

A Small Farmer's
Practical Guide to Food Safety:

Deep Dive Guide

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NATIONAL YOUNG FARMERS COALITION (THE COALITION)

The National Young Farmers Coalition unites young farmers and ranchers to ensure a brighter, more sustainable future for American agriculture. The Coalition tackles the most critical structural and economic barriers that prevent motivated young people from building successful farming careers.



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The PSL Law Group is a small firm based in Boulder, Colorado dedicated to partnering with start-ups and small businesses to make big firm quality advice accessible innovators and entrepreneurs, and especially those engaged in food and agriculture. Its attorneys have extensive experience in developing compliance programs for FDA regulated food businesses, handling FDA enforcement actions, and advising clients through national recalls related to foodborne illness outbreaks.



LOCAL FOOD SAFETY COLLABORATIVE (LFSC)

The Local Food Safety Collaborative (LFSC) is a three-year project funded by a cooperative agreement with the Food and Drug Administration (FDA). National Farmers Union Foundation (NFUF) is the lead organization for this work and core partners are Cornell University, Maryland Department of Agriculture (MDA), Washington State Department of Agriculture (WSDA), National Young Farmers Coalition (the Coalition), Deep South Food Alliance (DSFA), and New England Farmers Union (NEFU). Many other organizations contribute to the steering committee or receive funding through the collaborative. The aim of this group is to provide training, education, and outreach to local producers and processors with an emphasis on organic, sustainable, value-added, and diversified farmers and processors.

The Legal Stuff

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This guide was written to provide you with accurate information on the limited subject matters covered. However, all content was not necessarily prepared by a person licensed to practice law in a particular jurisdiction. This guide is designed to provide general information on pertinent compliance topics, and the statements made here are for educational purposes only. All examples in this guide are fictitious and do not represent actual people or operations. The statements in this guide do not constitute legal advice. Nor are these statements intended to create an attorney-client relationship between you and the PSL Law Group and they do not necessarily reflect the views of the PSL Law Group or any of its attorneys other than Jeni Lamb Rogers.

Table of Contents

Introduction: Is this Guide For Me?	5
Chapter 1: The Food Safety Modernization Act and its Produce Safety Rule	8
Chapter 2: Where does my farm fit in the Produce Safety Rule	14
Chapter 3: Compliance Basics	37
Chapter 4: Worker Health and Hygiene	45
Chapter 5: Soil Amendments	59
Chapter 6: Animals and Adjacent Land	72
Chapter 7: Production Water	80
Chapter 8: Postharvest Water	94
Chapter 9: Harvest and Postharvest Handling	102
Chapter 10: Farm Food Safety Plan	112
Chapter 11: Inspections	119



Introduction

IS THIS GUIDE FOR ME?

Hi (again)! This is Jeni Lamb Rogers. You've probably found your way to this Deep Dive Guide through the NYFC website, or because you received a copy of our print "Small Farmers Practical Guide to Food Safety" and are looking for more information about complying with FSMA. While our print guide is for produce growers who are qualified exempt or exempt from the Produce Safety Rule, this guide is meant for small growers and packing houses that *do* expect to be inspected by the FDA or their state for compliance with the Produce Safety Rule. This guide is also aims to help growers identify if they might be subject to additional FDA regulations, so that they can seek further guidance. In the [final chapter](#), we provide guidance and tips on how to navigate your first Produce Safety Rule inspection.

When working on this Deep Dive Guide, I drew heavily on my professional experience as an attorney and working with growers as an agricultural economist and entrepreneur. I decided to become a food lawyer because early experiences in my career made me want to help growers and food manufacturers build a safer and more sustainable food system. Those experiences included things like covering Congressional hearings with the House and Senate Committees on Agriculture after the 2006-2007 spinach *E. coli* outbreaks, starting a non-profit soybean processing business in Western Kenya, working for a non-profit food hub in Appalachia getting hands-on training in produce safety in GAP/GHP and implementation in a packing house and on-farm, and drafting influential comments on the Produce Safety Regulation on behalf of small growers while it was being developed. Since then, I have practiced with two national law firms. I have guided companies through product recalls, foodborne illness related outbreak litigation, consumer fraud demands relating to product labeling, drafted food safety plans as a Preventive Controls Qualified Individual, drafted commercial contracts, written policies to help facilities prepare for FDA inspection, and diffused FDA enforcement actions. Now, as a partner in a small law firm -- I haven't forgotten what it is to try to do a lot with a little. I say all this because when I speak directly to you in this guide or highlight areas of risk where I think you should get more advice, it's not to scare you or sell you on anything or anyone, rather its rooted in my experiences so you can avoid major pitfalls.

HOW TO USE THIS GUIDEBOOK AND THE RESOURCES WE USED TO WRITE IT

Like the print guide, this Deep Dive Guide is organized to complement the trainings and materials developed by the Produce Safety Alliance (PSA), a government collaboration that is setting food safety best practice for produce growers. If you've attended a training, you received a very large binder with specifics on the rule.

This Deep Dive Guide also mentions many of the same additional resources as the print guide that you can find in the [online resource library](#). We've compiled supporting documents, templates, example SOPs, signs, and other resources on our website. We've tried to organize them to be easily searchable and curated them to be the resources that we find most helpful.

Both the print guide and this Deep Dive Guide focus on explaining requirements of the Produce Safety Rule and providing practical guidance. Both guides put the rules of the law in straightforward, simple language, but sometimes you might need to read the text of the law to answer more detailed questions.

The Final Rule can be found at:

<https://www.federalregister.gov/documents/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption>.

I've also drawn more extensively on some other sources of information for this Deep Dive Guide, and I think it's helpful to know a bit about them in case you decide you want to learn more about a particular issue. So I've discussed how to use that resource, what its legal value is, and some "hacks" I have developed from experience.

One key resource is the "Preamble" to the Final Produce Safety Rule. As part of any federal agency's legal obligations in promulgating a new regulation under notice and comment rulemaking, that agency must address all substantive comments.¹ This often occurs in the Preamble to a Final Rule. Because the Produce Rule was such a major change in how the produce industry and farms are regulated, FDA received thousands of comments from farmers and trade associations on its contents raising questions about how the rule might apply to their particular circumstances. Many of those growers were smaller growers, and their comments might be relevant to your situation. As a result, the Preamble can be a fabulous source of information. While the preamble of a rule does not have the force of law like the regulation itself, by consulting the Preamble you can see if anyone has already addressed your specific question when the rule was being developed – and see what the agency had to say about it before it began enforcing the rule. The Preamble to the Produce Safety Rule is actually much longer than the Rule itself and sometimes the agency comments on an issue in a place you would not expect

¹ 5 U.S.C. § 553 (c); *Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1203 (2015) ("An agency must consider and respond to significant comments received during the period for public comment."); *Am. Mining Cong. V. EPA*, 965 F.2d 759,771 (9th Cir. 1992).

based on the order of the Rule. So, rather than sitting down and trying to read it line by line, I suggest accessing it electronically. A CTRL+F or Command+F search for your keyword is magical for Preamble hunting.

I have also frequently cited to the Federal Food and Drug Administration's (FDA's) Guidance Documents on the Produce Safety Rule and related FSMA regulations. Understand that FDA Guidance Documents are not law. However, I use them frequently in my legal practice because guidance documents do often provide practical insight into the agency's expectations for how growers can comply with the Rule. However, the procedures and suggestions outlined in Guidance documents are not the only way to comply with the Rule. At the time this guide was finalized, FDA had not finalized its comprehensive draft guidance on the Produce Safety Rule. However, the draft version was published on October 22, 2018. In addition to using this guide as a practical resource, we encourage you to review FDA's guidance, especially once it is finalized.

Sometimes, these FDA Guidance Documents take the form of an enforcement discretion policy. What does that mean, exactly? "Enforcement discretion" is just the agency's way of saying that, for now, it is not going to take legal action against a farm or facility to enforce a certain part of a regulation as written. There are many reasons that this might happen, but often it is simply because carrying out the law as written would create extreme practical difficulties for growers or manufacturers, or result in similar operations being treated differently because of a technical definition instead of a difference in level of risk to public health.

Lastly, we frequently cite to the FDA's website. It is a really great source of information, but sometimes the agency moves things around, and as this Guide ages, that will inevitably happen to some of the resources here. I suggest that when you are relying on the website for information, you get into the habit of taking a screenshot of the full page and putting it in your food safety binder. It will save you time and effort later when inevitably things change and move around.

One final thing to note. The Produce Safety Rule uses the word "must" for requirements. However, PSA curriculum, the Preamble to the Rule, and FDA guidance documents often use the word "should" for practices FDA would like to see, or practices that can help you reach a must. We've tried to keep those words throughout this guide for clarity. Additionally, please keep in mind this guide mentions some practices that might help you reach a should or must, but that aren't clearly outlined in the rule or guidance documents.



Chapter 1

The Food Safety Modernization Act and Its Produce Safety Rule

COMPLIANCE IS A SAFETY MEASURE FOR YOUR FARM

You've likely heard about outbreaks of foodborne illness from contaminated produce. Because most produce is marketed as a commodity, the actions of one farmer or a group of farmers can often have devastating effects for all the growers of that product as consumers avoid that particular kind of produce that's become subject to a highly publicized outbreak and recall. This happens not only in grocery stores, but also in farmers markets – if one grower's practices make customers sick, customers may simply avoid that market. In addition to the market impacts, lawsuits against the grower that grew the produce might fall outside of or exceed the limits of the grower's insurance policies and put the farm that grew the produce out of business.

Once produce has left a farm, the realities of distribution, short shelf life, and long incubation periods for many foodborne illnesses can make it practically impossible to identify a problem and actually recall contaminated produce before it makes people sick. Indeed, when it comes to produce safety, an ounce of prevention is truly worth a pound of cure. You can protect your consumers, your fellow growers, and reduce the chance of your farm causing a future outbreak by minimizing the risk of microbiological contamination of your produce on farm. That's what the Food Safety Modernization Act (FSMA)'s Produce Safety Rule is all about.

BACTERIA AND PATHOGENS

This guidebook is intended for farmers, not microbiologists. (There might be some of you who are both farmers AND microbiologists and if so, this guidebook is probably in your wheelhouse!) We don't believe that you need to know the details of microbiology in order to decrease the risk of dangerous pathogens on your farm, but some basic information is helpful. Sharing this information with anyone who comes into contact with produce or food contact surfaces on your farm may encourage them to report, identify, understand, and take action that can prevent foodborne illness.

Produce safety isn't about eliminating all bacteria or creating a sterile working environment. In fact, our bodies need bacteria to perform even the most basic bodily functions.² Soil bacteria are instrumental in growing produce.³ Bacteria also make fermented foods like yogurt and sauerkraut, taste delicious. A lot of people are concerned with having a healthy microbiome and feel that getting a little dirt in your food is actually beneficial for the immune system. Well, we agree, but it's also true that pathogenic bacteria can make people very sick.

THE FOOD SAFETY MODERNIZATION ACT AND THE PRODUCE SAFETY RULE IS A LEGAL REQUIREMENT

Food safety is not only important for consumer health, but it's also now a legal requirement. Federal law under FSMA requires all growers⁴ to take food safety seriously and to comply with the rule, even if only by proving they are exempt.

² See Stearns, J. et al. Bacterial biogeography of the human digestive tract. *Sci Rep* 1:170 (synthesizing studies and explaining that microbial communities are intimately linked with metabolism, maturation of the immune system and gut health).

³ Jacoby R, Peukert M, Succurro A, Koprivova A, Kopriva S. The Role of Soil Microorganisms in Plant Mineral Nutrition-Current Knowledge and Future Directions. *Front Plant Sci.* 2017;8:1617. Published 2017 Sep 19. doi:10.3389/fpls.2017.01617

⁴ Growers of produce likely to be consumed raw and consumed off the farm. See 21 C.F.R. § 112.1 (including produce defined as a raw agricultural commodity and excluding produce consumed solely on the farm under 21 C.F.R. § 112.2(a)(2)).

The foodborne illnesses that the Produce Safety Rule aims to reduce are ones that come from pathogens, not long-term exposure to chemicals. Understanding how pathogens survive and thrive can be key to reducing risk on the farm.

VIRUSES cannot reproduce outside of a host, so they're tough little critters who have evolved to make you sick with only a few cells. They usually travel from a sick person to a soon-to-be-sick person via poor post-toilet practices. They are hardy enough to withstand many hand sanitizers-- and can withstand freezing¹-- but handwashing with soap and water can clean off most viruses.

PARASITES can also only reproduce inside of an animal or human host. Like viruses, they're hard to kill with hand sanitizers. Water, especially water that carries human or animal poop, can transmit many types of parasites and some viruses. Some parasites can live in the body for a long time before making us sick.

BACTERIA, unlike parasites or viruses, *can* multiply very quickly outside of a host if given a hospitable environment. We can control the spread of bacteria by managing temperature, water, pH, food, and by using good cleaning and sanitizing procedures. Many types of bacteria can be killed with heat, but because produce is often enjoyed raw, bacteria are not killed during a cooking process.

Check out youngfarmers.org/foodsafety for a chart of food borne illnesses with incubation times and historical outbreak info.

FSMA was signed into law on January 4, 2011 and is the first comprehensive law that attempts to prevent foodborne illness outbreaks across the food system. Although the Federal Food and Drug Administration (FDA) previously enforced laws against produce growers⁵ and issued guidance for specific agricultural products,⁶ FSMA directed FDA to develop the first mandatory requirements for produce growers to prevent foodborne illness outbreaks,⁷ and now subjects growers to routine regulatory oversight for food safety through inspections by FDA or states. FSMA also covers the majority of the food

⁵ See, e.g. Plea Agreement for Eric Jensen, United States v. Jensen Farms, Crim. No, 13-mj-01138-MEH (D. Colo 2015) (guilty plea to six counts under 21 U.S.C 331(a) and 333(a)(1) for introduction of adulterated food into interstate commerce).

⁶ See, e.g. FDA, Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, (October 26, 1998); FDA, Guide to Minimize Microbial Food Safety Hazards of Leafy Greens (July 2009); FDA, Guide to Minimize Microbial Food Safety Hazards of Melons (July 2009); FDA, Guide to Minimize Microbial Food Safety Hazards of Tomatoes, (July 2009) each is available at: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/default.htm> .

⁷ 21 USC § 350h.

value chain⁸ and food that is imported into the U.S. needs to be grown and/or processed under these rules, too.⁹ In Chapter 2, we'll discuss who needs to be in full compliance with the Produce Safety Rule and what other FDA regulations with which you might need to comply if you are performing certain additional activities.

You as the owner and operator of your farm, are legally on the hook.

FSMA amended the Federal Food Drug and Cosmetic Act, which is a federal criminal statute. That means that you can be prosecuted criminally for violating the Produce Safety Rule.¹ What's more, the Supreme Court has long held that the responsible owner or operator is strictly liable for the conditions in their operation.¹ That means you can't plead ignorance to serious conditions on your farm that may cause your produce to become adulterated. In other words, you can't say, "Well, I just didn't know that the wash water wasn't being replaced frequently enough, that wildlife was ravaging my cantaloupe, or that my workers were coming in sick to pack produce." If you are the owner or operator in charge, it is your responsibility to discover these risks and to fix them— or you could be criminally liable— especially if someone becomes seriously ill or dies because of the conditions on your farm.

THE PRODUCE SAFETY RULE

Remember, FSMA's Produce Safety Rule is concerned with keeping pathogens off of produce.¹⁰ More specifically, the Produce Safety Rule applies to growing, harvesting, packing, and holding produce (these are called **covered activities**) relating to **covered produce on farms**. We'll dig into who is covered, who is exempt, and what is covered produce in the next chapter.

⁸ See, e.g. 21 U.S.C. § 350e & 350g and accompanying regulations promulgated thereunder, including the Hazard Analysis and Risk Based Preventive Controls Regulation for Human Food for the production of processed foods (21 C.F.R. § 117) and the Sanitary Transportation Regulation for the distribution of foods (21 C.F.R. § 1.900-34).

⁹ See the Foreign Supplier Verification Program Requirements contained at 21 C.F.R. 1.500-512

¹⁰ See 21 C.F.R. § 112.1, and specifically 21 C.F.R. § 112 Subpart M.

GOOD AGRICULTURAL PRACTICES AUDITS VERSUS THE FSMA PRODUCE SAFETY RULE INSPECTIONS

Many growers ask if the FSMA Produce Safety Rule is the same as Good Agricultural Practices (GAPs). Though they are different, the purpose of both programs is to address produce safety risks, and there are many similarities.

The main difference is that GAPs audits are voluntary. Started in 2002, there are now many different government and industry backed GAPs protocols with names like Harmonized GAP, GroupGAP, and Global GAP. Auditors can come from the USDA, state departments of agriculture, or private industry. Grocery store buyers or institutions often require farms to have a GAPs audit to obtain an assurance that the farm is following appropriate food safety practices. GAPs are voluntary because farms can sell to plenty of customers who do not require GAPs audits (like through farmers markets, CSAs, etc.) and the decision not to have a GAPs audit does not have potential legal consequences. That said, if your largest buyer requires a GAPs audit to purchase your produce, it may not feel voluntary! Because audits are voluntary, growers usually foot the bill for GAPs audits, but some states have cost-share programs that can help, and occasionally buyers will cover some or all of the cost.

Produce Safety Rule inspections and compliance are not voluntary. FDA (or state agencies with which the FDA has entered into a cooperative agreement to perform inspections on behalf of the FDA) will monitor compliance with the Produce Safety Rule during routine regulatory inspections.¹¹ For a routine regulatory inspection, FDA does not charge fees, and the FDA State Cooperative Agreement Program for the Produce Safety Rule has provided funding to the states to build compliance and inspection programs.¹² However, refusing to be inspected or failing to comply with the Produce Safety Regulation is a prohibited act under the Federal Food Drug and Cosmetic Act,¹³ and could have legal consequences for you and your operation.¹⁴

Many farms that sell through wholesale channels will need both a GAPs audit and will also be subject to Produce Safety Rule inspection. The good news is that farms that have already been adhering to GAPs guidelines will probably find many Produce Safety Rule requirements familiar. As of June 5, 2018, the USDA Agricultural Marketing Service Harmonized GAPs Audit Program has been “aligned” with the minimum requirements of

¹¹ See FDA, Produce Safety Inspections, *available at*:
<https://www.fda.gov/ICECI/Inspections/ucm627767.htm>

¹² See FDA, State Produce Implementation Cooperative Agreement Program (CAP), *available at*
<https://www.fda.gov/ForFederalStateandLocalOfficials/FundingOpportunities/GrantsCoopAgrmts/ucm517991.htm> Updated July 12, 2018.

¹³ 21 C.F.R. 112.192.

