



CHAPTER 5

FOOD SAFETY



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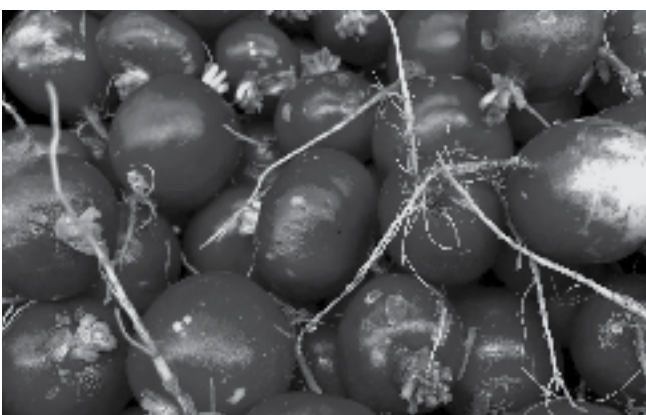
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FOOD SAFETY

CREATING A FOOD-SAFE ENVIRONMENT

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You likely started your farm or ranch business because you're passionate about providing good quality food for your community. One important aspect of that is making sure the food you produce is safe to eat. No matter your operation's size, you need to be aware of the opportunities for bacteria, viruses, or parasites to contaminate your products, and actively work to prevent that from happening.

CREATING A CULTURE OF FOOD SAFETY

Everyone in your operation needs to understand the importance of food safety. You as the owner need to establish your expectations and lead by example. When onboarding a new employee, or at the beginning of a new season, you'll need to train everyone in food safe practices and explain why they are important. If you produce a product that makes others sick, your whole farm or ranch could be held liable, be forced to recall all similar products, lose out on major sales, lose customers' trust, or worst case, seriously harm someone or even take their life. Beyond the threat of a food safety issue closing your doors, it also affects the farmers and ranchers around you: if one of your products is recalled, the entire farming and ranching community loses sales when customers avoid that product type. Taking care in your production methods is taking care of your community.

Make sure employees, volunteers, your family members, and others understand this and are working with you to keep your operation safe. Encourage them to report any issues they see immediately so you can work together towards a solution. When you see an issue, address it quickly and work to reduce the situation that caused it. For example, if employees are forgetting to sanitize sinks with chlorine bleach before cleaning produce, buy

several spray bottles for bleach solution and keep them on hooks right by the sink at eye level to serve as a visual reminder and make sure employees don't have to spend valuable time searching for the product they need.

CLEAN SOIL

Whether you're farming or ranching, you depend on soil. This great asset can also harbor dangers, however. Pathogens like *E. coli*, salmonella, and listeria can be present in our soils, especially those mixed with manure. If you have an integrated system with animals and produce crops, keep them separate as much as possible. Taking steps to exclude wild animals from your fields is important as well. If you rely on animal manures as fertilizer, take steps to avoid contaminating fresh produce with any pathogens that are present. Common strategies include only using manure on non-produce crops, composting all manures before application using a scientifically validated thermophilic (heat) composting process, or waiting 90 days after applying manure before harvesting crops that grow above the ground, and 120 days before harvesting crops that grow in or touch the soil. Fresh or even aged manure should never be used directly on produce crops during the growing season.

CLEAN HANDS

Clean hands are an essential part of producing clean foods! Make sure everyone on your farm, even visitors, are washing their hands for 20 seconds using potable water after using the bathroom, eating, handling animals, and before harvesting or handling any food products. Make sure you provide soap, clean water, and single-use towels in your facilities, especially adjacent to your restroom facilities.

CLEAN SURFACES

You need clean working surfaces to process clean food. When sourcing materials, look for surfaces that are smooth and non-porous (i.e. stainless steel or plastic) so they can be thoroughly cleaned and sanitized. Inspect and clean all surfaces thoroughly before using them, including harvest bins. Take care to ensure that bins don't come in contact with the soil, or if they do that those bins are not placed on processing tables. Always clean with potable (drinkable) water and detergent, and then sanitize and dry. The process is not complicated, but effective cleaning and sanitation depends on using the right products for the application and materials. The Produce Safety Alliance and University of Idaho Extension Educators working in food safety can direct you toward additional helpful resources related to cleaning and sanitation on the farm and in packing.

CLEAN WATER

Water can carry and quickly transfer pathogens. How much risk is associated with your water depends on where you source it and when and how you use it.

The water source you use will affect what considerations you need to take with your water. Water sources are generally: regulated public water (like city water), ground water (from wells), and surface water (like irrigation ditches).

Regulated Public Water System

Municipal drinking water systems can include publicly managed and treatment of wells, groundwater, and surface water. Because this water is regulated by the Environmental Protection Agency (EPA), your local government, and the public water utility, it is frequently tested and has the least amount of risk associated with its use. If you use water from a regulated public water system in your operation, there is no requirement to further test your agricultural water, but you may want to review periodic water testing documents.

Ground Water Sources

Water drawn from wells outside of a publicly regulated system is not as low risk but is generally less likely to be contaminated with pathogens because it typically filters through many layers of ground before it reaches the aquifer. You still need to consider maintenance, construction, and location of your well when assessing the risk of contamination. For example, if your well is not capped, and therefore exposed to rodents, other animals, and the environment, it is essentially an open surface water source. If your property floods and water enters the well, that well water is now as contaminated as surface water. Similarly, if you are pumping groundwater into a pond or ditch, that water is now considered surface water. For your own family's safety as well as that of your customers, you should test your well water annually for nitrates, coliform bacteria, and other contaminants.

Surface Water

Any water source that is open to the environment, including canals, irrigation ditches, ponds, and reservoirs, presents the highest amount of risk. Quality of the water depends on the location, uses and users of the water. If using surface water in your operation, you will want to assess how and when you are using it and consider testing periodically throughout the growing season to understand how the quality might change and what risks are present. Untreated surface water should never be used for any handwashing or post-harvest activities, including cleaning produce or equipment that contacts produce, cooling or ice making.

Water Application Methods

In addition to the source of water used in your operation, the method and timing of water use impacts the potential for contamination. For example, drip irrigation used in an orchard is low risk because it does not directly contact the produce, where a sprinkler application would. Produce grown in the ground will likely always come in contact with your water, so it is at a higher risk for contamination than produce grown off the ground.

