/foodsci/pages/in-hea-1309-info.aspx>

¹⁰https://dia.iowa.gov/sites/default/files/documents/2017/08/approved_sales_at_temporary_events_and_farmers_markets.pdf

¹¹<https://www.bookstore.ksre.ksu.edu/pubs/MF3138.pdf>

¹²http://www.michigan.gov/mdard/0,4610,7-125-50772_45851-240577--,00.html

¹³<https://www.mda.state.mn.us/licensing/licensetypes/cottagefood.aspx>

¹⁴<http://health.mo.gov/safety/foodsafety/pdf/FarmersMarketsBrochure.pdf>

¹⁵http://www.nda.nebraska.gov/publications/foods/food_safety_farmers_markets_craft_shows.pdf

¹⁶<https://www.ndhealth.gov/FoodLodging/CottageFood.asp>

¹⁷www.ndhealth.gov/FoodLodging/PDF/Cottage%20Food/cottage_Foods_Frequently_Asked_Questions_9.01.17_Final.pdf

¹⁸<http://www.agri.ohio.gov/foodsafety/food-cottageindex.htm>

¹⁹<https://doh.sd.gov/food/farmers-markets.aspx?>

²⁰https://datcp.wi.gov/Pages/Licenses_Permits/FoodLicenses.aspx

²¹docs.legis.wisconsin.gov/statutes/statutes/97.pdf

Figure 5 (continued).

Iowa Scenario Quiz

1. I want to sell home canned green beans at my local farmers' market. Is this allowed?
 - Yes – You are incorrect. Canned fruits and vegetables cannot be sold at farmers' market. To sell canned fruits or vegetables at a farmers' market, you are required to follow Food and Drug Administration's rules which includes attending Better Process Control School and obtaining a canning license.
 - **No** – You are correct. Canned fruits and vegetables cannot be sold at farmers' market. To sell canned fruits or vegetables at a farmers' market, you require to follow Food and Drug Administration's rules which includes attending Better Process Control School, validating your canning method, obtaining a license, and more. Guidance on can be found at <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM569792.pdf>

2. Can I sell homemade apple jelly at my local farmers' market?
 - **Yes** – You are correct. Any fruit jam/jelly is allowed as long as it is meets the Standard of Identity for a jam or jelly. You can find a list of fruits at 21 CFR 150, <https://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol2/pdf/CFR-2012-title21-vol2-part150.pdf>.
 - No – You are incorrect. Homemade fruit jams and jellies are allowed to be sold at Iowa farmers' markets as long as it is meets the Standard of Identity for a jam or jelly. You can find a list of fruits at 21 CFR 150, <https://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol2/pdf/CFR-2012-title21-vol2-part150.pdf>. Homemade vegetable jams and jellies (peppers, cucumber, etc.) cannot be sold at the farmers' market. Two exceptions are tomato and rhubarb. The full list can be found in 21 CFR 150.160, <https://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol2/pdf/CFR-2012-title21-vol2-part150.pdf>.

3. Can I sell homemade canned salsa to my local grocery store?
 - Yes – You are incorrect. To sell to a grocery store, you are required to manufacture the salsa in a licensed and inspected facility. Your operation must also have a supervisor who has attended an FDA recognized course specifically designed for canning acidified foods. Depending on your size, you may also have to be in compliance with the Preventive Controls for Human Food Rule from the Food Safety Modernization Act.
 - **No** – You are correct. To sell to a grocery store, you are required to manufacture the salsa in a licensed and inspected facility. Your operation must also have a supervisor who has attended an FDA recognized course specifically designed for canning acidified foods. Depending on your size, you may also have to be in compliance with the Preventive Controls for Human Food Rule from the Food Safety Modernization Act.

Figure 6. Iowa scenario quiz.

4. Low/no sugar jams and jellies can be less safe than full sugar jams/jellies. True or false?
 - **True** – You are correct. Sugar is used to bind water in the jam/jelly and reduce the water activity. Water activity below 0.85 in jams and jellies prevents bacterial growth. If the water activity is too high, pathogens can grow and cause illness.
 - False – You are incorrect. Sugar is used to bind water in the jam/jelly and reduce the water activity. Water activity below 0.85 in jams and jellies prevents bacterial growth. If the water activity is too high, pathogens can grow and cause illness.

5. Can I sell low or no sugar added jams/jellies in my state?
 - **Yes** – You are correct. Any jam/jelly is allowed as long as it meets the Standard of Identity for a jam or jelly which requires specific pH, water activity and solids compositions. You can find a list of fruits at 21 CFR 150, <https://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol2/pdf/CFR-2012-title21-vol2-part150.pdf>.
 - No – You are incorrect. Any jam/jelly is allowed as long as it meets the Standard of Identity for a jam or jelly which requires specific pH, water activity and solids compositions. You can find a list of fruits at 21 CFR 150, <https://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol2/pdf/CFR-2012-title21-vol2-part150.pdf>.

6. Can I add vegetables to fruit jams/jellies to be sold at my local farmers' market?
 - Yes – You are incorrect. Jams/jellies defined by 21 CFR 150, <https://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol2/pdf/CFR-2012-title21-vol2-part150.pdf>, must be made of fruit ingredients as specified. Two exceptions are tomato and rhubarb. The full list can be found in 21 CFR 150.160 with group 1 and 2 vegetables listed as in 21 CFR 150.
 - **No** – You are correct. Jams/jellies defined by 21 CFR 150, <https://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol2/pdf/CFR-2012-title21-vol2-part150.pdf>, must be made of fruit ingredients as specified. Two exceptions are tomato and rhubarb. The full list can be found in 21 CFR 150.160 with group 1 and 2 vegetables listed as in 21 CFR 150.

7. Can I sell dried apricots in my state?
 - **Yes** – You are correct. You are able to sell home dried fruit or vegetables as long as it does not require refrigeration for safety. Degree of dryness or water activity below 0.86 are expected with these products.
 - No – You are incorrect. In Iowa, you can sell home dried fruit or vegetables as long as it does not require refrigeration for safety. Degree of dryness or water activity below 0.86 are expected with these products.

Figure 6 (continued).

8. Can I sell frozen whole strawberries at a wholesale market without a license in my state?
- Yes – You are incorrect for a wholesale market but you are correct for farmers markets. You are able to sell frozen whole strawberries at a farmers market without a license because they are not potentially hazardous foods in the frozen or thawed state.
 - **No** – You are correct for a wholesale market. You are required to carry a warehouse licenses to sell frozen whole strawberries to a wholesale market. According to the Food Safety Modernization Act, freezing acts as a refrigeration for safety step and requires record keeping for the freezer unit.
9. Can I sell home canned pickles to a grocery store in my state?
- Yes – You are incorrect. You are not allowed to sell home canned pickles for two reasons: One they are an acidified food and two they are canned. Each of these reasons requires a licensed food processing plant, education, and product testing to be acceptable for the grocery store
 - **No** – You are correct. Home canned fruits and vegetables are not allowed to be sold at a grocery store or a farmers’ market. Any food in a hermetically sealed container to be sold must be obtained from a licensed food processing plant, education and product testing to be acceptable for the grocery store. Additional farmer market licensing is required for the market to sell canned pickles as well.
10. Can I sell kombucha at a farmers’ market in my state?
- Yes – You are incorrect. Kombucha is made with fermented juice and is considered acidified. Acidification requires licensed food processing plant, education, and product testing to be acceptable. If homemade juice is utilized to make the kombucha, then Juice HACCP must be followed. More information on Juice HACCP can be found XX. If you use store bought juice, then no additional guidance outside of the acidified food standards must be followed.
 - **No** – You are correct. Kombucha is considered an acidified food and requires additional licenses, education, and product testing.

Figure 6 (continued).

11. What is the highest pH legally considered safe for canning and fermentation?
- 3.2 – You are incorrect. While a pH of 3.2 is considered safe for canning and fermentation, it is not the highest pH considered safe. The lower pH a food has, the more protected it is from pathogens. The highest safe pH for canning and fermentation is 4.6.
 - 4.6 – You are correct. The highest pH allowed for canning and fermentation. *Clostridium botulinum* grows at pH values greater than 4.6 and produces a deadly toxin in canned foods
 - 7.0 – You are incorrect. A pH of 7.0 is neutral, meaning it has no effect on most microorganisms and pathogens. *Clostridium botulinum* grows at pH values greater than 4.6 and produces a deadly toxin in canned foods, making 4.6 the highest pH safe for canning and fermentation.
 - 8.4 – You are incorrect. A pH of 8.4 is basic does not control the growth of many pathogens. *Clostridium botulinum* grows at pH values greater than 4.6 and produces a deadly toxin in canned foods, making 4.6 the highest pH safe for canning and fermentation.
12. Can I sell my dried spice blend at my local farmers' market?
- Yes – You are correct. Dried spices are considered non-potentially hazardous food products, that is products that do not require refrigeration, since they are shelf-stable. By drying the spices, you remove moisture and lower the water activity of the product, the available water for microbial growth. Dried spices should have a water activity below 0.86. However, all ingredients in the blend must be listed in order by weight.
 - No – You are incorrect. Dried spices are considered non-potentially hazardous food products, that is products that do not require refrigeration, since they are shelf stable. By drying the spices, you remove moisture and lower the water activity of the product, the available water for microbial growth. Dried spices should have a water activity below 0.86.
13. Can I sell chopped lettuce in a bag at my local farmers' market?
- Yes – You are incorrect. Fresh produce must be whole and uncut to be sold at farmers' markets. Chopping produce is a processing step that requires additional licensing. This means you would have to follow the regulations of the Food Safety Modernization Act with proper licensing to sell to a farmers' market.
 - No – You are correct. Fresh produce must be whole and uncut to be sold at farmers' markets. Chopping produce is a processing step that requires a preventive control. This means you would have to follow the regulations of the Food Safety Modernization Act with proper licensing to sell to a farmers' market.

Figure 6 (continued).

CHAPTER 4. CHECKLIST

Introduction

Around \$7 billion is spent each year on food safety incidents in the US (Hussain & Dawson, 2013). Rather than reacting to these incidents, the Food Safety Modernization Act (FSMA) seeks to prevent food safety problems before they happen. Food companies are always looking for new, innovative ways to increase sales and decrease costs. The adoption of FSMA is estimated to cost the food industry an additional \$500 million on top of the \$900 million from previous regulation (Ribera & Knutson, 2011). These high costs encourage the food industry to find quick, cheap, and effective methods of compliance with food safety regulation. Most food processors are required to follow the Current Good Manufacturing Practice (cGMPs) and Hazard Analysis and Risk-Based Preventive Controls for Human Food Rule (Preventive Controls for Human Food Rule), the Sanitary Transportation of Human and Animal Food Rule (Sanitary Transportation Rule), and Amendments to Registration of Food Facilities (Table 2).

To determine the information needs for fruit and vegetable growers who require compliance with FSMA, a needs assessment was completed within the North Central Region (NCR) of the US. The results on this needs assessment (n=299 growers) showed that growers identified checklists as a preferred method of receiving FSMA information by growers. Checklists have been identified as simple tools that can be implemented to reduce cost and error for organizations. For example, the military and medical industries have utilized checklists to minimize errors made by pilots, surgeons, and nurses (Berenholtz et al., 2004; Gawande, 2007; Hales & Pronovost, 2006; Pronovost et al., 2006). The Boeing Corporation entered a competition put on by the US Army Air Corps in 1935 with the Model 299, a bomber plane which outclassed every other at the time (Gawande, 2007). During the

competition, the plane crashed due to the complex set of new controls the pilot was required to operate. This led to the development and implementation of a checklist for pilots to complete before, during, and after operating the aircraft to simplify and ensure completion the required tasks (Gawande, 2007). In the medical field, checklists have been used to reduce catheter-related infections and non-cardiac surgery-related deaths by making doctors and nurses follow a standard method of care, including a complete list of items to follow to minimize missed steps (Berenholtz et al., 2004; Haynes et al., 2009; Pronovost et al., 2006).

The goal of this paper is to display the methodology and product of a checklist to help fruit and vegetable processors with compliance with the FSMA Preventive Controls for Human Food Rule, the Sanitary Transportation Rule, and Amendments to the Registration of Food Facilities as a useful self-auditing tool to aid the food industry with the transition to FSMA.

Methods

Information within the checklist (Figures 7, 8, 9, and 10) comes from Title 21 of the Code of Federal Regulations (CFR), which covers food and drugs typically under the jurisdiction of the Food and Drug Administration (FDA). The term ‘checklist’ refers to all four mini-checklists in Figures 7, 8, 9, and 10. Within the checklist are four ‘mini-checklists’ each of which correspond with a part of FSMA (Table 2). The first two mini-checklists cover the Preventive Controls for Human Food Rule, the first focuses on Hazard Analysis and Risk-Based Preventive Controls (Table 3.1) and the second focuses on Current Good Manufacturing Practice (Table 3.2). The third checklist covers the Sanitary Transportation Rule (Table 3.3) and the fourth checklist covers the Registration of Food Facilities (Table 3.4). Each mini-checklist contains parts of each Rule and are referred to as ‘parts’. Each part

typically corresponds to a sub-heading in the law. For example, the Recall Plan part is the sixth part of the first mini-checklist coming from 21 CFR 117.139. Each part consists of points and these points can come from any sublevel below the sub-heading of the law. In most parts, such as the Recall Plan part, this would mean a reference to 117.139(a) or similar.

There are a couple exceptions to the Part definition. The Preventive Controls Qualified Individual [21 CFR 117.180(c)(1)], General Requirements for Transportation Operations [21 CFR 1.908(b)], Loader and Receiver Requirements [21 CFR 1.908(c and d)], and Carrier Requirements [21 CFR 1.908(e)] parts all stem from portions of the law below the subheadings. It was deemed, in the case of the Preventive Controls Qualified Individual, that particular section was the most important part for the purpose of the checklist. The purpose was to describe what is required of the Preventive Controls Qualified Individual. Information from the several parts from 21 CFR 1.908 was best presented when broken into multiple parts rather than one larger part. There were also three parts in the checklist that covered multiple sub-headings in the Code of Federal Regulations, Verification (21 CFR 117.155 and 165), Warehousing and Distribution (21 CFR 117.93 and 21 CFR 1.908) and Waiver Requests (21 CFR 1.914-21 CFR 1.934). Verification includes 21 CFR 117.155 and 165 and Warehousing and Distribution includes 21 CFR 117.93 and 21 CFR 1.908 because they are important aspects of each part and are directly related. Waiver requests are all combined as they are all interconnected topics under the “Waiver” topic from the Sanitary Transportation Rule.

The highlights of the checklist are the hints, comments, and definitions. The hints accompany each point and act as a secondary word of advice from Iowa State Extension and FDA. Each hint is designed to provide additional information that is not found in the Rules

themselves or to further describe a point through the use of examples that could be found in a food facility.

Comments serve a similar purpose as the hints. Where hints cover each individual point, comments cover each individual part. One of the largest parts in the entire document is Part 7 of the Current Good Manufacturing Practice mini-checklist, Processes and Controls. It has eighteen total points, each with their own hint. However, the comments section for this Part is short and concise, reading “Every process in the plant should be done in a way that prevents biological, physical, and chemical contamination. Document all processes throughout production.” This part covers many different processes that could occur in a processing facility and the comment quickly sums the entire section. Comments can be short reminders such as this one or can include bonus information that is not included in the Rule itself.

Definitions are also included for each part, directly below the comments section, to complete the all-inclusive document that requires processors to minimize the number of sources they must access to implement the three discussed Rules. The definitions included in the checklist come from different places of 21 CFR depending on the mini-checklist used. The ‘Hazard Analysis and Risk-Based Preventive Controls’ and the ‘Current Good Manufacturing Practice’ mini-checklists use 21 CFR 117.3, the ‘Sanitary Transportation Rule’ mini-checklist uses 21 CFR 1.904, and the ‘Registration of Food Facilities’ mini-checklist uses 21 CFR 1.227. Any term found in the checklist that is defined by the location in 21 CFR is included in that part.

The effectiveness of the checklist was measured in two ways prior to the release of it on the ncrfsma.org website. The checklist was sent to FDA for a courtesy review on two

separate occasions. During this courtesy review, FDA officials commented on mistakes in the work, further explanations and clarifications, rearrangement of the document, and provided very precise wording to be used to prevent legal confusion between the processors and FDA investigators. The largest critique from FDA about information in the checklist were the subjective nature of the hints. Originally, the hints were used as a space to provide information on what a processor could do to fulfill the requests of a particular point. FDA did not agree that this would be beneficial and preferred information that was directly pertinent to the law. There were several hints that were based on opinion or observation from one of the pilot studies. Information about record keeping in the Food Safety Plan part of the first mini-checklist. The hint reiterated the importance of record keeping in the food safety plan and provided examples of what needs to be included in the food safety plan. FDA found that the wording “blurs the written procedures required in the food safety plan and the implementation records that are required.” To fix this, the wording was changed to reflect that the food safety plan is a working document that is being updated almost daily with documents of the implementation of preventive controls, not just their existence.

Five food processing companies (3 fruit and vegetable and 2 non-fruit and vegetable) within the Midwest region were utilized to pilot the checklist within their facilities to validate the ease of use, language use, and clarity of use. Processors completed the checklist with their food safety team and made comments throughout the document on areas to modify as well as provided overall feedback for improvement. A Food and Drug Administration (FDA) courtesy review was completed with the Preventive Control Technical Assistance Network (TAN) group. This courtesy review focused on language appropriateness and use of hints and

definitions. All of these suggestions were incorporated into the final document by the pilot companies and the FDA team.

Results & Discussion

The final checklist (Figures 7, 8, 9, and 10) is 70 pages total, includes four mini-checklists (Table 3). The checklist was well-received by the food industry after distribution to professionals at conferences and via network connections. Several extension groups, auditors, and food companies have requested additional information about the checklist to further aid their clientele. The FDA courtesy audits were key to the development of the checklist as they provided advice on the connotation of the wording in some parts of the checklist. The interpretation of the checklist by processors is dependent on the way it is written and the message conveyed to the processors should reflect the ideals of FDA, as FDA is the group who will be auditing the results of the checklist. Implementation of FSMA has been a headache for many groups in the food industry and this checklist provides some aid to those who need it.

Checklists have been used in several food safety applications at the farmer and grower level. A checklist used as a guide for audits found wide success assisting farmers with self-evaluation of the farm safety practices (Infante-Casella, Bamka, Komar, Melendez, & Schilling, 2018). By providing a simple, comprehensive set of checklists, farm operations changed their training and food safety outcomes improved on over 200 farms. Rafie & Nartea (2012) developed a checklist tool for new entrepreneurs to evaluate their ability to run successful farming operations. This checklist provides new business owners an idea of shortcomings they may have that, if addressed seriously, can be changed to promote success of the farm. Checklists have been shown to be effective self-assessment tools in the food

industry as well. Kafetzopoulos, Psomas, & Kafetzopoulos (2013) created a successful HACCP food safety management system checklist. Internal auditing schemes can be useful for minimizing, identifying, and correcting problems in a food processing environment (James, 2005; Powell et al., 2013).

Food safety related checklists are often related to training courses. Shaw, Strohbehn, & Naeve (2015) used a checklist during on-farm food safety third party auditing workshops as a mock governmental audit tool. In this instance, those attending the course were walked through the audit form by Iowa State extension auditors. This checklist was designed for independent use; however, the review of the checklist was facilitated by extension personnel with several of the companies in the pilot study, showing the checklist can be used for both purposes. Another study of butcher hygiene showed utilizing a checklist in conjunction with a training course led to “significant improvement in food safety practices” (Vaz, Novo, Sigulem, & Morais, 2005). There was no significant decrease in compliance with food safety practices after six months, however, those authors suggest refresher activities to be beneficial in the continued use of these food safety practices. This checklist in combination with the Food Safety Preventive Controls for Human Food Alliance training course could lead to improved and continuous food safety outcomes across the region.

Conclusion

The development of this checklist has led to a final product that is convenient and helpful for food processors to utilize in their facilities. Food processors will have an outline of what is required by FSMA for their plant and can perform self-audits accordingly. The checklist allows the processor to only have one document to refer to, rather than searching the Code of Federal Regulations for help. The comments and hints provide applicable and

relevant feedback and guidance for food processors to further develop their food safety plan while the definitions contribute a quick reference for perplexing terms. The checklist is available for download on the NCR Center for FSMA Training, Extension, and Technical Assistance website under the Resources tab in the Resources by Topic section (<https://ncrfsma.org/resources-topic>). Anyone is able to access the checklist for use in their facility. In some cases, other extension groups and auditors have used the checklist to assist their own constituents.