¹⁴ These include, but are not limited to the FDA requesting that you recall your produce (21 C.F.R. 7.45), ordering that your produce be administratively detained (21 U.S.C. § 334(h)), seized in interstate commerce (21 U.S.C. § 334 (a)(1)), or in an extreme case, referring the case to the department of Justice to proceed against you criminally (21 U.S.C. § 333 (a)(1)).

the Produce Safety Rule so that growers who pass a Harmonized GAPs audit can be comfortable knowing they'll likely pass their FSMA inspection too.¹⁵

STOP FOR SPROUTS

You should be aware that because of the particular history of foodborne illness outbreaks associated with the production of sprouts, the FDA has developed specific and more rigorous requirements for sprout production.¹ Sprouts are harvested with their roots, as compared to microgreens, where the root is separated. The sprout requirements are not the focus of this guide, you can find more information about the additional requirements for sprouts through the Sprout Safety Alliance, <https://www.ifsh.iit.edu/ssa>.

¹⁵ Scott Gottlieb, Letter from Commissioner Gottlieb to Secretary Perdue Recognizing Joint Produce Safety Achievement Under Formal Agreement (June 5, 2018).



Chapter 2

Coverage and Exemptions: Is My Farm Covered by the Produce Safety Rule or Another FDA Regulation?

WHO MUST FOLLOW THE PRODUCE SAFETY RULE?

Every produce grower needs to assess whether and what they need to do to comply with the Produce Safety Rule, even if that simply means keeping records to prove that their farm isn't covered by the rule or qualifies for an exemption. Qualifying for an exemption doesn't mean you can ignore this Guide; if the farm meets one of the exemptions, however, the requirements are dramatically fewer. You will also want to know what changes in your farm operation would trigger changes in your status. Whether you are covered or exempt, you want your produce to be safe and healthy for your consumers.

PRODUCE SAFETY RULE COVERAGE AND EXEMPTIONS

Farms can be classified as Not Subject, Exempt, Qualified Exempt, or Covered under the Produce Safety Rule. Farms that are Not Subject to the Rule because of what they grow, how or where their produce is consumed, or the overall amount of produce sales shouldn't expect Produce Safety Rule inspections unless their products make someone sick. Farms that qualify for an exemption will need to keep some basic records to prove to an inspector how the farm is exempt. We know this is confusing but stick with us. Exemptions generally fall into the following categories:

- **NOT SUBJECT** because what you produce does not fall under the rule -- i.e. it is not covered produce:
 - **Not Subject** because it is not produce
 - **Not Subject** because it is not a "raw agricultural commodity"
 - **Not Subject** because it is rarely consumed raw
- **NOT SUBJECT or EXEMPT** based on where or how it is consumed:
 - **Not Subject** because it's only consumed on-farm

- **Exempt** because it goes through a kill step before being sold for consumption
- **NOT SUBJECT or QUALIFIED EXEMPT** based on quantity of produce you sell and/or who you sell it to:
 - **Not Subject:** less than \$25K in produce sales per year, on average
 - **Qualified Exempt:** less than \$500K in food (not just produce) sales on average per year and a majority of sales directly to consumers or to other qualified end users
- **COVERED** means you do not fall into the above categories and must comply when you are doing covered activities. Sometimes we call these “covered farms” or farm that are fully covered.

NOT SUBJECT BASED ON WHAT YOU GROW

Not Subject: Food that is not produce

- Food grains: like barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat
- Oilseeds: like cotton seed, flaxseed, rapeseed, soybean and sunflower seed
- Crops that are only intended for propagation: like onion sets sold as seed, as long as you reasonably expect that the seed won’t be eaten
- Saps: like maple, agave, or palm
- Algae: like seaweed

Obviously, produce is a fruit or vegetable. The rule *does* extend to some crops that we might not think of as “produce,” like mushrooms, peanuts, tree nuts, edible flowers, and medicinal herbs.¹⁶ Another common question is *when*, during the production cycle, is the crop is considered covered produce. We discuss this in the next section on **Covered Activities**.

Not Subject: Produce that is not a “raw agricultural commodity”

Produce in its natural state is covered by the Produce Safety Rule until it is processed.¹⁷ In other words, the processed foods made from produce like salad mixes, baby carrots, zucchini noodles, and fresh salsas aren’t subject to the rule. But the lettuce, whole carrots, zucchini, and tomatoes that were used to make each of these products were subject to the rule before they were processed. Indeed, for some facilities using covered produce and subject to the Preventive Controls for Human Food Rule, part of the compliance responsibility that food facility is to verify that the covered produce was produced in compliance with the Produce Safety Rule. We’ll discuss this in more detail in the following section, when we introduce how to assess whether your operation may be covered by another regulation.

¹⁶ 21 C.F.R. §112.3 “produce”.

¹⁷ 21 U.S.C. § 321

Not Subject: Produce that is rarely consumed raw

The Produce Safety Rule focuses on produce that is usually eaten raw because these products rarely go through processing where pathogens would be killed by high temperatures, so they're more likely to make consumers sick.

The following list includes produce that FDA calls "not covered" because it is rarely eaten raw. Any produce that is NOT on this list is called "**covered produce**" in the rule.

asparagus; black beans, Great Northern beans, Kidney beans, Lima beans, Navy beans, Pinto beans; garden beets (roots and tops), sugar beets; cashews; sour cherries; chickpeas, cocoa beans, coffee beans, collards, sweet corn, cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash, sweet potatoes; water chestnuts.¹⁸

We won't list all **covered produce** because there are lots of rare edibles (looking at you ulluco and atemoya), new crop varieties (kalettes™), or wild harvested foods (like swamp cabbage) that people eat. It is most clear to say that any produce that is not on the fairly limited list of "not covered produce" above qualifies as "**covered produce.**" There are a few crops not on this list, specifically wine grapes, hops, certain pulse crops, and almonds for which FDA is exercising enforcement discretion, meaning that FDA does not expect growers to meet the requirements of the Produce Safety Rule.¹⁹

If you only grow "not covered" produce, then your farm isn't subject to the Rule. Diversified farms likely grow a combination of not covered and **covered produce.**

¹⁸ 21 C.F.R. § 112.2 (a)(1).

¹⁹ FDA, Produce Safety Rule: Enforcement Policy for Entities Growing, Harvesting, Packing or Holding Hops, Wine Grapes, Pulse Crops, and Almonds, Guidance for Industry (March 27, 2019), available at: <https://www.fda.gov/media/122904/download>



Mushrooms

If you're a mushroom grower this Rule still applies to you, but there might be whole parts of the rule that don't feel applicable, especially if you grow indoors on a sanitized medium. However, there's a **MUST** that is targeted specifically to you. Clostridium botulinum toxin is most likely to arise in packaging where oxygen is reduced. If you are using vacuum packaging you should assess the risks presented by your practices and take measures to prevent the formulation of this toxin.²⁴

What if I grow, harvest, or pack “covered” and “not covered” or “exempt” produce?

You might grow a combination of “**covered produce**,” “not covered produce,” or “exempt produce.” For instance, you grow tomatoes destined for processing that will receive a “kill step” as well as tomatoes for fresh market. Or maybe you grow sweet potatoes, potatoes, onions, carrots, beets, and radishes (you love roots and tubers!), some of which are considered “not covered” because they're rarely consumed raw and some are “**covered produce**.”

In cases like these you have a few choices. You could treat all of the produce you grow as if it were covered by the Produce Safety Rule, or you could follow the Produce Safety Rule for **covered produce** and not follow the rule for not covered produce. If you choose this second approach, you need to ensure that your **covered produce** and not covered produce are always separate from one another up to the point of distribution.²⁰ To be clear, that means that the covered produce is grown, harvested, packed, and held separately from not covered produce. However, if your sale platform is a mixed box of CSA distribution, then it would be appropriate to mix your potatoes with your carrots in the same box at distribution.

Most diversified farms won't have the resources to have equipment and packing areas separately dedicated to the production of covered produce and not covered produce. If you use shared equipment, tools, or surfaces for both covered and not covered produce, you **MUST** fully clean and sanitize after the not covered produce touches the

²⁰ 21 C.F.R. § 112.111(a).

surfaces and before the **covered produce** touches the surfaces.²¹ This is called a “clean break,” and we’ll talk more about it in Chapters 9 and 10.

NOT SUBJECT OF PROCESSING EXEMPTION BASED ON WHERE OR HOW PRODUCE IS CONSUMED:

Not Subject: Only consumed on-farm

If the produce you grow is only consumed on the farm, you aren’t covered by the Produce Safety Rule.²² An easy example is a large carrot farm where the family keeps a separate vegetable garden and a little orchard for their own food needs. The produce from that garden and orchard isn’t sold off farm and doesn’t fall under the Rule. However, the carrots sold off the farm would be covered by the rule. Two less obvious examples are a retreat center with a large garden that feeds the visitors or a restaurant that is located on a farm where all of the food from the farm goes to the restaurant. In these examples, while the food isn’t solely for personal consumption of the folks growing it, it still is only consumed on the farm, and therefore is not covered by the Produce Safety Rule.²³ However, state laws for operating in food service or as a restaurant likely do apply to such operations.

Exempt: Processing Exemption

Any produce that goes through some kind of commercial processing that “adequately reduces the presence of microorganisms of public health significance” before being sold to consumers is exempt as long as adequate records are kept. This type of processing can be called a “kill step” and includes cooking, pasteurizing, chemically treating, irradiating, fermenting, beer or wine making.²⁴ For example, tomatoes that go to a sauce company, plums that go to a baby food manufacturer, or apples for hard cider are each exempt. You may either sell the produce to a processor who carries out a kill step or you might do the processing on-farm.²⁵ If you aren’t processing the produce yourself, but selling to someone else who will, you’ll probably want to develop some labeling and documentation practices to show your produce qualifies for this commercial processing or kill step exemption. However, FDA is currently exercising enforcement discretion with respect to these documentation requirements, meaning the FDA does not expect you to have this documentation during an inspection.²⁶

²¹ 21 C.F.R. § 112.111(b).

²² 21 C.F.R. § 112(a)(2).

²³ Draft Guidance at 10.

²⁴ 21 C.F.R. § 112.2(b)(1)-(6).

²⁵ Again, processing on-farm may fall under the Preventive Controls for Human or Animal Food Rules, Low Acid Canned Foods Rule, Acidified Foods Rule, Juice HACCP Rule and/or other local rules about processing and you must to be aware of and follow those rules as applicable.

²⁶ FDA, Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Program: Guidance for Industry

Washing or freezing are *not* considered a kill step. As recent foodborne illness outbreaks have shown, pathogenic *E. coli* and *salmonella* can survive a wash step, and *listeria monocytogenes* and Hepatitis A can survive freezing.

NOT SUBJECT OF PROCESSING EXEMPTION BASED ON QUANTITY OF PRODUCE YOU SELL AND/OR WHO YOU SELL IT TO

You may qualify for an exemption or not be subject to the Rule based on how much produce or food you sell. Calculations for these exclusions and exemptions are based on an *average* of farm sales for the last three years, adjusted for inflation. You can find the FDA's inflation cut offs here:

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm554484.htm>

Not Subject to the Rule:

If you can show with dated sales records that you sell less than \$25,000 in produce (average of three years, adjusted for inflation) you are not subject to the Rule. Note that this exemption includes all types of produce, including **covered produce** and not covered produce. As an example, if you were calculating whether you qualified for an exemption in 2019, the average amount, adjusted for inflation would need to be \$27,528 or less based on sales in 2016, 2017, and 2018.

Qualified Exemption from the Rule:

To be qualified exempt, you must to meet two criteria:

(1) You sell less than \$500,000 in **food** per year adjusted for inflation. FDA considers all **food** sales—not just **produce**—as part of this threshold. "**Food**" in this case includes animal feed, like hay or grain, value-added food products, chewing gum, dairy, live animals that are sold for food, and any food that the farm bought and then resold. Again, this is an average over the last three years, adjusted for inflation. The \$500,000 threshold was established in 2011 and is adjusted for inflation. In 2019, the three-year average cut off was actually \$550,551.²⁷ FDA has stated that it will publish the inflation cut offs for each year in April.

AND

(2) A majority of the **food** sold over the last three years, by value, goes directly to a **qualified end user**.

(Jan 2018), available at:

<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM590661.pdf>

²⁷ FDA, FSMA Inflation Adjusted Cut-offs, available at:

<https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm>

What is a **qualified end user**?

All consumers are **qualified end users**. That includes direct to consumer sales from the farm though online sales, CSAs, farmers markets, roadside stands, or on-farm retail, no matter where the consumer lives.²⁸

Qualified end users also include **retail food establishments** and **restaurants** that are local. “Local” means that the retail establishment or restaurant is located within your state or Indian reservation, or within 275 miles of your farm.²⁹ Some examples include grocery stores (if you are selling direct to the store rather than through a wholesaler), roadside farm stands, meal kit services, apothecaries, farmers markets, or convenience stores.³⁰ In addition to a traditional restaurant, a bakery, food truck, or soup kitchen would count as a **qualified end user**.³¹

Sometimes this **qualified end user** definition can feel sticky. Think about the number of receipts that will be provided before the produce is available to the consumer. If only one receipt from farm to grocery store, then the grocery store is a **qualified end user**. If there are two receipts—from farm to distribution co-op and from co-op to grocery store, for example—then the sale is not considered to be a **qualified end user**.

QUIZ: Know the Rule! Is this farm covered?

SCENARIO 1: Your parents own and operate a large beef operation selling \$750,000 in live animals and beef cuts. You have begun growing vegetables on a corner of the farm. You made \$30,000 from potatoes and less than \$25,000 on **covered produce**.

COVERED! The farm is grossing more than \$500,000 and the produce is more than \$25,000. While not **covered produce**, income from all produce counts when considering exemptions.

SCENARIO 2: Your parents own and operate a large beef operation selling \$750,000 in live animals and beef cuts. You have begun growing vegetables on a corner of the farm. You sell extra produce at a roadside stand and make less than \$25,000.

NOT SUBJECT! Less than \$25,000 in produce.

SCENARIO 3: Your parents own and operate a large beef operation selling \$750,000 in live animals and beef cuts. You have begun growing vegetables on a corner of the farm. You earned \$20,000 from potatoes, \$6,000 in sweet corn, and \$15,000 from pumpkins.

²⁸ 21 C.F.R. § 112.5.

²⁹ 21 C.F.R. § 112.3 “qualified end user”.

³⁰ 21 C.F.R. § 1.227 “retail food establishment”.

³¹ 21 C.F.R. § 1.227 “restaurant”.

NOT COVERED! These crops aren't covered by the Produce Safety Rule.

SCENARIO 4: You are a four-acre diversified veggie farm. You sell your produce at a few farmers markets, through a CSA, and to your local farmer-owned co-op food hub. You make more than \$25,000 a year but less than \$500,000, 40% of sales from farmers markets, 40% from CSA, and 20% from the co-op food hub.

QUALIFIED EXEMPT! This farm has less than \$500K in food sales and more than half of sales (80%) are direct to consumers at farmers markets and CSA distributions. The food hub is not a **Qualified End User**, but it's less than half of the farm's sales.

SCENARIO 5: You are a four-acre diversified veggie farm. You sell your produce through a CSA and your local farmer-owned co-op food hub that sells to restaurants and stores around your state. You make \$80,000 a year and 40% of sales are from your CSA and 60% are from the co-op.

COVERED! Because the co-op isn't considered a **Qualified End User**, less than half of the sales by value are direct to consumer or **qualified end user**.

SCENARIO 6: You are a new orchard selling wholesale and the weather has been pretty tough in your first years. The first year, you sold \$8,000 of tree fruit. In your second year, you sold \$65,000. In your third year, you sold \$15,000. All of your sales were to a wholesale company.

COVERED! The average of those three years is more than \$28K, which, adjusted for inflation, is more than \$25,000 per year.

YOU'RE EXEMPT, NOT SUBJECT, OR NOT COVERED, NOW WHAT?

Say your farm is not covered by the Rule, you sell to a commercial processor, or you are **Qualified Exempt**. This doesn't mean that you can toss out this guidebook! There are some basic recordkeeping and labeling tasks that you will need to do to demonstrate your exempt status. We also believe that all farmers should learn more about food safety. If your farm is associated with a foodborne illness outbreak, you can lose your qualified exemption—no matter your scale.³²

³² 21 C.F.R. § 112.201. There is also language that says that if an inspector visits your farm and determines that "the conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm," you can lose your qualified exemption. § 112.203(c).

PROVE YOU ARE EXEMPT BY BECOMING A RECORDKEEPING PRO

To prove your exemption, you MUST keep records that show that you're exempt. All records MUST be kept according to the recordkeeping rules described in Chapter 3.³³

- **Qualified Exemption Annual Review:** Each year, preferably at the beginning of the year, you'll need to perform a written annual review of the last three years' sales to be sure that you still qualify for an exemption. The Produce Safety Alliance has a tip sheet and template for this review. On this review, you'll show:
 - All food sales for the last three years, and the average of those amounts;
 - All food sales to **qualified end users** and all food sales to non-qualified end users, like wholesalers (see above for a description of **qualified end user**), proving that you are selling more than half, by value to a **qualified end user**;
 - Signature, job title, and date of the supervisor who reviewed the annual review (this SHOULD happen within a week of the creation of this annual review); and
 - To support this review, you'll need to have dated receipts.
- **Less than \$25,000 in annual produce sales exclusion records:** The actual Rule isn't as specific about how farms in this category need to prove that they aren't subject, but FDA noted in the Preamble to the Rule that "[t]he ...threshold is based on sales of produce" which it "expect[s] a farm to be able to demonstrate using existing sales records."³⁴ So, simply keeping records of all of your produce sales, holding onto them for three years, and calculating the three year average adjusted for inflation should be all you need to show you are not covered by the rule. If you think your sales might increase over the \$25,000 average adjusted for inflation, consider beginning to do a Qualified Annual Review above.
- **Produce Exempt due to commercial processing.** FDA is currently exercising enforcement discretion for this part of the Rule, meaning that at this point FDA will NOT take enforcement action if you do not have the extensive documentation currently required by the Rule. Specifically, this is what the final version of the Rule required:
 1. In every shipment that goes to the processor, you MUST have a:
 - (a) A letter or label that goes with or on your produce to the processor that says these exact words "not processed to adequately reduce the presence of microorganisms of public health significance."³⁵
 - (i) Although it may not seem like it, even in letter form, this written disclosure qualifies as "labeling" under the Federal Food, Drug and Cosmetic Act (FDCA) as a written

³³ 21 C.F.R. § 112.161.

³⁴ Preamble. 80 Fed. Reg. at 74407.

³⁵ (§ 112.2 (b)(1)).

article accompanying the sale of a food product.³⁶

(ii) Even though the agency is not exercising enforcement discretion, clearly labeling product this way acts as a disclaimer and could help you protect your farm.

2. On annual basis, the regulation requires you obtain a written assurance from your customer and maintain this written assurance on file for two years after selling your produce. That assurance could take one of two forms:

(a) A letter (or other written communication) from the processor that buys and processes your produce that says:

(i) That the processor has “established and is following procedures that adequately reduce the presence of microorganisms of public health significance” and identifies the actual procedures followed by the processor³⁷

b. A letter (or other written communication) from your buyer stating that it

(i) will only sell your produce with a document accompanying the produce stating that the produce was “not processed to adequately reduce the presence of microorganisms of public health significance;” AND

(ii) that it will only sell to a customer that agrees in writing it will either

(1) “follow procedures that will adequately reduce the presence of microorganisms of public health significance” and identify those procedures OR

(2) obtain a similar letter (or other written communication) from its customer satisfying conditions (a) and (b).³⁸

Practically, with the complexity of produce supply chains actually getting and maintaining this level of assurance may be quite difficult, and that’s probably one of the reasons that FDA is exercising enforcement discretion.