Timing of Water Use

The risks associated with contaminated water can be associated with the timing of application. Pre-harvest water is any water used before harvesting, including water for irrigation, mixed into spray applications, and any other situation in which water comes in direct contact with your produce while it is growing. The closer you get to harvest time, the more cautious you should be if using surface water to irrigate produce crops. Harvest and post-harvest water refers to water used during cleaning and sanitation of harvest equipment and tools, harvesting, washing produce, cleaning and sanitizing packing areas, handwashing, making ice, cooling, or any other post-harvest practices. All post-harvest water must be potable. Many farms choose to go the extra step and add a sanitizer to produce wash water to reduce cross contamination of produce by the water, not to sanitize produce.

CLEAN HARVEST

Beyond keeping your growing environment clean, you need to minimize the opportunities for pathogens to be introduced as you are harvesting and processing your produce as well.

Harvest Records

For many reasons, it is a good habit to keep harvest and production records. It is beneficial to record what was harvested, harvest weights or volume, who was responsible for the harvesting, what field or plot was harvested, and the date. Animal production records would include specific information about the animal sold or processed. Many farms develop standardized lot codes to track this information in their records as well as on boxes or packaging. If your product is ever suspected or implicated in a foodborne illness outbreak, you will be able to pinpoint the source of the product and remove associated products quickly if you have a system for tracking this information. Harvest data is also essential for understanding your overall farm yields, sales, and profitability.

Manage Produce Quality

Any damaged produce, like those with cuts, blemishes, bruised spots, etc., should be culled. That damaged area can harbor harmful microorganisms, which can then be transferred to unblemished produce or pose a risk to humans if consumed. Keep “seconds” separate from the products you intend to sell from harvest onward. Don’t pile unsold or blemished produce in the fields, but instead compost them away from your production fields.

Cleaning or Washing Produce

If you’ve ever washed salad greens in a tub of cold water, you’ve probably noticed the greens perk up after the washing. This is because produce can draw water colder than itself into its cells. This phenomenon, called infiltration, is helpful when you’re spritzing greens at a market stand on a hot day, but also a potential source of food safety hazards. If your water is contaminated, the contamination infiltrates the produce with the water. This is why you must only use potable water when washing your produce, change your wash water frequently, or consider adding a sanitizer approved for this use.

Water can also encourage your produce to rot faster. Great care should be taken in how and when you use water to clean your produce. For many crops, like winter squashes or tomatoes, avoid washing with water all together. Knock excess dirt off in the fields with a dry brush or cloth that you clean often.

CLEAN STORAGE & TRANSPORTATION

The packaging, storage, and transportation of your products present additional opportunities to evaluate and take steps to ensure food safety. Unless a package can be cleaned and sanitized adequately, new packaging should be used. Make sure all of your packaging materials are food contact grade and stored off the ground and sealed from insects, rodents, dust, and dirt. In addition to being a good safety practice, this ensures your costly storage materials last! Do your research on what packaging materials work best and are most appropriate for your products and keep them in good repair.

Coolers, refrigerators, walk in coolers, and freezers should be inspected prior to use, cleaned, and sanitized regularly. Use a thermometer or other device to monitor the temperature.

Your vehicles are a hardworking part of your operation's equipment and often serve many purposes. Your truck bed may have transferred dogs, diesel, manure, chemicals, or many other important aspects of your operation. But this can create issues of cross contamination if you are also packing your fresh produce or other food items in the same vehicle before heading to market. Make sure your truck bed or interior of trucks and vans is clean before transferring any food products. If the vehicle cannot be adequately cleaned and sanitized, consider using a liner or some other barrier when transporting produce and food products.

While transferring your products, make sure your products are kept cool. A shade cloth or clean plastic tarp over your truck bed can help keep temperatures low. Many foods, like dairy products and meats, must be kept below certain temperatures. Make sure you have the proper containers to ensure this (coolers with dry ice, ice, or ice packs, for example), or consider investing in a refrigerated truck if transporting large quantities longer distances.

FOOD SAFETY
**FOOD SAFETY
MODERNIZATION ACT**



The U.S. Food and Drug Administration's Food Safety Modernization Act (FSMA), H.R. 2751, is the largest reform of food safety laws since the Food, Drug and Cosmetic Act of 1938. FSMA aims to ensure the U.S. food supply is safe by shifting the focus from responding to food contamination and outbreaks to preventing them. The law has a farm-to-fork approach and impacts all parts of the supply chain, including growers and farmers, processors, and distributors and shippers.

FSMA MAJOR RULES

FSMA is made up of seven major rules that address fresh produce, human food, animal food, transportation, and imported food. The descriptions here are adaptations from those found on the FDA website.

Preventive Controls for Human Food

Establishes minimum safety standards for manufacturing, processing, packing, and holding human food. This includes: employee training requirements, Good Manufacturing Practices (GAPs), and Hazard Analysis and Risk-based Preventive Controls. (See *Fact Sheet 5.8 Good Agricultural Practices for more information*). Requires that human food facilities registered with FDA have a written plan that identifies hazards and outlines appropriate preventive controls. (See *Fact Sheet 5.4 Preventative Controls for Human Food for more information*).

Preventive Controls for Animal Food

Establishes Current Good Manufacturing Practices and preventive controls for the production of food for animals. (See *Fact Sheet 5.5 Preventative Controls for Animal Food for more information*).

Standards for Produce Safety

Establishes science-based safety standards for growing, harvesting, packing, and holding of fruits and vegetables on domestic and foreign farms. (See *5.6 Produce Safety Rule for more information*).

Foreign Supplier Verification Program

Importers will be required to verify that food imported into the United States has been produced in a manner that provides the same level of public health protection as that required of U.S. food producers.

Third Party Certification

This rule establishes a framework, procedures, and requirements for the certification of third-party organizations to conduct food safety audits. Establishes a program for the accreditation of third-party auditors to conduct food safety audits and issue certifications of foreign facilities producing food for humans or animals.

Sanitary Transportation

Requires those who transport food by rail or motor vehicle, including shippers, receivers, loaders, and carriers to use sanitary practices to ensure the safety of food. It addresses the design of vehicles, refrigeration, and sanitation practices to ensure safe transportation of food.

Intentional Adulteration

This rule is aimed at preventing wide-scale harm through intentional adulteration of the food supply through the development of food defense plans. Requires domestic and foreign food facilities registered with the FDA develop a plan that assesses contamination vulnerabilities and document a mitigation strategy to achieve certifications.