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Tables

Table 2. Rules of the Food Safety Modernization Act affecting fruit and vegetable processors

Title	Law location
Hazard Analysis and Risk-Based Preventive Controls	Title 21 CFR Part 117, Subpart C
Current Good Manufacturing Practices	Title 21 CFR Part 117, Subpart B
Sanitary Transportation of Human and Animal Food Rule	Title 21 CFR Part 1, Subpart O
Amendments to the Registration of Food Facilities	Title 21 CFR Part 1, Subpart H
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	Title 21 CFR Part 112
Food Supplier Verification Programs for Importers of Food for Humans and Animals	Title 21 CFR Part 1, Subpart L
Accredited Third-Party Certification	Title 21 CFR Part 1, Subpart M
Mitigation Strategies to Protect Food Against Intentional Adulteration	Title 21 CFR Part 121

Table 3. Breakdown of Food Safety Modernization Act Rules

Title	Law location
Table 3.1. Hazard Analysis and Risk-Based Preventive Controls	
Preventive Controls Qualified Individual	21 CFR 117.180(c)(1)
Contents of a Food Safety Plan	21 CFR 117.126
Hazard Analysis	21 CFR 117.130
Preventive Controls for Hazards	21 CFR 117.135
When Preventive Controls are not Required	21 CFR 117.136
Recall Plan	21 CFR 117.139
Monitoring	21 CFR 117.145
Corrective Actions	21 CFR 117.150
Verification	21 CFR 117.155 and 165
Validation	21 CFR 117.160
Reanalysis	21 CFR 117.170
Records Required	21 CFR 117.190
Table 3.2. Current Good Manufacturing Practice	
Qualified Individual	21 CFR 117.4
Personnel	21 CFR 117.10
Plants and Grounds	21 CFR 117.20
Sanitary Operations	21 CFR 117.35
Sanitary Facilities and Controls	21 CFR 117.37
Equipment and Utensils	21 CFR 117.40
Processes and Controls	21 CFR 117.80
Warehousing and Distribution	21 CFR 117.93, 21 CFR 1.908
Holding and Distribution of Human Food By-Products for Use as Animal Food	21 CFR 117.95
Defect Action Levels	21 CFR 117.110
Table 3.3. Sanitary Transportation of Human and Animal Food	
Who is subject to the Sanitary Transportation rule?	21 CFR 1.900
How does this information apply under the Food, Drug, and Cosmetic Act?	21 CFR 1.902
What requirements apply to vehicles and transportation equipment?	21 CFR 1.906
What are the general requirements for transportation operations?	21 CFR 1.908(a)
What requirements are applicable to shippers engaged in transportation operations?	21 CFR 1.908(b)

Table 3 (continued).

What are the requirements applicable to carriers engaged in transportation operations?	21 CFR 1.908(c) and (d)
What training requirements apply to carriers engaged in transportation operations?	21 CFR 1.908(e)
What record retention and other records requirements apply to shippers, receivers, loaders, and carriers engaged in transportation operations?	21 CFR 1.910
How are waiver requests submitted?	21 CFR 1.912

Table 3.4. Amendments to Registration of Food Facilities

Who must register?	21 CFR 1.225
Who does not have to register?	21 CFR 1.226
When must you register or renew your registration?	21 CFR 1.230
How and where do you register or renew your registration?	21 CFR 1.231
What information is required in the registration?	21 CFR 1.232
How and when do you update your facility's registration information?	21 CFR 1.234
How and when do you cancel your facility's registration information?	21 CFR 1.235
How are waiver requests submitted?	21 CFR 1.245

Hazard Analysis and Risk-Based Preventive Controls Checklist

Hazard Analysis and Risk-Based Preventive Controls Part 1 – 21 CFR 117.180(c)(1)

Preventive Controls Qualified Individual		Yes	No	N/A	Documents
1.1	Identify a preventive controls qualified individual with food safety training and/or education.				
<p><i>Hint: A preventive controls qualified individual has job experience in the development and application of a food safety system or has successfully finished training in the development and application of risk-based preventive controls at least equivalent to the standardized curriculum recognized as adequate by FDA. Currently, the standardized curriculum recognized as adequate by FDA is that offered by the Food Safety Preventive Controls Alliance. The preventive controls qualified individual does not have to be an employee of the company.</i></p>					

Figure 7. Hazard Analysis and Risk-Based Preventive Controls for Human Food Checklist

1.2	Documentation of training of the preventive controls qualified individual.				
	Hint: Records of training completed by preventive controls qualified individuals should include the date, type of training, the people trained, if applicable.				
1.3	You may wish to establish a food safety team.				
	Hint: A multifaceted team with a variety of expertise that can contribute to food safety risk assessment. This can help bring expertise from various areas of operation as well as provide a well-informed group to help develop and implement the food safety plan.				
<p>Comments: A preventive controls qualified individual must do or oversee: the preparation of the food safety plan, validation of the preventive controls, review of records, reanalysis of the food safety plan, and if necessary, the determination that validation is not required.</p> <p>Definitions (21 CFR 117.3): Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of 21 CFR 117. FDA means the Food and Drug Administration. Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis. Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment. Preventive controls qualified individual (PCQI) means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system. Significantly minimize means to reduce to an acceptable level, including to eliminate. Validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.</p>					

Figure 7 (continued).

Hazard Analysis and Risk-Based Preventive Controls Part 2 – 21 CFR 117.126

Contents of a Food Safety Plan Overview		Yes	No	N/A	Documents
2.1	Food Safety Plan includes a hazard analysis.				
	Hint: Identify and evaluate all known or foreseeable hazards for each food manufactured, processed, packed, or held at the facility.				
2.2	Food Safety Plan must include preventive controls if the hazard analysis concludes there is/are a hazard(s) requiring preventive controls.				
	Hint: Identify and implement preventive controls to provide assurance that hazards requiring a preventive control appropriate to the food being processed would be significantly minimized or prevented. The food safety plan may also include documentation as to why a critical control point is not a preventive control.				
2.3	Food Safety Plan may include supply-chain program.				
	Hint: Establish a program to accept or reject raw materials and other ingredients for which hazard(s) requiring a preventive control have been identified before they enter the facility. Written procedures should describe how each item is received and/or rejected. They should also describe how supplier verification activities are conducted for each supplier, including temporary and replacement suppliers. Replacement and temporary suppliers should have the same acceptance criteria as regular suppliers.				
2.4	Food Safety Plan must include a recall plan if a preventive control is identified.				
	Hint: Written protocol that describes steps to be taken during a recall.				
2.5	Food Safety Plan must include monitoring procedures when appropriate to the preventive control.				
	Hint: Establish written procedures that ensure preventive controls are consistently performed as written in the food safety plan.				
2.6	Food Safety Plan includes corrective action procedures if a preventive control is identified.				
	Hint: Written procedures to be taken if preventive controls are not properly implemented to correct the issue.				
2.7	Food Safety Plan includes written validation and verification procedures if a preventive control is identified.				
	Hint: See the FDA definition of validation below. Validation is required for process preventive controls. Validation documentation explains how the established preventive controls are scientifically and technically acceptable for the control of a hazard requiring a preventive control. Verification includes the application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.				

Figure 7 (continued).

2.8	Food Safety Plan must include record keeping.				
<p>Hint: If a preventive control is identified then records for implementation must be kept on the monitoring, corrective actions, verification of validation, reanalysis, and record review procedures of the preventive control. Records that may need to be included (depending on food safety plan) are supply-chain, the reasoning for not establishing a preventive control, calibration, and environmental monitoring. Records must be kept for the training of preventive control qualified individual and qualified individuals.</p> <p>Comments: The food safety plan is the backbone for the application and documentation of Hazard Analysis and Risk Based Preventive Controls in the plant. The preventive controls qualified individual must do or oversee preparation of the food safety plan. Remember the plan is dynamic. As your facility goes through everyday operations, the optimization of processes, and additional products, check your plan to see what may need to be updated. This link gives you access to a variety of resources that may be beneficial throughout this checklist: https://www.ifsh.iit.edu/fspca/resources/resources-chapter-preventive-controls-human-food.</p> <p>Definitions (21 CFR 117.3): Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of 21 CFR part 117. Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients. Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury. Hazard requiring a preventive control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system. Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food. Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended. Plant means the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.</p>					

Figure 7 (continued).

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Preventive controls qualified individual means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Supply-chain-applied control means a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.

Validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Hazard Analysis and Risk-Based Preventive Controls Part 3 – 21 CFR 117.130

Hazard Analysis		Yes	No	N/A	Documents
3.1	Documented assessment of biological, chemical, radiological, and physical hazards to determine whether any hazards require a preventive control.				
	Hint: Biological hazards include undesirable bacteria, fungi, parasites, and other pathogens. Chemical hazards include pesticide and drug residues, toxins, unapproved food or color additives, food allergens, and radiological hazards. Physical hazards include stones, glass, metal fragments, and other undesirable or unsafe physical objects in a food.				
3.2	Describe hazards known or reasonably likely to occur in the food being processed in the facility in the hazard analysis.				
	Hint: These include natural, unintentionally introduced, or intentionally introduced hazards. This is based on experience, illness data, scientific reports, and other information about food safety.				
3.3	Written evaluation of hazards (likelihood that the hazard will occur in the absence of control(s) and the severity of illness/injury caused by the hazard).				
	Hint: This evaluation must include an evaluation of environmental pathogens whenever a ready-to-eat food, such as cut fruit, is exposed to the environment prior to packaging and the packaged food does not receive a treatment or other control measure to minimize the pathogen.				

Figure 7 (continued).

3.4	The hazard evaluation must consider the safety of the finished food for the intended consumer.				
<p>Hint: Areas to focus on include but are not limited to: the formulation of the food, the condition/function/design of the facility and equipment, raw materials and other ingredients, transportation practices, manufacturing/processing procedures, packaging activities and labeling activities, storage and distribution, intended or reasonably foreseeable use (including age and health of intended consumer), sanitation of the facility, employee hygiene, and seasonal hazards.</p>					
3.5	Document hazard evaluations of formulations, manufacturing and processing procedures, packaging activities and labeling activities, and sanitation procedures of the finished food.				
<p>Hint: Determine if there are any biological, chemical, radiological, and physical hazards in the production of the food that can cause injury or illness to humans and animals.</p>					
3.6	Written hazard evaluation of the condition, function, and design of the facility and equipment.				
<p>Hint: Ensuring the production facility does not introduce, transfer, or promote (growth or survival of) hazards requiring a preventive control into the production of the food.</p>					
3.7	Written hazard evaluation of raw materials and other ingredients, transportation practices, storage and distribution, and the intended and foreseeable use of the product.				
<p>Hint: Minimizing the risks and effects of contamination of the product outside of facility. Also, understanding how the product will be used and how it can affect at-risk consumers. Describe how raw, rework, and finished items are kept separate and identified.</p>					
<p>Comments: The hazard analysis is about identifying all the points, from entering the processing facility to the end consumer, where a hazard requiring a preventive control is likely to occur. A hazard analysis should be conducted for each different process and product your facility has. However, if you have two products that have the same process, unless there are different health concerns, they can be grouped together.</p> <p>Definitions (21 CFR 117.3): Environmental pathogen means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens for the purposes of this part include <i>Listeria monocytogenes</i> and <i>Salmonella</i> spp. but do not include the spores of pathogenic spore-forming bacteria. Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of 21 CFR 117.</p>					

Figure 7 (continued).

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

Hazard requiring a preventive control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

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

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Figure 7 (continued).

Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Packing means placing food into a container other than packaging the food and also includes repacking

and activities performed incidental to packing or repacking a food (e.g., activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen means a microorganism of public health significance.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Hazard Analysis and Risk-Based Preventive Controls Part 4 – 21 CFR 117.135

Preventive Controls for Hazards		Yes	No	N/A	Documents
4.1	Identify and implement preventive controls for hazards requiring a preventive control to significantly minimize or prevent illness, injury, or death to a consumer of the food. Preventive controls are required for hazards at critical control points and other points that minimize or prevent these risks.				
Hint: The hazards requiring a preventive control were identified in Part 3 of this checklist. Preventive controls include any process controls, food allergen controls, sanitation controls, supply-chain-applied controls, the recall plan, certain Good Manufacturing Practice, and any other controls appropriate for food safety.					

Figure 7 (continued).

4.2	Process controls include procedures, practices, and processes to ensure the control of parameters during operations.				
<p>Hint: Process controls may include heat, acidification, irradiation, and refrigeration. Minimum and maximum values of parameters must be determined and must be based on scientific and technical evidence.</p>					
4.3	Food allergen controls include procedures, practices, and processes to control food allergens.				
<p>Hint: These controls must include preventing allergen cross-contact through processing, storage, handling, and use, as appropriate, as well as proper labeling of potential allergens in finished products.</p>					
4.4	Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition to significantly minimize or prevent hazards.				
<p>Hint: Sanitation controls help prevent hazards requiring preventive controls due to employee handling, food allergens, and environmental pathogens. These controls include proper cleaning of food-contact surfaces, utensils, and equipment as well as preventing any cross contamination from personnel, packaging, or other surfaces to food and raw product to finished product.</p>					
<p>Comments: Be sure to think past microbiological concerns and also think about physical and chemical hazards. Allergen control is a large focus of FSMA. To control hazards, think about process, allergen, and sanitation controls.</p> <p>Definitions (21 CFR 117.3): <i>Acid foods/acidified foods/acidification</i> means foods that have an equilibrium pH of 4.6 or below. <i>Allergen cross-contact/contamination</i> means the unintentional incorporation of a food allergen into a food. <i>Food allergen</i> means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act. <i>Critical control point</i> means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level. <i>Environmental pathogen</i> means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens for the purposes of this part include <i>Listeria monocytogenes</i> and <i>Salmonella</i> spp. but do not include the spores of pathogenic spore-forming bacteria.</p>					

Figure 7 (continued).

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of 21 CFR 117.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. “Food-contact surfaces” includes utensils and food-contact surfaces of equipment.

Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

Hazard requiring a preventive control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

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

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.

Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Packing means placing food into a container other than packaging the food and also includes repacking

and activities performed incidental to packing or repacking a food (e.g., activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Figure 7 (continued).

Pathogen means a microorganism of public health significance.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Receiving facility means a facility that is subject to subparts C and G of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Supplier means the establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.

Supply-chain-applied control means a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.

Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Hazard Analysis and Risk-Based Preventive Controls Part 5 – 21 CFR 117.136

When Preventive Controls Are Not Required		Yes	No	N/A	Documents
5.1	When selling a food that could not be consumed without application of a control.				
	Hint: These are foods, such as milled grains and seeds for oil, which have a required control step to create a final product. Must document why preventive controls are not required for the particular hazard in the food.				
5.2	You rely on your customer to provide assurance it is manufacturing, processing, or preparing food in accordance with food safety requirements.				
	Hint: You must disclose in documents accompanying the food that the food is “not processed to control [the identified hazard]”. You must annually obtain written assurance from the customer that the customer is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements. If the customer is subject to requirements for hazard analysis and risk-based preventive controls, you must obtain written assurance that the customer has established and is following procedures that will significantly minimize or prevent the identified hazard. The customer also needs to provide proof through records that the controls are in place.				

Figure 7 (continued).

5.3	You rely on your customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain after the customer.				
<p>Hint: You must disclose in documents accompanying the food that the food is “not processed to control [the identified hazard]”. You must annually obtain from your customer written assurance that your customer will disclose in documents accompanying the food that the food is “not processed to control [the identified hazard]” and will only sell to another entity that prepares the food in accordance with applicable food safety requirements or, if the entity is subject to the requirements for hazard analysis and risk-based preventive controls, will follow procedures, identified in a written assurance, that will significantly minimize or prevent the hazard, or the entity will obtain written assurance from the entity’s customer as described above.</p>					
<p>Comments: Communication between suppliers and customers is crucial when claiming a preventive control is not required. Extensive written documentation and proof is necessary.</p> <p>Definitions (21 CFR 117.3): <i>Food</i> means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients. <i>Hazard</i> means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury. <i>Preventive controls</i> means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis. <i>Significantly minimize</i> means to reduce to an acceptable level, including to eliminate. <i>Supplier</i> means the establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a <i>de minimis</i> nature. <i>You</i> means, for purposes of this part, the owner, operator, or agent in charge of a facility.</p>					

Figure 7 (continued).

Hazard Analysis and Risk-Based Preventive Controls Part 6 – 21 CFR 117.139

Recall Plan		Yes	No	N/A	Documents
6.1	Step by step written protocol detailing how a recall will take place.				
	Hint: This should include who should have access to the plan, who needs to know how to execute it, all the contacts and responsibilities, different levels of recall, how contaminated product is isolated from safe product, and how to address recalls initiated by suppliers.				
6.2	Written procedure with steps to directly notify the direct consignees and the public of the food being recalled.				
	Hint: Process to follow when customers need to be notified of hazards requiring a preventive control in the food and how to return or dispose of the food.				
6.3	Written procedure with steps to conduct effectiveness checks verifying the recall has been carried out.				
	Hint: Process to follow to verify recall has been carried out fully.				
6.4	Written procedure on how to properly dispose of recalled food.				
	Hint: Process to follow when disposal of food is needed through reprocessing, reworking, using the food in a way that does not present a safety concern, or simply destroying the food.				
<p>Comments: These procedures should be well documented and understood to be effectively executed when needed. Mock recalls can help practice these situations. Review the steps taken during a mock recall and adjust the plan accordingly. When making phone calls to other companies for mock recalls, ensure to emphasize that it is a mock recall or give the practice recall a different name. Using the term recall can cause other companies to go into panic mode even though it is only a practice recall.</p> <p>Definitions (21 CFR 117.3): Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients. Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury. Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.</p>					

Figure 7 (continued).

Hazard Analysis and Risk-Based Preventive Controls Part 7 – 21 CFR 117.145

Monitoring		Yes	No	N/A	Documents
7.1	Written procedures must be established and implemented including the frequency with which they are to be performed if a preventive control is identified in the food safety plan.				
	Hint: The protocol should include a description of the products and hazards, what specifications are checked, how it is monitored, when and how often it is checked, and records of monitoring results.				
7.2	Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.				
	Hint: How frequently are thorough checks being performed?				
7.3	Records documenting the monitoring of preventive controls to verify the written procedures.				
	Hint: Check the monitoring documentation. Who is monitoring? Who is checking monitoring? How is the check of monitoring being completed?				
<p>Comments: Monitoring is a check to ensure the processing of the food is going as expected. Corrective actions (Part 9) are taken when monitoring procedures uncover an issue with the food.</p> <p>Definitions (21 CFR 117.3): <i>Adequate</i> means that which is needed to accomplish the intended purpose in keeping with good public health practice. <i>Manufacturing/processing</i> means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding. <i>Mixed-type facility</i> means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered. <i>Monitor</i> means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.</p>					

Figure 7 (continued).

Packing means placing food into a container other than packaging the food and also includes repacking and activities performed incidental to packing or repacking a food (e.g., activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Hazard Analysis and Risk-Based Preventive Controls Part 8 – 21 CFR 117.150

Corrective Actions and Corrections		Yes	No	N/A	Documents
8.1	After identifying preventive controls, describe and document the procedures in place to correct a food safety issue.				
	Hint: Should address the appropriate actions to take when hazards requiring preventive controls are detected in food.				
8.2	If an unanticipated food safety problem occurs, identify and correct the problem, evaluate all food for safety, and ensure any distributed food does not enter commerce.				
	Hint: Equipment breaks, employees make errors, and accidents happen. Identify when the problem occurred and isolate all food produced after that point. Evaluate the food to determine if it is safe for distribution and consumption. Determine whether the unanticipated problem may reoccur in the future and adjust the food safety plan accordingly, if necessary. Be sure to address how to reduce the likelihood of reoccurrence of the problem.				

Figure 7 (continued).

8.3	Corrections are actions taken to correct a minor and isolated problem that does not directly impact product safety.				
Hint: Take note of these incidents. Minor incidents may affect product quality or cost money but are not required to be documented in records if food safety is not affected.					
8.4	Continuously monitor and update food safety plans as needed.				
Hint: If corrective actions are taken, you must identify the root cause of the problem to prevent reoccurrence.					
<p>Comments: Corrective actions can minimize waste and prevent recalls. Corrective actions must be taken in situations where a preventive control failed or was not implemented. When food safety is compromised, take corrective actions. Corrections address less serious issues that are not food safety issues but may affect product quality. Corrections do not have to be documented but they should be to prevent reoccurrence.</p> <p>Definitions (21 CFR 117.3): Correction means an action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce). Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients. Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury. Hazard requiring a preventive control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system. Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended. Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis. Significantly minimize means to reduce to an acceptable level, including to eliminate.</p>					

Figure 7 (continued).

Hazard Analysis and Risk-Based Preventive Controls Part 9 – 21 CFR 117.155, 165

Verification		Yes	No	N/A	Documents
9.1	Verify implementation of food safety plan. <i>Hint: Check records of verification, monitoring, and corrective actions to ensure they are implemented as written in the food safety plan. Review testing procedures identified in the food safety plan.</i>				
9.2	Check calibration and accuracy of monitoring and verification instruments <i>Hint: A third-party group may be used to check instruments to ensure correct calibration.</i>				
9.3	Record all verification processes and/or activities. <i>Hint: You must have written procedures for the method and frequency of calibrating process monitoring instruments and verification instruments (or checking them for accuracy), product testing, and environmental monitoring.</i>				
<p>Comments: Verification procedures are necessary to ensure that the preventive controls are consistently implemented and effectively controlling the identified hazards. A preventive controls qualified individual must perform or oversee verification activities. Remember, verification happens routinely. Verification is done to ensure both that the preventive control(s) are implemented according to plan, and that the preventive control(s) that are implemented according to plan are effectively controlling the hazards. It is a process to provide evidence that the food safety plan is working as planned. Examples of verification are equipment calibrations, environmental monitoring, label review for allergens, and other sampling and testing. Verification of records is important because these are the documents that will be audited.</p> <p>Definitions (21 CFR 117.3): <i>Monitor</i> means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended. <i>Validation</i> means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards. <i>Verification</i> means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.</p>					

Figure 7 (continued).