That said, if you are not following the Produce Safety Rule for produce that would ordinarily be covered produce, to reduce your product liability exposure in the event that someone eats one of those products before it is processed you should strongly consider adopting labeling practices and entering into written agreements with your customers that help make it clear that the product was not produced in compliance with

³⁶ 21 USC § 321 (m) (“The term “labeling” means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.)

³⁷ (112.2(b)(3)(i)).

³⁸ (112.2(b)(3)(ii)).

the Produce Safety Rule and should not be consumed raw. State laws for foreseeable misuse of products and disclaimers of warranties vary, and such labeling practices and agreements should be reviewed by an attorney with appropriate experience in food safety product liability.³⁹

REQUIRED SIGNS AND LABELS FOR QUALIFIED EXEMPT GROWERS

If you are **Qualified Exempt**, you have some additional labeling requirements in addition to keeping records to prove your exemption. At the point of sale, you **MUST** “prominently display” the name and complete business address of your farm.⁴⁰ At a farmers market or CSA distribution, this could be in the form of a sign with your farm name and complete business address. In a wholesale or restaurant sale, having the address on the invoice that is delivered with the produce is sufficient.⁴¹ With online sales, you can include an electronic message with your farm name and address.

Additionally, if you are required to label the product under the Federal Food, Drug, and Cosmetic Act, the label **MUST** have the name and address of the farm. However, the label doesn’t need to include the physical address of your farm, if you have a separate business address or even a PO Box as long as it includes the full street address, city, state, and zip code.⁴² A label is required when produce is sold in packaged form, meaning any container or wrapping in which the produce is fully enclosed.⁴³

This guide is not intended to cover labeling requirements, but you should be aware that there are numerous, and detailed additional FDA (and sometimes Federal Trade Commission and state law) regulatory requirements for labeling a food product, including requirements to include certain information and limiting claims that you can make about your products (such as geographic, environmental benefit, nutrition, and health claims). Not following these requirements may limit the markets in which you are able to sell your products as many retailers will have a review process for packaged products and could create consumer fraud liability exposure. Some states will do a limited review of label regulatory compliance, however review by a state regulator does not insulate you from consumer fraud liability and doesn’t guarantee FDA compliance. If you are packaging product, my opinion is that you should seek the guidance of an appropriately qualified attorney in this area, especially if you are making environmental benefit, geographic claims that imply you are producing a premium product, health

³⁹ See National Farmers Union, Farm and Ranch Business Health Assessment, available at: <https://1yd7z7koz052nb8r33cfxyw5-wpengine.netdna-ssl.com/wp-content/uploads/2019/07/BHA-Master.pdf>

⁴⁰ 21 C.F.R. § 112.6(b)(1).

⁴¹ 21 C.F.R. § 112.6(b)(1).

⁴² 21 C.F.R. § 112.6(b)(3).

⁴³ See 21 U.S.C. § 343 (e) (explaining that all food in package form is misbranded unless it contains a label); 21 CFR § 1.20 (enclosure requirement).

claims, or nutrient content claims on your product labels to ensure you are meeting regulatory requirements and protect yourself from litigation risk.

IS MY FARM POTENTIALLY COVERED BY ANOTHER REGULATION?

When trying to figure out whether the Produce Safety Rule applies to your activities on the farm, the first thing to remember is that Rule only applies to **covered activities** on **covered produce** on **covered farms**. If you are not doing covered activities, on covered produce, on a covered farm, then you don't need to comply with the Produce Safety Rule. It may be that you do not need to comply with any regulations for the activity you are doing. However, you might instead need to comply with one or more other FDA regulations for the manufacturing or processing of food. To understand this better, it is worth digging in a bit to understand what covered activities, and the FDA definition of a farm.

Practically speaking, in working with different grower operations trying to figure out what FSMA regulations apply to them, I have found that going through these definitions is most useful under two scenarios:

- 1) A grower is doing something that they think the Produce Safety Rule *might* address, but just can't figure out how. Sometimes, it's not regulated under the Produce Safety Rule because it's not a covered activity. Or, its regulated under a different part of the Rule because the way FDA thinks about covered activities-- like harvesting-- isn't the way most farmers think about them. I've tried to call out a couple of those places here and elsewhere in this guide. So, if you get through this guide, and can't figure out what part of the Rule applies or if the Rule applies to that activity, come back here first and see if working through these definitions helps.
- 2) A grower is trying to figure out if they have additional compliance responsibilities *in addition* to the Produce Safety Rule.

ARE YOU PERFORMING A COVERED ACTIVITY UNDER THE PRODUCE SAFETY RULE?

FDA has defined covered activities under the Produce Safety Rule as the **growing**, **harvesting**, **packing**, and **holding** of covered produce.

When you are wondering whether the Produce Safety Rule applies, sometimes the easiest question is to simply ask whether you are doing one of these activities below, or maybe something else. I'd encourage you to work through them like a checklist, knowing that you have to be doing at least one of these activities to be covered by the Rule.

Are you Growing covered produce? The Produce Safety Rule never actually defines “growing.” You probably think of yourself as a grower the whole year round, and about your growing areas broadly. It’s helpful to think more narrowly than that in determining when and how you need to comply with the Produce Safety Rule. I want you to think about growing activities and areas only as they relate to covered produce. In the exemption section above, we talked about the kinds of produce is covered produce in the next section. Now though, we’ll focus on *when* you start actually growing covered produce to be subject to the Rule.

Currently, the way that FDA interprets the Rule, you are growing **covered produce** only when the harvestable portion of the crop is present. For any fruiting crop, like apples, berries, beans, zucchini, or tomatoes, flowering is the moment that the covered produce is present. However, for a root crop, that is *very* soon after planting. More generally, the crop is considered “covered produce” as soon as the harvestable portion is present, regardless of maturity level.⁴⁴ This has major implications for things we’ll discuss throughout the rest of this guide. A lot of what the rule restricts (biological soil amendment or agricultural water application) requires contact, or foreseeable contact, with covered produce. Similarly, a lot of what the rule requires, like toilet and handwashing facilities, only pertains to growing areas (or growing areas during harvesting activities) for covered produce. So, early in the season and after the harvest, bear in mind that there may be more flexibility than you think.

Are you Harvesting? Harvesting means activities traditionally performed on farms for the purpose of removing raw agricultural commodities from the place where they were grown or raised and preparing them for use as food. FDA includes the following as harvesting activities:

- Cutting or removing the edible portion of the produce from the crop plant
- Cooling
- Field coring
- Filtering
- Gathering

⁴⁴ This is a tricky area under current language of the law, preamble, and guidance. Covered produce under 21 CFR §112.3 means the “harvestable” portion of the crop. The preamble to the final Produce Safety Rule states that water used on a tree crop prior to flowering or fruit production does not constitute agricultural water because it is not intended to or likely to contact covered produce, suggesting that for fruit crops the agency interprets the emergence of the flower as emergence of covered produce. “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” 80 Fed. Reg. 44354, 74449 (hereinafter the “Preamble”). The FDA draft guidance for the Produce Safety Rule, which was released in October 2018 and has not been finalized at the time of this printing, states the following: “Once the harvestable or harvested part of the crop is present, “produce” is present. Ripeness or maturity level does not matter.” FDA, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry (Draft Guidance), (Oct 22, 2018) at 9 (hereinafter the “Draft Guidance”). This is an area to watch for further development if you are particularly unsure about how the Produce Safety Rule may apply to practices on your farm.

- Hulling
- Shelling
- Sifting
- Threshing
- Trimming outer leaves, foliage, husks, roots, or stems
- Washing⁴⁵

Growers often tend to think of harvesting as field work. But under this definition, realize that sometimes a “harvesting activity” might be performed in the packhouse – such as washing or even trimming of the outer leaves, or removal of husks, roots or stems—to ready a raw agricultural commodity for the market. Remember, regardless of whether it occurs in the packhouse or in the field, if the activity is on the above list and done to covered produce while it is still a raw agricultural commodity, it is likely classifiable as a harvesting activity under the Produce Safety Rule.

Are you Holding? Holding is the activity of storing food in a manner to protect it from contamination until it can be sold. Holding can include activities performed that are necessary to distribute food, such as:

- fumigating during storage,
- drying/dehydrating where such activity does not create a new commodity
 - (think dried herbs not raisins),
- blending whole agricultural commodities
 - (think a fruit basket, not a smoothie)
- holding does NOT include activities that transform a raw agricultural commodity into a processed food⁴⁶

Are you Packing? Packing is the activity of placing food into a container that is not packaging and includes activities necessary to packing -- such as:

- re-packing
- sorting,
- culling,
- grading,
- weighing, and
- conveying⁴⁷

Are you a “farm”?

We also raise this issue of **covered activities** because it is necessary to understanding whether, in the eyes of the FDA, your operation is a farm -- or not.

⁴⁵ 21 C.F.R. §112.3 “harvesting”

⁴⁶ 21 C.F.R. § 117.3 “holding”

⁴⁷ 21 C.F.R. §112.3 “packing”

Under FDA regulations, generally ALL facilities that prepare, pack, or hold food for human consumption – including produce – must register with the FDA as “Registered Food Facilities.”⁴⁸ However, “farms” (and a few other limited exceptions) are NOT required to register with the FDA.⁴⁹ Being a Registered Food Facility triggers a number of additional FDA compliance responsibilities.

So, how does FDA define as a farm? FDA has included definitions for primary production and secondary activities farms under the “farm” definition.

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 the above.⁵⁰

Additionally, as long as a **Primary Production Farm** does any of the above, the farm can also

- pack or hold raw agricultural commodities
- pack or hold processed food that will be consumed on that farm or at a farm under the same management or solely consists of a dried or dehydrated raw agricultural commodity
- manufacture processed food that will be consumed on that farm or farm under the same management (think: a farm with an onsite restaurant or tap house that prepares only food or drink sold onsite)
- manufacture processed food that is not consumed on that farm when the manufacturing activity solely involves
 - drying or dehydrating a raw agricultural commodity (more raisins!)
 - treating an agricultural commodity to manipulate ripening
 - packaging and labeling the raw agricultural commodity

A **Secondary Activities Farm** is an operation dedicated to harvesting or holding activities NOT located on a primary production farm and can conduct any of the additional activities described above.

Common examples of “**Secondary Activities Farms**” include a grower shared packhouse, food hub, or produce aggregator in a separate location from where growing activities occur. Under the Final Produce Safety Rule, FDA included a majority interest ownership

⁴⁸ 21 C.F.R. §1.225.

⁴⁹ 21 C.F.R. §1.226(b). Retail food establishments, restaurants, nonprofit food establishments which prepare food, or directly serve food the consumer, fishing vessels, and facilities exclusively regulate by the USDA under the Federal Meat Inspection Act, Poultry Products Inspection Act, or Egg Products Inspection Act are also exempt from registration. See 21 C.F.R. §§ 1.226 (c)-(g).

⁵⁰ 21 C.F.R. §112.3 “primary production farm”

requirement for Secondary Activities Farms⁵¹ – which essentially meant that to fall under the Produce Safety Rule and be exempt from Food Facility registration requirements, the Secondary Activities Farm had to be majority owned by the farmers whose covered produce was being harvested, packed, or held there. FDA has since issued a policy of enforcement discretion for these operations, allowing facilities that don't meet this majority ownership requirement but would otherwise meet the Secondary Activities Farm definition to also be inspected under the Produce Safety Rule.⁵² **Bottom line -- if you are a packhouse, aggregator, or food hub doing solely the covered activities above, you don't need to register as a facility with the FDA and you can also use this guide to help you implement appropriate practices for Produce Safety Rule Compliance.**

There's one more important thing to flag here. Note that farms are allowed to do some very limited manufacturing/processing activities, such as drying or dehydrating a raw agricultural commodity and packaging and labeling a raw agricultural commodity. If these are the *only* additional activities you are performing in addition to the covered activities under the Produce Safety Rule, then you do not need to register as a food facility with the FDA.

Farm Mixed-Type Facilities

What if your farm is doing these covered activities or an incidental activity to a raw agricultural commodity (such as drying, packaging or labeling) AND something else with your produce? The short answer is that, depending on that "something else," FDA will probably no longer consider you to be solely a "farm." Specifically, if you are doing something that transforms produce from a raw agricultural commodity into a processed food product, you are a **Farm Mixed-Type Facility**. Some types of manufacturing/processing that change produce from a raw agricultural commodity include:⁵³

- Canning (like making salsa or even a tea)
- Juicing
- Cutting (like romaine heads into salad mix)
- Chopping (like to sell melon cubes)
- Spiralizing (to create zucchini noodles)
- Grinding (such as grinding cashews to make cashew butter)
- Cooking

⁵¹ 21 C.F.R. §112.3 "secondary activities farm"

⁵² FDA, Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Program: Guidance for Industry (Jan 2018), *available at*: <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM590661.pdf>

⁵³ 21 C.F.R. § 117.3 manufacturing/processing definition

- Irradiation

Once your farm starts performing a manufacturing/processing activity, your farm is considered a Farm Mixed-Type Facility. Farm Mixed-Type Facilities, regardless of the specific FDA regulation that covers their manufacturing/processing activity, have some additional common responsibilities. Unlike Farms, Farm Mixed-Type Facilities MUST register with the FDA, as we discussed above.⁵⁴ And, in the event that a Farm Mixed-Type Facility discovers that a food has left the facility and could create a risk of serious adverse health consequences or death for humans or animals, they have to report that food to FDA through the Reportable Food Registry within 24 hours of that discovery.⁵⁵ Finally, food not in a fully enclosed packaging or containers (like many types of produce in ventilated boxes or bins) or that must be temperature controlled for safety departing from a food facility (of a certain size) are also subject to the Sanitary Transportation regulation, which has requirements for shippers, loaders, carriers, and receiving facilities.⁵⁶

Additionally, the actual activities that transform produce from a raw agricultural commodity to a processed product are covered by a variety of FDA regulations. States also often have additional registration requirements for these activities, and your state may also have a cottage food law that modifies these requirements and often make compliance easier at a state level. While such activities are not the focus of this guide, we'll give you some information to get you started if you happen to be doing (or thinking about doing) one of the activities from the list above.

First, if you are canning, depending on the finished pH of the product, your activities could fall under the Acidified Foods Rule⁵⁷ or the Low Acid Canned Foods Rule,⁵⁸ each of which require that you have an individual from your operation attend Better Process Control School⁵⁹ and that you register your scheduled process with the FDA.⁶⁰

Second, the making of juice—including cider—is covered by the Juice Hazard Analysis and Critical Control Point (HACCP) regulation.⁶¹ This regulation requires that you develop and follow a HACCP plan for controlling food safety hazards in juice.

Third, the remaining activities on this list above are all covered by the Preventive Controls for Human Food Rule (PCHF). The full requirements of the Preventive Controls for Human Food Regulation are involved, and focus on controlling biological, chemical,

⁵⁴ 21 C.F.R. § 1.225.

⁵⁵ 21 U.S.C. §350f (a)(1) defining the responsible party as a person who registers the food facility.

⁵⁶ See 21 C.F.R. § 1.900 and 1.904.

⁵⁷ 21 C.F.R. § 114.

⁵⁸ 21 C.F.R. § 113.

⁵⁹ 21 C.F.R. § 113.10; 21 C.F.R. § 114.10.

⁶⁰ 21 C.F.R. § 108.25(c)(1); 21 C.F.R. § 108.35(c)(1).

⁶¹ 21 C.F.R. § 120.

physical, and economically motivated adulteration hazards in food products.⁶² They include following current good manufacturing practices for food production, and having a Preventive Controls Qualified Individual (your employee or potentially a contractor) develop a Food Safety Plan for your operation which identifies, implements, and verifies the performance of risk based preventive controls and verification activities; and usually building a supply chain program and drafting a recall plan.⁶³ Specifically, a supply chain program is required when a biological, chemical, or physical hazard in a raw material (like produce) must be controlled by the supplier.⁶⁴

Qualified Facilities under the PCHF regulation are exempted from the food safety plan, supply chain program and recall plan requirements. To be a qualified facility you must either:

1. Average less than a total of one million in the value of products prepared, packed, or held without sale (held for a fee) at your facility for the past three years, adjusted for inflation; or
2. Sell the majority of your products to qualified end users (same definition we just covered) and have averaged less than \$500,000 in food sales over the past three years, adjusted for inflation.⁶⁵

The inflation cut offs for Qualified Facilities are listed on the FDA website in the same place as they are for the Produce Safety Rule. To claim “Qualified Facility” status you must file a Qualified Facility Attestation and follow the Current Good Manufacturing Practice Requirements of the Preventive Controls for Human Food Rule and renew that submission biennially until you no longer qualify for this status.⁶⁶ When you no longer qualify you must withdraw the attestation.

However, even if you are a Farm Mixed-Type Facility, if you are doing any of the covered activities above with covered produce, you should continue to use this guide. Here’s why: depending on the type of processing performed on the produce, the produce may actually fall under multiple FSMA regulations at the same location. For example, someone who has a combined operation that grows carrots and processed them into baby carrots is subject to both the Produce Safety Rule and the Preventive Controls for Human Food Rule. For the growing, harvesting, packing and holding of the carrots pre-processing, the farm would follow the Produce Safety Rule. Once the facility chops and

⁶² Economically motivated adulteration is where someone intentionally acts to defraud the consumer in a way that could impact food safety— one example is the inclusion of melamine in powdered milk products to increase protein content, putting people and animals at risk.

⁶³ 21 C.F.R. § 117 Subparts C & G.

⁶⁴ 21 C.F.R. § 117.405(a)(1).

⁶⁵ 21 C.F.R. § 117.3 see definitions for “very small business” and “qualified facility.”

⁶⁶ The Qualified Facility Attestation form and more about your compliance responsibilities are available here: <https://www.fda.gov/food/registration-food-facilities-and-other-submissions/qualified-facility-attestation>

polishes the carrots into babies, and then ultimately packages and labels those baby carrots for distribution, with it would follow the Preventive Controls for Human Food Rule. Additionally, because the baby carrots do not undergo a kill step and may introduce a microbiological or physical hazard into the production process, the facility will need to verify compliance with the Produce Safety Rule as part of its supply chain program.

Before we leave this chapter, let's work through some examples of farms and activities and management changes to a farm that could cause it to become a Farm Mixed-Type Facility. For each example, we'll ask the following questions:

1. Farm or Farm Mixed-Type Facility?
2. Required to register with the FDA?
3. Covered by the Produce Safety Rule?
4. Covered by additional FDA regulation(s)?

Season #1 -- 2017

Your family's farm has been growing a variety of vegetables, including tomatoes, zucchini and summer squash, for the past 20 years. Your family has an established packhouse on the farm, where you, and sometimes other growers, cool, wash, and pack the smaller veggies into ventilated single-use cardboard boxes and hold them until you can ship them out to a wholesaler. To meet wholesale demand quantities, you often aggregate produce from different growers. Your parents manage the growing side of the operation, while you run the packhouse and trucks. You and your parents own the packhouse jointly.