FOOD SAFETY

HAZARD ANALYSIS CRITICAL CONTROL POINT

Hazard Analysis Critical Control Point (HACCP) is a food safety management system that addresses biological, chemical, and physical hazards from raw material production, procurements, and handling, to manufacturing, distribution, and consumption of the finished product. HACCP is a logical, simple, effective, and systematic approach to food safety recognized globally and widely adopted throughout industry. It is designed for all levels of the food system and is comprised of preliminary steps and seven principles, outlined below.

The Idaho State Department of Agriculture and your local Health District can help you determine whether HACCP or Preventative Controls for Human Foods is better for you and your operation. (See *Fact Sheet 5.4 Preventative Controls for Human Food for more information*). Make sure to contact those agencies for specific requirements before diving into your food safety plan.

CREATING YOUR HACCP PLAN

Your food safety plan is a very important step towards ensuring you are creating safe food products. Your plan needs to reflect your facility, equipment, practices, and procedures. It is not something that is a one-and-done—your food safety plan needs to be a living document and is continuously improved. Beware of websites and businesses that will write your HACCP plan for you. Your HACCP plan needs to be applicable to your process, your equipment, and your programs to prevent food safety incidents from happening. A generic HACCP plan can be used to get you started but you still need to make sure it is applicable to your facility and product.

PREREQUISITE PROGRAMS

Prerequisite programs include Good Manufac-

turing Practices, Sanitation Programs, Chemical Control, Allergen Control, Water and Air Quality Programs, Supply Chain or Approved Supplier Programs, Maintenance Programs, Training, Storage and Shipping, Traceability and Recall, Pest Control, and others. These programs can help you build a solid foundation of food safety processes and requirements to build upon in your HACCP food safety plan. More information on these programs can be found on FDA's website: <https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/haccp-principles-application-guidelines>.

HACCP PRELIMINARY STEPS

There are important steps to take to inform your HACCP Food Safety Plan and ensure it is safe, effective, and thorough. Those steps are: assembling a HACCP team, describing the product and product distribution, describing the intended use and consumers of the product, developing a flow diagram that describes the process, and verifying that flow diagram.

Assemble the HACCP Team

For any food safety plan to be adopted, the whole operation must understand the importance of food safety and work together to implement and uphold the food safety plan. Develop a core food safety team to help in this goal. If you have a large staff, try to fill this team with representatives from across all skill sets, management levels, and portions of your operation.

Do not be afraid to change members of the team as needed and to invite subject matter experts.

Describe the Product & Product Distribution

In this step, the HACCP team needs to decide how many food safety plans your facility needs. All

products must be made with a food safety plan; however, each product does not need its own food safety plan. If products have similar processes and similar hazards, they can be combined under one food safety plan. The product description contains the product's common name, processing description, food safety characteristics, types of packaging, any labeling requirements, length of shelf life, and storage and distribution conditions.

Describe the Intended Use & Consumers of the Product

Frequently, the intended use and consumers of the food is included in the product description. Describe the normal expected use of the food and who are the intended users of the product. Intended users could include retail, food service, or further manufacturing at your facility or other facilities. Be aware of specialized groups who are especially susceptible to foodborne that illness will consume your product. Those groups include infants and kids, pregnant women, immunocompromised individuals, and the elderly. Determine how your consumers will use and misuse the product, if the product is RTE (ready to eat), requires further cooking, needs stored at refrigerated/frozen temperature, etc.

Develop a Flow Diagram which Describes the Process

Create a flow diagram that provides a clear, simple outline of the steps involved in manufacturing the food product. This diagram needs to encompass everything from receiving to when it changes ownership and illustrate all product inputs and outputs. Every piece of equipment and ingredient or processing aid needs to be included in the flow diagram.

Verify the Flow Diagram

After you have completed the flow diagram, the food safety team needs to walk through the process and review for accuracy and completeness.

HACCP PLAN SEVEN KEY PRINCIPLES

Once you have completed the above steps, you should have a thorough understanding of your product and the production process of it. That prepares you to launch into HACCP's seven key principles: hazard analysis, CCP identification, establishing critical limits, monitoring procedures, corrective actions, verification procedures, and record-keeping and documentation.

Conduct a Hazard Analysis

The hazard analysis is a two-part process, the first identifies the food safety hazards and the second requires evaluation of likelihood and severity of the hazards identified. The hazards are classified into one of three categories: microbiological, chemical, or physical.

HAZARD CLASSIFICATIONS

Microbiological hazards include harmful bacteria, viruses, or parasites such as listeria, salmonella, or E. coli.

Chemical hazards could include materials that can cause illness or injury due to immediate and long-term exposure such as allergens, heavy metals, pesticide and herbicide residues, food additives, building and equipment maintenance fluids, etc.

Physical hazards include any potentially harmful extraneous matter, causing injury or choking to the consumer. Materials like metal, wood, stones, plastic, bones, rubber, and glass fragments are included.

Once you have analyzed the ingredients and process for potential hazards the food safety team now needs to determine the likelihood and severity of that hazard occurring.

Determine the Critical Control Points

Once the food safety team has determined the hazards, their potential severity, and likelihood, the food safety team needs to determine the appropriate control mechanisms to reduce or eliminate the hazards. What policies, procedures, and programs do you have in place to eliminate or reduce the hazard to an acceptable level? These prevention methods should be implemented at a critical control point, or CCP. CCPs are a step at which control can be applied and are essential to prevent or eliminate a food safety hazard or reduce to an acceptable level. At this step the food safety team needs to look at the hazard and determine if the prerequisite programs control the hazard or not. If not, then the step is a critical control point. Common critical control points include cooking or pasteurization, acidifying, dryers that reduce the water activity, labeling, organic acid sprays, metal detection/X-ray, etc.

Establish Critical Limits

The critical limit is the maximum or minimum value to which the hazard must be controlled to reduce the hazard to an acceptable level. Critical limits can be one or a combination of factors including temperature, pressure, time, physical dimensions, water activity, pH, aroma and visual appearance.

Establish Monitoring Procedures

Monitoring includes observation and measurements to assure your food safety plan is functioning properly. Monitoring helps you track the process and indicate when changes need to be made in order to keep the process in control, determine when control was lost, and which product is impacted, and provide written documentation to verify the food safety plan and programs.

Establish Corrective Action

When issues arise, the food safety plan must detail how to handle the violations and deviations. The corrective action plans must consist of two components: how to get the process back into control and how to handle the impacted product.