Hazard Analysis and Risk-Based Preventive Controls Part 10 – 21 CFR 117.160

Validation		Yes	No	N/A	Documents
10.1	A preventive controls qualified individual must validate or oversee validation of preventive controls to ensure the hazards requiring preventive controls will be controlled as expected.				
	Hint: The person from 1.2 of this checklist must personally conduct validation or ensure that it is done. Validation is not required for sanitation, allergen, and supply-chain preventive controls, or the recall plan.				
10.2	Must revalidate when there is a change in control measures that could affect the hazard.				
	Hint: Whenever there is a change in process, revalidate.				
10.3	Must have scientific evidence to show control of hazards.				
	Hint: Find peer reviewed literature to support your process or perform your own validation studies. Utilize search engines, such as Google Scholar, to find papers that must reference your specific product, specifications, and process. If conducting your own study, three strains of the pathogen of concern should be used. One of those strains must be isolated from an outbreak. When preparing the product for the trial, include customer preparation deviations to add a safety buffer to your process.				
<p>Comments: Validation is the evidence for the efficacy of a particular process. Ask yourself “can the plan, when implemented, actually control the identified hazards?” Validation demonstrates that following the plan will actually control the identified hazards. It should be done before the implementation of the food safety plan. This link has draft guidance for some validation of controls: https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM517399.pdf.</p> <p>Definitions (21 CFR 117.3): <i>Hazard</i> means any biological, chemical, radiological, or physical agent that has the potential to cause illness or injury. <i>Hazard requiring a preventive control</i> means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system. <i>Pathogen</i> means a microorganism of public health significance.</p>					

Figure 7 (continued).

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Preventive controls qualified individual means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Supply-chain-applied control means a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.

Validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

Hazard Analysis and Risk-Based Preventive Controls Part 11 – 21 CFR 117.170

Reanalysis		Yes	No	N/A	Documents
11.1	Must occur minimally every 3 years.				
11.2	Must occur whenever there is a change in processes, hazards requiring a preventive control, information, or whenever FDA determines it is necessary to respond to new hazards and developments in scientific understanding that may change safety concerns about a product.				
Hint: When something changes that could impact food safety, reanalyze food safety plan.					
11.3	Must be completed by a preventive controls qualified individual.				
Hint: Individual from 1.2 of this checklist.					
<p>Comments: Keep records of each reanalysis. The food safety plan is dynamic and must be reanalyzed to ensure it is current with your processes and general food safety information.</p> <p>Definitions (21 CFR 117.3): FDA means the Food and Drug Administration. Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.</p>					

Figure 7 (continued).

Hazard requiring a preventive control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Preventive controls qualified individual means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Hazard Analysis and Risk-Based Preventive Controls Part 12 – 21 CFR 117.190

Records Required		Yes	No	N/A	Documents
12.1	Required for documentation of the food safety plan. Hint: Based on section 2 of this checklist.				
12.2	Required for documentation of hazard analysis. Hint: Based on section 3 of this checklist.				
12.3	Required for documentation of any established preventive controls. Hint: Based on section 4 of this checklist.				
12.4	Required for documentation for not establishing a preventive control. Hint: Based on section 5 of this checklist.				
12.5	Required for documentation of a recall plan. Hint: Based on section 6 of this checklist.				
12.6	Required for documentation of monitoring preventive controls and corrective actions. Hint: Based on sections 7 and 8 of this checklist.				

Figure 7 (continued).

12.7	Required for documentation of verification procedures.				
Hint: Include verification for validation, monitoring, corrective actions, calibration, product testing, environmental monitoring, reanalysis, and record review.					
12.8	Required for documentation of supply-chain program and employee training.				
Hint: Based on General Provisions, Good Manufacturing Practice, and Supply-Chain Program, 21 CFR 117 Subparts A, B and G.					
<p>Comments: Record and document everything in processing listed in this checklist. If in doubt, document. Required records include the hazard analysis, any identified preventive controls, supply-chain requirements, the recall plan, monitoring procedures, corrective action procedures, verification procedures, and employee training.</p> <p>Definitions (21 CFR 117.3): Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.</p> <p>Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.</p> <p>Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.</p> <p>Packing means placing food into a container other than packaging the food and also includes repacking and activities performed incidental to packing or repacking a food (e.g., activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.</p> <p>Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.</p>					

Figure 7 (continued).

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Figure 7 (continued).

Current Good Manufacturing Practice Checklist

Current Good Manufacturing Practice Part 1 – 21 CFR 117.4

Note: CGMP provisions do not require records or written procedures, although establishments are certainly encouraged to have written procedures as necessary

Qualified Individual		Yes	No	N/A	Documents
1.1	All individuals involved in manufacturing, processing, packing, or holding food must be trained as qualified individuals.				
	Hint: Each employee (qualified individual) must receive training in the principles of food hygiene and food safety that is appropriate to the food, facility, and the individual's assigned duties.				
1.2	Documentation of appropriate training of qualified individuals as appropriate for the job.				
	Hint: Training should be specific to the food safety and hygiene requirements of the job. Records of training completed by qualified individuals should include the date, type of training, and the people trained (21 CFR 117.4(d)).				
Comments:					
All employees engaged in the manufacturing, processing, packing, or holding of human food must be qualified individuals and have food hygiene and food safety training as appropriate to each individual's role in the facility.					

Figure 8. Current Good Manufacturing Practice Checklist

Definitions (21 CFR 117.3):

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of 21 CFR 117.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

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

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Packing means placing food into a container other than packaging the food and also includes repacking and activities performed incidental to packing or repacking a food (*e.g.*, activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

Figure 8 (continued).

Current Good Manufacturing Practice Part 2 – 21 CFR 117.10

Note: CGMP provisions do not require records or written procedures, although establishments are certainly encouraged to have written procedures as necessary

Personnel		Yes	No	N/A	Documents
2.1	Training of all employees of the risks of unhygienic practices and appropriate hygienic practices to prevent contamination of food.				
	Hint: Written standard operating procedures for handwashing and when to wash hands. Planned training for employees on handwashing that is documented.				
2.2	Employees must report any health conditions to their supervisors including illness, open lesions, and any other sources of possible contamination.				
	Hint: Written policy on reporting health conditions explaining that employees will be sent home if signs are shown.				
2.3	Written dress code policy for all personnel is enforced.				
	Hint: All personal belongings including jewelry should be stored in a designated area away from possibly becoming a source of contamination.				
2.4	Written policy on personal protective attire is enforced.				
	Hint: Employees are trained on the outer garments like gloves, hair nets, and aprons that are needed.				
2.5	Written policy on food and tobacco use is enforced.				
	Hint: No eating, drinking, or use of tobacco, including electronic cigarettes and vaporizers, in the food production areas. Designated areas are available for eating, drinking, and tobacco use.				
2.6	Training for all employees on proper food handling, food protection principles, and standard working conditions.				
	Hint: Written standard operating procedures for proper food handling and food protection. Ensure employees are able to identify when processing is going correctly and when it is not. Training in food safety and food hygiene requires documentation.				
2.7	Designate personnel to identify and document when plant sanitation fails to meet expectations and when food contamination occurs.				
	Hint: Document failures and contamination. Have written procedures to deal with repeat offenders of poor sanitation practices.				

Figure 8 (continued).

Comments:

Personnel who understand how and why to do something is a very important component in ensuring a thorough job is done. Standard operating procedures and trainings should be written in plain language to assist with the understanding of the material. Designate personnel to ensure the facility and personnel meet all the above requirements. Be sure to keep records of all training.

Definitions (21 CFR 117.3):

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of 21 CFR 117.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Plant means the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Current Good Manufacturing Practice Part 3 – 21 CFR 117.20

Note: CGMP provisions do not require records or written procedures, although establishments are certainly encouraged to have written procedures as necessary

Plant and Grounds		Yes	No	N/A	Documents
3.1	Within the immediate vicinity of the plant, removal of litter, waste, weeds and grass occurs regularly.				
	<i>Hint: Regular checking of the grounds, including roads and parking lots, surrounding the facility to ensure the plant doesn't attract or harbor pests.</i>				
3.2	Store all unused and broken equipment in the proper area.				
	<i>Hint: When equipment does not work, isolate it from working equipment to prevent confusion and clutter. Regularly dispose of unused and broken equipment.</i>				
3.3	Areas around and within the facility are well-drained.				
	<i>Hint: Drains are checked and cleared to allow proper drainage to prevent pest infestation.</i>				
3.4	The grounds, buildings, fixtures and other biological hazard areas are regularly maintained and repaired.				
	<i>Hint: Broken items are fixed or removed in a timely manner.</i>				
3.5	The plant must be suitable in size, construction, and design to allow for sanitation and maintenance.				
	<i>Hint: Plant gives adequate space for equipment, bulk storage, and ingredients while still being able to clean.</i>				

Figure 8 (continued).

3.6	Have a written and validated plan to control allergen cross contact.				
	<i>Hint: Separate allergens from non-allergenic productions by using a different processing location, time between runs to clean and sanitize equipment, air and dust flow, etc.</i>				
3.7	Plant design allows for separation of production by location, time, or other means reducing cross contamination.				
	<i>Hint: Keep production areas separate from storage and shipping areas.</i>				
3.8	Proper lighting throughout the facility that is protected to prevent product contamination.				
	<i>Hint: All fixtures should have shatter resistant light bulbs or non-breakable covers.</i>				
3.9	Dust and vapors are controlled through adequate ventilation.				
	<i>Hint: This helps to prevent allergen and microbial contamination.</i>				
<p>Comments: The grounds surrounding a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. Be certain your plant and its surrounding environment are not sources of contamination for the food you are producing.</p> <p>Definitions (21 CFR 117.3): <i>Adequate</i> means that which is needed to accomplish the intended purpose in keeping with good public health practice. <i>Allergen cross-contact/contamination</i> means the unintentional incorporation of a food allergen into a food. <i>Facility</i> means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of 21 CFR 117. <i>Food allergen</i> means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act. <i>Hazard</i> means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury. <i>Holding</i> means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.</p>					

Figure 8 (continued).

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Packing means placing food into a container other than packaging the food and also includes repacking and activities performed incidental to packing or repacking a food (*e.g.*, activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant means the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Figure 8 (continued).

Current Good Manufacturing Practice Part 4 – 21 CFR 117.35

Note: CGMP provisions do not require records or written procedures, although establishments are certainly encouraged to have written procedures as necessary

Sanitary Operations		Yes	No	N/A	Documents
4.1	Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated.				
	<i>Hint: Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.</i>				
4.2	All cleaning compounds and sanitizing agents are free from microorganisms and must be safe and adequate under the condition of use.				
	<i>Hint: Certification of chemicals or supplier guarantee of safety.</i>				
4.3	Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be held and stored to protect against contamination of food, food-contact surfaces, and food-packaging.				
	<i>Hint: Designated location away from the food production areas for all chemicals with documentation of the chemicals in the designated location. Be sure to keep track of material safety data sheets.</i>				
4.4	Only toxic materials that are relevant to the food being processed may be stored or used in the plant.				
	<i>Hint: Only materials required for cleaning, sanitation, maintenance, and laboratory testing may be in the plant.</i>				
4.5	Effective pest control program should be established. Guard dogs may be allowed in some areas of a plant if they are unlikely to result in food contamination. Use pesticides only in ways that will protect against the contamination of food, food-contact surfaces, or food-packaging materials.				
	<i>Hint: Pest management system that documents the presence and prevention methods to exclude pests. If using pesticides, ensure they are used in a manner to prevent contamination. Limit the areas a guard dog is allowed within the plant to ensure no contamination occurs.</i>				

Figure 8 (continued).

4.6	All equipment including food contact surfaces, utensils, and non-food contact surfaces are cleaned on a scheduled basis. All equipment should be stored in a manner that prevents contamination.				
<i>Hint: Documentation of cleaning that occurs on a regular basis is not required but may be beneficial. Be sure to regularly check for cleaning residues and have a written protocol to account for improperly cleaned equipment.</i>					
4.7	Single-serve articles must be stored, handled, and disposed of in a manner that protects against allergen cross-contamination and contamination of food, food-contact surfaces, and food-packaging.				
<i>Hint: Designated storage areas for these areas and written standard operating procedure for use.</i>					
<p>Comments: Sanitation is one of the first and most focused on parts of a food safety inspection. Many plant issues, such as recalls and failed inspections, can be attributed to poor sanitation and pest management. This is the first area to focus on with standard procedures and follow-up verification.</p> <p>Definitions (21 CFR 117.3): <i>Adequate</i> means that which is needed to accomplish the intended purpose in keeping with good public health practice. <i>Allergen cross-contact/contamination</i> means the unintentional incorporation of a food allergen into a food. <i>Facility</i> means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of 21 CFR 117. <i>Food</i> means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients. <i>Food allergen</i> means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act. <i>Food-contact surfaces</i> are those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. “Food-contact surfaces” includes utensils and food-contact surfaces of equipment. <i>Microorganisms</i> mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and include species that are pathogens. The term “undesirable microorganisms” includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated. <i>Monitor</i> means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended. <i>Pathogen</i> means a microorganism of public health significance. <i>Pest</i> refers to any objectionable animals or insects including birds, rodents, flies, and larvae.</p>					

Figure 8 (continued).

Plant means the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Supplier means the establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.

Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Current Good Manufacturing Practice Part 5 – 21 CFR 117.37

Note: CGMP provisions do not require records or written procedures, although establishments are certainly encouraged to have written procedures as necessary

Sanitary Facilities and Controls		Yes	No	N/A	Documents
5.1	The water supply must be adequate for operations intended and must be derived from an adequate source. Any water, steam, or ice that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature and, under pressure as needed, must be provided in all areas of processing, cleaning, packaging, and employee sanitation.				
	Hint: All water coming into the plant needs to be as sanitary as necessary for the intended use.				
5.2	Plumbing must be of adequate size and design, be able to carry adequate quantities of water, remove waste, not become a source of contamination of food or water, be adequately drained from the floor, and not allow backflow or cross-connection from wastewater and sewage.				
	Hint: Plumbing must be able to provide adequate quantities of safe water and drain adequate quantities of wastewater and sewage.				
5.3	Sewage treatment systems and septic systems are free of leaks and are functioning properly.				
	Hint: Regularly inspect sewage treatment and septic systems.				

Figure 8 (continued).

5.4	Toilets and handwashing stations must be readily accessible, clean, and not a source of contamination.				
Hint: There must be clean toilets and handwashing stations of a suitable temperature throughout the plant.					
5.5	Rubbish and offal should be labelled. It must be stored and disposed of to minimize the development of odor, the potential to be an attractant for pests, and to not allow contamination of food, water, or surfaces throughout the plant.				
Hint: Waste must be removed regularly and in a way that minimizes cross-contamination.					
<p>Comments: Each plant must be equipped with adequate sanitary facilities and accommodations.</p> <p>Definitions (21 CFR 117.3): <i>Adequate</i> means that which is needed to accomplish the intended purpose in keeping with good public health practice. <i>Food</i> means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients. <i>Food-contact surfaces</i> are those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. “Food-contact surfaces” includes utensils and food-contact surfaces of equipment. <i>Manufacturing/processing</i> means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding. <i>Mixed-type facility</i> means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered. <i>Packing</i> means placing food into a container other than packaging the food and also includes repacking and activities performed incidental to packing or repacking a food (e.g., activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.</p>					

Figure 8 (continued).

Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant means the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Current Good Manufacturing Practice Part 6 – 21 CFR 117.40

Note: CGMP provisions do not require records or written procedures, although establishments are certainly encouraged to have written procedures as necessary

Equipment and Utensils		Yes	No	N/A	Documents
6.1	All equipment used in the plant must be designed to be readily cleanable and maintained to prevent allergen cross-contact.				
	Hint: Everything must be able to be thoroughly cleaned and also must be cleaned regularly.				
6.2	Equipment must be designed and maintained to avoid the adulteration of food.				
	Hint: Equipment cannot allow lubricants, fuel, metal fragments, contaminated water, etc. into food. Equipment should be constructed from metal detectable parts.				
6.3	Food contact surfaces must be made of nontoxic materials and must withstand the environment and foods they are used with.				
	Hint: Food contact surfaces must be able to withstand heat, corrosion, and other processing conditions.				
6.4	Seams on food contact surfaces must be smoothly bonded or maintained to minimize the accumulation of food, dirt, and organic matter.				
	Hint: This helps prevent microorganism establishment and growth and minimize allergen cross-contact.				
6.5	All equipment in a food processing area must be kept clean and sanitary.				
	Hint: This includes non-food contact surfaces, hoses, brooms, etc.				
6.6	Any cold storage area must have a thermometer that records accurate temperatures, and temperature must be recorded routinely throughout the day.				
	Hint: The thermometer must be able to accurately display temperatures so that it is obvious when temperatures have not been properly maintained.				

Figure 8 (continued).

6.7	Devices used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise, maintained, and regularly calibrated.				
Hint: Such devices include thermometers, pH meters, water activity meters, etc.					
6.8	Any gases introduced into a food or used to clean food-contact surfaces must not be contaminated.				
Hint: Gases should be free of allergen and microbial contamination as well as physical and chemical hazards.					
<p>Comments: Clean equipment and processing areas frequently. Records may include records of dates and times of cleaning and notes about the condition of equipment being used. Cleanup after unusual situations (leaks, equipment breakdown) should be noted and explained. Notes regarding equipment that needs immediate repair or replacement should be made and the repair/replacement documented.</p> <p>Definitions (21 CFR 117.3): Allergen cross-contact/contamination means the unintentional incorporation of a food allergen into a food. Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients. Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act. Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. “Food-contact surfaces” includes utensils and food-contact surfaces of equipment. Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury. Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding. Microorganisms mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and include species that are pathogens. The term “undesirable microorganisms” includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.</p>					

Figure 8 (continued).

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Packing means placing food into a container other than packaging the food and also includes repacking

and activities performed incidental to packing or repacking a food (*e.g.*, activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen means a microorganism of public health significance.

Plant means the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Water activity (aw) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Current Good Manufacturing Practice Part 7 – 21 CFR 117.80

Note: CGMP provisions do not require records or written procedures, although establishments are certainly encouraged to have written procedures as necessary

Processes and Controls		Yes	No	N/A	Documents
7.1	All operations involving food must be conducted under adequate sanitation principles and must be supervised by one or more trained individuals assigned this duty.				
	Hint: This includes manufacturing, processing, packing, holding, receiving, inspecting, transporting, and segregating food.				

Figure 8 (continued).

7.2	The establishment must have appropriate quality control operations for all food to ensure it is safe for human consumption.				
	Hint: Quality control operations are crucial to confirm the product is safe.				
7.3	Overall plant sanitation should be supervised by one or more trained individuals.				
	Hint: All sanitation procedures should be written and documented. The individual is responsible for training employees in sanitation procedures and how to identify contamination issues.				
7.4	Ensuring all steps and precautions are taken to prevent allergen cross-contamination.				
	Hint: Be careful to make certain there is no allergen cross-contamination at any step of the process, from the supplier to the customer.				
7.5	Testing procedures must be in place to identify sanitation failures or possible contamination of product.				
	Hint: Use chemical, microbial, and other tests (such as a metal detector) to find any points of allergen or other food contamination.				
7.6	All food that is contaminated to the point of adulteration must be rejected, treated, or processed to eliminate the contamination.				
	Hint: If product was processed incorrectly and does not eliminate microbial contamination, it may be deemed appropriate to be reintroduced into the raw materials stream. It must be labelled as rework. Otherwise, when in doubt, throw it out.				
7.7	Raw materials must be inspected and handled to ensure suitability for processing into final product. Raw materials should be washed, cleaned, and stored appropriately to avoid contamination.				
	Hint: Raw ingredients must be inspected for safe levels of microorganisms, pests, and toxins (such as aflatoxin) and stored in a way that prevents future allergen or other food contamination.				
7.8	Raw materials must be held in containers designed to prevent allergen cross-contact and contamination.				
	Hint: Storage conditions, such as temperature, relative humidity, or a rework schedule, may be used to reduce risk for allergen cross-contact and contamination (21 CFR 117.80(b) (5)).				
7.9	Frozen raw materials and ingredients must be kept frozen.				
	Hint: If thawing is necessary, do so in a way that prevents adulteration of the food.				
7.10	Any materials that are food allergens must be labelled and handled in a way to prevent allergen cross-contact.				
	Hint: Label all boxes with allergens as allergen and be mindful of their travels through the facility.				

Figure 8 (continued).

7.11	All food manufacturing, processing, packing, and holding must be conducted under conditions and controls that minimize the potential for the growth of microorganisms, allergen cross-contact, food contamination, and food deterioration.				
	Hint: If a food requires temperature control for safety, temperature must be used to control that food.				
7.12	Work-in-progress, rework, and finished food must be protected at all times to prevent allergen cross-contact, contamination, and growth of undesirable microorganisms.				
	Hint: This applies to all steps in your process, from receiving to distribution.				
7.13	When measures are taken to destroy or prevent the growth of undesirable microorganisms, the measures must be adequate for the food to not become adulterated.				
	Hint: These measures include sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or water activity. There should be documented proof that the correct controls were applied.				
7.14	Heat blanching must heat the food to and hold at the required temperature, then cool or process the food immediately.				
	Hint: Growth of microorganisms in blanchers must be minimized by the use of proper operating temperatures and regular cleaning and sanitizing.				
7.15	Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time must be treated or maintained as to protect against allergen and other contaminants while minimizing the growth of undesirable microorganisms.				
	Hint: Be mindful of the use and storage of these products as they can also be important for food safety.				
7.16	Foods that rely on water activity control to prevent growth of undesirable microorganisms must be processed to and maintained at a safe-moisture level.				
	Hint: When making dry mixes, nuts, and other low moisture foods, ensure the correct water activity and moisture level is reached and maintained.				
7.17	Foods that rely on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below.				
	Hint: Acid and acidified foods must be kept below a pH of 4.6 at all times.				