A few years ago, you started packing for a number of the surrounding farms. Previously, you or other local growers had just eaten the seconds yourselves or spread them over the fields because you couldn't identify an appropriate market. Last year though, your partner, hearing about the imperfect produce trend, began driving the packhouse seconds to a large farmers market in a nearby city.

For the past three years, your parents have sold about \$250,000 in tomatoes, zucchini, and summer squash per year that are packed in your packhouse. The packhouse has sold an additional \$750,000 in produce grown and packed by other local growers, for a total of \$1,000,000 in wholesale sales from the packhouse. Your partner's direct sales of seconds provided an additional \$50,000 in 2016.

This year, your partner thinks that in addition to imperfect produce, you should cash in on the millennial vegetable noodles craze. She has been experimenting in the kitchen, and she has realized that a combination of two imperfect zucchini and one imperfect summer squash is enough to make the perfect a veggie noodle dinner. She calls her invention the "Voodle Pack."

She designs a killer label that walks the millennial consumer step-by-step through how to spiralize veggies at home and finds some compostable clamshells online. You tell her that she can section off a corner of the packhouse, and package and label her imperfect zucchini and summer squash combination to sell at the farmers market. In 2017, your parents' sales are \$200,000 in wholesale and the packhouse sells an additional \$800,00 in others wholesale produce. Your partner does \$75,000 in direct sales of seconds and Voodle Packs in 2017.

Farm or Farm Mixed-Type Facility? Farm. This is a Primary Production Farm dedicated to the growing, packing and holding of produce. The farm is also performing a permissible incidental activity on a raw agricultural commodity by packaging and labeling the summer squash and zucchini in their natural state for sale in the Voodle Pack.

Required to register with the FDA? No. Farms, including Primary Production Farms, are not required to register with the FDA.

Covered by the Produce Safety Rule? Yes, the farm is growing, harvesting, packing, and holding covered produce for sale to the wholesale market, and combined produce sales from the farm and packhouse are well over \$25,000 for the past three years. Moreover, the majority of sales are to wholesale and food sales are well in excess of \$500,000, so the farm is not Qualified Exempt.

Covered by additional FDA regulation(s)? Yes, you are placing the products into an enclosed container, which must be labeled in accordance with FDA regulations. However, you are not subject to additional food safety regulations, like the Preventive Controls Regulation, or the Reportable Foods Registry, because those requirements only apply to facilities required to register with the FDA.

Season #2 -- 2018

During the 2017 holidays, your dad presented your mom with a new RV and they decided to visit the National Parks the following summer. No vegetables were grown on the farm this 2018 growing season. However, they left you to run the packhouse and your partner to continue her seconds and Voodle Pack sales at the farmers market. You took this opportunity to expand the packhouse business, and in part due to the closure of another packhouse in the neighboring county, it sells more than \$900,000 in wholesale produce in 2018. Your partner's direct sales brought in a combined total of \$100,000 from the seconds and the Voodle Packs in 2018.

Farm or Farm Mixed-Type Facility? Farm. Under FDA's current policy of enforcement discretion with respect to the majority ownership requirement, you can operate as a Secondary Activities Farm because it is dedicated to the harvesting, packing, and holding

of produce, even though it will only be performing those activities on covered produce grown on other farms. What's more, Secondary Activities Farms are allowed to do the same additional incidental activities for raw agricultural commodities, and thus your partner can continue to package and label the products.

Required to register with the FDA? No. Farms, including Secondary Activities Farms, are not required to register with the FDA.

Covered by the Produce Safety Rule? Yes. The Secondary Activities Farm is performing the covered activities of harvesting, packing, and holding of covered produce at your packhouse and is selling more than \$25,000 in produce, so it must follow the Produce Safety Rule. Also, because the majority of the sales are wholesale and food sales exceed \$500,000, the farm is not qualified exempt.

Covered by additional FDA regulation(s)? Yes, as before, your partner is placing the summer squash and zucchini into an enclosed container, which must be labeled in accordance with FDA regulations. However, you are not subject to additional food safety regulations, such as the Preventive Controls Regulation or Sanitary Transport regulations, because those regulations only apply to facilities required to register with the FDA.

Season #3 -- 2019

You parents came back from vacation and are ready to jump back into their tomatoes, zucchini, and squash. Your parents' wholesale veggies sales are about \$150,000 this year. The packhouse does an additional \$1,100,000 in wholesale sales from others' produce.

Meanwhile the millennials at the market told your partner last year that while they just love her Voodle Pack, they find it to be so much work to spiralize the veggies themselves. Your partner got a spiralizer attachment for her KitchenAid for the holidays, and instead of packaging the whole zucchini and summer squash, she uses the section of the packhouse to start spiralizing the veggies before packaging them for sale. It's a huge success, she does more than \$125,000 in direct sales of her Voodle packs and seconds.

Farm or Farm Mixed-Type Facility? Farm Mixed-Type Facility. Your partner would be transforming zucchini and the summer squash from a raw agricultural commodity to a processed food (spiralized veggie noodles), and the product will be consumed off of the farm.

Required to register with the FDA? Yes. All facilities that prepare, pack, process, manufacture, or hold food are required to register with the FDA, unless they are farms,

or another exception applies. Here, you are processing the produce in a manner that is not permitted on a farm, so you must register as a food facility.

Covered by the Produce Safety Rule? Yes. Even though you are a Farm Mixed-Type Facility, the farm responsibilities continue under the Produce Safety Rule. The farm is performing the covered activities of harvesting, packing, and holding of covered produce at your packhouse and is selling more than \$25,000 in produce. The farm is not qualified exempt because the majority of the sales are wholesale and food sales exceed \$500,000. You must likewise ensure the harvesting, packing, and holding activities for the zucchini and summer squash that will be processed are conducted in compliance with the Produce Safety Rule until the products are processed.

Covered by additional FDA regulation(s)? Yes. Yes, as before, your partner is placing the summer squash and zucchini into an enclosed container, which must be labeled in accordance with FDA regulations. Additionally, now that the packhouse will be a registered food facility, the Preventive Controls for Human Food regulation would now apply, as would Reportable Food Registry requirements, and the Sanitary Transport Rule would potentially apply to product shipped in not fully enclosed containers and to the voodles that must be kept refrigerated to prevent growth of pathogens.

Season #4 -- 2020

Your partner decides that making the voodles herself is just too much work. She thinks that a better way to boost sales would be to start selling the Voodle Packs as a meal kit, and has already identified a local creamery from whom she can purchase cheese, and a friend has a commercial kitchen where she makes her own pasta sauce to sell at the farmers market, and who can fill small packets to go inside the kit for a meal. It would be so simple -- the creamery and her friend will deliver the products pre-packaged, she will get a refrigerator for them, and package them together in a single-serve meal package in her section of the packhouse.

Farm or Farm Mixed-Type Facility? Farm Mixed-Type Facility. Secondary Activities Farms are only allowed to pack or hold processed foods that will be consumed on the farm or another farm under the same management. The cheese and pasta sauce are processed foods and will be consumed off the farm.

Required to register with the FDA? Yes. All facilities that prepare, pack, or hold food are required to register with the FDA, unless they are farms, or another exception applies. Here, you are holding and packing processed foods for consumption off the farm.

Covered by the Produce Safety Rule? You must ensure the covered activities of growing, harvesting, packing, and holding are performed in compliance with the Produce Safety Rule.

Covered by additional FDA regulation(s)? Yes. As before, your partner is placing the summer squash and zucchini into an enclosed container, which must be labeled in accordance with FDA regulations. However, now that the packhouse will be a registered food facility, the Preventive Controls for Human Food Regulation would now apply, as would Reportable Food Registry requirements, and the Sanitary Transport Rule would potentially apply to product shipped in not fully enclosed containers and to the pasta sauce and cheese that must be kept refrigerated to prevent growth of pathogens.

FINAL THOUGHTS ON ASSESSING AND COMPLYING WITH ADDITIONAL RESPONSIBILITIES

As you can see from these fanciful examples, the compliance responsibilities increase quickly and change dramatically once you start doing some sort of value-added processing on farm. From a policy standpoint, this makes a lot of sense – there is a lot more risk to public health involved when you start making voodles or packaging and labeling processed foods produced by others compared to when you are selling whole produce.

If you want to venture into value added processing, here's our key advice: don't go it alone. There are lots of great people to help you if you want to start doing value adding processing. We recommend that you build a team of qualified professionals—including appropriate members of cooperative extension, sanitation and sanitary design folks, chemical suppliers that are also service providers who will come in and help you figure out how to clean, and yes, attorneys -- to understand your specific compliance responsibilities under these regulations and to build appropriate compliance systems for your operation. With respect to this particular fanciful example, there is a lot of ways that this business could have been structured a bit differently so that the higher risk processing activities didn't create a higher risk for the produce operation, and so that the packhouse didn't have to meet so many regulatory requirements (especially before putting in the time to design multiple sets of packaging). Moreover, calculating whether the facility was eligible for qualified exemption or other small business exemptions under the Sanitary Transport rule could also have made that transition easier.



Chapter 3

Where to Start with Food Safety on Your Farm

In this chapter we'll discuss the concepts and building blocks of creating a food safety program on your farm. Some of these elements are required by the Rule and others are helpful ways to implement good practices.

LEARN MORE THROUGH A TRAINING

You don't know what you don't know, but the best way to start building a strong food safety program is to build your knowledge base. We strongly recommend that all produce growers, exempt or not, attend a training and learn a little more about FSMA and the Produce Safety Rule. Farms that are fully covered by the Rule (read more about this in Chapter 2) **MUST** send one supervisor or responsible party to a produce safety training that is approved by the FDA.⁶⁷ The Produce Safety Alliance Grower Training meets this requirement. That is a day-long course and attendees get a certificate that proves they attended, which is valid for life. While the training is obviously very focused on the Produce Safety Rule, attending a training can benefit farms of any scale. These trainings are often subsidized to make them more affordable—sometimes the cost is as little as \$25. To find a training visit:

<https://producesafetyalliance.cornell.edu/training/grower-training-courses/upcoming-grower-trainings/>

While the Produce Safety Alliance Grower Training is currently the only workshop that has been recognized by the FDA to satisfy the Produce Safety Rule training requirement, there are many workshops, basic or in-depth, that will help you learn more about growing food safely. The FDA has also released a draft guidance for comment that proposes key criteria for another training to be considered equivalent to the standardized curriculum, meaning that there may be more training options in the future.⁶⁸

Even though the PSA Grower Training is the only FDA recognized curriculum for **covered produce**, you may wish to consider attending additional food safety trainings.

⁶⁷ 21 C.F.R. § 112.22(c).

⁶⁸ See FDA, Evaluating Alternate Curricula for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry (Draft Guidance) (June 2019) available at: <https://www.fda.gov/media/126868/download>.

If you think you might be a **Mixed-Type Facility** or are thinking about undertaking manufacturing or processing activities in the future, then someone from your operation should strongly consider attending a Preventive Controls Qualified Individual training. You can find a PCQI for human food course at www.fspca.com.

Bear in mind that the Preventive Controls Rule is very broad – covering everything from dietary ingredients to bakery to produce. If produce is the focus of your operation, naturally you'll get the most out of a PCQI course focused on produce, so it's worth the time and effort to research and find a course with this focus. Most PCQI lead instructors will be happy to talk to you about their intended audience for a course and refer you to instructors that might specialize in produce. Or, you can feel free to contact any of us for that kind of referral.

In addition to attending a Produce Safety Rule training to meet regulatory requirements, participating in other produce safety certification and audit programs can add value to your operation in permitting you to access additional markets.

Not all of these will apply to your operation, but some examples include:

- USDA Good Agricultural Practices (GAPs) is national and has various levels
 - Produce GAPs Harmonized Audit
 - USDA GAP & GHP Audits
 - GroupGAP
 - Tomato Food Safety Audit Protocol
 - Mushroom GAP
- California Leafy Greens Marketing Agreement (LGMA)
- Arizona LGMA
- Global G.A.P. -- Internationally recognized voluntary Good Agricultural Practices Certification
- CAPs (in Vermont and parts of New York and New England) through UVM
- CQP (in Massachusetts)

Many of these certifications make their standards available online, along with videos, templates, and educational resources that may provide helpful additional examples to you as you build your on-farm compliance program.

CREATING A CULTURE OF FOOD SAFETY

Everyone on the farm needs to buy into the importance of food safety for your program to be effective. In order to create a positive culture of food safety on your farm, you must first believe in the importance of food safety yourself. You probably got into this business because of your passion for producing safe, healthy food. Preventing foodborne illness is just part of growing healthy food for your community. Your workers need to perceive that you take food safety seriously to take it seriously themselves.

Encourage employees, volunteers, working family members, and others to report concerns to a supervisor (likely you) immediately. When a worker mentions a concern, treat them respectfully and take their concerns seriously. When an issue arises, address it swiftly and consider what improvements to the process or infrastructure could reduce challenges. For example, if your worker is wearing their apron into the bathroom, you could install hooks right outside to make it easy for them to remove. Make sure to communicate food safety policies to everyone who works or spends time on the farm, including visitors.

RISK ASSESSMENT

There are a few phrases that we use often throughout this guidebook and that you might hear in trainings, see on record templates, or be raised by an inspector. One of those phrases is “risk assessment.” As you might guess, it refers to “A process to identify potential hazards on a farm and/or in a packinghouse as well as the likelihood the hazards will impact the safety of fruits and vegetables.”⁶⁹ You know your system better than anyone, and where its weak points are likely to be. Often, in the context of food safety training, we discuss risk assessment as a formal process, but you likely do this every day: you see an issue and gauge how dangerous it is.

CORRECTIVE ACTIONS

Like risk assessment, “corrective action” is a jargon-y way to describe something you’re already likely doing all day long. It just means fixing a problem. This can refer to a preplanned reaction (which you might write out in a food safety plan) or it can refer to an on-the-fly solution that you create when a problem arises (which you might document on a recordkeeping document).

Once you’ve identified potential risks, you’ll want to write down how you will fix any problem that might arise. For example, under the Rule you **MUST** train harvest workers not to harvest produce which may be contaminated.⁷⁰ This means that you **MUST** have at least one pre-planned corrective action (not harvesting contaminated produce) for what to do if you (or one of your workers) sees poop in the field at harvest time. However, you might want to think about additional pre-planned corrective actions -- such as whether, and how you should clean up that poop-- especially if it could present a risk to later harvests or by workers walking potentially tracking that poop around the field.

⁶⁹ Produce Safety Alliance Grower Training Course • Version 1.1 • © 2017. Please note that the current version of the Produce Safety Alliance Grower Training Course is available in version 1.2. available at: <https://producesafetyalliance.cornell.edu/curriculum/download-V1-2/>. You should refer to version 1.2 for the most current information on the Rule.

⁷⁰ 21 C.F.R. § 112.22(b).

A library of FSMA templates, like sample SOPs, recordkeeping templates, and sample food safety plans, can be found at youngfarmers.org/foodsafety.

STANDARD OPERATING PROCEDURES (SOP)

A Standard Operating Procedure (SOP) is a written list of directions describing all of the people, tools, and steps needed to complete a given task.

SOPs aren't required by the Produce Safety Rule, but a well-written SOP can make any job more straightforward. They set clear expectations for workers, which makes your job as a manager easier, and help ensure that your food is safer. You'll be able to train workers more quickly and reference this SOP if jobs aren't being executed correctly. SOPs are a critical food safety tool and can be used in all areas of the farm and can increase your overall efficiency. Each chapter of this guidebook points out some possible associated SOPs, like what to do if you see animal poop in the field, how to wash your hands, how to clean totes, or how to determine if wash water needs to be changed.

SOPs can play a particularly important if a variety of people are doing the same job – for example if you are a Secondary Activities Farm and different growers are actually participating in harvesting or packing activities, a consistent SOP can help ensure the job is done the same way every time, protecting the safety of the produce packed by that farmer and farmers coming after them.

How to write a good SOP:

- Include:
 - ✓ Name of author and a title (if they have one)
 - ✓ Date Written and Revised
 - ✓ Version Control – Though you might be able to figure out when an SOP was changed date written or revised, but you might also want a numbering system so that you can know how many times you have revised the SOP and confirm that you have updated an SOP when you make a change to your operation, and to help you keep track of what version of the SOP your workers have been trained on.
 - ✓ Purpose of the SOP (can be as simple as a title)
 - ✓ Why: sometimes including details on a task is necessary and can help create a culture of food safety
 - ✓ Who is responsible
 - ✓ Tools needed for the job and where they are located

- ✓ Exact measurements, for example of a sanitizer or detergent
- ✓ Recordkeeping requirements (post recording template near the SOP and mention the names of those records on the SOP)
- **Formatting and Display**
 - ✓ Write each step as clearly as possible. We recommend fewer than 10 steps.
 - ✓ Use bullets or numbers.
 - ✓ Pictures can be useful. For farms with low-literacy workers or speakers of other languages, a full pictorial SOP might be best.
 - ✓ Translate into the languages that your workers use.
 - ✓ Print in a readable font and laminate if the environment is wet.
 - ✓ Post the SOP where the worker will need to do the job. You may also choose to keep a master binder with all of your SOPs. Clear plastic sleeves let you keep all of your SOPs together, to bring the binder of SOP into the field or washing space, and quickly replace the SOP with a new version when you make a change to your operation or practice.
- **Test it.**
 - ✓ Test the SOP with someone who has never done the job before and someone who has. Revise as necessary.
 - ✓ Change the SOP whenever you need: as you upgrade tools or equipment, buy new types of product, or make other changes.

A library of FSMA templates, like sample SOPs, recordkeeping templates, and sample food safety plans, can be found at youngfarmers.org/foodsafety.

SIGNS

Signage is an affordable, easy way to help remind workers (including yourself) about food safety best practices. They show visitors and inspectors that you care about food safety and have implemented good practices. Signs can act as prompts or reminders: we'll mention signs reminding workers to wash hands, and to put toilet paper in the toilet, not the trash. Another reminder sign might be a simple note on the appropriate sanitizer ratio posted where the sanitizer is kept. Other signs can include reminders of where dirty produce vs. clean produce goes, where eggs should be stored in a cooler, where dirty bins or clean bins are stored, how to administer first aid, where to take breaks, where to store personal belongings, and how to identify symptoms of communicable diseases. Clear signs and labels certainly promote a culture of food safety. Change and update your signs as your policies and procedures change.

RECORDS

Good record keeping is important for a simple reason: if you haven't written something down, there isn't an easy way to verify that it happened. Keeping organized food safety records can be helpful in many ways. Records can show you when tasks are or are not occurring. They can show rising issues, like a slowly failing refrigeration unit. Also, you might need to keep records for other reasons, like a GAPs audit, organic certification, or because a buyer wants proof of certain practices.

Some records are required by the Rule and others are just good practice.