Establish Verification Procedures

In addition to monitoring, the food safety plan needs to be verified to ensure that the system is operating according to the program requirements. Verification activities could include a supervisor reviewing paperwork at the end of the shift, a quality assurance person reviewing the documentation before releasing product for distribution, calibration of instrumentation, microbiological testing of ingredients and finished products, or more.

Establish Record-Keeping & Documentation Procedures

The last principle involves all the documentation and records that have been kept in the process of making the product and ensuring the food safety plan is functioning. If it is not documented, it did not happen. All records need to be signed and dated with accurate references. Good documentation practices and document control are required for all documents associated with your product production and your food safety plan. Remember, your food safety plan, and all documentation associated with your safety plan, are legal documents.



FOOD SAFETY PREVENTIVE CONTROLS FOR HUMAN FOOD

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One of the seven major rules of the Food Safety Modernization Act, the Preventive Controls for Human Food Rule, establishes Current Good Manufacturing Practices (CGMP), hazard analysis, and risk-based preventive controls for the production of human foods. The rule's purpose is to ensure that products are safe for consumption.

REGULATORY BODIES

There are two federal bodies that majorly influence food safety plans and requirements: the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA). The USDA is primarily concerned with meat, poultry, and eggs. The FDA is responsible for everything else. USDA requires a food safety plan that follows the HACCP concept (*See Fact Sheet 5.3 Hazard Analysis Critical Control Point for more information*). FDA requires a food safety plan that follows the Preventive Controls for either Human Foods or Animal Foods.

In addition to the regulations set out by federal bodies, you will need to follow Idaho state food safety requirements. The Idaho State Department of Agriculture (ISDA) and Idaho Health Districts may require either food safety system. Always check with these agencies about what food safety regulations affect you and your business.

GOOD MANUFACTURING PRACTICES

The Preventive Controls for Human Foods Rule updated the Current Good Manufacturing Practices (cGMP). Good Manufacturing Practices (GMP) are the minimum sanitary requirements to produce a safe food product. GMPs include the following headings: personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, processes and controls, ware-

housing and distribution, holding and distribution of human food by-products for use as animal food, and defect action levels.

FOOD SAFETY PLAN

The Rule requires that a facility (if you manufacture, process, pack, or hold human food for consumption in the United States) have a food safety plan that is compliant with the rule. Your food safety plan builds on the HACCP methodology with some additional requirements. (*See Fact Sheet 5.3 Hazard Analysis Critical Control Point for more information*). The following are some of the differences between HACCP and the Preventive Controls requirements.



PREVENTIVE CONTROLS

In addition to prerequisite programs, the PC rule includes preventive controls to help significantly reduce or minimize hazards. Preventative control classifications include process controls, food allergen controls, sanitation controls, and other controls.

PREVENTATIVE CONTROL CLASSIFICATIONS

Process controls include cooking/pasteurization, freezing/refrigeration, acidifying foods, etc.

Food allergen controls include how to ensure that the Big 9 allergens (milk, eggs, peanuts, tree nuts, crustacean shellfish, fish, soy, wheat, and sesame) are labeled if they are included in the food. If they are not, that no inadvertent cross contamination exposes your product to those allergens.

Sanitation controls are the procedures and program to ensure the facility and equipment is maintained according to sanitary design principles.

Other controls are those that significantly reduce or prevent the hazard from occurring but are not categorized in the previous preventive controls' classifications. metal, wood, stones, plastic, bones, rubber, and glass fragments are included.

RECALL PLAN

A recall plan is required for all facilities that have identified any hazard that requires a preventive control. This includes most manufacturers, as most food production involves some level of hazard.

QUALIFIED INDIVIDUAL

The person that oversees the food safety plan must have the training and knowledge to be considered a preventive controls qualified individual (PCQI). The requirements for becoming a PCQI are

outlined in the rule. The Food Safety Preventive Controls Alliance (FSPCA) (<https://www.ifsh.iit.edu/fspca>) has a standardized curriculum that is recognized by the FDA that can help you meet the requirements of a PCQI.

HAZARD ANALYSIS CRITICAL CONTROL POINTS

Preventative Controls for Human Food relies on key principles outlined in Hazard Analysis Critical Control Point (HACCP).

HACCP SEVEN KEY PRINCIPALS:

- ✓ Hazard Analysis
- ✓ Critical Control Point Identification
- ✓ Establishing Critical Limits
- ✓ Monitoring Procedures
- ✓ Corrective Actions
- ✓ Verification Procedures
- ✓ Record-Keeping & Documentation

EXEMPTIONS

Not all facilities have to comply with all sections of the Preventive Controls for Human Foods (PC) rule. Retail stores, restaurants, and farms are not subject to the rule. Other facilities could be classified as qualified or exempt; those facilities must still comply with some sections like cGMPs and modified requirements. However, those facilities may not be responsible for all sections of the PC rule. Some reasons for exemptions include: low-risk on-farm activities, type of storage facilities, products already covered by other specific regulations (seafood, juice, low acid canned food, alcoholic beverages), or the size of your business. Visit the FDA website (fda.gov) or the Who Can Help section at the end of this chapter for more information.

FOOD SAFETY PREVENTIVE CONTROLS FOR ANIMAL FOOD

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Preventive Controls for Animal Foods is one of the seven major rules of the Food Safety Modernization Act (FSMA). The rule establishes Current Good Manufacturing Practices (CGMP), hazard analysis, and preventive controls for the production of animal foods. The rule's purpose is to ensure that animal feed is safe for animal consumption, and for humans who consume animals fed on these products. Animal food facilities covered under this rule must have a food safety plan in place, analyze their production for potential hazards, and implement controls to reduce risk. The rule takes into consideration the unique aspects of the animal food industry and provides flexibility for various types of animal food facilities.

WHO IS REQUIRED TO COMPLY?

Businesses in the United States that manufacture, process, pack, or hold food for consumption by animals are covered. Examples include livestock and poultry feed manufacturers, pet food and treat manufacturers, ingredient manufacturers, processors, and holding facilities. Businesses that ship animal food or animal food ingredients to the U.S. are also required to comply. Even if determined to be exempt from the Animal Food Rule, it is important to check if your facility is covered by local or state regulations.

FEED MILLS

Feed mills are sometimes covered by the Preventive Controls for Animal Food Rule. If you have a feed mill to feed cattle you raise for beef, and both are in the same geographic location, your feed mill is not subject to the rule. If the two operations are not under the same owner (i.e. the food mill on your ranch is not yours), then the feed mill is subject to the Preventive Controls for Animal Food rule.