Figure 8 (continued).

7.18	When ice is used in contact with food, it must be of safe and sanitary quality and must only be used if it has been manufactured in accordance with Current Good Manufacturing Practice as outlined in this part.				
Hint: Water and ice used in contact with food should always be treated like a food in relation to this checklist.					
<p>Comments: Every process in the plant should be done in a way that prevents biological, physical, and chemical contamination. Document all processes throughout production.</p> <p>Definitions (21 CFR 117.3): <i>Acid foods or acidified foods</i> mean foods that have an equilibrium pH of 4.6 or below. <i>Adequate</i> means that which is needed to accomplish the intended purpose in keeping with good public health practice. <i>Allergen cross-contact/contamination</i> means the unintentional incorporation of a food allergen into a food. <i>Batter</i> means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods. <i>Blanching</i>, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for an adequate time and at an adequate temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food. <i>Facility</i> means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of 21 CFR 117. <i>Food</i> means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients. <i>Food allergen</i> means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act. <i>Holding</i> means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.</p>					

Figure 8 (continued).

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and include species that are pathogens. The term “undesirable microorganisms” includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Packing means placing food into a container other than packaging the food and also includes repacking

and activities performed incidental to packing or repacking a food (*e.g.*, activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen means a microorganism of public health significance.

Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant means the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Figure 8 (continued).

Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

Safe-moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for a food is related to its water activity (aw). An aw will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given aw will not support the growth of undesirable microorganisms.

Sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Supplier means the establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.

Water activity (aw) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

Figure 8 (continued).

Current Good Manufacturing Practice Part 8 – 21 CFR 117.93, 21 CFR 1.908

Note: CGMP provisions do not require records or written procedures, although establishments are certainly encouraged to have written procedures as necessary

Warehousing and Distribution		Yes	No	N/A	Documents
8.1	Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical, and physical contamination of food, as well as against deterioration of the food and the container.				
	Hint: Food should be stored and labeled appropriately. Keep allergens separate; properly seal containers when not in use, store materials and products in refrigerated storage when necessary.				
8.2	Upon receipt of food that requires temperature control for safety under the conditions of shipment, the receiver must take steps to adequately assess that the food was not subjected to significant temperature abuse.				
	Hint: Methods of assessment include determining the food's temperature, the ambient temperature of the vehicle and its temperature setting, and conducting a sensory inspection, e.g., for off-odors.				
8.3	Stock rotation should be documented.				
	Hint: First in, first out.				
8.4	Finished product containers must be clearly labelled to identify contents and the presence of any allergens.				
	Hint: Someone with no knowledge of the container should be able to easily understand what ingredients and allergens are present.				
<p>Comments: It is important to keep warehouses and distribution centers clean to prevent contamination of final product.</p> <p>Definitions (21 CFR 117.3, 21 CFR 1.904): Allergen cross-contact/contamination means the unintentional incorporation of a food allergen into a food. Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act. Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.</p>					

Figure 8 (continued).

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Packing means placing food into a container other than packaging the food and also includes repacking

and activities performed incidental to packing or repacking a food (*e.g.*, activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Receiver means any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.

Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

Shipper means a person, *e.g.*, the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

Figure 8 (continued).

Current Good Manufacturing Practice Part 9 – 21 CFR 117.95

Note: CGMP provisions do not require records or written procedures, although establishments are certainly encouraged to have written procedures as necessary

Holding and distribution of human food by-products for use as animal food		Yes	No	N/A	Documents
9.1	Containers and equipment used to hold human food by-products for use as animal food must be designed, constructed, cleaned, and maintained to protect against the contamination of human food by-products for use as animal food.				
Hint: The equipment for human food by-products for use as animal food should be treated similarly to equipment used for human food.					
9.2	Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash.				
Hint: Keep human food by-products in safe and separate containers to prevent contamination.					
9.3	Human food by-products for use as animal food must be accurately identified.				
Hint: Properly label all human food by-products for use as animal food as such.					
9.4	Shipping containers and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against contamination of the by-products.				
Hint: Totes, drums, tubs, and vehicles etc. must be visually examined prior to use. Containers and vehicles should be labelled and properly cleaned to prevent contamination.					
<p>Comments: Human food by-products are parts of human foods or are foods generated during human food production that are not sold as human food commercially.</p>					

Figure 8 (continued).

Definitions (21 CFR 117.3):

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

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Current Good Manufacturing Practice Part 10 – 21 CFR 117.110

Note: CGMP provisions do not require records or written procedures, although establishments are certainly encouraged to have written procedures as necessary

Defect action levels		Yes	No	N/A	Documents
10.1	The manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level possible.				
	Hint: There are unavoidable defects with legal limits. If you exceed defect action levels, the food may be considered adulterated. Additionally, poor manufacturing practices may result in enforcement action without regard to the action level.				
10.2	Have written procedures for the handling of defective foods.				
	Hint: How will defective foods be disposed? What defects are in the food and can defective food be reworked?				
10.3	The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the food adulterated.				
	Hint: Do not mix food with defects above the legal limit with any other food. The final product is not permitted, regardless of the final level of defects.				

Figure 8 (continued).

Comments:

See the Defect Levels Handbook for examples, which is accessible at <http://www.fda.gov/pchfrule> and at <http://www.fda.gov>.

Definitions (21 CFR 117.3):

Defect action level means a level of a nonhazardous, naturally occurring, unavoidable defect at which FDA may regard a food product “adulterated” and subject to enforcement action under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act.

FDA means the Food and Drug Administration.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Lot means the food produced during a period of time and identified by an establishment's specific code.

Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

Figure 8 (continued).

Sanitary Transportation of Human and Animal Foods Rule Checklist

Sanitary Transportation Rule Part 1 – 21 CFR 1.900

Who is subject to the Sanitary Transportation rule?		Yes	No	N/A	Documents
1.1	The Sanitary Transportation rule applies to shippers, receivers, loaders, and carriers engaged in transportation operations.				
	<i>Hint: This rule applies whether or not the food your business sells is sold into interstate commerce.</i>				
1.2	The requirements of the Sanitary Transportation rule apply to those involved in transportation operations in addition to any other requirements involving food.				
	<i>Hint: These include 21 CFR parts 1, 117, 118, 225, 507, and 589.</i>				

Figure 9. Sanitary Transportation for Human and Animal Food Rule Checklist

1.3	The requirements of the Sanitary Transportation rule do not apply to shippers, receivers, loaders, or carriers when they are in transportation operations of food that is transshipped through the United States to another country.				
Hint: Food sent through the United States to another country (for example, transportation of food between Mexico and Canada) and is not sold in the United States is exempt from this rule.					
1.4	The requirements of the Sanitary Transportation rule do not apply to shippers, receivers, loaders, or carriers when they are in transportation operations of food that is imported for future export that is neither consumed nor distributed in the United States.				
Hint: This is in accordance with section 801(d)(3) of the Food, Drug, and Cosmetic Act. If your business imports food into the United States and exports it out of the United States without sales or distribution in the United States, the Sanitary Transportation rule does not apply to you.					
1.5	Any facilities that are regulated exclusively by the U.S. Department of Agriculture under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act are exempt from this rule.				
Hint: If the Food and Drug Administration comes to your facility, you must comply with this rule.					
<p>Comments: The shipper is the person/group who arranges the transport of food. This may be the manufacturer itself or a freight broker. A loader is the person who puts food onto the vehicle for transportation. A carrier is the person/group that transports the food. A receiver is the person/group who receives the shipped food.</p> <p>Definitions (21 CFR 1.904): Carrier means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service. Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of this chapter. Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients. Loader means a person that loads food onto a motor or rail vehicle during transportation operations. Receiver means any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food. Shipper means a person, e.g., the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.</p>					

Figure 9 (continued).

Transportation means any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

Transportation operations means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

Sanitary Transportation Rule Part 2 – 21 CFR 1.902

How does the information in the Sanitary Transportation rule apply under the Food, Drug, and Cosmetic Act?		Yes	No	N/A	Documents
2.1	The Sanitary Transportation rule applies in determining whether food is adulterated with the meaning of section 402(i) of the Food, Drug, and Cosmetic Act in that the food has been transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, loader, or receiver engaged in transportation operations under conditions that are not in compliance with this rule.				
Hint: This means food that was transported in conditions that are not acceptable by this rule is considered adulterated.					
2.2	The failure by a shipper, carrier by motor vehicle or rail vehicle, loader, or receiver engaged in transportation operations to comply with the requirements of this rule is a prohibited act under section 301(hh) of the Food, Drug, and Cosmetic Act.				
Hint: It is illegal to go against this rule if you are subject to it.					

Figure 9 (continued).

Comments:

Adulterated food cannot be sold or distributed. It is important to prevent adulteration within the plant as well as during transport and storage.

Definitions (21 CFR 1.904):

Carrier means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Loader means a person that loads food onto a motor or rail vehicle during transportation operations.

Receiver means any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.

Shipper means a person, *e.g.*, the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

Transportation means any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

Transportation operations means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

Vehicle means a land conveyance that is motorized, *e.g.*, a motor vehicle, or that moves on rails, *e.g.*, a railcar, which is used in transportation operations.

Sanitary Transportation Rule Part 3 – 21 CFR 1.906

Vehicles and transportation equipment		Yes	No	N/A	Documents
3.1	Vehicles and transportation equipment used in transportation operations must be so designed and of such material and workmanship as to be suitable and adequately cleanable for their intended use to prevent the food they transport from becoming unsafe during transportation operations.				
	Hint: Any vehicles used must be designed to transport food and prevent contamination of the product.				

Figure 9 (continued).

3.2	Vehicles and transportation equipment must be maintained in such a sanitary condition for their intended use as to prevent the food they transport from becoming unsafe during transportation operations.				
Hint: Any vehicles used must be cleaned and maintained to prevent food safety issues from occurring.					
3.3	Vehicles and transportation equipment used in transportation operations for food requiring temperature control for safety must be designed, maintained, and equipped as necessary to provide adequate temperature control to prevent the food from becoming unsafe during transportation operations.				
Hint: Vehicles and equipment used for transported refrigerated or frozen foods must be designed and maintained to have the correct and safe operating temperature in the vehicle.					
3.4	Vehicles and transportation equipment must be stored in a manner that prevents it from harboring pests or becoming contaminated in any other manner that could result in food for which it will be used becoming unsafe during transportation operations.				
Hint: Do not allow vehicles and transportation equipment to harbor pests or allow contamination of the food product during transport.					
<p>Comments: Vehicles and transportation equipment are required to be designed, maintained, operated, and stored in a way to prevent the adulteration of food.</p> <p>Definitions (21 CFR 1.904): Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients. Transportation means any movement of food in by motor vehicle or rail vehicle in commerce within the United States. Transportation equipment means equipment used in food transportation operations, <i>e.g.</i>, bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor.</p>					

Figure 9 (continued).

Transportation operations means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h) (6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

Vehicle means a land conveyance that is motorized, e.g., a motor vehicle, or that moves on rails, e.g., a railcar, which is used in transportation operations.

Sanitary Transportation Rule Part 4 – 21 CFR 1.908(a)

General requirements for transportation operations		Yes	No	N/A	Documents
4.1	Responsibility for ensuring that transportation operations are carried out in compliance with all sanitary transportation requirements must be assigned to competent supervisory personnel.				
	Hint: Someone who is knowledgeable about food safety concerns with transportation operations must be assigned the responsibility of compliance to this rule.				
4.2	All transportation operations must be conducted under such conditions and controls necessary to prevent the food from becoming unsafe during transportation operations.				
	Hint: This includes taking effective measures to protect food from contamination by raw foods and nonfood items in the same load, protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations, and ensure that food that requires temperature control for safety is transported under adequate temperature control.				
4.3	The type of food must be considered in determining the necessary conditions and controls for the transportation operation.				
	Hint: Make sure transportation operations are appropriate for that food.				
4.4	Shippers, receivers, loaders, and carriers, which are under the ownership or operational control of a single legal entity, may conduct transportation operations in conformance with common, integrated written procedures that ensure the sanitary transportation of food consistent with the requirements of this section.				
	Hint: If the entire transportation process is under one company or legal entity, the operations can be integrated with each other as long as individual records are kept for each part of the operation.				

Figure 9 (continued).

4.5	If a shipper, loader, receiver, or carrier becomes aware of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe during transportation, the food shall not be sold or otherwise distributed, and these persons must take appropriate actions to ensure that the food is not sold or otherwise distributed unless a determination is made by a qualified individual that the temperature deviation or other condition did not render the food unsafe.				
<p>Hint: If there are any issues detected that may cause food to be unsafe, the food cannot be sold or distributed unless actions must be taken to ensure the issues associated with the food did not make it unsafe.</p>					

Comments:

It is important to have qualified individuals who are trained in food safety in the plant as well as food safety as it applies to transportation to monitor the operation to ensure food is safe.

Definitions (21 CFR 1.904):

Bulk vehicle means a tank truck, hopper truck, rail tank car, hopper car, cargo tank, portable tank, freight container, or hopper bin, or any other vehicle in which food is shipped in bulk, with the food coming into direct contact with the vehicle.

Carrier means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service.

Cross-contact means the unintentional incorporation of a food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act into food, except animal food.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Loader means a person that loads food onto a motor or rail vehicle during transportation operations.

Receiver means any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.

Shipper means a person, *e.g.*, the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

Transportation means any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

Figure 9 (continued).

Transportation operations means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

Sanitary Transportation Rule Part 5 – 21 CFR 1.908(b)

Requirements applicable to shippers engaged in transportation operations		Yes	No	N/A	Documents
5.1	The shipper must specify to the carrier and, when necessary, the loader, in writing, of all necessary sanitary specifications for the carrier's vehicle and transportation equipment to ensure sanitary conditions.				
	<i>Hint: This includes any specific design specifications and cleaning procedures. A one-time notification is sufficient unless the design and/or cleaning requirements of the vehicle and transportation equipment changes based upon the type of food being transported. When changes occur, the shipper must notify the carrier in writing before the shipment. See exception in Section 4.4 of this checklist.</i>				
5.2	When shipping foods that requires temperature control for safety, the shipper must specify in writing to the carrier and the loader, the appropriate operating temperature for the transportation operation, including the precooling phase.				
	<i>Hint: One time notification is sufficient unless the conditions of the shipment causes a change in the appropriate operating temperature. When changes occur, the shipper must notify the carrier in writing before the shipment.</i>				
5.3	A shipper must develop and implement written procedures adequate to ensure that vehicles and equipment used in its transportation operations will prevent the food from becoming unsafe during the transportation of the food.				
	<i>Hint: The written procedures must prevent the transportation operation from making food unsafe. The measure to implement these procedures may be accomplished by the shipper or carrier under a written agreement.</i>				

Figure 9 (continued).

5.4	A shipper of food transported in bulk must develop and implement written procedures, adequate to ensure that a previous cargo does not make the food unsafe.				
<i>Hint: Measures are put in place to prevent cross-contamination from previous loads of transported goods. These measures to ensure the safety of the food may be accomplished by the shipper or the carrier under a written agreement.</i>					
5.5	The shipper of food that requires temperature control for safety under the conditions of shipment must develop and implement written procedures to ensure that the food is transported under adequate temperature control.				
<i>Hint: Measures to ensure the safety of the food may be accomplished by the shipper or the carrier under written agreement.</i>					
<p>Comments: It is the responsibility of the shipper to inform the carrier and loader of all temperature, sanitation, and other specifications they know are important to the safety of the transported food. This information must be documented in writing.</p> <p>Definitions (21 CFR 1.904): <i>Adequate</i> means that which is needed to accomplish the intended purpose in keeping with good public health practice. <i>Bulk vehicle</i> means a tank truck, hopper truck, rail tank car, hopper car, cargo tank, portable tank, freight container, or hopper bin, or any other vehicle in which food is shipped in bulk, with the food coming into direct contact with the vehicle. <i>Carrier</i> means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service. <i>Food</i> means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients. <i>Loader</i> means a person that loads food onto a motor or rail vehicle during transportation operations. <i>Shipper</i> means a person, <i>e.g.</i>, the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially. <i>Transportation</i> means any movement of food in by motor vehicle or rail vehicle in commerce within the United States. <i>Transportation equipment</i> means equipment used in food transportation operations, <i>e.g.</i>, bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor.</p>					

Figure 9 (continued).

Transportation operations means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

Vehicle means a land conveyance that is motorized, e.g., a motor vehicle, or that moves on rails, e.g., a railcar, which is used in transportation operations.

Sanitary Transportation Rule Part 6 – 21 CFR 1.908(c) and (d)

Requirements applicable to loaders or receivers engaged in transportation operations		Yes	No	N/A	Documents
6.1	Before loading food not completely enclosed by a container onto a vehicle or into transportation equipment, the loader must determine that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food.				
	Hint: This can be judged by the specifications provided by the shipper, if the shipper is in compliance with section 5.1 of this checklist. The vehicle or transportation equipment must be in adequate physical condition, free of visible evidence of pest infestation, and free of previous cargo that could cause the food to become unsafe during transportation.				
6.2	Before loading food that requires temperature control for safety, the loader must verify that each mechanically refrigerated cold storage compartment or container is adequately prepared for the transportation of food.				
	Hint: This can be judged by the specifications provided by the shipper, if the shipper is in compliance with section 5.2 of this checklist. It includes indicating that the container has been properly pre-cooled and meets other sanitary conditions for food transportation.				
6.3	Upon receipt of food that requires temperature control for safety under the conditions of shipment, the receiver must take steps to adequately assess that the food was not subjected to significant temperature abuse.				
	Hint: This includes determining the food's temperature, the ambient temperature of the vehicle and its temperature setting, and conducting a sensory inspection for qualities such as off-odors.				

Figure 9 (continued).

Comments:

Loaders are responsible for ensuring transportation equipment is adequately sanitary and has the proper controls in place. Both receivers and loaders are responsible for checking the temperature of the vehicle and equipment prior to performing their respective duties.

Definitions (21 CFR 1.904):

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food not completely enclosed by a container means any food that is placed into a container in such a manner that it is partially open to the surrounding environment. Examples of such containers include an open wooden basket or crate, an open cardboard box, a vented cardboard box with a top, or a vented plastic bag. This term does not include food transported in a bulk vehicle as defined in this subpart.

Loader means a person that loads food onto a motor or rail vehicle during transportation operations.

Receiver means any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.

Shipper means a person, e.g., the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

Transportation means any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

Transportation equipment means equipment used in food transportation operations, e.g., bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor.

Vehicle means a land conveyance that is motorized, e.g., a motor vehicle, or that moves on rails, e.g., a railcar, which is used in transportation operations.

Sanitary Transportation Rule Part 7 – 21 CFR 1.908(e)

Requirements applicable to carriers engaged in transportation operations		Yes	No	N/A	Documents
7.1	When the carrier and shipper have a written agreement that the carrier is responsible for sanitary conditions during the transportation operation, the carrier is responsible for the functions listed in sections 7.2-7.6.				
	Hint: These responsibilities may be shared with the shipper depending on the logistics of the written agreement.				

Figure 9 (continued).

7.2	A carrier must ensure that vehicles and transportation equipment meet the shipper's specifications.				
	Hint: These specifications must be appropriate to prevent the food from becoming unsafe during the transportation operation.				
7.3	A carrier must provide the operating temperature and, if requested by the receiver, demonstrate that it has maintained temperature conditions during the transportation operation consistent with the operating temperature specified by the shipper.				
	Hint: This can be judged by the specifications provided by the shipper, if the shipper is in compliance with section 5.2 of this checklist. This can be done by any appropriate means agreeable to the carrier and shipper, such as the carrier presenting measurements of the ambient temperature upon loading and unloading or time/temperature data taken during the shipment.				
7.4	Before offering a vehicle or transportation equipment with an auxiliary refrigeration unit for use for the transportation of food that requires temperature control for safety under the conditions of the shipment during transportation, a carrier must pre-cool each mechanically refrigerated cold storage compartment as specified by the shipper.				
	Hint: This must be in accordance with 5.2 of this checklist.				
7.5	A carrier that offers a bulk vehicle for food transportation must provide information to the shipper that identifies the previous cargo transported in and most recent cleaning of the vehicle.				
	Hint: This is if the shipper requests the information.				
7.6	A carrier must develop and implement written procedures subject to records requirements.				
	Hint: These procedures must specify practices for cleaning, sanitizing, and inspecting vehicles and transportation equipment that the carrier provides for use in the transportation of food to maintain the vehicles and transportation equipment in sanitary condition. The procedures must also describe how the carrier will comply with rules for temperature control (7.3) and the use of bulk vehicles (7.5).				

Figure 9 (continued).

Comments:

Carriers are ultimately responsible for the successful and safe transportation of food from shipper to receiver. They must have the written procedures from the shipper and be sure that those specifications are followed. Any previous cargo transported with the same transportation equipment must be identified to the shipper and it must be cleaned prior to transporting new cargo.