RECORD REQUIREMENTS OF THE PRODUCE SAFETY RULE

Here is a list of the required records:

Not-Subject

Records to prove your produce sales

Qualified Exempt

Qualified Exemption Annual Review Record

Covered

If your farm is fully covered by the Rule, there are certain records that you must keep, and specific requirements for those records. Under the Produce Safety Rule there are only six types of required records, some of which might not apply to your farm. These include records relating to:

- Produce that is not covered due to receiving commercial processing (though the FDA is exercising enforcement discretion for this) ⁷¹
- Personnel Qualifications and Training ⁷²
- Agricultural Water ⁷³
- Biological Soil Amendments of Animal Origin and Human Waste ⁷⁴
- Equipment, Tools, Buildings, and Sanitation ⁷⁵

Each section in this guidebook will have a more detailed list of required and recommended records.

⁷¹ 21 C.F.R. § 112.2(b)(4))

⁷² 21 C.F.R. § 112.30.

⁷³ 21 C.F.R. § 112.50.

⁷⁴ 21 C.F.R. § 112.60.

⁷⁵ 21 C.F.R. § 112.140.

How and where you must keep your records

Records can be kept electronically (in something like Google Sheets), in photos (of dry erase board records or paper lists), or in hard copies of the paper records.⁷⁶ You can also keep your records offsite.⁷⁷ However, you must be able to provide records to the FDA within twenty-four (24) hours of an oral or written request.⁷⁸

How long you must keep records

You **MUST** keep all records for at least two years after the record is created.⁷⁹ Records supporting a qualified exemption **MUST** be retained for each of the prior three years used to calculate the exemption.⁸⁰

Please note that because records are kept for multiple years, you **MUST** have a way of distinguishing between this year's record and last year's record. The easiest way to do this is to get in the habit of listing the day, month, and year on every record, every time.

You must make records at time of performance

Finally, all records you keep under the Produce Safety Rule **MUST** be created at the time the activity is performed or an observation is made.⁸¹ To meet this requirement, a good practice may be to keep the actual record close to where the activity is performed. For example, you could keep a log of your wash water turbidity measurements next to your dunk tank – that way it is easy for your worker to record their measurement when they take it.

Required content

For all records you keep, certain information must be included.

- Farm name and location (probably an address)
- Date and time of the activity documented
- Actual values and observations that were recorded
- Description that identifies the produce being recorded
 - This **SHOULD** be specific to the type of commodity, or variety if needed to distinguish from other varieties you produce
 - **SHOULD** provide a lot number, if available.
- Signed or initialed and dated by person completing the task⁸²

⁷⁶ 21 C.F.R. § 112.165(a)-(c).

⁷⁷ 21 C.F.R. § 112.162(a).

⁷⁸ 21 C.F.R. § 112.166(a).

⁷⁹ 21 C.F.R. § 112.164(a)(1).

⁸⁰ 21 C.F.R. § 112.164(a)(2).

⁸¹ 21 C.F.R. § 112.161(a)(2).

⁸² 21 C.F.R. § 112.161(a)(1)-(4).

Records requiring review

Some Records Require Review by a Supervisor or Responsible Party within a reasonable time:

- These records MUST be reviewed, dated at the time of review, and signed by a supervisor or responsible party ⁸³
- These records are
 - Annual review of a qualified exemption ⁸⁴
 - Training logs documenting the required training of personnel, including date of training, topics covered, and person(s) trained ⁸⁵,
 - Documentation of the results of all analytical tests conducted on agricultural water⁸⁶,
 - Documentation of the results of water treatment monitoring,⁸⁷
 - Documentation of calculation of the log reduction applied and time intervals between appropriate activities,⁸⁸
 - The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring,⁸⁹ and
 - Documentation of date and method of cleaning and sanitizing of equipment used in harvesting, packing, or holding⁹⁰

A common question I get is “what is a reasonable time to review a record?” It really depends on the record and your operation. However, the purpose of having the record reviewed by a supervisor is that, hopefully, the supervisor or responsible individual will be able to catch a problem in time to correct it before the produce leaves the farm. So, documentation of water monitoring record might need to occur within hours of the shift if produce is being shipped out the same day. However, you would probably have more time to review a qualified exemption annual review, especially if you put this together early in the off season and well before you plant the following year.

⁸³ 21 C.F.R. § 112.161(b)

⁸⁴ 21 C.F.R. § 112.7(b).

⁸⁵ 21 C.F.R. § 112.30(b)(2).

⁸⁶ 21 C.F.R. § 112.50(b)(2).

⁸⁷ 21 C.F.R. § 112.50(b)(4).

⁸⁸ 21 C.F.R. § 112.50(b)(6).

⁸⁹ 21 C.F.R. § 112.60(b)(2)

⁹⁰ 21 C.F.R. § 112.140(b)(2).

members, volunteers, contract or hired labor, temporary help, seasonal workers, or part time or full-time employees.⁹³ The Produce Safety Rule uses the term “personnel.”

Visitor: Any person, other than a worker, that enters your farm with your permission, whether they’re handling produce or not.⁹⁴

FOOD SAFETY BOSS!

If your farm needs to be in full compliance with the Rule, you **MUST** identify at least one person to be in charge of produce safety and your compliance.⁹⁵ Depending on the size of the operation, you should also appoint one or more supervisors who will oversee the work being done by your workers. At least one of the **supervisors** **MUST** attend a training, as mentioned in previous chapters.⁹⁶ They only need to attend the training one time.

WORKER TRAININGS

The Rule focuses a lot on worker training and the food safety details that need to be covered in these trainings. Produce safety information can be part of your regular broader worker trainings. If your workers are likely to read it, including food safety information in your worker or employee handbook can be an additional way to convey the importance of food safety to your farm.

Farms that need to be in full compliance **MUST** make sure that workers who handle covered produce or food contact surfaces

- receive training needed to do their jobs,⁹⁷
- in a way that they are capable of easily understanding,⁹⁸
- have a supervisor who is capable of supervising and training;⁹⁹

There are also requirements for frequency of worker training. You **MUST**:

- train workers upon hiring,¹⁰⁰
- after that at least annually,¹⁰¹
- retrain workers if they’re not meeting food safety standards;¹⁰²

Finally, if it is not written down, it didn’t happen. You **MUST**:

⁹³ 21 C.F.R. § 112.21(a). The Produce Safety Rule uses the term “personnel”

⁹⁴ 21 C.F.R. § 112.3.

⁹⁵ 21 C.F.R. § 112.23.

⁹⁶ 21 C.F.R. § 112.22 (c).

⁹⁷ 21 C.F.R. § 112.21 (a).

⁹⁸ 21 C.F.R. § 112.21 (c).

⁹⁹ 21 C.F.R. § 112.21 (a).

¹⁰⁰ 21 C.F.R. § 112.21 (b).

¹⁰¹ 21 C.F.R. § 112.21 (b).

¹⁰² 21 C.F.R. § 112.21(d).

- keep a supervisor reviewed record¹⁰³ of the training, including the date, topics, and people trained.¹⁰⁴

Sample training agendas and training videos can be found
in our online resource library at youngfarmers.org/

Trainings **MUST** cover:

- ✓ The basics of food safety¹⁰⁵ This SHOULD include:
 - Sources of foodborne pathogens
 - People and their waste
 - Animals and their waste
 - Ways **covered produce** can become contaminated
 - **Workers** with a health condition
 - Animal and pest excreta
 - Contaminated soil or water contacting **covered produce**
 - Unclean and un-sanitized surfaces contacting **covered produce**
 - Practices to prevent **covered produce** contamination
 - Corrective actions if **covered produce** contamination occurs¹⁰⁶
- ✓ The importance of personal hygiene¹⁰⁷
 - This MUST include:
 - Maintaining adequate personal cleanliness to protect **covered produce**.¹⁰⁸
 - Avoiding contact with animals except working animals, and how to minimize likelihood of contamination if in contact with working animals.¹⁰⁹
 - How to wash hands with soap, clean water, and thoroughly dry hands.¹¹⁰
 - When to wash hands.¹¹¹
 - Appropriate glove use (if gloves are used).¹¹²

¹⁰³ 21 C.F.R. § 112.161 (b).

¹⁰⁴ 21 C.F.R. § 112.30 (b).

¹⁰⁵ 21 C.F.R. § 112.(a)(1).

¹⁰⁶ FDA, Draft Guidance Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry (Oct 22, 2018) at 32-33.

¹⁰⁷ 21 C.F.R. § 112.22(a)(2).

¹⁰⁸ 21 C.F.R. § 112.32(b)(1).

¹⁰⁹ 21 C.F.R. § 112.32(b)(2).

¹¹⁰ 21 C.F.R. § 112.32(b)(3).

¹¹¹ 21 C.F.R. § 112.32(b)(3)(i)-(v).

¹¹² 21 C.F.R. § 112.32(b)(4).

- Removal or covering of hand jewelry that cannot be adequately cleaned and sanitized during contact of **covered produce** with hands. ¹¹³
 - Not to eat, chew gum, or use tobacco in an area where produce is grown, harvested, packed, or held. ¹¹⁴
 - Measures to exclude potentially ill persons from contacting produce ¹¹⁵
 - How to recognize if the **worker, supervisor, or visitor** may have an illness or health condition that could cause contamination of produce. ¹¹⁶
 - Health conditions you **MUST** teach **workers** to self-report to a **supervisor** if they have (or reasonably could have) and to recognize in others:
 - Vomiting; ¹¹⁷
 - Diarrhea; ¹¹⁸
 - Open wounds (e.g. boils, cuts, or sores) ¹¹⁹
 - Symptoms of communicable diseases presenting a public health risk. ¹²⁰ This **SHOULD** include:
 - Abdominal cramps;
 - Sore throat with fever;
 - Jaundice (yellowish discoloration of the skin or of parts of the eyes) (main symptom of *Hepatitis A*)
- ✓ Any other requirements from the produce safety rule that the worker needs to know to complete their job, such as rules around making compost, managing animals and their waste, cleaning and sanitizing, and making and keeping records. ¹²¹
- ✓ If your workers are also harvesting, the training **MUST** also cover
- Knowing when not to harvest covered produce because it could be contaminated
 - How to inspect harvest containers and equipment to make sure they are safe and clean (this includes inspecting washing equipment in the packhouse!)

¹¹³ 21 C.F.R. § 112.32(b)(5).

¹¹⁴ 21 C.F.R. § 112.32(b)(6).

¹¹⁵ 21 C.F.R. § 112.31(b)(1).

¹¹⁶ 21 C.F.R. § 112.31(a).

¹¹⁷ 21 C.F.R. § 112.31(a).

¹¹⁸ 21 C.F.R. § 112.31(a).

¹¹⁹ 21 C.F.R. § 112.31(a).

¹²⁰ 21 C.F.R. § 112.31(a).

¹²¹ 21 C.F.R. § 112.22 (a).

- How to report or correct issues with harvest containers or equipment¹²²

Tips for an effective training:

- ✓ **Teach in workers' native language**, including any signs or written materials. Some language-free signs are available to help farms with low-literacy workers or farms where many languages are spoken.
- ✓ **Make it relevant and important**. Everyone learns best when they know *why* they need to follow a certain rule. Explain a bit about foodborne illness and why a practice creates risk. Share info about how and where bacteria grows quickly. The more the workers understand, the more they can evaluate risks and let you or a supervisor know when appropriate.
- ✓ **Outline clear expectations and detailed practices**. Be very specific so that workers can follow the rules you're setting in place.
- ✓ **Use a variety of learning media and methods**, like verbal explanations, posters, activities, small group discussions, short videos, etc. Provide an opportunity for participants to practice skills they are expected to use. For example, if you are asking someone to measure turbidity (amount of soil in the water) to know when to change wash water, show them how and then ask them to try while you watch. Having workers practice the skills you want them to use helps them learn and gives you a chance to make your expectations clear.
- ✓ **Provide "refresher" trainings when needed**. If you notice a problem, get a new piece of equipment, or want to change a method, that's a time when you might need to train or retrain workers. Neither these records nor these meetings need to be super fancy. Have you or your supervisors keep a record template in their food safety binder. If you're chatting with your team at the beginning of the harvest day and cover some food safety activities, just fill in the template with the topic of the training, when it happened, and have each worker sign that they were there. Make sure a **supervisor** reviews, signs, and dates the record within a reasonable time, and it can count as a "worker training."

¹²² 21 C.F.R § 112.22 (b).

SICK WORKERS

Sick or injured workers **MUST** not contact **covered produce** or food contact surfaces.¹²³ Also, workers **MUST** also must be instructed to let their **supervisor** know if they're sick.¹²⁴

Farmers are a tough bunch and sometimes pride themselves on their work ethic. You might also have a small crew where a sick worker might worry that the day will be longer or harder for their friends if they stay home. For these reasons and more, have a policy in place so workers know not to come to work if they have an illness that could contaminate produce, like vomiting or diarrhea. In some instances, you may be able to reassign workers to a job that does not involve produce or food contact surfaces. However, if an ill worker on "desk duty" doesn't properly wash their hands and then touches a doorknob that another worker who is handling produce that day uses, pathogens could ultimately be transferred to produce. Workers who handle **covered produce** or touch **food contact surfaces** **MUST** be trained to recognize symptoms of illnesses that pose a risk of contamination and how contamination spreads.¹²⁵ So talk to them about how to know when they're sick and which symptoms might mean that they have an illness that could contaminate produce.

HYGIENE

Anyone who is handling **covered produce** or **food contact surfaces** on the farm **MUST** follow good hygiene practices,¹²⁶ but what does that mean, specifically?

Good Hygiene Practices

- Wear clean clothing at work;
- Bathe regularly (and at least after work and before returning to the field or packhouse the following day to reduce risk of contamination);
- Avoid touching animals at work (other than working animals);
- Only use gloves that are intact and clean;
- Cover or remove hand jewelry that cannot be cleaned;
- Only use gum and tobacco in designated areas (The Chewing Zone—just kidding!);
- Only eat in designated areas and on breaks;¹²⁷and
- Wash hands:
 - After using the toilet;
 - Before starting or returning to work;

¹²³ 21 C.F.R. § 112.31 (a).

¹²⁴ 21 C.F.R § 112.31.

¹²⁵ 21 C.F.R. § 112.22 (a)(2).

¹²⁶ 21 C.F.R. §§ 112.32; 112.33

¹²⁷ See 21 C.F.R. §§ 112.32(b) (1)-(6). Please note that each of the bullets is a distinct regulatory requirement.

- Before and after eating and smoking;¹²⁸
- Before putting on gloves;
- After touching animals or animal waste; and
- Any other time they may become contaminated.¹²⁹

WORKER PRACTICES

Everyone's hands, skin, footwear, and clothing can be a source of contamination on the farm, especially if you or your workers work with animals as well as produce.

Don't bring it to work: Consider whether your workers might have animal chores at their own homes before coming to your farm and be clear about your expectations about minimizing that potential source of cross-contamination.

Bathing regularly: Maintaining adequate personal cleanliness is part of the requirement of the rule. That means that workers should be showering after work each day or before they come to work every day to prevent cross contamination.

Clean clothes every day: Though it may be your inclination to wear the same unwashed work pants all week to reduce laundry tasks, it is important to wear clean clothes every day to help prevent cross-contamination.

Different shoes for vegetables and livestock tasks: At the very least, you and your workers SHOULD change footwear and wash hands between animal and vegetable tasks. Some farmers have a separate pair of coveralls for animal tasks.

Work aprons, gloves: Equipment like gloves and aprons need to be cleaned on a regular basis, kept intact, and tossed when they can't be cleaned anymore. Give workers a place to remove aprons or gloves before using the bathroom and designate a clean place to store them when they're not being worn.

Don't forget rain gear: Consider other clothing that is worn, like rain gear or rubber bibs, and the impact that gear might have on produce safety. Create a schedule for cleaning those items.

No hand jewelry: Hand jewelry that can't be cleaned and sanitized MUST be removed or covered with a glove when handling **covered produce**.¹³⁰ Watches and rings with stones or etching are generally considered hard to clean and sanitize because they have little crevices where bacteria can hide out. Smooth bands are easier to clean. Earrings and other face jewelry are not so risky from a microbial angle but could fall out and be a physical hazard.

Snacking: Workers MUST not eat, chew gum, or use tobacco in an area used for a covered activity.¹³¹ That includes the growing and harvesting areas. Some growers munch on arugula leaves to see if they're too spicy, radishes to see if they're too pithy, or cherry tomatoes because they're delicious. Incorporate this taste testing by collecting

¹²⁸ 21 C.F.R. § 112.32 (b)(3)(vi). Also, Tobacco Mosaic Virus! Lots of farmers don't allow workers to smoke or chew on farm due to the potential impact on tomatoes.

¹²⁹ 21 C.F.R. § 112.32 (b)(3)(i)-(vi). Please note that each of the bullets is a distinct regulatory requirement.

¹³⁰ 21 C.F.R. § 112.32 (b)(5).

¹³¹ 21 C.F.R. (§ 112.32 (b)(6).

the produce during a pre-harvest walk instead of during harvest and consume it in a break area to model the appropriate behavior and help your workers understand the risk of eating while handling produce.

Cell phones: Cell phones can be a source of contamination (especially because who doesn't use their phone on the toilet!). You could designate a spot to leave them while performing covered activities, like harvesting, washing, or packing. If you or workers will have cell phones with you while harvesting, washing, or packing, consider cleaning the phones with disinfectant wipes before harvest days if you'll need to call customers. You **MUST** wash your hands after touching them before returning to a covered activity.¹³²

HAND WASHING

Hand washing is one of the most important food safety practices, and it is no surprise that the Produce Safety Rule creates certain requirements for how and when workers **MUST** wash their hands.¹³³ Some people say how to wash your hands is common sense, but anyone paying attention in a public restroom knows that many people could use a refresher. Here is the recommended hand washing procedure:

1. Wet hands with clean running water
2. Apply soap (liquid soap is preferred over bar soap)
3. Scrub for at least 20 seconds, that's the length of the ABCs or Happy Birthday sung *twice*. It's longer than you think!
4. Pay extra attention to nail beds and the backs of hands
5. Rinse with clean running water
6. Dry with a single use towel or air drier (not your pants!)
7. Use the towel, if reasonable, to turn off the faucet
8. Throw the towel away. According to the Produce Safety Rule, you can use reusable towels, but they need to be washed after each use.¹³⁴

Hand sanitizers **MUST NOT** be used as a replacement for hand washing.¹³⁵

There are many signs available about how to wash your hands. Choose or make one that is consistent with the Produce Safety Rule. Also, hang signs reminding workers to wash their hands near places where their hands might become contaminated, like break areas, bathrooms, areas with working or domesticated animals, and at the entrances of washing, packing, or harvesting areas.

¹³² 21 C.F.R. § 112.32 (b)(3)(vi).

¹³³ 21 C.F.R. § 112.32 (b)(3).

¹³⁴ 21 C.F.R. § 112.32 (b)(3).

¹³⁵ 21 C.F.R. § 112.130 (d).