BUSINESSES NOT COVERED

- ✓ Farms that only grow crops used for animal food
- ✓ Feed mills that are part of fully vertically integrated farming operations (with all components under the same ownership) producing feed only for those animals
- ✓ Retail establishments that sell animal feed or pet food directly to consumers
- ✓ Home-based pet food producers

BYPRODUCTS

Whether or not byproducts are subject to the rule depends on the intention of the original products. If the byproduct comes from a company that produces human food, the company is subject to the human food rule and not the animal food rule. However, if the byproduct is then processed or finished into an animal food product through an activity like drying or pelleting, then Preventive Controls for Animals Food Rule will apply.

KEY REQUIREMENTS OF THE ANIMAL FOOD RULE

Businesses that fall under the regulation of the Preventive Controls for Animal Food Rule must comply with the below requirements.

Current Good Manufacturing Practices

The FDA finalized cGMPs for safe animal food production, including best practices for personnel, cleaning and sanitation, holding, distribution, equipment, etc. Businesses covered must comply with the cGMPs.

Hazard Analysis

Facilities should first identify any known or reasonably foreseeable hazards - biological, chemical, radiological, and physical. Based on an assessment of severity and probability, preventive controls must be written and implemented for any hazards identified that require additional mitigation.

Preventive Controls Food Safety Plan

Written preventive controls address hazards that may occur during any step of the animal food process. These controls will ensure that any hazards will be significantly minimized or prevented to ensure that the animal food is not contaminated. Types of controls include process controls, sanitation controls and supply-chain controls. The control must be verified and monitored to confirm its effectiveness. Record keeping provides documentation of these activities and is required.

FOOD SAFETY PRODUCE SAFETY RULE

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The Produce Safety Rule is one of seven rules included in the Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA). The Produce Safety Rule (PSR) establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. This rule covers aspects of worker health, hygiene, and training; agricultural water (for both production and post-production harvest uses); biological soil amendments; domesticated and wild animals; equipment, tools, buildings, and sanitation; and the production of sprouts. Many small farms will not be required to comply with all the federal food safety regulations in the Food Safety and Modernization Act (FSMA) Produce Safety Rule (PSR). How the rule will affect you and your farm will depend on what you grow, how much you sell, and who your customers are.

COVERED PRODUCE

Foods that are eaten raw are at increased risk of foodborne illnesses because cooking reduces the presence of microorganisms of public health significance. For that reason, the FSMA PSR is focused on produce that is commonly consumed raw. Check with the FDA for a final list on produce not subject

to the Produce Safety Rule. Any crops not specifically listed as not subject to PSR by the FDA are subject to the rule. Below was the list of not covered crops at the time of this guide's publication.

Value Added Products

What about value added fresh foods made from covered raw agricultural commodities? While the production of the fruits and vegetables would be subject to the Produce Safety Rule, products made from them, ready-to-eat or processed products like cut and washed salad mixes, peeled baby carrots, zucchini noodles, and salsas are not regulated under the Produce Safety Rule. These products are potentially subject to other food rules under the FSMA Preventative Controls for Human Food Rule or rules determined by your public health department. (See *Fact Sheet 5.4 Preventative Controls for Human Food* for more information).

Sprout Production

Unfortunately, many foodborne illnesses have resulted from the production of sprouts. Because of this, the FDA has developed specific and rigorous standards for sprout production that are separate

SOME CROPS NOT SUBJECT TO PSR

<i>Asparagus</i>	<i>Cashews</i>	<i>Eggplants</i>	<i>Peanuts</i>
<i>Beans, black</i>	<i>Cherries, sour</i>	<i>Figs</i>	<i>Pecans</i>
<i>Beans, great northern</i>	<i>Chickpeas</i>	<i>Food grains</i>	<i>Peppermint</i>
<i>Beans, kidney</i>	<i>Cocoa beans</i>	<i>(such as wheat,</i>	<i>Potatoes</i>
<i>Beans, lima</i>	<i>Coffee beans</i>	<i>oats, or rice)</i>	<i>Pumpkins</i>
<i>Beans, navy</i>	<i>Collards</i>	<i>Ginger</i>	<i>Squash, winter</i>
<i>Beans, pinto</i>	<i>Corn, sweet</i>	<i>Hazelnuts</i>	<i>Sweet potatoes</i>
<i>Beets, garden (roots</i>	<i>Cranberries</i>	<i>Horseradish</i>	<i>Water chestnuts</i>
<i>and tops)</i>	<i>Dates</i>	<i>Lentils</i>	
<i>Beets, sugar</i>	<i>Dill (seeds and weed)</i>	<i>Okra</i>	

from the Produce Safety Rule. For resources refer to the Sprout Safety Alliance (<https://www.iit.edu/ssa>).

Note: Microgreens are not considered sprouts and would be subject to the general requirements for covered produce.

DOES THE PRODUCE SAFETY RULE APPLY TO YOUR FARM?

Any farm engaged in growing, harvesting, packing, or holding produce identified as a raw agricultural commodity (RAC) that is not on the rarely consumed raw list provided by FDA is potentially subject to the FSMA Produce Safety Rule. Documentation is required to establish whether your farm is subject to the rule or not, and if subject, whether you qualify for an exemption. It is helpful to start by assessing your operation and answering a few key questions about your operation. You may use the anonymous, self-guided decision tool created by University of Idaho Extension or view the flow-chart developed by the Food and Drug Administration. You may also wish to use an annual produce sales and qualified exempt worksheets developed by the Idaho State Department of Agriculture. These tools and the material in this Fact Sheet are intended for general information only. It is recommended that you verify any assumed coverage or exemptions with the Idaho State Department of Agriculture Produce Safety Program, who serves as the FSMA PSR regulator in the state of Idaho.

University of Idaho Extension has developed a step-by-step guide to recordkeeping for covered and qualified exempt farms that can be requested through their Food Safety for Produce Growers website (<https://www.uidaho.edu/extension/food-safety-for-produce-growers>).

Legal Responsibility

Compliance with the rule is serious and federally mandated. If you violate the FSMA PSR, you can be prosecuted criminally. You, as the owner of your business, are strictly liable for your operation—you

cannot plead ignorance to FSMA's rules, or any conditions of your farm. Even if you qualify for an exemption from inspection or other requirements in the rule, you could forfeit your exemption if hazardous practices on your farm lead to a food-borne illness outbreak. Make sure you're aware of the food safety risks in your operation and how to mitigate them.