Definitions (21 CFR 1.904):

Carrier means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Shipper means a person, *e.g.*, the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

Transportation means any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

Transportation equipment means equipment used in food transportation operations, *e.g.*, bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor.

Transportation operations means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

Vehicle means a land conveyance that is motorized, *e.g.*, a motor vehicle, or that moves on rails, *e.g.*, a railcar, which is used in transportation operations.

Sanitary Transportation Rule Part 8 – 21 CFR 1.910

Training		Yes	No	N/A	Documents
8.1	When the carrier and shipper have agreed in a written contract that the carrier is responsible, in whole or in part, for the sanitary conditions during transportation operations, the carrier must provide adequate training to personnel engaged in transportation operations.				
	Hint: This training must provide an awareness of potential food safety problems that may occur during food transportation, basic sanitary transportation practices to address those potential problems, and the responsibilities of the carrier.				

Figure 9 (continued).

8.2	Carriers must establish and maintain records documenting the training described in 5.1.				
<p>Hint: The training must be provided upon hiring and as needed thereafter. The records of the training must include the date of the training, the type of training, and the person(s) trained.</p>					
<p>Comments: Any individual involved in the transportation of food must be trained to facilitate the transport of safe food.</p> <p>Definitions (21 CFR 1.904): <i>Adequate</i> means that which is needed to accomplish the intended purpose in keeping with good public health practice. <i>Carrier</i> means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service. <i>Shipper</i> means a person, e.g., the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially. <i>Transportation</i> means any movement of food in by motor vehicle or rail vehicle in commerce within the United States. <i>Transportation operations</i> means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.</p>					

Sanitary Transportation Rule Part 9 – 21 CFR 1.912

Records		Yes	No	N/A	Documents
9.1	<p>Shippers must retain records that demonstrate that they provide specifications and operating temperatures to carriers as a regular part of their transportation operations for a period of 12 months beyond the termination of the agreements with the carriers.</p> <p>Hint: Shippers must have these records for a period of 12 months beyond when the agreements and procedures are in use in their transportation operations.</p>				
9.2	<p>Carriers must retain records of the written procedures in section 7.6 of this checklist.</p> <p>Hint: These records must be retained for 12 months beyond when the agreements and procedures are in use in their transportation operations.</p>				

Figure 9 (continued).

9.3	Carriers must retain training records required by section 8.2 of this checklist.				
	Hint: These records must be retained for 12 months beyond when the person identified in any such records stops performing the duties for which the training was provided.				
9.4	Anyone that is subject to any part of this checklist is required to retain any other written agreements assigning tasks that are in compliance with the Sanitary Transportation Rule.				
	Hint: These records must be retained for 12 months beyond the termination of the agreements.				
9.5	Shippers, receivers, loaders, and carriers that are under the ownership or control of a single legal entity must retain records of the written procedures for a period of 12 months beyond when the procedures are in use in their transportation operations.				
	Hint: Even though these are under one entity, they are each required to have their own records.				
9.6	Shippers, receivers, loaders, and carriers must make all records required by this subpart available to a duly authorized individual promptly upon oral or written request.				
	Hint: If records are requested by authorized individuals, such as FDA investigators, the records must be available to that individual.				
9.7	All records are required to be kept as original records, true copies, or electronic records.				
	Hint: True copies include photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records.				
9.8	Offsite storage of records, except for procedures for cleaning, sanitizing, and inspecting vehicles and transportation equipment, is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review.				
	Hint: The procedures for cleaning, sanitizing, and inspecting vehicles and transportation equipment must remain onsite as long as the procedures are in use in transportation operations. Electronic records are considered to be onsite if they are accessible from an onsite location.				

Figure 9 (continued).

Comments:

All records required by this section are subject to the disclosure requirements in 21 CFR 20.

Definitions (21 CFR 1.904):

Carrier means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service.

FDA means the United States Food and Drug Administration.

Loader means a person that loads food onto a motor or rail vehicle during transportation operations.

Receiver means any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.

Shipper means a person, *e.g.*, the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

Transportation equipment means equipment used in food transportation operations, *e.g.*, bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor.

Transportation operations means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

Vehicle means a land conveyance that is motorized, *e.g.*, a motor vehicle, or that moves on rails, *e.g.*, a railcar, which is used in transportation operations.

Sanitary Transportation Rule Part 10 – 21 CFR 1.914 - 21 CFR 1.934

Waiver Requirements		Yes	No	N/A	Documents
10.1	FDA will waive any requirement of this subpart with respect to any class of persons, vehicles, food, or nonfood products when FDA determines that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health and the waiver will not be contrary to public interest.				
Hint: These are the circumstances given by FDA on how they will waive a requirement.					

Figure 9 (continued).

10.2	Waivers must be requested via a petition.				
	Hint: FDA will respond with their decision in writing. If the petition is denied, FDA will explain the reasons for denial.				
10.3	FDA will make filed waiver petitions readily accessible to the public.				
	Hint: This will be periodically updated with the status of each petition (pending, granted, or denied).				
10.4	Petitions may be denied because the petition does not provide the required information, FDA believes the waiver could result in the transportation of food under conditions that would be unsafe for human or animal health, or the waiver could be contrary to public interest.				
	Hint: The requirements for information in the waiver come from 21 CFR 1.918 and 21 CFR 10.30.				
10.5	Granted waivers will become effective on the date that the notice of the waiver is published in the Federal Register.				
	Hint: Until then, maintain compliance with the law.				
<p>Comments: Always be in compliance with the law until FDA officially grants the waiver. If a waiver is granted, be sure to still keep food safety in mind during operations.</p> <p>Definitions (21 CFR 1.904): <i>FDA</i> means the United States Food and Drug Administration. <i>Transportation</i> means any movement of food in by motor vehicle or rail vehicle in commerce within the United States. <i>Vehicle</i> means a land conveyance that is motorized, e.g., a motor vehicle, or that moves on rails, e.g., a railcar, which is used in transportation operations.</p>					

Figure 9 (continued).

Registration of Food Facilities Checklist

Registration of Food Facilities Part 1 – 21 CFR 1.225

Who must register?		Yes	No	N/A	Documents
1.1	You must register your facility if you are the owner, operator, or agent in charge of either a domestic or foreign facility engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States.				
Hint: Most facilities are covered under this. Exemptions will be covered Part 2.					

Figure 10. Registration of Food Facilities Checklist.

1.2	If you are an owner, operator, or agent in charge of a domestic facility, you must register your facility whether or not the food from the facility enters interstate commerce.				
Hint: Any facility in the United States covered under 1.1 must register the facility even if their products do not cross state lines.					
1.3	If you are the owner, operator, or agent in charge of a facility, you may authorize an individual to register your facility on your behalf.				
Hint: Anyone can register your facility for you if you allow him or her to do so.					
<p>Comments: Facilities which manufacture, process, pack, or holding food for human or animal consumption in the United States must register. To register, go to http://www.fda.gov/furls.</p> <p>Definitions (21 CFR 1.227): Facility means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.</p> <p>(1) <i>Domestic facility</i> means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.</p> <p>(2) <i>Foreign facility</i> means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.</p> <p>Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act:</p> <p>(1) Except for purposes of this subpart, it does not include:</p> <p>(i) Food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act; or</p> <p>(ii) Pesticides as defined in 7 U.S.C. 136(u).</p> <p>(2) Examples of food include: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.</p>					

Figure 10 (continued).

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

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

You or registrant means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

Registration of Food Facilities Part 2 – 21 CFR 1.226

Who does not have to register?		Yes	No	N/A	Documents
2.1	A foreign facility does not have to register if food from that facility is further manufactured, processed, or packaged by another facility outside of the United States.				
<p><i>Hint: Foreign facilities who send products to other foreign facilities do not have to register unless the further manufacturing, processing, or packaging only includes labeling or another similar activity of a <i>de minimis</i> nature.</i></p>					

Figure 10 (continued).

2.2	Farms, retail food establishments, restaurants, and nonprofit food establishments in which food is prepared for, or served directly to, the consumer do not have to register.				
Hint: Farms may have to register if they also process food. These businesses are covered by other laws.					
2.3	Fishing vessels that harvest and transport fish do not need to register.				
Hint: Such fishing vessels may engage in practices such as heading, eviscerating, or freezing fish intended solely to prepare fish for holding on board a harvest vessel.					
2.4	Any facilities that are regulated exclusively and throughout the entire facility by the U.S. Department of Agriculture under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act do not have to register.				
Hint: If your facility handles any products under FDA jurisdiction, you may be required to register if the facility does not meet any of the above mentioned exemptions.					
<p>Comments: These facilities do not have to register as it applies to this checklist. However, these facilities may be subject to other provisions of the Federal Food, Drug, and Cosmetic Act that may apply.</p> <p>Definitions (21 CFR 1.227): <i>Facility</i> means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.</p> <p>(1) <i>Domestic facility</i> means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.</p> <p>(2) <i>Foreign facility</i> means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.</p>					

Figure 10 (continued).

Farm means:

- (1) **Primary production farm.** A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term “farm” includes operations that, in addition to these activities:
- (2) (i) Pack or hold raw agricultural commodities;
- (ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and
- (iii) Manufacture/process food, provided that:
- (A) All food used in such activities is consumed on that farm or another farm under the same management; or
- (B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:
- (1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);
- (2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and
- (3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or
- (2) **Secondary activities farm.** A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act:

- (1) Except for purposes of this subpart, it does not include:
- (i) Food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act; or
- (ii) Pesticides as defined in 7 U.S.C. 136(u).
- (2) Examples of food include: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

Figure 10 (continued).

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. “Restaurant” does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

- (1) Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants; and
- (2) Pet shelters, kennels, and veterinary facilities in which food is provided to animals are restaurants.

Retail food establishment means an establishment that sells food products directly to consumers as its primary function. The term “retail food establishment” includes facilities that manufacture, process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term “consumers” does not include businesses. A “retail food establishment” includes grocery stores, convenience stores, and vending machine locations. A “retail food establishment” also includes certain farm-operated businesses selling food directly to consumers as their primary function.

Figure 10 (continued).

(1) Sale of food directly to consumers from an establishment located on a farm includes sales by that establishment directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(2) Sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(3) For the purposes of this definition, "farm-operated business" means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s).

You or registrant means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

Registration of Food Facilities Part 3 – 21 CFR 1.230

When must you register or renew your registration?		Yes	No	N/A	Documents
3.1	You must register before your facility begins to manufacture, process, pack, or hold food for consumption in the United States.				
	Hint: Registration should be done before production begins. You may allow someone else to register the facility for you.				

Figure 10 (continued).

3.2	You must submit registration renewal with the information in Part 5 (21 CFR 1.232) of this checklist between October 1 and December 31 of each even-numbered year.				
Hint: For example, you would need to renew registration between October 1, 2018 and December 31, 2018.					
3.3	If you are the owner, operator, or agent in charge of a facility, you may authorize an individual to renew registration of your facility on your behalf.				
Hint: Anyone can renew your facility's registration for you if you allow him or her to do so. If this is done, the renewal must include a statement in which the individual certifies that the information submitted is true and accurate, certifies that they are authorized to submit the registration renewal, and identifies the individual who authorized submission of the registration renewal by name, address, and telephone number.					
3.4	Each renewal must include the name of the individual submitting the registration renewal and the email address of the individual who authorized submission of the registration renewal unless FDA has granted a waiver under 21 CFR 1.245 .				
Hint: The signature of the individual submitting the registration renewal must be included if the renewal is done on paper. The signature is not required for electronic registration renewal.					
3.5	If there are no changes to any information required in Part 5 of this checklist since the prior renewal or registration, you may use the abbreviated registration renewal process.				
Hint: You must confirm that no changes have been made to the information required in Part 5 of this checklist since the preceding registration or renewal and certify all information is truthful and accurate. Each abbreviated renewal must include the name of the individual submitting the abbreviated renewal (and that individual's signature on the paper version). If the owner, operator, or agent in charge of the facility is not the one submitting the abbreviated registration renewal, the abbreviated renewal must provide the email address of the individual who authorized submission of the abbreviated renewal unless FDA has granted a waiver under 21 CFR 1.245. You must use Form FDA 3537 to submit abbreviated registration renewals to FDA.					

Figure 10 (continued).

Comments:

Form 3537 can be found at

<https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM071977.pdf>
<https://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm?Page=7>. This links you to the PDF and online (HTML) versions of the form. This form is used for registration, renewal, and abbreviated renewal.

Definitions (21 CFR 1.227):

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

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act:

(1) Except for purposes of this subpart, it does not include:

- (i) Food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act; or
- (ii) Pesticides as defined in 7 U.S.C. 136(u).

(2) Examples of food include: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

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

Figure 10 (continued).

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixedtype facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Packing means placing food into a container other than packaging the food and also includes repacking and activities performed incidental to packing or repacking a food (*e.g.*, activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Registration of Food Facilities Part 4 – 21 CFR 1.231

How and where do you register or renew your registration?		Yes	No	N/A	Documents
4.1	To register or renew a registration electronically, you must go to http://www.fda.gov/furls .				
	Hint: This website is available 24 hours a day, 7 days a week and from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes.				
4.2	Beginning on January 4, 2020, you must submit your registration or registration renewal to FDA electronically.				
	Hint: This is required unless FDA has granted you a waiver under 21 CFR 1.245.				
4.3	After electronic submission, FDA will verify the accuracy of your unique facility identifier (UFI) recognized as acceptable by FDA and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration.				
	Hint: FDA will not confirm your registration or provide you with a registration number until FDA verifies the accuracy of your facility's UFI and address. When this is done, FDA will provide you with an electronic confirmation of your registration renewal. UFI's are not required until October 1, 2020.				

Figure 10 (continued).

4.4	When the registration is not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration, FDA will verify that the individual identified as having authorized submission of the registration in fact authorized the submission on behalf of the facility.				
Hint: FDA will not confirm the registration or provide a registration number until that individual confirms that they authorized the submission. This also happens for registration renewal.					
4.5	For a foreign facility, after you submit your electronic registration, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent.				
Hint: FDA will not confirm your registration or provide you with a registration number until that person confirms they agreed to serve as your U.S. agent. After electronic registration renewal is complete, FDA will provide you with an electronic confirmation of your registration renewal.					
4.6	You will be considered registered once FDA electronically sends you your confirmation and registration number.				
Hint: You are registered only after registration is confirmed by FDA.					
4.7	For registration by mail or fax, use form FDA 3537. It must be filled out completely and legibly.				
Hint: To obtain a copy of this form, write to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS-681), College Park, MD 20740 or request the form by phone at 1-800-216-7331 or 240-247-8804. The finished registration must be mailed to the address above or faxed to 301-436-2804.					
4.8	FDA will enter complete and legible mailed and faxed registration submissions into its registration system, as soon as practicable, in the order FDA receives them.				
Any contact between you and FDA will be sent via the same means as what was originally received by FDA (if you sent it in by mail, they will respond by mail).					
4.9	There is no registration fee required and all registration information must be in the English language. Any incorrect information must be corrected immediately and resubmitted.				
Hint: The individual's name, the company's name, the name of a street, and a trade name may be submitted in a foreign language. All information, including all names, must be submitted using the Latin (Roman) alphabet.					

Figure 10 (continued).

Comments:

In addition to the requirements described in this checklist, you must comply with any other Federal, state, or local registration requirements that apply to your facility as well as 21 CFR 108. Consequences of failing to register, update, renew, or cancel your registration are described in 21 CFR 1.241. Assignment of a registration number to a facility means that the facility is registered with FDA. Assignment of a registration number does not in any way convey FDA's approval or endorsement of a facility or its products.

The form can be found at

<https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM071977.pdf>

<https://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm?Page=7> .

Definitions (21 CFR 1.227):

FDA means the United States Food and Drug Administration.

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

(1) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.

(2) *Foreign facility* means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

UFI means the Unique Facility Identifier.

Figure 10 (continued).

Registration of Food Facilities Part 5 – 21 CFR 1.232

What information is required in the registration?	Yes	No	N/A	Documents
5.1 The name, full address, and phone number of the facility; the preferred mailing address, if different from that of the facility; the name, full address, and phone number of the parent company, if the facility is a subsidiary of the parent company; all trade names the facility uses; the name, full address, email address (unless FDA has granted you a waiver under 21 CFR 1.245), and phone number of the owner, operator, or agent in charge of the facility; the applicable food product categories of any food manufactured/processed, packed, or held at the facility as identified on Form FDA 3537; the type of activity conducted at the facility for each food product category identified (discussed further in 5.2); a statement in which the owner, operator, or agent in charge provides an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the Federal Food, Drug, and Cosmetic Act; and a statement in which the owner, operator, or agent in charge certifies that the information submitted is true and accurate.				
Hint: This information is required for domestic and foreign facilities. More information is required for domestic facilities (5.3) and foreign facilities (5.4).				
5.2 The type of activities conducted at the facility for each food product category as mentioned 5.1 are as follows: ambient human food storage warehouse/holding facility; refrigerated human food warehouse/holding facility; frozen human food warehouse/holding facility; interstate conveyance caterer/catering point; contract sterilizer; labeler/relabeler; manufacturer/processor; acidified food processor; low-acid food processor; farm mixed-type facility; packer/repacker; salvage operator (reconditioner); animal food warehouse/holding facility; and other activity.				
Hint: For any food product categories identified, select at least one activity type.				

Figure 10 (continued).

5.3	A domestic facility must also have the email address for the contact person of the facility and an emergency contact phone number and email address if different from the email address for the contact person.				
Hint: This is required if the facility is in the United States or territory of the United States.					
5.4	A foreign facility must provide the name, full address, phone number, and email address of the foreign facility's U.S. agent and an emergency contact phone number and email address.				
Hint: This is required for facilities that manufacture/process, pack, or hold food for consumption in the United States but are not located in the United States.					
5.5	There are optional items in the registration form.				
Hint: FDA encourages, but does not require, you to submit items indicated as optional on the Form FDA 3537 that you submit.					
<p>Comments: Use the following link to preview the form but be sure to file registration online: https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM071977.pdf</p> <p>Beginning October 1, 2020, the facility's UFI recognized as acceptable by FDA will be required to be submitted with the registration information (21 CFR 1.232(a)(2)).</p> <p>Definitions (21 CFR 1.227): Facility means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.</p> <p>(1) <i>Domestic facility</i> means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.</p> <p>(2) <i>Foreign facility</i> means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.</p> <p>FDA means the United States Food and Drug Administration.</p>					

Figure 10 (continued).

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act:

(1) Except for purposes of this subpart, it does not include:

- (i) Food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act; or
- (ii) Pesticides as defined in 7 U.S.C. 136(u).

(2) Examples of food include: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

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

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixedtype facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixedtype facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixedtype facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Packing means placing food into a container other than packaging the food and also includes repacking and activities performed incidental to packing or repacking a food (e.g., activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Figure 10 (continued).

Trade name means the name or names under which the facility conducts business, or additional names by which the facility is known. A trade name is associated with a facility, and a brand name is associated with a product.

U.S. agent means a person (as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(e))) residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of this subpart. A U.S. agent may not be in the form of a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's agent is not physically present.

(1) The U.S. agent acts as a communications link between FDA and the foreign facility for both emergency and routine communications. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies another emergency contact.

(2) FDA will treat representations by the U.S. agent as those of the foreign facility, and will consider information or documents provided to the U.S. agent the equivalent of providing the information or documents to the foreign facility. FDA will consider the U.S. agent the equivalent of the registrant for purposes of sharing information and communications. The U.S. agent of a foreign facility may view the information submitted in the foreign facility's registration.

(3) Having a single U.S. agent for the purposes of this subpart does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes. A firm's commercial business in the United States need not be conducted through the U.S. agent designated for purposes of this subpart.

Registration of Food Facilities Part 6 – 21 CFR 1.234

How and when do you update your facility's registration information?		Yes	No	N/A	Documents
6.1	You must update a facility's registration within 60 calendar days of any change to any of the information previously submitted from Part 5 except for a change of the owner.				
	<p>Hint: Similar to registration and renewal, an individual who is not the owner, operator, or agent in charge of the facility may update the facility's registration. However, the update must provide the email address of the individual who authorized submission of the update, unless FDA has granted a waiver under 21 CFR 1.245. Electronic updates must be done at http://www.fda.gov/furls. FDA will not confirm the update until FDA has verified that the individual identified as having authorized submission in fact authorized the submission. Your registration will be considered updated once FDA sends you your update confirmation.</p>				

Figure 10 (continued).

6.2	If the reason for the update is that the facility has a new owner, the former owner must cancel the facility's registration as mentioned in Part 6 of this checklist (21 CFR 1.235) within 60 calendar days of the change and the new owner must submit a new registration for the facility.				
Hint: The former owner may authorize an individual to cancel and submit a new registration for the facility.					
6.3	After you submit your electronic update, FDA will provide you with an electronic confirmation of your update. When updating UFI information, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration.				
Hint: As the case with registration and renewal, FDA will not provide an electronic confirmation of your registration update until FDA verifies the accuracy of your facility's UFI and verifies the address.					
6.4	For foreign facilities, when updating information about your U.S. agent, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent.				
Hint: FDA will not provide an electronic confirmation of your registration update until that person confirms that the person agreed to serve as your U.S. agent.					
6.5	To update by mail, you must update your registration using Form FDA 3537.				
Hint: This can be obtained by writing to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS-681), College Park, MD 20740 or by requesting the form by phone at 1-800-216-7331 or 240-247-8804.					
6.6	You must fill out the sections of the form reflecting your updated information. If any updated information submitted is incorrect at the time of submission, you must immediately resubmit your update.				
Hint: If you make a mistake, mail the corrections to the address in the hint of 6.5 or fax to 301-436-2804. FDA will contact you throughout the process using the same method as you submitted the updates.					
6.7	When FDA completes its update of your facility, it will mail or fax a copy of the update as entered and confirm the update.				
Hint: FDA's process for confirmation is the same as the electronic version. Your registration will be considered updated once FDA enters your facility's update data into the registration system and the system generates an update confirmation.					