FACILITIES

Hand washing stations

Hand washing stations **MUST** be accessible during all covered growing activities within an enclosed building, and all covered harvesting, packing, and holding activities.¹³⁶ All handwashing stations **MUST**:

- be stocked with soap,¹³⁷
- have clean running water with no detectable generic *E. coli*,¹³⁸
- provide have a way to dry hands that is sanitary, like paper towels, or reusable single use towels (but only if they are washed after *every* use), or a hand dryer.¹³⁹
- provide a way to dispose of paper towels (trash can) and wastewater (catch basin).¹⁴⁰

There are many designs for building your hand washing stations in the field or other spots where a sink isn't practicable. We have links to designs, tutorials, and a slideshow at youngfarmers.org/foodsafety.

If you have plumbing connected to your hand washing stations, it **MUST**:

- provide sufficient water pressure to ensure proper functioning of hand washing facilities
- properly convey the wastewater from handwashing away from the sink or basin
- not become a source of contamination to covered produce, food contact surfaces, areas used for covered activities, or agricultural water sources
- not allow for cross connection or backflow between wastewater and piping for covered activities¹⁴¹

Bathrooms

You **MUST** provide toilets that are accessible during harvesting, packing, and holding activities.¹⁴² Design, locate and maintain your bathroom to:

- Prevent contamination of **covered produce, food contact surfaces**, agricultural water sources, and water distribution systems (these are discussed in Chapters 7 & 8)
- Be accessible and serviced regularly
- Adequately supplied with toilet paper

¹³⁶ 21 C.F.R. § 112.130 (a).

¹³⁷ 21 C.F.R. § 112.130(b)(1).

¹³⁸ 21 C.F.R. § 112.30(b)(2).

¹³⁹ 21 C.F.R. § 112.130(b)(3).

¹⁴⁰ 21 C.F.R. § 112.130(c).

¹⁴¹ 21 C.F.R. §112.133 (a)-(d).

¹⁴² 21 C.F.R. § 112.129 (a). Note that this means you do not have to provide a toilet when only growing and not harvesting activities are taking place outdoors or in a partially enclosed building. When growing takes place in a fully-enclosed building, access to a toilet and handwashing facility is required.

- Provide for sanitary disposal of waste and toilet paper
- The hand washing station **MUST** be near enough to the toilet to make it practical for **workers** to wash their hands after using the bathroom. ¹⁴³

If you have plumbing connected to your toilet facilities, it **MUST**:

- provide sufficient water pressure to ensure proper functioning of toilet facilities
- properly conveys sewage and liquid disposable waste
- not become a source of contamination to covered produce, food contact surfaces, areas used for covered activities, or agricultural water sources
- not allow for cross connection or backflow between wastewater and piping for covered activities ¹⁴⁴

Make sure that everyone on the farm has access to toilets. This can be a bathroom with a flush toilet located in a house or barn, a port-a-potty, or an outhouse. The Rule isn't specific about where the restrooms should be.

However, when there are eleven or more employees engaged in hand operations (using their hands or hand tools) in a field on a given day,¹⁴⁵ the Occupational Safety & Health Administration (OSHA) Field Sanitation regulations require that there be at least one toilet and one handwashing facility per 20 workers,¹⁴⁶ that the toilets be within a ¼ mile of where each worker is working, and that the toilet and wash station must be in close proximity to one another.¹⁴⁷

OSHA also creates a number of additional requirements for the toilet facilities used during hand labor in agricultural fields. These include that the toilets must:

- be properly ventilated,
- adequately screened,
- have self-closing doors that can be closed and latched from the inside, and
- must be constructed to ensure privacy.¹⁴⁸

Since workers are supposed to wash their hands before returning to work, you may want to provide a hand washing station where workers are working if toilets are a longer distance away.

¹⁴³ 21 C.F.R. § 112.129.

¹⁴⁴ 21 C.F.R §112.133 (a)-(d).

¹⁴⁵ 29 C.F.R. § 1928.110 (a).

¹⁴⁶ 29 C.F.R. § 1928.110(c)(2)(i).

¹⁴⁷ 29 C.F.R. § 1928.110 (c)(2)(iii).

¹⁴⁸ 29 C.F.R. § 1928.110 (c)(2)(ii).

You **MUST** make sure the bathroom can be easily cleaned¹⁴⁹ and **SHOULD** do so on a regular schedule. Be clear with workers that they need to put soiled toilet paper in the toilet, never in the garbage can. (Signs are available on youngfarmers.org.) You might want to have color-coded cleaning supplies, like brooms or mops, that are only used to clean the bathroom to minimize cross-contamination. These cleaning supplies should also be stored separately from cleaning supplies used to clean **food contact surfaces**.

Sewage from the bathrooms and port-a-potties, and wastewater from hand washing stations must be handled safely so that it doesn't contaminate produce.¹⁵⁰ If you have port-a-potties, get them pumped out frequently. Secure port-a-potties to a stable object, if possible. You **SHOULD** place port-a-potties downhill or downslope from your **covered produce** fields or water source, in case of accidental tip-over. You'll want to place the port-a-potties somewhere accessible by truck so that the honeywagons can pump them out without creating ruts or driving through fields. If you have a leach field, consider its capacity and where it is located on your farm and locate your **covered produce** fields and areas for covered activities well away from it.

Break Areas

Since workers aren't allowed to eat, chew gum, or use tobacco while handling or harvesting produce, you should provide a specific break area.¹⁵¹ This doesn't have to be a fancy space, but can simply be a designated tree, a picnic bench, or a part of the barn that you've taped off to differentiate it from the other areas.

It's nice to have indoor or shaded area if your workers will need to eat lunch there, but you might want to have a designated smoking area outside if you have workers that smoke. You can define this area in your employee handbook or mention it in your training, or even hang a sign.

Drinking

Workers **MUST** not eat in areas used for covered activities, but workers can drink in designated areas.¹⁵² One suggestion for creating a "designated area" is to have water at the end of the row where workers are harvesting. Provide your workers cool, potable water, and in sufficient quantity taking into account things like temperature and humidity.¹⁵³ Don't allow your workers to share cups,¹⁵⁴ instead you can provide single use cups, or they can bring reusable water bottles. Note that the OSHA agricultural field sanitation regulations (which apply when eleven or more employees are engaged in

¹⁴⁹ 21 C.F.R. § 112.129(b)(2).

¹⁵⁰ 21 C.F.R. § 112.130 (c) (handwashing wastewater); 21 C.F.R. § 112.129(b)(1) (sewage from toilets). Additional requirements apply if plumbing is hooked up to either your handwashing facility or toilet. See 21 C.F.R. § 112.133.

¹⁵¹ 21 C.F.R. § 112.32 (b)(6).

¹⁵² 21 C.F.R. § 112.32 (b)(6).

¹⁵³ 29 C.F.R. § 1928.110(c)(1)(ii).

¹⁵⁴ 29 C.F.R. § 1928.110(c)(1)(iii).

hand-labor operations in the field) only permit potable water to be dispensed in single use cups or by fountains, and expressly prohibit the use of common cups or dippers.¹⁵⁵ Plastic and metal are less risky than glass, which can break in the fields. Encourage workers to take precautions in extreme temperatures, including drinking plenty of water in the heat.

First Aid

While not specifically required by the Produce Safety Rule, first aid kits are a practical necessity on your farm. They SHOULD be located in convenient locations, which may include your farm trucks, packing areas, the office, or anywhere else workers are spending time. Have a protocol for checking first aid kits to be sure that they're well stocked. If there aren't gloves, for instance, workers might go back to work with just a bandage.

If a worker is injured on the job, the first thing to do is assess whether or not 911 should be called. Bandage minor wounds and if they're on the hands, a secondary barrier—like a finger bob or a glove—will help protect the worker and keep blood and bandages out of **covered produce**.

A First Aid kit checklist can be found at youngfarmers.org/foodsafety.

VISITORS

You **MUST** communicate with visitors about your food safety policies, take steps to make sure that they're following your rules, and give them access to a toilet and a place to wash their hands.¹⁵⁶ This is important for CSAs, educational farms, and pick-your-own operations.

Farms with U-pick operations or frequent volunteers need to consider how to communicate food safety rules to these visitors. Informing visitors of your food safety policies is important and required by the Produce Safety Rule. Visitors SHOULD know not to visit while they're ill, and to leave their pets at home—this is not only a food safety concern but could also create a liability risk for your farm if their animal injures another person. Let them know which areas of farm they are allowed to visit, including where the toilets and hand washing stations are located. Provide instructions on how to wash their hands, following the same steps as outlined for workers in the “Training Agenda” (on page [47](#)). Your food safety information can be communicated on your website, verbally when they enter the farm, via written materials and maps, and/or on signage when they enter or in relevant areas. ([Sample signs and visitor policies online.](#)) Some farms find it helpful to direct the flow of traffic on the farm so that visitors need to check-in in a specific area where you might choose to have all visitors sign a log. In

¹⁵⁵ 29 C.F.R. § 1928.110(c)(1)(iii).

¹⁵⁶ 21 C.F.R. § 112.33 (a) &(b).

controlling the flow of traffic, you can ensure that visitors see the toilet and handwashing facilities. Also, you SHOULD direct traffic to visit U-pick fields *before* animal petting zoos to reduce the risk of contamination.

If you have U-pick customers and workers harvesting for sale, you may want to take some extra precautions as you have less control over the practices of the U-pick visitors. You could consider having workers harvest in a specific area first, and then allow U-pick in that zone. Growers who have substantial educational components to their farm in addition to commercial production may consider separating areas where children are able to handle produce or enter fields from areas of commercial production.

Be sure to tell visitors:

- ✓ Which areas of the farm they can visit
- ✓ To stay home if they're sick
- ✓ How and where to wash their hands
- ✓ To keep pets at home

I'd also recommend you also tell visitors to wear clean clothes and not to handle animals before they come to the farm. Just like wearing dirty clothes or coming into contact with working animals and pets on your farm can potentially introduce pathogens to your produce, your visitors could potentially bring such contamination onto your farm.

You SHOULD also strongly consider talking to visitors about food safety when they arrive on your farm – you don't know until you know! Sharing your food safety practices lets consumers know you care about them and their family's health and gives them the "why" for following your signs and for practicing singing the ABC's when they wash their hands. Making sure that they know where the restroom is and where they are allowed to go on farm also helps to keep them safe and to ensure their visit is as comfortable as possible!

Once **visitors** are on your farm:

- ✓ Remind them where (and where not) to go with signs
- ✓ Show them how, where, and when to wash their hands
- ✓ Tell them where they can use the restroom

Remember, you are responsible for ensuring that visitors follow your policies as well. This means making sure that if you find someone in an area that they are not supposed to be, you MUST do something about it.¹⁵⁷

¹⁵⁷ 21 C.F.R. § 112.33(a).

Records for Worker Training, Health, and Hygiene

REQUIRED:

- Training log: date of training, topics covered, and individual(s) trained²⁵

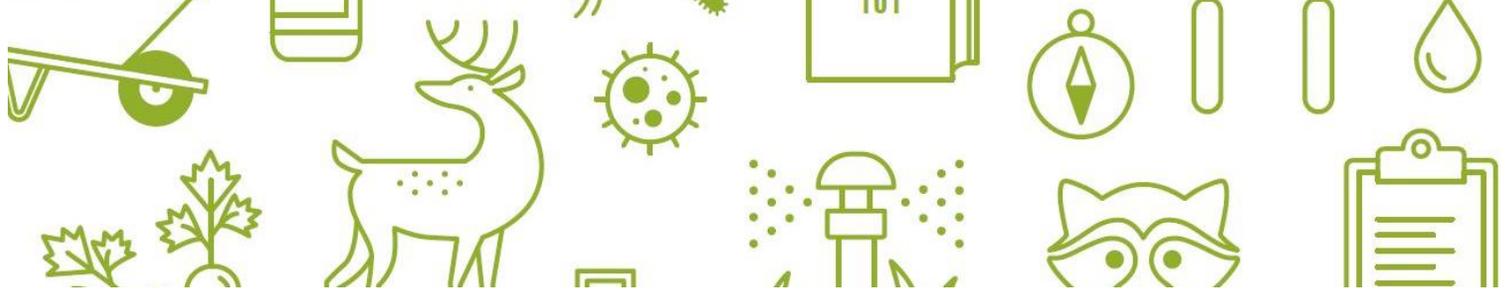
SUGGESTED:

- Monitoring and restocking of toilet and handwashing facilities
- Worker illness and injury reporting
- Restocking of first aid kits
- Worker attendance

RECOMMENDED HEALTH AND HYGIENE STANDARD OPERATING PROCEDURES (SOPs)

- On-farm illness and injury
- Bodily fluid clean-up and corrective action
- Cleaning aprons or gloves
- Cleaning bathrooms
- Cleaning the handwashing facility
- Handwashing

Templates for all of these Standard Operating Procedures can be found at youngfarmers.org/foodsafety.



Chapter 5

Soil Amendments

FOOD SAFETY AND SOIL AMENDMENTS

We all know that adding compost, minerals, or manure to our soil is beneficial. As produce farmers, we take a lot from our land and this is a chance to give back. Soil amendments can balance our soil, add fertility and beneficial soil microbes, improve water-holding capacity, and more. Raising animals creates manure that needs an outlet, so adding raw or composted manure to your soil can reduce waste while creating fertility at the same time.

Soil amendments, however, especially types that originate from animals, can pose food safety risks. Animals can host many of the same bacteria or parasites that make humans sick.¹⁵⁸ The Produce Safety Rule only regulates biological soil amendments of animal origin.¹⁵⁹ Synthetic soil amendments can be dangerous, too, but their risks are rarely from human pathogens.

We recommend you start by reviewing the key concepts below and making a list of all soil amendments you use, and then learn more about the risks associated with those amendments.

Key Concepts

Soil Amendment: Any chemical, biological, or physical material intentionally added to the soil to improve the chemical or physical condition of soil in relation to plant growth or to improve the capacity of the soil to hold water. Includes: elemental fertilizers, stabilized compost, manure, non-fecal animal byproducts, peat moss, perlite, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea and yard trimmings, and growth media that serve as the entire substrate during growth of covered produce (e.g. mushrooms or sprouts).^{160 161}

Biological Soil Amendment: Any soil amendment containing biological materials, alone or in combination. Includes: stabilized compost, manure, non-fecal animal byproducts,

¹⁵⁸ Do you have a citation for this?

¹⁵⁹ 21 C.F.R § 112.51.

¹⁶⁰ 21 C.F.R. § 112.3.

¹⁶¹ The Produce Safety Rule doesn't specifically mention potting soil as a soil amendment, but we believe it would fall under this definition.

peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings.¹⁶²

Biological Soil Amendment of Animal Origin (BSAAO): A biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts including animal mortalities, or table waste, alone or in combination. The term “biological soil amendment of animal origin” does not include any form of human waste.¹⁶³ Note: we hate using acronyms and try to avoid it as much as possible, however, we’re going to use this one.

Pre-Consumer Vegetative Waste: Solid waste that is purely vegetative in origin, not considered yard trash, and derived from commercial, institutional, or agricultural operations without coming in contact with animal products, byproducts or manure or with a consumer. Includes: material generated by farms, packing houses, canning operations, wholesale distribution centers and grocery stores; products that have been removed from their packaging (such as out-of-date juice, vegetables, condiments, and bread); and associated packaging that is vegetative in origin (such as paper or corn-starch based products). Excludes: restaurant waste, table waste, packaging that has contacted non-vegetative materials.

Table Waste: Any post-consumer food waste, irrespective of whether the source material is animal or vegetative in origin, derived from individuals, institutions, restaurants, retail operations, or other sources where the food has been served to a consumer.¹⁶⁴

Agricultural Tea: An agricultural tea is a water extract of biological materials, excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components, typically as a solution in water.¹⁶⁵ Examples could be compost-based, manure-based, plant-based, fish emulsion, or biodynamic preparations.

Agricultural Tea Additive: Nutrient source (such as molasses, yeast extract, or algal powder) added to agricultural tea to increase microbial biomass.¹⁶⁶

Composting: The process to produce stabilized compost in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated period of time (for example, three days) at a designated temperature (for example, 131 °F), followed by a curing stage under cooler conditions.

Stabilized Compost: Finished biological soil amendment produced through a controlled composting process.

Human waste: The Rule expressly prohibits the application of any human waste or soil amendment from human waste for growing covered produce, except for sewage sludge biosolids used in accordance with the requirements of 40 CFR 503 Subpart D.¹⁶⁷

¹⁶² 21 C.F.R. § 112.3.

¹⁶³ 21 C.F.R. § 112.3.

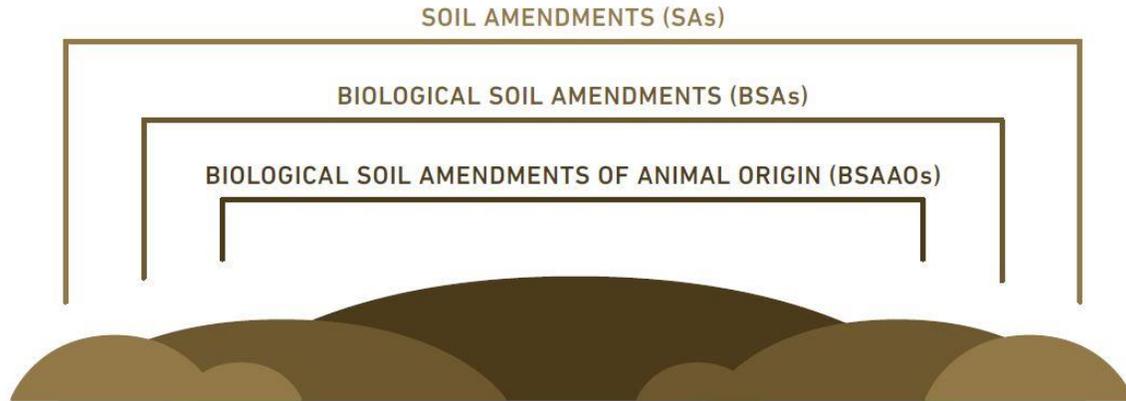
¹⁶⁴ 21 C.F.R. § 112.3.

¹⁶⁵ 21 C.F.R. § 112.3.

¹⁶⁶ 21 C.F.R. § 112.3.

¹⁶⁷ 21 C.F.R. § 112.3.

Here is a visual to help you understand the relationships between various types of soil amendments:



UNDERSTANDING RISK

The first step in understanding how to use soil amendments best is to begin with understanding some of the associated risks:

As mentioned in Chapter 1, the Rule is mostly concerned with biological pathogens, not chemical contamination. Chemical soil amendments, such as fertilizer, SHOULD be stored safely, used according to label instructions—including using personal protective equipment—and workers SHOULD be trained to handle them safely.¹⁶⁸ The Produce Safety Rule doesn't spend much time talking about the dangers or rules related to chemical fertilizers, as they're regulated by EPA and state laws.

Even if your soil amendment isn't from animals or humans, it could still present other dangers. Pre-consumer vegetative waste, like your wash station culls, could contain chemical, physical, or biological hazards, but are usually considered low risk from a microbiological perspective. FDA only regulates Biological Soil Amendments of Animal Origin (BSAAOs) under the Produce Safety Rule. So, we're going to discuss the rules about making, storing, and applying both treated and untreated BSAAOs.