COVERAGE CLASSIFICATIONS

Farms can be classified as Not Covered, Qualified Exempt, or Covered. These classifications are determined by what activities are conducted on a farm, what crops they grow, whether the crop is consumed raw or processed, how the produce is sold, and by volume of sales. Documentation is required to establish whether a farm is subject to the rule or not, and whether they qualify for an exemption. Need to know how this affects your farm? Use the anonymous, self-guided decision tool created by University of Idaho Extension. Note: this section is intended as general information only, please verify any assumed coverage or exemptions with the Idaho State Department of Agriculture Produce Safety Program.

FARMS NOT COVERED BY THE PRODUCE SAFETY RULE

In general, your farm would not be likely to be subject to the rule if you:

- ✓ *Do not grow, harvest, pack, or hold any produce on your farm.*
- ✓ *Do not grow, harvest, pack, or hold any produce covered by the rule.*
- ✓ *Grow covered produce that is processed in a way that adequately reduces the presence of microorganisms of public health significance (for example, you grow tomatoes that are sold and processed into a cooked sauce).*
- ✓ *Grow only for personal consumption, not sale.*
- ✓ *Sell less than \$25K worth of produce per year, on average, in the previous three years.*

FARMS ELIGIBLE FOR A QUALIFIED EXEMPTION

Your farm may be eligible for a qualified exemption to inspection and some of the record-keeping requirements of the Produce Safety Rule if your farm sells less than \$500,000 (gross) per year of all food, adjusted for inflation. (Note, this is not just your sales of produce. The FDA defines food as any product that is intended for human or animal consumption), and more than 50% of your food is sold directly to either 1) an individual consumer (not a business), including those reached through direct marketing, or 2) a restaurant or retail establishment located in the same state or Indian reservation or within 275 miles of your location (direct marketing examples include CSA subscribers, Farmers' Market customers, etc. Retail establishments can include grocery stores, farmstands, convenience stores, and even vending machines).

Requirements of Qualified Exempt Farms

Exempt growers in Idaho will be asked to verify their exemption annually with the Idaho State Department of Agriculture. Qualified Exempt farms are required to establish and keep sales records and documentation that supports their exemption.

Qualified exempt farms are also required to comply with modified labeling requirements. You must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard or documents delivered contemporaneously with the produce. See example below:



Withdrawal of Exemption

If your farm's total food sales exceed \$500,000 per year, adjusted for inflation, over a three year period, or if you sell less than 50% of your products to a qualified end user as defined in the rule, you will cease to qualify for an exemption and will be subject to all parts of the rule and inspection.

Also, according to FDA, your farm's qualified exemption may be withdrawn if there is an active investigation of an outbreak of foodborne illness directly linked to your farm, or if the FDA determines it is necessary to protect public health and prevent or mitigate an outbreak based on conduct or conditions associated with your farm. All the more reason to make it a priority to increase your knowledge and application of on-farm food safety practices!

FARMS COVERED BY THE PRODUCE SAFETY RULE

Farms covered by the Produce Safety Rule must comply with the below requirements.

Inspections

Covered farms are subject to mandatory compliance inspections. In Idaho, these inspections on behalf of FDA are conducted by the Idaho State Department of Agriculture (ISDA). There is no charge for an inspection. ISDA has published a helpful fact-sheet outlining what to expect from an inspection, titled "What to Expect of a Regulatory Inspection – Informational Handout for Farmers." Refusing the inspection of your operation is prohibited and carries legal consequences for you as the owner and for your operation. If your farm is GAP certified and has gone through the audit process, you will notice similarities between an audit and an inspection. (See *Fact Sheet 5.8 Good Agricultural Practices for more information*). The primary difference is that a GAP audit is voluntary, and a FSMA PSR inspection of a covered farm is not. If you participate in the USDA Agricultural Marketing Service Harmonized GAPs Audit Program, your Harmonized GAP audit is aligned with a FSMA Produce Safety Inspection, but does not replace it.

Food Safety Training for a Designated Individual

If your farm is covered by the Produce Safety Rule, you are required to send a designated farm food safety individual from your farm to a produce safety training approved by the FDA. Currently, the Produce Safety Alliance Grower Training, developed by Cornell University, is the only approved training that meets this requirement. This training is available in Idaho thanks to a collaboration between the University of Idaho Extension and the Idaho State Department of Agriculture. They offer one day in-person trainings or two half-day live online trainings in the fall and winter of each year. These trainings are offered for free or a significantly reduced rate thanks to grant funding, and they are open and available to all Idaho growers, regardless of size or coverage by the rule. Attending this training is beneficial to you and your operation regardless of your farm's size and whether you are exempt from the PSR, and most growers consider it time well spent. Find the trainings here: <https://www.uidaho.edu/extension/food-safety-for-produce-growers>.