Figure 10 (continued).

Comments:

Any updates will be done using the Form 3537. The form can also be found at <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM071977.pdf>
<https://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm?Page=7> .

Definitions (21 CFR 1.227):

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

(1) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.

(2) *Foreign facility* means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

FDA means the United States Food and Drug Administration.

U.S. agent means a person (as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(e))) residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of this subpart. A U.S. agent may not be in the form of a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's agent is not physically present.

(1) The U.S. agent acts as a communications link between FDA and the foreign facility for both emergency and routine communications. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies another emergency contact.

(2) FDA will treat representations by the U.S. agent as those of the foreign facility, and will consider information or documents provided to the U.S. agent the equivalent of providing the information or documents to the foreign facility. FDA will consider the U.S. agent the equivalent of the registrant for purposes of sharing information and communications. The U.S. agent of a foreign facility may view the information submitted in the foreign facility's registration.

(3) Having a single U.S. agent for the purposes of this subpart does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes. A firm's commercial business in the United States need not be conducted through the U.S. agent designated for purposes of this subpart.

Figure 10 (continued).

Registration of Food Facilities Part 7 – 21 CFR 1.235

How and when do you cancel your facility's registration?		Yes	No	N/A	Documents
7.1	You must cancel a registration within 60 calendar days of the reason for cancellation.				
	Hint: Reasons may include your facility stops operations, stops providing food for consumption in the United States, or is sold to a new owner.				
7.2	The cancellation of a facility's registration must include the following information: the facility's registration number; whether the facility is domestic or foreign; the facility name and address; the name, address, and email address of the individual submitting the cancellation; and a statement certifying that the information submitted is true and accurate and that the person submitting the cancellation is authorized by the facility to do so.				
	Hint: For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, the email address of the individual who authorized submission of the registration cancellation must be provided, unless FDA has granted a waiver under 21 CFR 1.245 .				
7.3	To cancel your registration electronically, you must cancel at http://www.fda.gov/furls .				
	Hint: Once you complete your electronic cancellation, FDA will provide you with an electronic confirmation of your cancellation. For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration cancellation, FDA will verify that the individual identified as having authorized submission of the cancellation in fact authorized the submission on behalf of the facility. FDA will not confirm the cancellation until that individual confirms that they authorized the cancellation. Your registration is considered cancelled once FDA sends you your cancellation confirmation.				
7.4	To cancel registration using mail or fax, you must cancel your registration using Form FDA 3537a.				
	Hint: Registration, renewals, updates, and cancellations must be done electronically after January 4, 2020. To get Form FDA 3537a, write to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS-681), College Park, MD 20740 or request the form by phone at 1-800-216-7331 or 240-247-8804.				

Figure 10 (continued).

7.5	The form must be filled out completely and legibly and mailed to the address in the hint of 7.4 or faxed to 301-436-2804.				
<p>Hint: FDA will contact you via mail or fax based on how the original cancellation was sent. Your registration will be considered cancelled once FDA enters your facility's cancellation data into the registration system and sends you your cancellation confirmation.</p>					
<p>Comments: Cancellation is completed using Form 3537a. You can cancel your registration electronically at http://www.fda.gov/furls or previewed in PDF format at this link: https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM072017.pdf</p> <p>Definitions (21 CFR 1.227):</p> <p>Facility means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.</p> <p>(1) <i>Domestic facility</i> means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.</p> <p>(2) <i>Foreign facility</i> means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.</p> <p>FDA means the United States Food and Drug Administration.</p> <p>Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act:</p> <p>(1) Except for purposes of this subpart, it does not include:</p> <p>(i) Food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act; or</p> <p>(ii) Pesticides as defined in 7 U.S.C. 136(u).</p> <p>(2) Examples of food include: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.</p> <p>You or registrant means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.</p>					

Figure 10 (continued).

Registration of Food Facilities Part 8 – 21 CFR 1.245

Waiver request		Yes	No	N/A	Documents
8.1	Beginning January 4, 2020, you must submit your registration, renewal, updates, and cancellations to FDA electronically, unless FDA has granted a waiver from such requirement.				
Hint: After January 4, 2020, registrations, renewals, updates, cancellations sent by mail or fax will not be accepted by FDA.					
8.2	You must provide the email address of the owner, operator, or agent in charge of the facility unless FDA has granted a waiver from such requirement.				
8.3	Registrations, registration renewals, abbreviated registration renewals, updates, and cancellations not submitted by the owner, operator, or agent in charge must include the email address for the individual who authorized the submission, unless FDA has granted a waiver.				
8.4	To request a waiver from these requirements, you must submit a written request to FDA that explains why it is not reasonable for you to submit your registration, registration renewal, update, or cancellation to FDA electronically or to provide the email address of the owner, operator, or agent in charge of the facility.				
Hint: You must submit your request to: U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS-681), College Park, MD 20740.					
<p>Comments: Waiver requests must be submitted in writing to the following address: U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition 5001 Campus Dr. (HFS-681) College Park, MD 20740.</p> <p>You may also submit your request by email to FURLS@fda.gov. The waiver request should include the facility name(s) and address(es) and the name of the owner, operator, or agent in charge of the facility. In addition, if the waiver request is being submitted by a U.S. agent on behalf of a foreign facility, the request should include the name of the U.S. agent authorized by the owner, operator, or agent in charge of the facility to submit the waiver request. Once FDA receives and reviews the request, they will notify you if the waiver has been granted or denied.</p> <p>Definitions (21 CFR 1.227): FDA means the United States Food and Drug Administration. You or registrant means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.</p>					

Figure 10 (continued).

CHAPTER 5. NEEDS ASSESSMENT

Introduction

The Food Safety Modernization Act (FSMA) of 2011 is the most recent and most significant change in American food safety regulation (Doyle et al. 2015). It sets new federal standards for food safety across the industry. There are several Rules, the Preventive Control for Human Food Rule, the Sanitary Transportation Rule, and Amendments to Registration of Food Facilities, which affect fruit and vegetable processors in the US. Prior to FSMA, these fruit and vegetable processors utilized Hazard Analysis and Critical Control Points (HACCP) to control their food safety concerns. HACCP principles form the basis of FSMA compliance allowing many companies to build upon their previously established HACCP plans (Bracket et al. 2014; Doyle et al. 2015). Prevention has become the focus of food safety regulation, attempting to thwart food safety outbreaks before they occur. The preventive focus of the Food and Drug Administration (FDA) brings traceability and recordkeeping to the forefront (Aung and Chang 2014). The additional recordkeeping is the primary change affecting fruit and vegetable processors which, in many cases, was not required by HACCP (Johnson and Lawson 2016).

One method that educators utilize to determine knowledge needs of a population are needs assessments. Needs assessment surveys identify problems, the current approach, and the ideal approach to education of a population (Thomas et al. 2016). They prompt the respondents to explain the difference between their current knowledge of a topic and the knowledge they should have about it (Witkin and Altschuld 1995). Training needs are also identified using systematic approaches, such as needs assessments (Wright et al. 1998). A preliminary needs assessment sent to fruit and vegetable growers, who are also affected by FSMA, showed there was a very high need for extension intervention. This led to an interest

in what materials and information processors in the NCR would find beneficial to their businesses. FSMA regulations apply to a wider array of processing facilities, most notably affecting small and medium-sized processing facilities. The needs assessment described in this chapter (Figure 11) was developed, specifically, to extract the questions, comments, and concerns of smaller sized fruit and vegetable processors within the region and relay those responses to the extension team. The objective of this study is to translate the results into a series of targeted educational and training materials developed specifically for this population.

Methods

Needs Assessment Development

A needs assessment was developed to determine the technical assistance needs of fruit and vegetable processors in 12 Midwestern states (Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, Wisconsin). The survey consists of 22 total questions. The first portion of the needs assessment asks the survey taker to rate their perceived knowledge and perceived information needs of content areas of FSMA. The five content areas covered in the needs assessment are Food Safety Plan, Current Good Manufacturing Practice, Sanitary Transportation Rule, Amendments to Registration of Food Facilities, and other information known or needed as it pertains to FSMA and processing facilities (Table 6). The Food Safety Plan area covers Preventive Controls Qualified Individuals, Hazard Analysis, Preventive Controls, Supply-Chain Program, Recall Plan, Monitoring, Corrective Actions, Validation, Verification, Rework, and Record Keeping (Table 6.1). The Current Good Manufacturing Practice content area covers personnel, plant and grounds, sanitary operations, sanitary facilities, equipment and utensils,

processes and controls, warehousing and distribution, holding and distribution of human food by-products for use as animal food, and defect action levels (Table 6.2). The Sanitary Transportation Rule content area covers vehicles and transportation equipment, transportation operations, training, and records (Table 6.3). The Amendments to Registration of Food Facilities content area covers who is required to register, when registration/renewal must occur, permissions of inspection for FDA, information required in registration, electronic registrations, and waiver requests (Table 6.4). These topics were deemed the most applicable to fruit and vegetable processors covered under FSMA.

Self-efficacy, or perceived efficacy, is defined as “a judgment of capability to execute given types of performances” (Bandura 2006). This perceived self-efficacy allows individuals to identify personal mastery expectations which are then the primary drivers of behavioral change (Sherer et al. 1982). Self-efficacy theory was applied to the development of the needs assessment by allowing fruit and vegetable processors to identify areas of strong and weak understanding of FSMA. Because these perceived capabilities do not also represent competence in a particular subject (Schunk and Pajares 2009), the needs assessment judges current knowledge and information needs of FSMA content areas. Both current knowledge and information needs use a 5-point scale. The scale for current knowledge ranges from 1 (the respondent has no knowledge of that content area) to 5 (the respondent has very high knowledge of that content area). Current knowledge allows the respondent to divulge the amount of information they are familiar with prior to receiving the survey. This information gives an idea of the information available to fruit and vegetable processors before the development of new materials. While the current knowledge answers describe what the respondents already know, the responses to information needs show what additional

information about FSMA is desired from the population. The scale for information needs ranges from 1 (the respondent has no need or desire for additional information) and 5 (the respondent most needs or desires additional information on the subject).

The next significant portion of the survey asked what format the respondent would prefer the educational materials to be presented in. Respondents were given the opportunity to provide their preferences again on a scale from 1 (the respondent would not use the material at all) to 5 (the respondent would definitely use the material). The survey included twelve different formats, online modules/short courses, videos, DVD, YouTube™ or other internet supported videos, extension publications/fact sheets, printed handouts, web-based handouts (PDF), online interactive tools, checklists, face-to-face workshops, one-on-one consultations, Facebook/Twitter, and an additional “other delivery methods” answer for the respondent to include their own ideas. This section identifies what targeted materials are preferred by processors for future development.

The final part of the survey was comprised of demographic questions. Gender, current job title and career length, age, location, and the processing facility information was collected to develop a profile of the respondents and businesses responding to the survey.

Understanding the types of fruits and vegetables processed by respondents, size of the business, and the processes involved allow future materials to use examples in developed materials based on these factors. For example, it would be beneficial to cucumber pickle operations to be taught using cucumber pickles in the materials rather than another process.

Implementation

The survey was sent to extension agents in Iowa, Illinois, Indiana, Ohio, North Dakota, South Dakota, Michigan, Minnesota, Wisconsin, Kansas, Missouri, and Nebraska

who were tasked to send emails to fruit and vegetable processors in their state which included a link to the survey and information about why those processors were chosen to complete it. These extension agents have relationships with the processors and sent 130 emails to contacts at possible fruit and vegetable processors in Iowa (Figure 12). Two to three weeks after the initial communication, a sent a second email to the contact. This email was to serve as a reminder email to the processors for those who had forgotten to respond and to show that the original email was not spam but was in fact, a true study (Figure 13).

Statistical Analysis

The survey was developed, and data was collected, using the Qualtrics Survey Tool. The statistics from these data were also generated by Qualtrics. Means, medians, minimums, maximums and standard deviations were reported for numerical values while categorical variables were reported by number of respondents and percentage of total respondents who answered the question.

Results & Discussion

The first question in the needs assessment asks, “Are you a fruit and vegetable processor? If no, thank you but no further information is needed.” This allowed for the answers of respondents who were not fruit and vegetable processors or in Iowa to be removed. There were 8 ‘yes’ answers to this question. Data reported comes from those 8 respondents. The next question asked about the current knowledge and the information needs for the Food Safety Plan. There were 7 or 8 responses for each section of current knowledge and 6 or 7 responses in each section for information needs.

The lowest rated knowledge items in the Food Safety Plan include rework, verification, validation, and supply-chain programs (Table 6.1). These four categories were

clearly separated from the others (3.57 as compared to the next highest 3.86) showing a great deal of concern among the processors in this study. The highest rated information needs in the Food Safety Plan were validation and supply-chain programs (3.00 for both) (Table 6.2). This again highlights the need for materials focused on validation, supply-chain programs, and verification. Preventive controls were high in current knowledge (4.25) as well as moderately high information needs (2.71), showing the processors have had a bit of background with preventive controls but are still not completely confident in their ability to implement them.

Current Good Manufacturing Practice is not new, rather, it has been moved and updated from Title 21 CFR Part 110 to Title 21 CFR Part 117. This is evident in both current knowledge items and information needs. Holding and distribution of human food by-products for use as animal food, warehousing and distribution, and defect action levels were rated as the lowest current knowledge items (Table 6.3). Curiously, holding and distribution of human food by-products for use as animal food was also the lowest information needs from the Current Good Manufacturing Practice section (2.00). This part of the Rule may not be applicable to every fruit and vegetable processor as they are not required to sell human food by-products. Many of the processors may not have this operation in their facility and do not need further information. Warehousing and distribution as well as processes and controls were the highest rated information needs (Table 6.4). The distribution chain seems to be a point of concern among processors in the North Central Region. Processes and controls, similarly to preventive controls, may be known by most processors but may not be fully understood.

Overall, the lowest rated knowledge items and highest rated information needs from the needs assessment come from the Sanitary Transportation Rule and Amendments to Registration of Food Facilities. Training of those covered by the Sanitary Transportation Rule was the lowest rated current knowledge area in that section (Table 6.5). Transportation operations were the highest rated information need for the Sanitary Transportation Rule. The highest current knowledge item, Vehicles and transportation equipment, was 3.50 which was not much higher than the lowest rated knowledge items from the Preventive Controls for Human Food Rule sections. This suggests the Sanitary Transportation Rule should have several documents developed specifically for it as it is overall a low subject knowledge area.

Even more needed than Sanitary Transportation Rule documents are documents for Amendments to Registration of Food Facilities. This section had the lowest overall scores for current knowledge and the highest for information needs (Tables 6.7 and 6.8). These numbers may have been a result of a lack in knowledge of changes to the Registration. The biggest change is the move to all online registration which may not affect many processors as most are completely online registration anyway. Waiver requests was the lowest current knowledge item while electronic registrations were the highest rated information need in this section. This, again, is probably due to a lack of knowledge that waivers could be granted.

All 8 respondents entered responses for each method of delivery (Table 6.9). The most preferred methods were checklists (4.38), online interactive tools (4.13), and web-based PDFs (4.00). DVD (2.88), one on one consultations (2.88) and social media (2.63) were the least preferred (data not shown). This information is reflective of the previous grower needs assessment that has led to the development of a checklist, fact sheets, and an interactive quiz for processors.

The respondents were predominantly white with supervisory food safety roles in Iowa. The average respondent was 42.71 years of age with 8.25 years of experience (Table 4). (Table 5.1). The results of this needs assessment should only be applied to Iowa as that state had the most responses by far. The markets for processed fruits and vegetable sales were restaurants/caterers (6), grocery stores and retail stores (8), institutional food service such as schools or hospitals (8), food hubs or cooperatives (5), wholesale distributors (6), contract buyers (2), and online sales (3) (Table 5.4). One facility had an on-site store. There were a plethora of different fruits and vegetables used by these processors; the most common were carrots (5), potatoes (5), and peppers (5) (Table 5.2). There were several different processing methods throughout these plants including canning (1), cutting/slicing/dicing (3), drying/dehydrating (1), fermenting (1), freezing (2), peeling (4), washing (4), blanching (1), and packing (1) (Table 5.3). The average total pounds of processed produce at each facility was 113,334.44 pounds, varying from 0-200,000 pounds per plant (Table 5.6). The number of people involved with the processing, manufacturing, receiving, packing, handling, transporting, and selling of produce at the facility averaged 104.5, ranging from 3-400 (Table 5.6). Languages spoken were Spanish (4), Burmese (1), Nepali (1), French (1), Marshallese (1), and Italian (1) (Table 5.5).

The needs assessment was marred by a lack of response from the target population. Less than half of the respondents answered 'yes' to the first question leaving thirteen respondents to complete the survey. Therefore, only Iowa data, which eight of the thirteen were located, were used. This non-response may be described by topic salience. Topic salience is an important determining factor in the decision for a respondent to complete the survey (Dillman et al. 2002; Groves et al. 2004; Marcus et al. 2007; Lavrakas 2008).

Processors already have experience with HACCP which is where many of the principles of the Preventive Controls for Human Food Rule are derived (Bracket et al. 2014; Doyle et al. 2015). These commonalities may give processors the confidence to not need external help. Companies also are required to attend training for the Preventive Controls for Human Food Rule which then diminishes the drive to attend or receive additional, voluntary training. As evident by the selection of desired materials, processors want items which fit in their schedule, can be used at their leisure, and have direct and immediate benefits on the company.

Several studies address possible other reasons and populations which are more likely to respond to surveys. Shih & Fan (2008) find college students were more likely to respond to web surveys while professionals were more likely to respond to mail surveys. A meta-analysis of the number of contacts before and during a survey show their important to elicit maximum response to a maximum of 3 contacts, diminishing with more (Cook et al. 2000). Archer (2007) describes other important aspects of the survey procedure such as increasing the total number of days the survey is open and sending two reminders to the population in the two weeks after the beginning of the study. The NCR needs assessment for processors was open for one month, beginning with an invitation email (Figure 12) and the respondents received one reminder at the mid-way point (Figure 13). Prior contact with the processors before the launch of the needs assessment would be beneficial. By reaching out to the processors beforehand and including another reminder, the response rate may have been higher.

The goal of this survey was to determine the best ways to service the NCR region and these results may not be representative of the population. The biggest and most glaring issue

with the needs assessment was the response rate. There were over 120 surveys sent out in Iowa alone and there were only 8 responses. The surveys were distributed to other states via their own extension offices. This is a concern as the total number of surveys distributed to the processors in each state and the method of distribution is unknown, and there were only four responses from those processors who are located outside of Iowa. This means there is little representation from the other eleven states and the few results collected can only be applied within Iowa.

These inconclusive results may have also been a status indicator of the target population. Even small processors sell to rather large distributors and many of these distributors require systems similar to FSMA. Because the processors already have had similar systems to work with, they would already have an idea of what their food safety plan and record keeping would look like. Upon receiving the email to complete the survey, they may have dismissed it as spam or unnecessary for their company to take part in. One individual responded after the reminder email stating this very point. Future studies should make more personal attempts (phone calls, letters, etc.) to reach the population, however, processors may not be completely interested in receiving aid from extension agencies as they already have much of the information they need to be successful.

The needs assessment for processors did not gather a robust amount of information because of the incredibly low response rate and the form was inconsistently filled out. To remedy this problem, the online form has become a phone interview script. The questions in the survey were modified to be more favorable for open-ended and thoughtful responses. Though the sample size may be small again, this method will collect high-quality data that can be utilized in the next phases of the NCR project. Phone interviews and focus groups

would be able to acquire additional information about the state of Iowa due to available contacts and proximity. Extension offices in other states did not allow Iowa State Extension to contact processors in their state.

Conclusion

FSMA has changed food safety regulation for the entire food industry, including fruit and vegetable processors. The number of respondents to this needs assessment show a lack of interest from food processors for educational materials that are not required. However, the results of the survey show processors are wanting quick reference materials to use in their business. This needs assessment will lead to the creation of new documents and has led to a better understanding of the population. New approaches to extracting information from processors in the region should be analyzed and considered.

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Needs Assessment

Part I. What do you think?

Are you a fruit and vegetable processor? If no, thank you but no further information is needed.

- Yes
- No

A. Please rate your knowledge and need for additional information for each of the following content areas of the Food Safety Modernization Act. Rate your knowledge of the Food Safety Modernization Act content using a 5-point scale with: 1 = No Knowledge and 5 = High knowledge. Also use a 5-point scale for information needs, with: 1 = No Need and 5 = High Need.

Figure 11. Needs assessment.