¹⁶⁸ See e.g. 15 U.S.C. 2601 et seq.

 AMOUNT OF RISK LESS RISKY MORE RISKY	Type of Amendment	Covered by Rule?
	Pre-consumer vegetative waste. Yard trimmings. Synthetic soil amendments.	No.
	Stabilized compost that is fully composted and cured using a validated method. Agricultural teas made without supplemental microbial nutrients (like molasses). See page 69 for more on agricultural teas.	Yes, called Treated BSAAO.
	Manure or biological soil amendments of animal origin that have not been composted and cured. Aged manure. Untreated slurries. Untreated manure teas. Compost that has had animal intrusion. Composted manure that has been mixed with un-composted manure.	Yes, called Untreated BSAAO.
	Raw animal manure.	Yes, called Untreated BSAAO.
	Untreated bio solids (human waste).	No, but prohibited.

TREATED OR UNTREATED?

Under the Rule, there are two types of **BSAAO**, **treated and untreated**. Whether the soil amendment is treated or not dictates how the **BSAAO** must be handled, transported, stored, and applied. A **BSAAO** has been **treated only** when it has been processed via a “validated process.”¹⁶⁹ If you’re making compost tea (here usually called **Agricultural Tea**) it is considered treated if the compost is treated AND the water, you use to make the tea has to be tested to prove it’s free from detectable generic *E. coli*.¹⁷⁰

All **BSAAOs** MUST be handled to minimize contamination.¹⁷¹ You MUST keep **treated** and **untreated BSAAOs** separate from one another.¹⁷² If the **treated BSAAOs** becomes contaminated after treatment, it MUST be considered an **untreated BSAAO**.¹⁷³ This could happen if your **treated BSAAO** is mixed with an **untreated BSAAO**, if an **agricultural tea additive** (like molasses) is added to an agricultural tea, and/or you have any reason to think that it was contaminated.

UNTREATED BSAAOS

Requirements for Storage and Handling of Untreated BSAAOs

- If you control the animal, you MUST control its poop!¹⁷⁴ You MUST think about how and where its manure is handled and stored to be sure that it does not contaminate **covered produce, food contact surfaces**, food packaging materials, water sources, and/or water distribution systems.¹⁷⁵
- You MUST consider and minimize runoff to prevent raw manure from potentially contaminating covered produce, agricultural water, or areas where covered activities are performed.¹⁷⁶ The concept of runoff will be discussed in more detail in the following chapter.
- You MUST locate your piles in areas that are protected from wind if there is the potential for wind to carry manure into covered areas, agricultural water sources or distribution systems, or areas where covered activities are performed.¹⁷⁷
- You MUST keep raw manure or untreated **BSAAOs** from contaminating any treated **BSAAOs**.¹⁷⁸ So, say you have a few BSAAO piles. You could have different equipment for different piles and keep them separate, or you could move from most finished to least finished. Then you’d need to clean and sanitize your equipment before working with your finished pile again.

¹⁶⁹ 21 C.F.R. § 112.51 (a).

¹⁷⁰ 21 C.F.R. § 112.51(a).

¹⁷¹ 21 C.F.R. § 112.52 (b).

¹⁷² 21 C.F.R. § 112.52 (b).

¹⁷³ 21 C.F.R. § 112.51 (b)(1)-(5).

¹⁷⁴ 21 C.F.R. § 112.134.

¹⁷⁵ 21 C.F.R. § 112.134 (a).

¹⁷⁶ 21 C.F.R. § 112.52 (a).

¹⁷⁷ 21 C.F.R. § 112.52 (a).

¹⁷⁸ 21 C.F.R. § 112.52 (b).

Good practices for handling untreated BSAOs

- Keep equipment and tools for **untreated BSAOs** and other tasks separate. For smaller farms, where shovels are used in manure piles, this could be as easy as investing in a few extra shovels, color coding them, and storing them apart from shovels used for non-poop tasks. For farms with bucket loaders or larger compost equipment, it might be a bit harder to have separate equipment or to clean and sanitize the equipment to minimize cross-contamination. Write SOPs to clean and sanitize equipment and tools that will touch soil amendments and covered produce. (See sample SOP [online](#).)
- Manage the flow of traffic to minimize the risk that an **untreated BSAO** will sneak into areas where **covered produce** is handled. Do not allow workers to walk through areas where **soil amendments** are stored, and don't let vehicles drive through these areas and then into other fields.
- Always wash hands after handling **soil amendments**, especially **untreated BSAOs**.¹⁷⁹
- Consider designating coveralls, clothing, gloves, and/or boots specifically for handling **soil amendments** to minimize the risk that a worker will contaminate **covered produce**.
- In addition to storing manure or **untreated BSAOs** in a location that will minimize the potential for runoff or wind to carry contamination to covered areas, some good practices include covering piles with tarps or compost covers. You can also build berms or swales to divert any runoff from rains.
- You SHOULD also exclude animals from your raw manure piles through fencing or other means, because animals can spread contamination quickly if they have access to other areas of the farm

Application Timing and Methods for Untreated BSAOs

FDA is still researching and discussing how long farmers should or must wait between application of **untreated BSAO** and harvest and expect it will be a few years before they have a final statement. For now, the FDA does not object to growers following the National Organic Program (NOP) standard.¹⁸⁰

The NOP standard requires that there is an interval of 120 days between the incorporation of raw manure into the soil and harvest (in this case, all untreated **BSAOs** should be treated like raw manure) if the edible part of the produce touches the soil, like carrots, lettuce, spinach, melons, and radishes.¹⁸¹ If the edible part of the crop is unlikely to have direct contact with the soil or soil particles—like trellised

¹⁷⁹See 21 C.F.R. § 112.32 (b)(3)(vi).

¹⁸⁰Read more on this in the Preamble: 80 Fed. Reg. 74354, 74463.

¹⁸¹7 C.F.R. § 205.203(c)(ii).

tomatoes, peppers, trellised peas, and tree fruit—growers can incorporate the raw manure or untreated soil amendments into the soil 90 days prior to harvest.¹⁸²

TREATED BSAAOS

To comply with the Rule, **treated BSAOs** must be made according to a scientifically valid controlled physical, chemical, or biological process (or combination of such processes) validated to one of two microbial standards.¹⁸³ Soil amendments produced through a process validated to the more moderate standard only permits that the soil amendment be applied in a way that minimizes contact with **covered produce**, while an amendment created using a process validated to the more rigorous standard allows the soil amendment to be applied without restriction.¹⁸⁴

If the process used to create the **treated BSAO** is validated to the standard below, the **treated BSAO** may be applied only in a manner that minimizes the potential for contact with **covered produce** during and after application.¹⁸⁵

Test	Standard
Fecal Coliform	not detected using a method that can detect three most probable numbers (MPN) <i>Salmonella</i> species per 4 grams (or milliliter, if liquid is being sampled) of total solids
<i>Salmonella</i> species	less than 1,000 MPN fecal coliforms per gram (or milliliter, if liquid is being sampled) of total solids

Before permitting unrestricted application of **treated BSAOs** FDA is concerned with contamination of two additional key microorganisms from BSAOs – undoubtedly you have heard about them in the news as key culprits in foodborne illness outbreaks. These microorganisms and corresponding standards are below:

Microorganism	Standard
<i>Listeria Monocytogenes</i>	Not detected using a method that can detect one colony forming unit (CFU) per 5 gram (or milliliter, if liquid is being sampled) analytical portion.
<i>Salmonella</i> species	Not detected using a method that can detect three MPN per 4 grams (or milliliter, if liquid is being sampled) of total solids.
<i>E. coli</i> O157:H7	Not detected using a method that can detect 0.3 MPN per 1 gram (or milliliter, if liquid is being sampled) analytical portion.

¹⁸² 7 C.F.R. § 205.203(c)(iii).

¹⁸³ 21 C.F.R. § 112.54.

¹⁸⁴ 21 C.F.R. § 112.55.

¹⁸⁵ 21 C.F.R. §§ 112.55(b); 112.60(a)(2).

If the process for generating compost is validated to the standard above, the compost may be applied without restrictions.¹⁸⁶

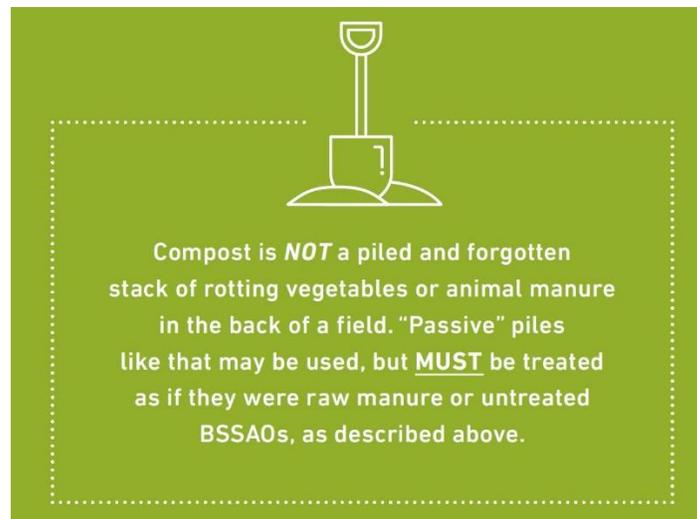
Documentation from Seller

If you buy **treated BSAOs** from a supplier, you **MUST** have annual documentation, such as a letter or “certificate of conformance,” that a process validated to one of the above standards was used to treat the **biological soil amendment** (depending on your proposed method of application), that the process was monitored, and that the **treated BSAO** was handled, conveyed, and stored in a manner and in a location that minimizes its risk of contamination from **untreated BSAOs**.¹⁸⁷

MUSTS For Making Compost

Musts for Making Treated BSAOs using a validated process

Making compost is an amazing process that can fairly quickly turn organic matter—even something pretty solid, like a dead animal—into a rich, fertile, healthy **soil amendment**. When we talk about **composting** under the Rule, it has a very specific definition, provided at the beginning of this section. Stabilized compost, under the Produce Safety Rule, is the product of a validated process where bacteria and fungi decompose organic matter.¹⁸⁸ Specific temperatures contribute to the decomposition and are the main way in which pathogens are reduced.



The Rule recognizes two specific **composting** techniques have been validated to the standard for application in a manner that minimizes the potential for contact with **covered produce** during and after application.¹⁸⁹ These validated processes are:

¹⁸⁶ (§ 112.55(a); § 112.60(a)(3))

¹⁸⁷ 21 C.F.R. §§112.60 (a) & (b).

¹⁸⁸ 21 C.F.R. § 112.3 “stabilized compost”

¹⁸⁹ 21 C.F.R. § 112.55 (b).

- Aerated static composting:
 - Aerobic, maintaining oxygenated conditions at a minimum 131°F (55°C) for three consecutive days AND
 - Cured “at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition. Curing may or may not involve insulation, depending on environmental conditions.”¹⁹⁰
- Turned composting:
 - Aerobic, maintaining oxygenated conditions at a minimum of 131°F (55°C) for 15 days (possibly not consecutive days)
 - Minimum five turnings AND
 - Cured “at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition. Curing may or may not involve insulation, depending on environmental conditions.”¹⁹¹
- You may also follow another scientifically valid, controlled composting processes.¹⁹² In other words, you can follow another validated process. This option requires the review and application of validation studies to show that the treatment process for the compost has been validated to one of the two microbial standards described. It is unlikely that farmers will have the time or resources to conduct a validation study (after all, you’re busy growing good food). Industry, extension, and academia, however, are likely to develop and validate additional appropriate processes to these standards.

Farmers following one of the two methods above, or another validated process, **MUST** monitor the process and keep records to prove that they have reached the temperatures required for the duration required and that they have turned the compost (if applicable).¹⁹³ Farmers are **NOT** required to test their compost to prove that pathogen load has decreased when using either of the methods above if they have documented their methods because FDA has recognized that these are validated processes. If the process is followed, that is enough to ensure that pathogens have been reduced. Farmers using the static or aerobic method may then apply that compost at a zero-day interval, meaning you could apply it up to the day of harvest, in a manner that minimizes potential for contact with **covered produce** during and after application.¹⁹⁴

¹⁹⁰ 21 C.F.R. §§ 112.54 (b) & 112.3.

¹⁹¹ 21 C.F.R. §§112.54 (b) & 112.3.

¹⁹² 21 C.F.R. §112.54.

¹⁹³ 21 C.F.R § 112.60 (b)(2).

¹⁹⁴ 21 C.F.R. § 112.56 (a)(2)

APPLYING A “TREATED” BSAAO

The only **validated processes** recognized by FDA require that the compost be applied in a manner that minimizes potential contact with **covered produce** during and after application, but what practically does that mean? The answer is context dependent, but here are some factors you should consider:

- How it is applied e.g. sprayed or incorporated into the soil through tilling
- The type of produce and proximity of edible portions to the soil
- The likelihood of a rain event after the application: could soil particles be splashed onto the produce?
- Irrigation practices which may cause the soil to be more saturated and encourage splashing in the event of an unexpected rain¹⁹⁵

Once you’ve thought this through, write out your rationale, and keep records of steps you’re taking to reduce risk.

OTHER SOIL AMENDMENTS

Vermipost

Some growers use vermipost, or worm castings, to provide fertility. FDA considers the worms animals. Since worms can’t survive the high temperatures required under any recognized validated process, this kind of compost doesn’t reach the temperature levels required by the Produce Safety Rule to be a treated BSAAO. That means you would must treat Vermipost like an untreated BSAAO. (However, if you had peer-reviewed research that shows that worms reduce pathogen load, similar to composting, you might choose to keep a copy of that research with your food safety plan.) Also, FDA is continuing to conduct research to see if vermicomposting sufficiently reduces pathogens, so we might see clearer guidance about this method in the coming years.

Aquaponics

Growing **covered produce** in a way where it could come into contact with poop—even fish poop—can be dangerous from a pathogenic standpoint. The Produce Safety Rule doesn’t prohibit aquaponics.¹⁹⁶ Fish excreta and fish emulsions are regulated as biological soil amendments of animal origin, however FDA has directed aquaponic growers to the agricultural water portions of the Rule as the most appropriate way to manage these risks.¹⁹⁷ We know that growers using these systems want some clearer suggestions on making their produce safe, and we’d point toward the agricultural water sections of this Rule as well as other guides in our [online resource library](#).

¹⁹⁵ Draft Guidance at 67-68.

¹⁹⁶ 21 C.F.R §§ 112.60 (b)(1) & 112.60 (b)(2).

¹⁹⁷ Preamble at 80 Fed. Reg. at 74401 -02.

Biosolids (Humanure)

You **MUST** not use untreated human waste to grow **covered produce** (see definition of covered produce on page 14).¹⁹⁸ There are biosolids available that have been treated in accordance with the Environmental Protection Agency (EPA) requirements of 40 CFR part 503, subpart D, for example Milorganite®, which may be used on agricultural land. Biosolids which meet the criteria for Class A biosolids may be applied without restriction to agricultural lands, including those used for the production of covered produce.¹⁹⁹ Class A biosolids must have no detectable pathogens.²⁰⁰ With use of Class A biosolids, you must consider heavy metals (for which there are established loading rates)²⁰¹ and may wish to consider other residuals (like hormones or pharmaceuticals) that can build up in the body. Fun fact: according to the EPA’s website, “About 50% of all biosolids are being recycled to land. These biosolids are used on less than one percent of the nation’s agricultural land.”²⁰² Bottom line, if you have a composting toilet, be safe and don’t use it on any food crops!

Compost Tea

Agricultural tea is a watery extract of biological materials (such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. **Agricultural teas** are held for longer than one hour before application. **Agricultural teas** are classified as **soil amendments** for the purposes of the Rule.²⁰³

Sometimes called compost tea, **agricultural tea** is usually an aerated mix of compost and water used as a foliar spray or a soil drench to provide nutrients or reduce disease. FSMA allows the use of **agricultural teas** but has a few requirements. If you make an **agricultural tea** from an amendment that is processed in accordance with the standards above and you use water that doesn’t have detectable generic *E. coli* (in keeping with the standards in chapter 8), you can use it like you would use compost produced by a process validated to the same standard. Specifically, it would have a zero days to harvest interval, meaning that the produce could be harvested the same day that the **agricultural tea** is applied. If it is made with water that isn’t tested or has *E. coli* present, is made from an untreated soil amendment (like unfinished compost), or if you added an **agricultural tea additive** (such as molasses, yeast extract or algal powder) to the **agricultural tea** for any reason, like to increase microbial biomass, you need to treat it

¹⁹⁸ 21 C.F.R. § 112.53.

¹⁹⁹ See 40 C.F.R. § 503.15(a).

²⁰⁰ 40 C.F.R. § 503.32(a).

²⁰¹ 40 C.F.R. § 503.13.

²⁰² EPA, Frequent Questions about Biosolids, available at: <https://www.epa.gov/biosolids/frequent-questions-about-biosolids>

²⁰³ 21 C.F.R. § 112.3 (defining a soil amendment as “any chemical, biological, or physical material intentionally added to the soil to improve the chemical or physical condition of soil in relation to plant growth or to improve the capacity of the soil to hold water.”)

like raw manure. Meaning, you have to have a 120- or 90-day interval to harvest if you follow the NOP guidelines. Many growers add molasses to their compost tea, but FDA believes this can give dangerous pathogens in the compost an upper hand, creating a hospitable environment for harmful bacteria to grow.²⁰⁴

RECORDS FOR SOIL AMENDMENTS

REQUIRED:

- On at least an annual basis, obtain documentation from your **treated BSAAO** supplier to ensure the supplier has used scientifically validated treatment processes and monitoring during the production of the treated amendment (including compost) and that the **treated BSAAO** was handled to prevent recontamination.²⁰⁵(see example [online](#))
- For on-farm **composting** to create a **treated BSAAO**, you MUST keep time, temps, and turning records as applicable to show you followed a validated process.²⁰⁶ (see templates [online](#)). A **supervisor** must review, sign, and date these records within a reasonable time after they are generated.²⁰⁷
- Worker training for handling of untreated BSAAOs on your farm²⁰⁸
- Worker training for **composting** and recordkeeping, if applicable, including the names of the workers, the topics covered and the date²⁰⁹

SUGGESTED RECORDS:

- Records that show when you spread **soil amendments**, the type and source of soil amendment used, when it was applied, how much was applied, and any analysis or testing that was done (see template [online](#)). Practically, if you are going to use either NOP application interval, you should document that for the FDA to be able to show that.
- Documentation of where and when you bought soil amendments including the name and address of the supplier, which soil amendments were purchased, the date and amount purchased, and lot information, if available (see template [online](#))
- Handling and sanitation practices used that reduce risks (see template [online](#))

SUGGESTED STANDARD OPERATING PROCEDURES FOR SOIL AMENDMENTS

- How to make **compost** using a validated method: when to take temps, turn, etc., how to wash up afterward
- How to spread **treated and untreated BSAAOs**
- How to make an **agricultural tea** using a validated method

²⁰⁴ Preamble 80 Fed Reg. at 74668-69.