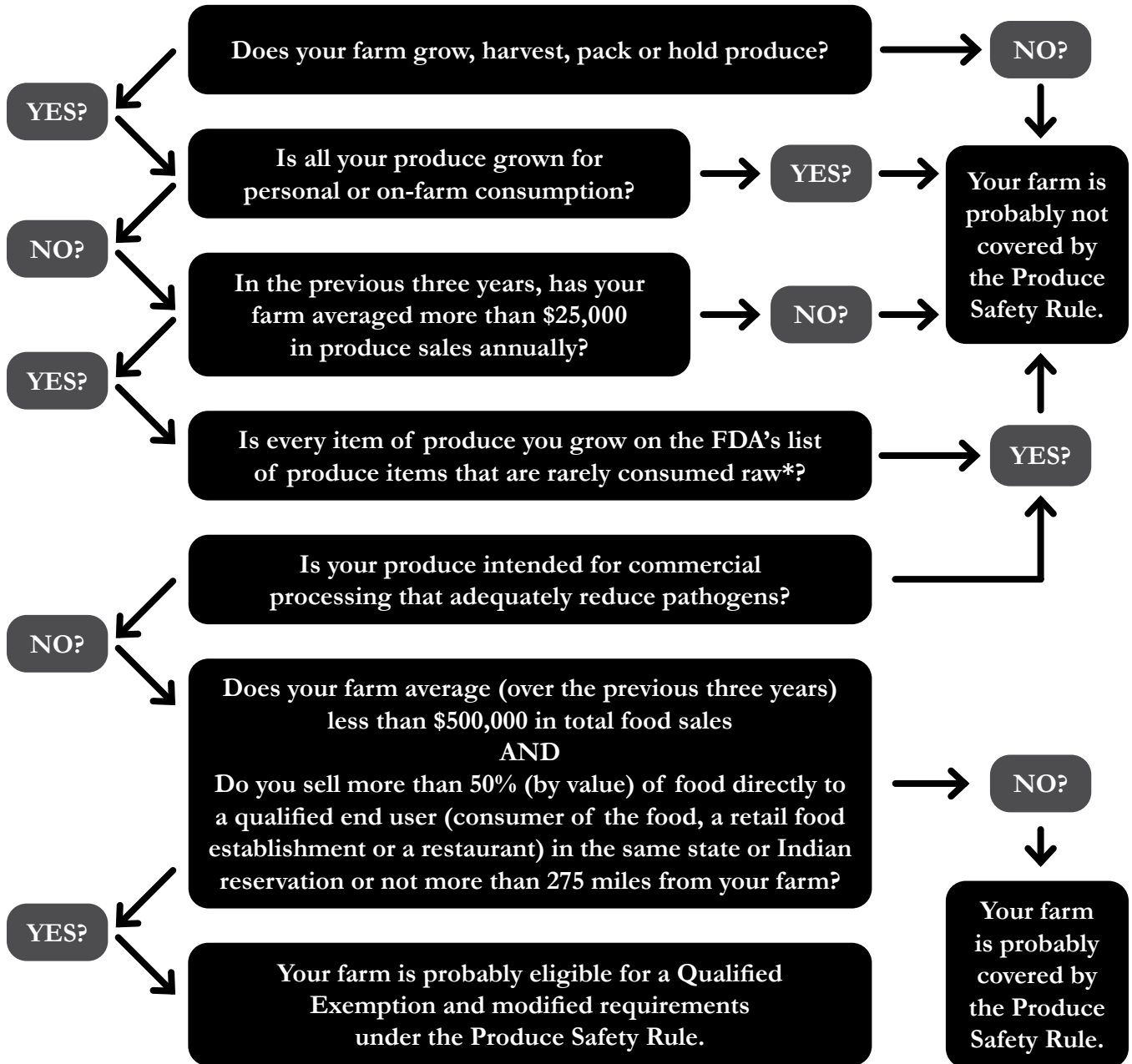
Recordkeeping for Qualified Exempt & Covered Farms

Keeping records that document your food safety practices related to the growing, harvesting, packing, and holding of fruits and vegetables under the FSMA Produce Safety Rule may be the most challenging task facing a covered farm. University of Idaho Extension has developed a step-by-step guide to recordkeeping for covered and qualified exempt farms. This guide can be requested through the University of Idaho Extension's Food Safety for Produce Growers website. (<https://www.uidaho.edu/extension/food-safety-for-produce-growers>).

FOOD SAFETY PRODUCE SAFETY RULE FLOW CHART



START HERE



**Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.*



FOOD SAFETY

GOOD AGRICULTURAL PRACTICES

If you are a produce grower wanting to access retail, wholesale, or institutional buyers, you're likely to hear about Good Agricultural Practices, or GAP Certification, as a requirement. GAP is a voluntary, third-party verification program. While there is no guarantee that produce from a GAP certified farm will be 100% free from disease-causing organisms, certification assures buyers of your farm's commitment to food safety and proven practices that reduce chemical, physical, and microbial contamination.

OPTING IN

Unlike the FDA Food Modernization Act's Produce Safety Rule, GAP is a voluntary program. Growers choose to participate in GAP to access many retail, restaurant, school, and wholesale markets for their products. While the practices, documentation, and requirements of GAP are similar to those of the Produce Safety Rule, they are different programs. A FSMA inspection does not certify you for GAP, and likewise a successful GAP audit does not exempt you from a FSMA inspection if you meet the definition of a covered farm.

It is important to note two other important differences between FSMA inspections and GAP audits. There are audit fees associated with GAP certification that the grower pays, based on standardized USDA rates. This hourly rate covers the auditor's preparation, travel, and on-site time, as well as their review, certification, and posting of results. GAP also requires that a written Farm Food Safety Plan be in place.

What can be GAP certified?

GAP certification is available for fruits and vegetables, tree nuts, dried fruits, horticulture, and nursery crops (including floriculture), defined by USDA as specialty crops. This definition includes many crops

such as pumpkins, potatoes, and sweet corn, that are not covered by the FSMA Produce Safety Rule.

GAP audit services and certification may also cover additional crops or products including culinary herbs, dried beans, edamame, edible flowers, fresh tea leaves, maple sap, hops, microgreens, pea shoots, and wheat grass.

GAP certification does not cover medicinal herbs, sprouts, mint or other oils, forage and grain products or seaweed. Visit the FDA website for a complete and up-to-date list of which products can be covered by a GAP certification.

Should you be GAP certified?

The decision to pursue GAP certification for your farm should be carefully made. If your current buyers do not require certification, it might be difficult to justify the time, expense, and record-keeping involved. However, basic GAP training can be very beneficial for all farms in evaluating and improving their on-farm food safety practices. If you see a future for your farm in sales to restaurants, retailers, institutions, or wholesale distributors, you might begin the process of preparing for an audit now, so that the transition to certification will be familiar and less overwhelming when you're ready to make the jump into larger scale markets.

Types of GAP Audits

There are several levels of GAP audits available to growers and groups of growers, depending on your operation, what you grow, and what your buyers demand. Growers may certify individually for GAP or together using Group GAP if they participate in a centrally managed group.

There are two additional categories of GAP that some buyers may require. Harmonized GAP is

aligned with and includes the metrics required by the FSMA Produce Safety Rule (but does not replace a FSMA inspection). Harmonized GAP Plus+ is designed to meet Global Food Safety Initiative (GFSI) Technical Equivalence Requirements. These levels are more expensive, time-consuming, and complex. Which audit category is appropriate for your farm will depend on the standards your potential buyer has set for their suppliers.

a crop ready to sell, as the application and audit process can be time consuming and dependent on the availability of auditors. The time to think about GAP certification is when you are planning your production, researching your markets, and determining if selling into these markets is a good fit for you and your farm's goals.

What is involved in GAP Certification?