Food Safety Plan

	Current Knowledge					Information Needs				
	1	2	3	4	5	1	2	3	4	5
Preventive Controls Qualified Individuals										
Hazard Analysis										
Preventive Controls										
Supply-Chain Program										
Recall Plan										
Monitoring										
Corrective Actions										
Validation										
Verification										
Rework										
Record Keeping										

Figure 11 (continued).

Current Good Manufacturing Practice

	Current Knowledge					Information Needs				
	1	2	3	4	5	1	2	3	4	5
Personnel										
Plant and grounds										
Sanitary operations										
Sanitary facilities										
Equipment and utensils										
Processes and controls										
Warehousing and distribution										
Holding and distribution of human food by-products for use as animal food										
Defect action levels										

Figure 11 (continued).

Sanitary Transportation Rule

	Current Knowledge					Information Needs				
	1	2	3	4	5	1	2	3	4	5
Vehicles and transportation equipment										
Transportation operations										
Training										
Records										

Amendments to Registration of Food Facilities

	Current Knowledge					Information Needs				
	1	2	3	4	5	1	2	3	4	5
Who is required to register?										
When registration/renewal must occur?										
Permissions of inspection for FDA										
Information required in registration										
Electronic registrations										
Waiver requests										

Figure 11 (continued).

Other information known or needed?

	Current Knowledge					Information Needs				
	1	2	3	4	5	1	2	3	4	5
Please describe other areas of need										
Please describe other areas of knowledge										

B. Please rate how likely you are to use educational materials delivered using the following methods. Use a scale of 1 through 5 with: 1 = Would not use and 5 = Definitely would use.

Feel free to include additional comments in the column on the right.

Method of delivery

	Preference Scale					Comments
	1	2	3	4	5	
Online modules/short courses						
Videos						

Figure 11 (continued).

DVD						
YouTube™ or other internet supported videos						
Extension publications/Fact Sheets						
Printed handouts						
Web-based handouts (PDF)						
Online interactive tools						
Checklists						
Face-to-face workshops						

Figure 11 (continued).

One-on-one consultations						
Facebook/Twitter						
Other delivery methods						

Part 2. What about you? To help us better customize materials, please respond to the following questions.

1. What is your gender?

- Female
- Male

2. What is your current role at your facility?

- Food safety manager
- Food safety personnel
- Plant manager
- Other supervisor, managerial or coordinator role
- Other; please specify: _____

3. What is your age in years?

4. How many years have you been in food processing throughout your career?

Figure 11 (continued).

5. In which state is your processing facility?
- | | | |
|--------------------------------|---------------------------------|------------------------------------|
| <input type="radio"/> Iowa | <input type="radio"/> Michigan | <input type="radio"/> North Dakota |
| <input type="radio"/> Illinois | <input type="radio"/> Minnesota | <input type="radio"/> Ohio |
| <input type="radio"/> Indiana | <input type="radio"/> Missouri | <input type="radio"/> South Dakota |
| <input type="radio"/> Kansas | <input type="radio"/> Nebraska | <input type="radio"/> Wisconsin |
6. What markets do you use to sell your processed fruits and vegetables? Check all that apply.
- | | |
|--|--|
| <input type="radio"/> Restaurants or caterers | <input type="radio"/> Food hubs or cooperatives |
| <input type="radio"/> Grocery stores and retail stores | <input type="radio"/> Wholesale distributors (i.e., SYSCO) |
| <input type="radio"/> Institutional food service, such as schools or hospitals | <input type="radio"/> Contract buyers |
| <input type="radio"/> On-site store or market | <input type="radio"/> Online sales |
| <input type="radio"/> Pick your own | <input type="radio"/> Other (please specify) |
-
7. Which of the following produce items are processed at your facility? Check all that apply.
- | | | |
|---|-----------------------------------|---|
| <input type="radio"/> Apples | <input type="radio"/> Green beans | <input type="radio"/> Radishes |
| <input type="radio"/> Arugula | <input type="radio"/> Grapes | <input type="radio"/> Raspberries |
| <input type="radio"/> Asparagus | <input type="radio"/> Herbs | <input type="radio"/> Tomatoes |
| <input type="radio"/> Beets | <input type="radio"/> Kale | <input type="radio"/> Salad mixes |
| <input type="radio"/> Blackberries | <input type="radio"/> Kohlrabi | <input type="radio"/> Spinach |
| <input type="radio"/> Blueberries | <input type="radio"/> Lettuce | <input type="radio"/> Sprouts |
| <input type="radio"/> Broccoli | <input type="radio"/> Melons | <input type="radio"/> Squash |
| <input type="radio"/> Cabbage | <input type="radio"/> Microgreens | <input type="radio"/> Strawberries |
| <input type="radio"/> Carrots | <input type="radio"/> Mushrooms | <input type="radio"/> Turnips |
| <input type="radio"/> Celery | <input type="radio"/> Onions | <input type="radio"/> Zucchini |
| <input type="radio"/> Cherries | <input type="radio"/> Peaches | <input type="radio"/> Other fresh produce typically eaten raw (please specify): |
| <input type="radio"/> Cucumbers | <input type="radio"/> Pears | _____ |
| <input type="radio"/> Dry beans (pinto, kidney, etc.) | <input type="radio"/> Peas | |
| <input type="radio"/> Garlic | <input type="radio"/> Peppers | |
| <input type="radio"/> Ginger | <input type="radio"/> Plums | |
| | <input type="radio"/> Potatoes | |
8. What types of processing are done at your facility?
- | | |
|--|---|
| <input type="radio"/> Cutting/Slicing/Dicing | <input type="radio"/> Peeling |
| <input type="radio"/> Canning | <input type="radio"/> Washing |
| <input type="radio"/> Freezing | <input type="radio"/> Other (please specify): |
| <input type="radio"/> Drying/Dehydrating | _____ |

Figure 11 (continued).

9. How many total pounds of fresh and fresh-cut produce are processed at your facility that are typically eaten raw?

10. How many people are involved with processing, manufacturing, receiving, packing, handling, transporting, and selling of fruits and vegetables at your facility?

10-a. How many people work seasonally?

10-b. How many work year-round?

11. What are the primary (top three) languages spoken in your plant (other than English)?

- Spanish
- Hmong
- Burmese
- Vietnamese
- Tagalong
- Other (please specify):

12. Do you have other needs, such as culture or language specific materials, not listed above? Please describe.

13. What is your ethnic background?

- White
- Black or African American
- Hispanic or Latino/a
- American Indian or Alaska Native
- Asian or Pacific American Islander
- Multi-ethnic
- Other (please specify):

Figure 11 (continued).

Figures and Tables

“Hello ‘Contact Name’,

My name is Jacques Overdiep and I work under Dr. Angela Shaw, the food safety extension specialist, at Iowa State University. We are trying to determine the educational needs for food manufacturers who process fruits and vegetables as part of their products or as a sole product. Would you take a 10 minute survey to determine what additional technical assistance and education we can provide you? The survey closes October 31.

You may access the survey by clicking or copying and pasting this link into your browser: https://survey.az1.qualtrics.com/jfe/form/SV_5jXAZrDGyivQuQl

We would love to talk to you about any of your FSMA Preventive Controls for Human Food Rule questions or technical assistance needs. Please reach out to Angela Shaw at XXX-XXX-XXXX or xxxxxx@iastate.edu.

Thank you,
Jacques Overdiep”

Figure 12. First email contact for needs assessment request.

“Good morning ‘Contact Name’,

My name is Jacques Overdiep and I work under Dr. Angela Shaw, the food safety extension specialist, at Iowa State University. At the end of September, we sent you a survey asking questions to determine the educational needs for food manufacturers who process fruits and vegetables as part of their products or as a sole product. If you haven't already, could you please take the 10 minute survey below before October 31? We greatly appreciate your help.

You may access the survey by clicking or copying and pasting this link into your browser: https://survey.az1.qualtrics.com/jfe/form/SV_5jXAZrDGyivQuQl

We would love to talk to you about any of your FSMA Preventive Controls for Human Food Rule questions or technical assistance needs. Please reach out to Angela Shaw at XXX-XXX-XXXX or xxxxxx@iastate.edu.

Thank you again,
Jacques Overdiep”

Figure 13. Second email contact for needs assessment request.

Table 4. Profile of respondents to needs assessment

Characteristic	Mean ± standard deviation	Minimum	Maximum
Age in Years (n=7)	42.71 ± 12.56	27	60
Career Length in Years (n=8)	8.25 ± 5.93	4	22
Characteristic			
# of respondents (%)			
Gender (n=8)			
Male	4 (50.00%)		
Female	4 (50.00%)		
Respondent's race (n=6)			
White	5 (83.33%)		
Multi-ethnic	1 (16.67%)		
Current role at facility (n=8)			
Food Safety Manager	1 (12.50%)		
Plant Manager	1 (12.50%)		
Other Supervisor Role	5 (62.50%)		
Owner	1 (12.50%)		

Table 5. Profile of facilities from needs assessment

Characteristic	Number of respondents (%)	Characteristic	Number of respondents (%)
Table 5.1. Location of processing facility (n=12)			
Iowa	8 (66.67%)	Wisconsin	2 (16.67%)
Illinois	1 (8.33%)	Other 8 states	0 (0%)
Michigan	1 (8.33%)		
Table 5.2. Types of produce (n=8)			
Carrots	5 (62.50%)	Grapes	1 (12.50%)
Potatoes	5 (62.50%)	Squash	1 (12.50%)
Peppers	5 (62.50%)	Kale	1 (12.50%)
Tomatoes	4 (50.00%)	Kohlrabi	1 (12.50%)
Apples	3 (37.50%)	Zucchini	1 (12.50%)
Turnips	2 (25.00%)	Celery	1 (12.50%)
Asparagus	2 (25.00%)	Blueberries	1 (12.50%)
Garlic	2 (25.00%)	Melons	1 (12.50%)
Broccoli	2 (25.00%)	Dry Beans (pinto, kidney, etc.)	1 (12.50%)
Radishes	2 (25.00%)	Beets	1 (12.50%)
Cabbage	2 (25.00%)	Strawberries	1 (12.50%)
Onions	2 (25.00%)	Green Beans	1 (12.50%)
Cucumbers	2 (25.00%)		

Table 5 (continued).

Table 5.3. Types of processing (n=8)			
Canning	1 (12.50%)	Washing	4 (50.00%)
Cutting/Slicing/Dicing	3 (37.50%)	Field Packing	1 (12.50%)
Drying/Dehydrating	1 (12.50%)	Blanching	1 (12.50%)
Fermenting	1 (12.50%)	Peeling	4 (50.00%)
Freezing	2 (25.00%)		
Table 5.4. Markets (n=8)			
Restaurants/Caterers	6 (75.00%)	Food Hubs/Cooperatives	5 (62.50%)
Grocery/Retail Stores	8 (100.0%)	Wholesale Distributors	6 (75.00%)
Institutional Food Service	8 (100.0%)	Contract Buyers	2 (25.00%)
On-Site Store/Market	1 (12.50%)	Online Sales	3 (37.50%)
Table 5.5. Languages spoken (n=5)			
Spanish	4 (80.00%)	Marshallese	1 (20.00%)
Burmese	1 (20.00%)	Italian	1 (20.00%)
Nepali	1 (20.00%)		
Table 5.6.			
	Mean ± standard deviation	Minimum	Maximum
# People Total (n=6)	104.50 ± 149.86	3	400
# People Seasonally (n=6)	7.50 ± 7.43	0	20
# People Year-Round (n=8)	103.00 ± 150.81	2	400
Pounds Processed Annually (n=5)	4000.00 ± 8000.00	0	20000

Table 6. Ratings of current knowledge, information needs, and educational materials

Survey items	Mean ± standard deviation
Table 6.1. Lowest rated knowledge items (Food Safety Plan)	
Verification (n=7)	3.14 ± 1.12
Validation (n=7)	3.43 ± 0.73
Supply-Chain Program (n=7)	3.57 ± 0.73
Rework (n=7)	3.57 ± 0.90
Table 6.2. Highest rated information needs (Food Safety Plan)	
Validation (n=6)	3.00 ± 1.29
Supply-Chain Program (n=7)	3.00 ± 0.93

Table 6 (continued).

Table 6.3. Lowest rated knowledge items (Current GMP)

Holding and Distribution of Human Food By-Products (n=8)	3.38 ± 1.41
Defect Action Levels (n=8)	3.50 ± 1.12
Warehousing and Distribution (n=8)	3.75 ± 0.83

Table 6.4. Highest rated information needs (Current GMP)

Processes and Controls (n=7)	2.57 ± 1.29
Warehousing and Distribution (n=7)	2.57 ± 1.18

Table 6.5. Lowest rated knowledge items (Sanitary Transportation Rule)

Training (n=8)	3.13 ± 0.93
Transportation Operations (n=8)	3.25 ± 1.20
Records (n=8)	3.25 ± 0.97
Vehicles and transportation equipment (n=8)	3.50 ± 1.12

Table 6.6. Highest rated information needs (Sanitary Transportation Rule)

Transportation Operations (n=7)	3.57 ± 1.29
Training (n=7)	3.14 ± 1.12
Records (n=7)	3.14 ± 1.12
Vehicles and Transportation Equipment (n=7)	3.00 ± 1.20

Table 6.7. Lowest rated knowledge items (Amendments to Registration of Food Facilities)

Waiver requests (n=8)	2.63 ± 1.41
Electronic registrations (n=8)	2.75 ± 1.30
Permissions of inspection for FDA (n=8)	2.88 ± 1.36

Table 6.8. Highest rated information needs (Amendments to Registration of Food Facilities)

Electronic registrations (n=7)	3.29 ± 1.56
When registration/renewal must occur? (n=6)	3.17 ± 1.67
Information Required in Registration (n=7)	3.14 ± 1.55
Permissions of inspection for FDA (n=7)	3.14 ± 1.55
Waiver requests (n=7)	3.14 ± 1.55

Table 6.9. Most preferred methods of educational delivery

Checklists (n=8)	4.38 ± 0.70
Online interactive tools (n=8)	4.13 ± 0.60
Web-based handouts (PDF) (n=8)	4.00 ± 0.71