Auditors will review your farm, your practices, and your documentation of food safety practices. The audit will be focused on the primary sources of fresh produce contamination linked to foodborne illness outbreaks. These sources include humans, soil and soil amendments, agricultural water, animals, equipment and tools, and facilities. The audit will review these sources in the context of your farm's pre-season, production, harvest, post-harvest, and market handling activities. Auditors refer to a standardized, comprehensive checklist that you can access and use as a guiding tool in evaluating your operation and implementing best practices, whether you choose to become certified or not.

If you choose certification, begin by researching the process and reviewing the requirements. You may even decide to take an online or in person preparation course. We have listed several sources for this information in the Who Can Help section at the end of this chapter. When you're ready, you can schedule an audit. The auditor will observe and ask questions about your operation and review your food safety plan and records. Following a successful audit, your auditor will prepare their report and post results to USDA, as well as send you a certificate and a copy of your audit report to share with buyers.

When should you pursue GAP certification?

Often when a grower approaches a new buyer, they find out that the buyer requires GAP certification as part of their contractual agreements. The time to start the GAP process is not when you have



The concept of traceability and recalling already sold produce (or other products) from the marketplace is not something many small-scale direct market growers have had to think about, let alone implement in an emergency. But it is something that deserves a closer look for the potential benefits it offers to your operation in terms of valuable information and risk management. And it could save a life (and your farm) if a worst-case scenario were to occur.

TRACEABILITY

In the most basic terms, traceability means being able to follow your product one step backward and one step forward in the production and distribution chain. This obviously has a different connotation and scale for a produce grower selling at one farmers market per week as opposed to a large and complex commercial operation selling to a national chain grocer or fast-food restaurant. But since microbes that cause foodborne illness can potentially occur in any size farm, knowing where your product is going, and the details about where it came from is important in any size farm. In addition, being able to trace a known quantity of produce when it leaves the farm benefits growers by providing a way to better understand how much product is being sold through various marketing channels and how quality is maintained throughout the process.

RECALL

A recall identifies a distinct portion, or “lot,” of a product sold that must be retrieved due to a known or suspected defect or error and removes it from commerce and potential customers. Sounds simple, but the actual practice can be very time consuming, costly, and confusing. And again, the procedure will look quite different according to

size, scale, and scope of an operation or product volume.

TRACING ONE STEP FORWARD, ONE STEP BACK

It would not be reasonable, or even possible, for a grower to know exactly where every individual produce item ends up once it enters commerce. However, with recordkeeping and a system of managing distinct lots of produce, it is possible to know details about how it was produced and where it went first when leaving the farm. For example, a grower does not need to know the identity of every person who purchased one of their peaches, but they should know the orchard block where the fruit was harvested, when it was harvested and packed, and at which farmers market the peaches were sold. If this grower sold their peaches to a local independent grocery store with several locations, it would be the retailer’s responsibility to be able to trace back to which farm the peaches were purchased from, and at which of their retail locations the peaches were sold to customers.

ESTABLISHING LOTS

To trace a distinct portion of a crop, it needs to be organized into “lots.” There is no recipe for how to set lot size or identify a lot. The larger the lot, the less recordkeeping may be required, but the harder it would be to recall all of the lot, especially if it was sold to multiple buyers. Some growers may choose to establish lots based on the crop type, day harvested, field or orchard block, or may establish several lots daily separated by cleaning breaks on packing lines. Give each lot a code that contains key information about that lot. For example, a lot code could contain a combination of letters and numbers that indicate the crop and variety, the day

harvested, the crew responsible, the field located, the day packed (if different from the day harvested), and any other pertinent information that could be useful in identifying key details about that portion of the crop.

LABELING

A lot code can only be useful if it follows the crop. Labeling the sellable container, whether that is a box, bag, clamshell or even the individual fruit or vegetable, ensures that the lot information stays with the crop when sold. Remember to include your farm name and business address on any labeling as well. One reason is that the FSMA Produce Safety Rule requires Qualified Exempt Growers to prominently and conspicuously display—on a label, poster, sign, placard or documents delivered contemporaneously with the produce at the point of purchase—the name and complete business address of the farm where the produce was grown. In practical terms, this can help a buyer find you more easily if there is an issue with your products, or, and this is more likely, quickly identify where to order from again in the future!



CHAPTER 5: FOOD SAFETY

WHO CAN HELP

IDAHO SPECIFIC RESOURCES

University of Idaho Extension <https://www.uidaho.edu/extension>

Idaho Cultivating Success

<https://www.cultivatingsuccess.org/idaho>

Small Acreages & Local Food

<https://www.uidaho.edu/extension/small-farms>

Idaho State Department of Agriculture (ISDA)

<https://agri.idaho.gov/main/>

Idaho State Department of Agriculture (ISDA) <https://agri.idaho.gov/main/>

Agricultural Marketing Service

<https://agri.idaho.gov/main/marketing/>

Idaho Preferred

<https://idahopreferred.com/>

ISDA Organic Program

<https://agri.idaho.gov/main/about/about-isda/ag-inspections/organic-certification-program/>

HELPFUL ORGANIZATIONS

Association of Food and Drug Officials (AFDO)

<https://www.afdo.org/>

Food and Drug Administration

<https://www.fda.gov/>

Food Safety Preventive Controls Alliance (FSPCA)

<https://www.ifsh.iit.edu/fspca>

International HACCP Alliance

<https://haccpalliance.org/>

National Sustainable Agriculture Coalition

<https://sustainableagriculture.net>

United States Department of Agriculture

<https://www.usda.gov/>

Small Plant Help Desk

[https://www.fsis.usda.gov/inspection/compliance-guidance/
small-very-small-plant-guidance/small-plant-help-desk](https://www.fsis.usda.gov/inspection/compliance-guidance/small-very-small-plant-guidance/small-plant-help-desk)

Food Safety Inspection Service (FSIS)

<https://www.fsis.usda.gov/>

**ADDITIONAL RESOURCES**

University of Idaho Extension Publications Farm-direct Marketing Food Safety and Product Quality

<https://www.uidaho.edu/extension/publications/publication-detail?id=pnw0687>

Food Safety Modernization Act (FSMA)

<https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma>

Guidance for Industry Determination of Status as a Qualified Facility

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-determination-status-qualified-facility>

Understanding FDA's FSMA Rule for Food Facilities

<https://sustainableagriculture.net/wp-content/uploads/2008/08/FSMA-FACILITIES-FINAL-.pdf>