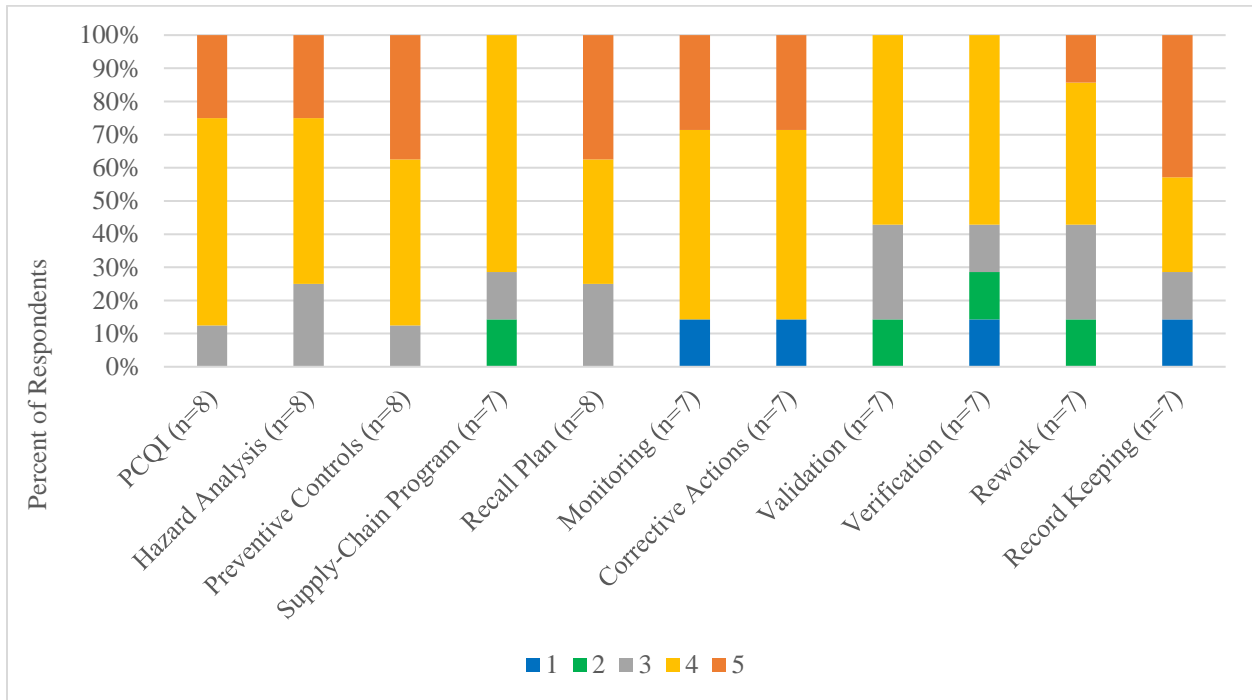


Figure 14. Food Safety Plan - Current Knowledge

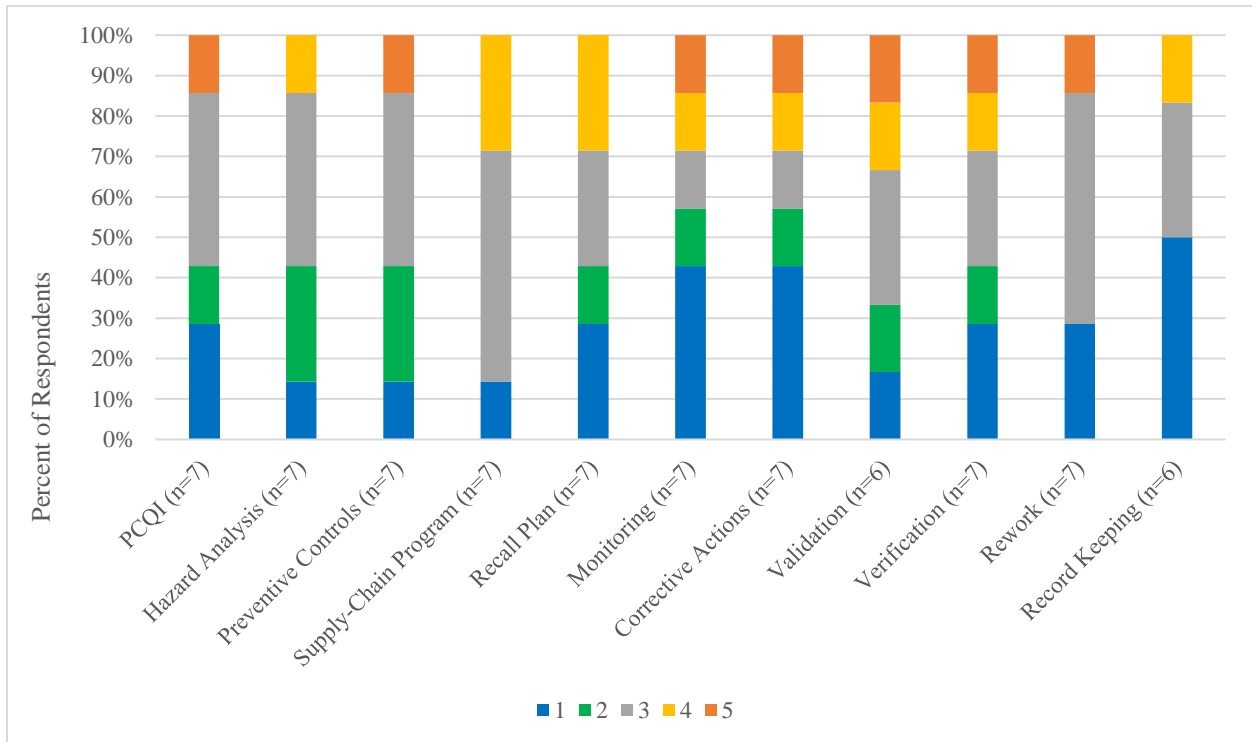


Figure 15. Food Safety Plan - Information Needs

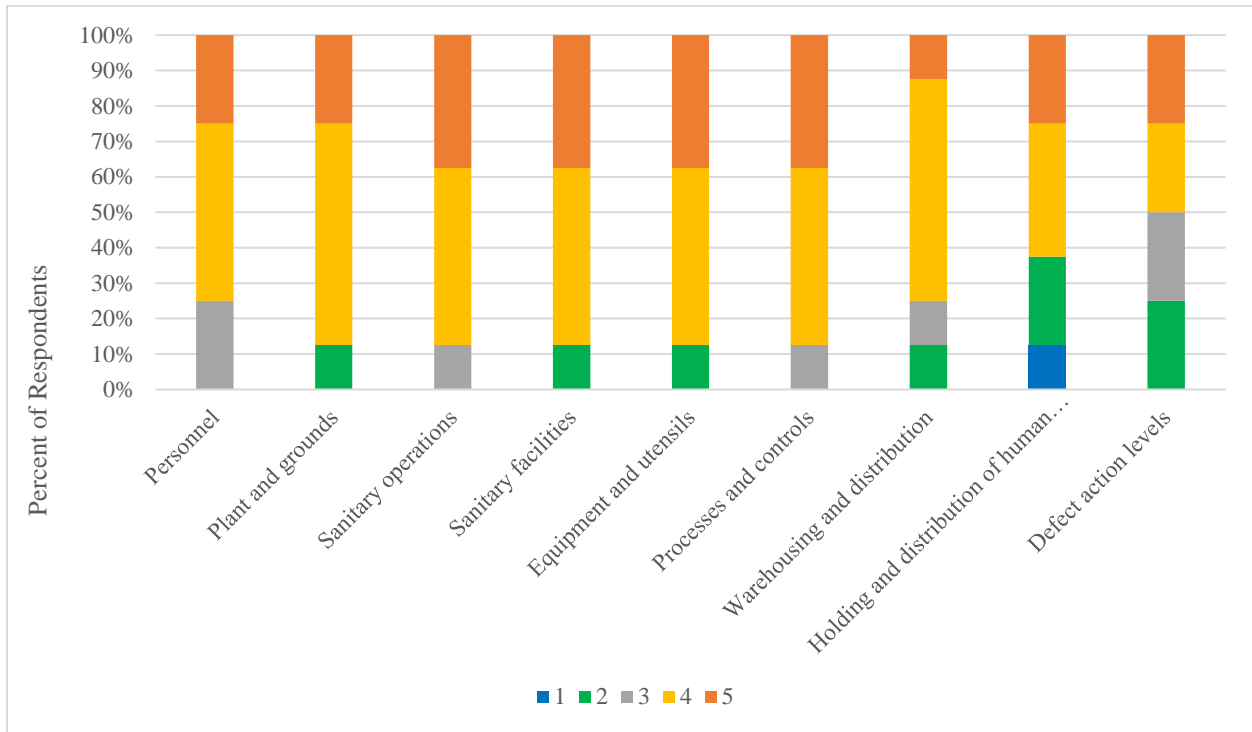


Figure 16. Current Good Manufacturing Practice - Current Knowledge

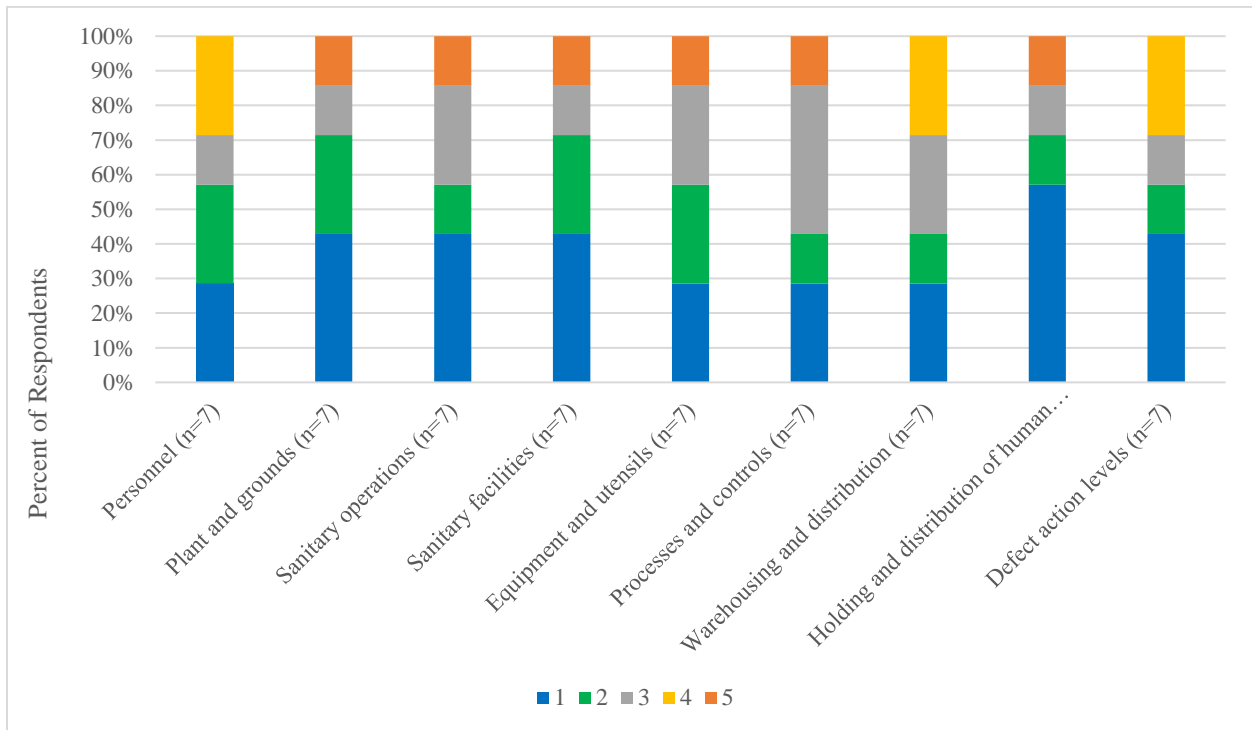


Figure 17. Current Good Manufacturing Practice - Information Needs

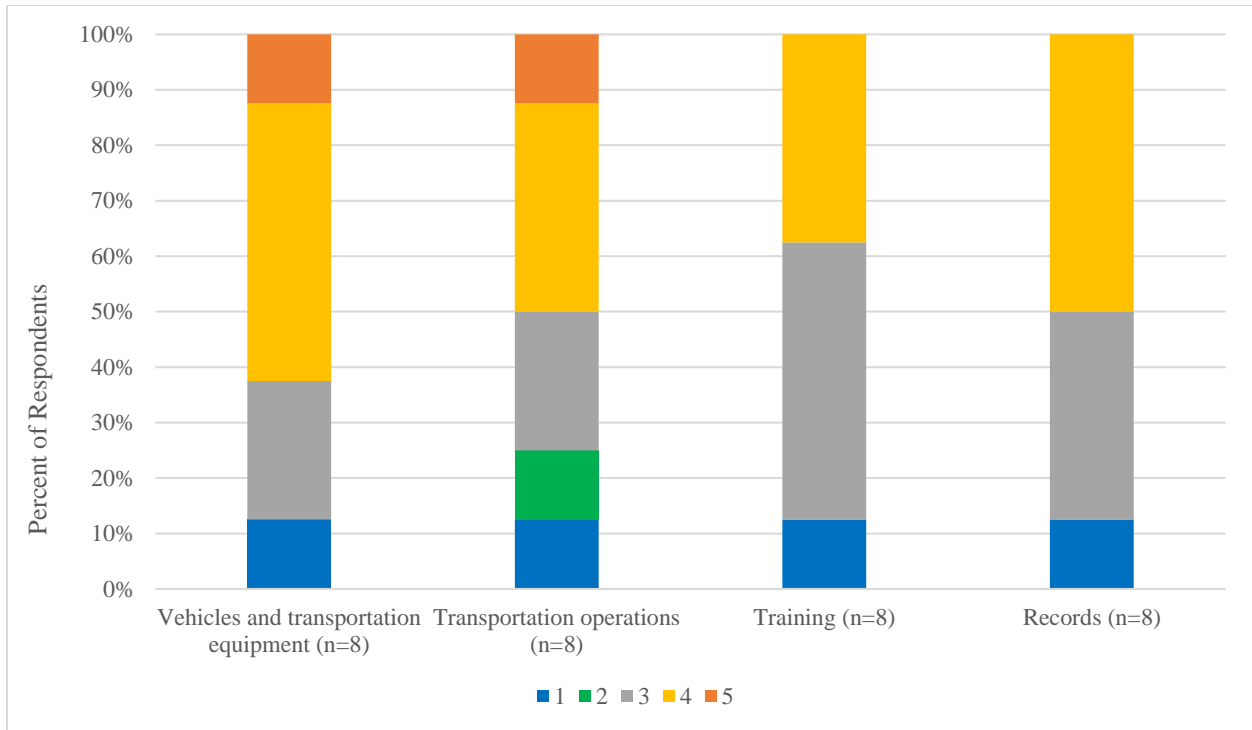


Figure 18. Sanitary Transportation Rule - Current Knowledge

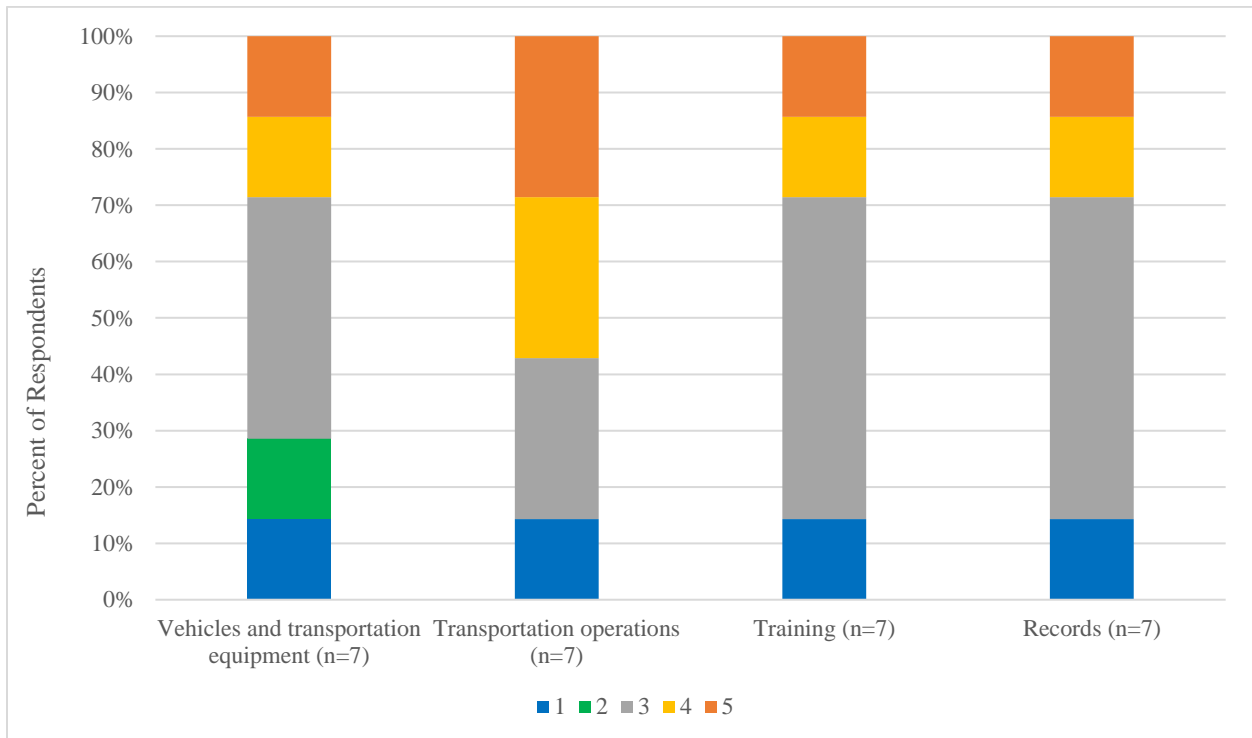


Figure 19. Sanitary Transportation Rule - Information Needs

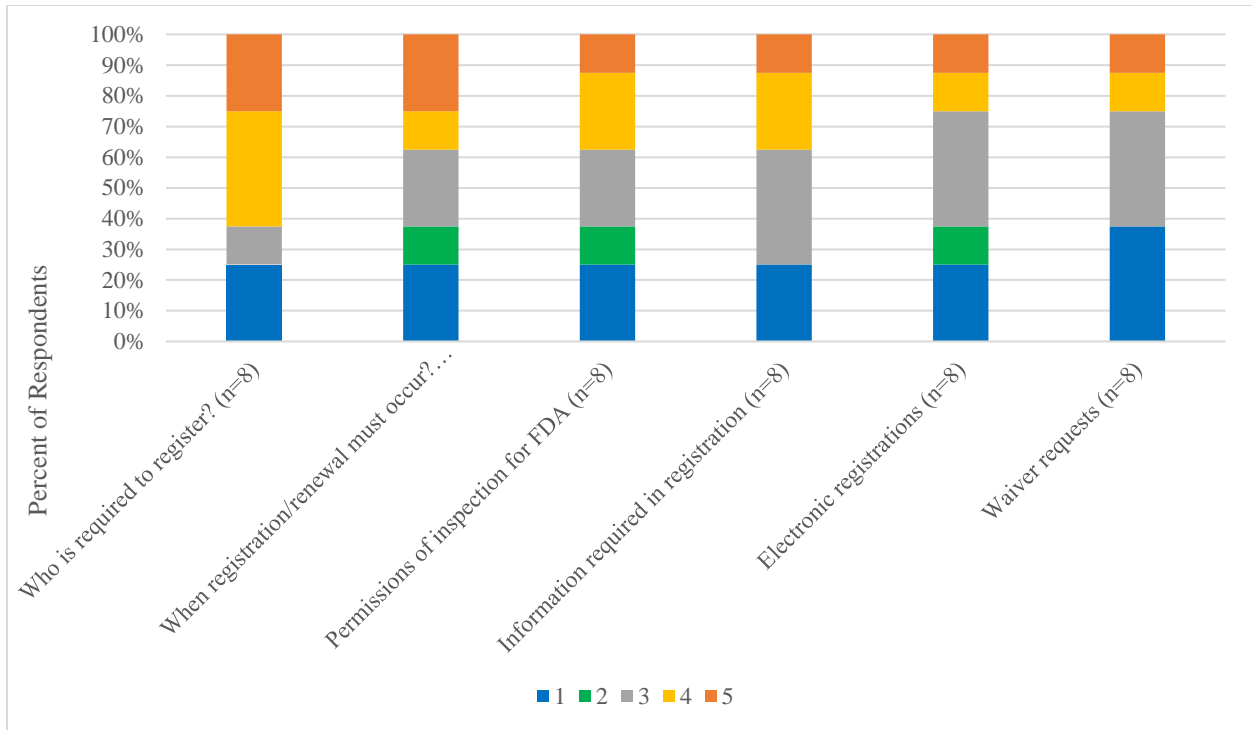


Figure 20. Registration of Food Facilities - Current Knowledge

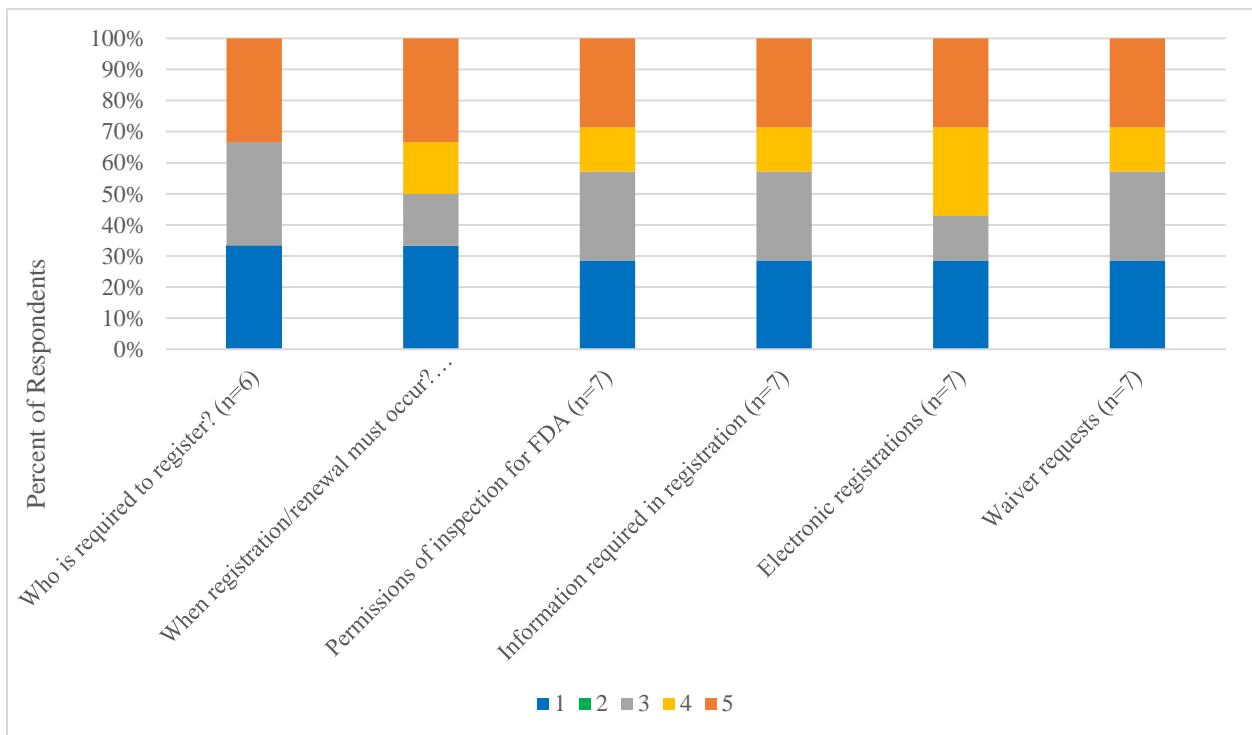


Figure 21. Registration of Food Facilities - Information Needs

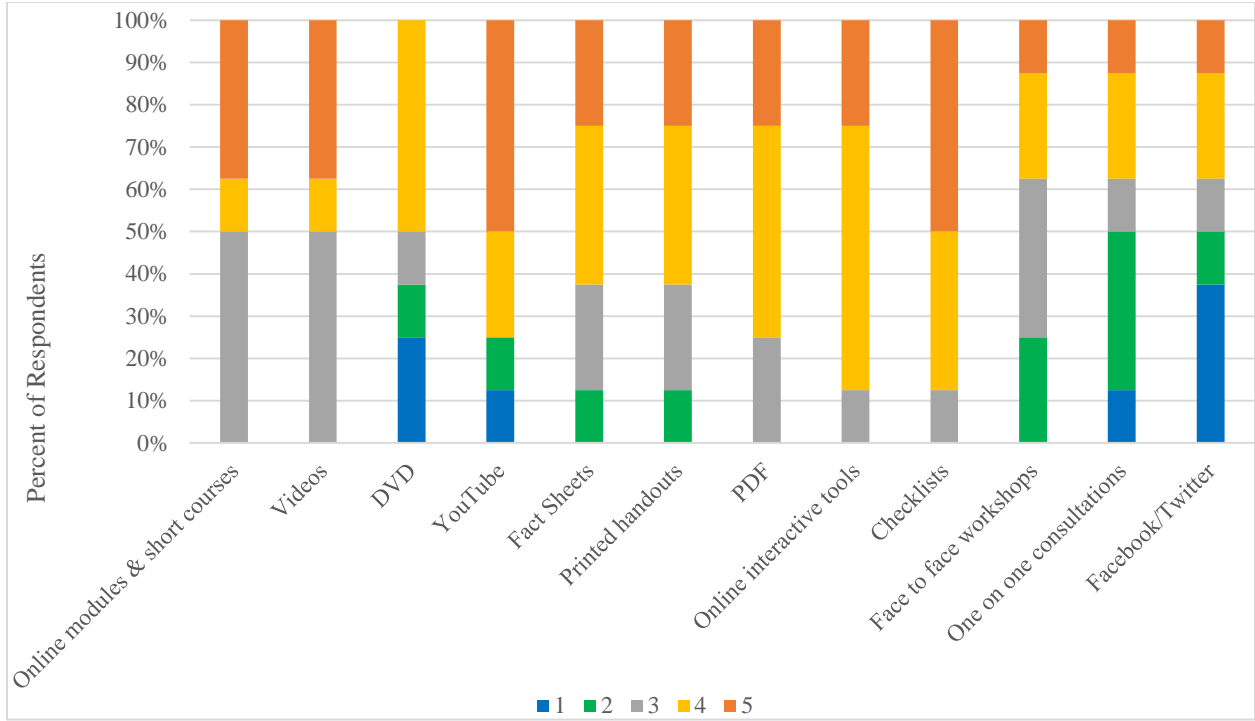


Figure 22. Delivery Method

CHAPTER 6. CONCLUSION

FSMA has brought about great change throughout the country. Many food processors in the realm of fruit and vegetables already had similar systems in place due to obligations to their buyers. This caused the needs assessment survey to suffer because of a decrease in topic salience. A stark difference in topic salience can be seen between the industry reaction to the checklist and the needs assessment. The checklist was widely accepted because it provides a simple, effective method of reminding processors of most of the steps necessary for Preventive Controls for Human Food, Sanitary Transportation rule, and Registration of Food Facilities compliance. Each plant directly and immediately benefits from the checklist. On the other hand, the needs assessment takes time out of a food safety specialist's day to respond to the questions. Prior food safety systems and required Preventive Controls for Human Food training decreases the need for additional outside training. A processing facility versed in the Food Safety Modernization Act would have minimal interest in attending an additional, voluntary training that gives no certificate or incentive, outside of extra knowledge.

Personal interaction with the processors would've made this project much more robust. There were limited any interactions between the extension team and actual processors. The idea of the sub-groups used to develop the facts sheets and scenario quizzes would have made the connection easier for the group, however, only one person who was not an extension agent attended one of the phone calls. This meant relationship with the processors was non-existent, which showed when the reminder emails were sent and multiple processors responded saying, "I thought the survey was spam". More personal interactions with the population would have aided the development and dissemination of this material, perhaps increasing responses to the needs assessment as well.

The needs assessment survey, though the response rate was incredibly low, verified the interest of processors in the checklist, scenario quizzes, and facts sheets. These materials are all beneficial to processors, do not require travel or training, and help improve their understanding of the FSMA. Phone interviews utilizing an open-ended question approach were suggested to develop additional materials. These additional materials may include more facts sheets, alternative checklists, in-person curricula developed specifically for the region, or other unforeseen materials.

This project led to the creation of some successful documents for fruit and vegetable processors in the NCR and beyond. Lessons learned from this project will be extremely helpful for the next phase of this work.

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