²⁰⁵ 21 C.F.R. §§ 112.60(b)(1)(i)-(ii).

²⁰⁶ 21 C.F.R. § 112.60 (b)(2).

²⁰⁷ 21 C.F.R. § 112.161 (b).

²⁰⁸ 21 C.F.R. § §112.21.

²⁰⁹ 21 C.F.R. § 112.21.

- How to make a pre-consumer vegetative waste **agricultural tea**
- How to clean equipment after spreading **BSSAOs**



Chapter 6

Animals and Adjacent Lands

Animals—such as wildlife, livestock, working animals, or pets—can carry and spread human pathogens, especially through their feces. The most important consideration for dealing with animals is how you are going to deal with their poop. Wildlife can refer to animals that live on or near the farm or pass through seasonally. If you have livestock, working animals or pets, chances are you already try to keep them out of the packhouse and fields, especially close to harvest time. Wildlife is harder to control, especially if they only pass through at certain times of the year. Knowing the risks associated with animals on your operation, and the wildlife in your area, can help you prevent the spread of disease.

One of the key takeaways from the conversation about animals and food safety is to never to harvest anything with poop on it! When considering the risks posed by animals, the Produce Safety Rule requires that you **MUST** assess whether there is a “reasonable probability” that your covered produce will be contaminated by animals,²¹⁰ take steps to prevent harvesting produce that has been contaminated by animal feeding or poop, and train workers to know when produce has been contaminated and not to harvest it.²¹¹

Key Concepts

- **Runoff:** Rainwater, leachate, or other liquid that drains over land, leaves the land surface, and enters unintended areas such as streams, fields, or packing areas. This water could carry pathogens from one spot to another. In this chapter, think about runoff risks not only from your own raw manure piles, but also from your neighbor’s property.
- **Co-Management:** Practices that conserve and protect soil, water, air, wildlife, and other natural resources while minimizing the risk of contamination of food from bacteria, viruses, and parasites.²¹²

²¹⁰ 21 C.F.R. § 112.22(b)(1).

²¹¹ 21 C.F.R. § 112.83 (a) Please note the requirement does NOT apply to activities which take place in a fully enclosed building or to fish used in aquaculture operations as stated in 21 C.F.R. §§ 112.81 (b)(1) & (2))

²¹² Preamble, 80 Fed. Reg. at 74365.

- **No-Harvest Buffer Zone:** A defined distance around an identified risk—like poop or other evidence of animal intrusion—where produce SHOULD not be harvested. The Produce Safety Rule doesn't define the distance, the farmer does.
- **Pre-Harvest Assessment:** A field walk to look for signs that animals were in the fields (or other problems) and determine if it is safe to harvest.
- **Pre-Plant Land Assessment:** A pre-planting field tour that helps a farmer understand if there is likely to be animal intrusion, run-off, or other issues that could impact food safety.

MAP YOUR FARM FOR RISK

Contamination can enter your produce fields or packing sheds from surrounding areas or from animals on your farm. A great way to begin to assess your risks is to draw a map of your farm and surrounding areas and conduct a **Pre-Plant Land Assessment**. This isn't a requirement of the Rule exactly but is a way to show that you are assessing the risk of contamination from animals. Both can help you understand the geography of your land and adjacent land and identify areas of risk, such as where contamination could easily spread. Before you decide which areas may or may not be good for planting, you should consider how the following could impact your growing, packing, and storage areas:

- **Current land use nearby:** What are your neighbors doing? Does their runoff affect your fields? Do their goats jump the fence? Do the fans from their chicken houses blow into your raspberries?
- **Previous land use, including of your farm and your neighbors' land:** Has the land on your property or nearby been used as a landfill? Have animals grazed the land? Has manure been stored near your farm? Have pesticides been applied in the past? Do your neighbors use their property for any residential or commercial purposes? Do you live near a chemical plant? If so, are you on their emergency call list?
- **Topography:** Are areas on your farm prone to flooding? Do you or your neighbors raise animals, make compost, or store manure uphill from your fields, and runoff affect your produce fields and packing areas? Have you erected berms or ditches to direct the flow of **runoff** to prevent this from occurring?
- **Wind patterns:** Will wind carry contamination from compost piles or an animal operation onto your produce fields?
- **Location of water sources:** Does a stream flow through your property? Do you have a pond near your produce fields? Where do animals have access to water? Where is your well head or riser? Do you have open irrigation ditches on or close to your property?
- **Septic tanks and sewage systems:** Where are they located? How and when are they maintained? Do you have a plan in case of a leak?
- **Packing areas and animals:** Where are your produce fields and packing areas in relation to animal pasture? Are there trees or bushes in proximity to your packing houses that would make it more or less likely for animals to enter them?

- **Driving Routes:** Do vehicles have to drive through the pastures or near your compost piles to arrive at the **covered produce** fields? The packing shed?
- **Wildlife and domesticated animal interaction:** Do your cows share grazing land with deer? Do geese use your duck pond as a landing pad?
- **Wildlife movement patterns:** What kinds of wildlife do you see on your farm? How often do you see them? Do they only come through at certain times of the year?
- **Animal population density:** Do you know how many deer live near your farm? Does one wild hog or twelve ravage your cantaloupe field? Do you need to set up trail cameras or get a scat identification guide to help you identify the animals or the scope of the problem?
- **Fecal contamination in production areas:** Do your workers often report fecal contamination in one field? What kind of animal does it come from?

BOTTOM LINE – It is your responsibility to manage risk

You must create and maintain a system for dealing with the waste from your domesticated animals that effectively controls their excreta and litter to prevent contamination of **covered produce, food contact surfaces**, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems.²¹³

Find sample maps for assessing animal contamination
risk in our online resource library.

PAY ATTENTION TO WILDLIFE INTRUSION

Your map and your personal experience will help you identify areas that are more or less likely to have animal intrusion so you can monitor according to risk. You may want to keep records of animal activity on your farm throughout the season to help identify what kinds of animals you are dealing with, where they may be coming from, what times of year they pass through (if migratory), and what parts of the farm they frequent. Trail cameras and scat identification guides can also help with this task.

CO-MANAGEMENT OF WILDLIFE AND FOOD PRODUCTION

Produce safety is only one of many concerns on your farm. You hopefully also manage conservation programs and natural resources responsibly. The Produce Safety Rule includes a clause about **co-management**.²¹⁴

²¹³ (112.134(a))

²¹⁴ 21. C.F.R. 112.84. See also Preamble, 80 Fed. Reg. at 74365.

Previously, when foodborne illness outbreaks associated with produce occurred, some farmers felt pressured to eliminate *all* wildlife habitat on their farms.²¹⁵ Riparian buffers, woods, wetlands, and other wildlife habitat were destroyed, disrupting the important ecological functions and food safety benefits these areas provide.²¹⁶

Destroying wildlife habitat on your farm can draw animals into your produce fields because they'll no longer have a place to live, eat, sleep, and mate. Keeping hedgerows and windbreaks can create habitat for raptors and pollinators, and also block dangerous pathogens from traveling on the wind. Grass strips between the fields and hedgerows and riparian buffers can filter water and slow the movement of pathogens from animal habitats to harvest areas, while allowing larger trees in hedgerows to thrive without providing roosts above fields.²¹⁷

It's a complicated balance to keep wildlife from creating a food safety risk (and from eating all of your produce), while also maintaining a farm that is rich in diverse ecosystems, habitats, and natural resources, but it can be done with careful consideration and a system for monitoring animal patterns.

WILDLIFE DETERRENTS

Any group of growers can have an extended conversation about wildlife deterrents, mostly talking about what hasn't worked. Obviously, for food safety reasons and for the protection of your crops, it's best to try to keep wildlife out of the production areas. Whether you put up fencing, hunt, or allow hunters on your land, use visual or noise deterrents, use trained dogs or birds of prey,²¹⁸ or employ some other method, keeping a record of your actions shows regulators that you are taking steps to prevent contamination, but it is not required. The Produce Safety Rule specifically says, "This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages."²¹⁹ Steps that you decide to take to deter wildlife must comply with the Endangered Species Act and with applicable state and local laws.²²⁰

²¹⁵ See e.g. Sasha Gennet, et al., Farm practices for food safety: an emerging threat to floodplain and riparian ecosystems, 11 FRONTIERS IN ECOL. & THE ENV'T 236 (2013).

²¹⁶ Wild Farm Alliance, Environmental Destruction in the Salinas Valley: 'Food Safety' Requirements to Remove Habitat Make Leafy Greens Less Safe, (2008),

<http://wildfarmalliance.org/resources/WFA%20FS%20EnvDestruct2.pdf>

²¹⁷ See Rivadeneira, P. (2019, February). Managing Wildlife in Fresh Produce Fields: A Natural Approach. Colorado Fruit & Vegetable Growers Association Annual Conference. Denver, Colorado: Colorado Fruit & Vegetable Growers Association. Dr. Rivadeneira has several articles in development at the time of this publication discussing these issues.

²¹⁸ See *id.*

²¹⁹ 21 C.F.R § 112.84.

²²⁰ See 16 U.S.C. § 1531 et seq.

PRE-HARVEST ASSESSMENT

A **pre-harvest assessment** is a check to be sure that the produce is safe to harvest. In this check, train workers to note any signs of animals in the field, like feces, trampled areas, or feeding. If there are areas that show animal activity, that should be noted, and some “action” should be taken and recorded. An example of an action could be: “Found rabbit scat at beginning of bed H4. Put in an orange flag that means no harvest zone of five feet. Informed harvest crew.” Similarly, train workers to report any potential contamination—signs of scat, feeding, rooting, bedding, or other activity—to their supervisor. There isn’t a rule about exactly how close to harvest this assessment needs to happen. It could simply be a quick walk through the patch right before harvest begins.

HOW TO DEAL WITH FECES IN THE FIELD

You should have a plan in place for how your workers are going to deal with proof of animals in your fields or partially enclosed packhouses. This “proof” can be piles of poop, lots of munched lettuce, or rooting or bedding areas. Deciding what to harvest when there are signs of animal activity is a time when an SOP can be very helpful to outline exactly what steps you or your workers need to take. This plan may be the same for both wildlife and working animals. It may also vary depending on the type of animal you are dealing with. See Sample SOP: Managing Wildlife and Domestic Animal Intrusion and Contamination [online](#).

- **No-Harvest Buffer Zone**

One way of dealing with scat is to form a “no-harvest buffer zone” around it. FSMA does not lay out specifics for the size of the zone, so you can determine a size that works for your operation, if this is the approach you choose. Some farmers will flag the contaminated area, and some will tape that zone off. Others might just have a rule that workers look for poop and create a no-harvest buffer zone. The California Leafy Green Marketing Agreement (LGMA) recommends that you do not harvest produce within a five-foot radius of the contamination, unless you can take some sort of remedial action that can adequately control the contamination²²¹ The size of the no-harvest buffer zone may vary depending on weather conditions, crop, amount of feces and its consistency, and the harvesting equipment you use. Consider any other corrective actions that could help reduce your risk of contamination and decide what is most appropriate for your farm.

²²¹ LGMA, Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens (April 19, 2019) at 82 available at: https://lgma-assets.sfo2.digitaloceanspaces.com/downloads/190419-CA-LGMA-Metrics_Accessible_0605.pdf

Additional corrective action might differ if the crop is a single or multiple harvest crop. You can remove, leave or bury it, or use other strategies, but consider other risks that might arise because of these actions, like cross contamination of equipment. You can use this same type of no-harvest buffer zone around other signs of significant animal activity, like eating or trampling. Keeping a record of any time you or your workers see poop and make a no-harvest buffer zone is a good practice. This could be as easy as a column or a note on your harvest list for that day.

DIVERSIFIED OPERATIONS - LIVESTOCK AND WORKING ANIMALS

Just like wildlife, livestock, working animals, and pets can potentially contaminate **covered produce**. The Produce Safety Rule does not require that you exclude working or domestic animals from your fields.²²² It is best not to have animals in fields while the edible portion of the crop is present. This may not always be possible, especially for animal powered farms, so you **SHOULD** develop an SOP for what to do if an animal poops in the field or use the same one you may have in place for wildlife. Consider creating paths for working animals to keep them out of growing areas as much as possible. If you run animals through your fields after harvest or to forage on cover crops, consider how much time will pass before the edible portion of the next crop emerges, and treat the field as if you are applying raw manure. Refer to the previous chapter on **soil amendments** for more on dealing with manure.

If you have workers on your farm who work with both animals and **covered produce**, you **MUST** train them to be aware of the risk of cross-contamination from their clothing, footwear, and any equipment used.²²³ One way to minimize risk is to work with animals on certain days of the week and harvest or handle produce on different days.

If you are in a situation where workers need to handle animals before working with **covered produce**, here are some steps you can take to reduce risk:

- Provide workers with dedicated clothing and gloves for working with animals, as appropriate;
- Create a space where clothing worn when working with animals is always removed and stored, and locate it in immediate proximity to a hand washing station so workers can wash up afterward;
- Require workers to change their shoes between animal chores and working with **covered produce**;
- Consider coveralls or separate clothing for animal chores; and

²²² See 21 C.F.R. § 112.81.

²²³ 21 C.F.R § 112.32 (b)(2).

- Ensure that workers wash exposed parts of their body—like their hands, arms, and face—if they need to work with animals before working with **covered produce**.

PETS

Farming with your furry friends might be one reason you love farming, but you **MUST** have a plan for managing the poop of all of your domesticated animals so that it won't contaminate **covered produce, food contact surfaces, or agricultural water**, and that includes dogs and cats.²²⁴ Also, animals **MUST** be excluded from the parts of fully enclosed buildings where covered activities take place to be sure that they don't affect **covered produce, food contact surfaces, or food packing materials**.²²⁵ Guard or guide dogs are allowed in a fully enclosed packhouse, as long as you're managing them to make sure they're not contaminating **food contact surfaces or covered produce**.²²⁶ Note that only dogs are permitted as guard and guide animals, so cats and other animals should be excluded from fully enclosed packhouses.

Visitors and workers **SHOULD** leave their pets at home, for food safety and liability reasons. You can make this rule very clear on your website, newsletter, or in other outreach materials. Some farmers recommend having a roped off area for visitors who show up with pets so that you don't have to turn the whole family away. Tips for dealing with visitors and their animals are provided in Chapter 4.

Records for Animals and Adjacent Land

REQUIRED

- Worker training, including knowing when produce cannot be harvested²²⁷ and understanding the risks of animals on-farm²²⁸

SUGGESTED

- **Pre-plant assessments**
- Monitoring for animal activity
- Actions taken to reduce the risks related to animal intrusion into crop (domesticated animals and wildlife)
- **Pre-harvest risk assessments**
- Records of intrusion and contamination events
- All corrective actions taken, like establishing and following a no-harvest buffer zone, trying a new animal deterrent, or use of nuisance permits

²²⁴ 21 C.F.R. § 112.83.

²²⁵ 21 C.F.R § 112.127 (a).

²²⁶ 21 C.F.R § 112.127 (b).

²²⁷ 21 C.F.R §112.22(b)(1).

²²⁸21 C.F.R §112.32(b)(1)(2).

Animals and Adjacent Land Standard Operating Procedures

SUGGESTED

- How to do a **pre-harvest assessment**, including what to do if poop is present
- Procedures you want workers to follow when switching from handling animals to touching **covered produce**
- An SOP for using specific deterrents, like how to set up an electric fence to keep out raccoons



Chapter 7

Production Water

WHY IS WATER A FOOD SAFETY RISK?

We don't have to tell you that water is necessary for life. While some farmers grow without adding irrigation water or washing produce, most vegetable growers do use water. Additionally, all farms need to have water available for hand washing.

Contaminated water sources can pose serious food safety risks on your farm. For example, a stream that has been contaminated with *E. coli* from an upstream animal operation can cause widespread contamination at a produce farm using that stream for frost protection, spraying, or irrigation. Water can also spread contamination from one piece of produce to an entire harvest during bulk washing. Once produce is contaminated with a pathogen, it can't be easily removed later. Post-harvest washing or sanitizing doesn't remove contamination, it just attempts to keep it from spreading.

Water—including both irrigation and wash water— have been implicated in previous produce foodborne illness outbreaks. It is well worth your time to pay attention to the quality of your water!

Key Concepts

Production water: Water that is intended or likely to touch the harvestable portion of **covered produce**, which starts at flowering.²²⁹ Some examples are irrigation, fertigation, application of fungicide or insecticide sprays, dust abatement, or frost protection.²³⁰

Postharvest water: Water that is intended or likely to touch the produce used during harvest or postharvest, for fluming, washing, waxing, handwashing, and more.

Microbial Water Quality Profile (MWQP): is a multi-test picture of water quality, intended to help a grower make water management decisions. It's created with up to four years of water test results and quantified with two statistical calculations: a geometric mean and a statistical threshold value.

²²⁹ See Preamble at 80 Fed. Reg. 44354, 74449

²³⁰ See 21 C.F.R. § 112.3 "agricultural water."

THE RULE, RE-EXAMINED

While there are many risks associated with water, both pre- and post-harvest, this is also a really tricky topic for many farmers. FDA heard lots of concerns from growers, as well as from food safety experts, and many details within this section are under review by FDA. Because water poses a risk, and we know you're trying to understand how to mitigate risk, we want to give you some clear and precise tips.

Additionally, because the water parts of the Rule are being re-examined, FDA finalized an extension for the water section until January 2022 at the earliest.²³¹ So, growers who need to be in full compliance have lots of extra time to prepare.²³² All of the provisions of Subpart E (Agricultural Water), other than those provisions related to sprouts, have extended compliance dates.

UNDERSTANDING PRODUCTION WATER RISKS

Risks by Type of Irrigation:

Different types of water application have different risk levels based on whether they contact the produce. Water applied to the roots of a tomato plant using drip irrigation might still touch produce if there is a problem but isn't as risky as water sprayed directly onto the harvestable portion of the crop. Different types of irrigation have different risks associated with them.

 AMOUNT OF RISK	Least Risk	More Risk	Most Risk
 TYPE OF IRRIGATION	Drip or Trickle	Flood or Furrow	Overhead

Risks by Type of Water Sources:

Similarly, each source of water has associated risks. As common sense suggests, municipal water is unlikely to have *E. coli* present, whereas a creek or pond where animals live is quite likely to have some bacteria, including pathogens. These tests are *per water source*. So, if you have a pond, a river, and two wells, that will be four separate water sources and you'll need to test and create an MWQP for each.

²³¹ FDA, Final Rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E, 84 Fed Reg. 9706, 9708 (hereinafter "water Extension"). Sprouts are NOT part of this extension.

²³² See the chart later in this Section for when you should start sampling to be prepared to comply.

 AMOUNT OF RISK	Least Risk	More Risk	Most Risk
 TYPE OF WATER	Municipal Water	Ground Water (like a well)	Surface Water (like a stream, pond, holding tanks, rainwater catchment, etc. where the water is open to the environment and springs, wells, or other sources that are impacted by surface water)

MAP YOUR SYSTEM

You **SHOULD** create a map of your irrigation systems, including the source and how the water gets to the field. You can add pumps, filters, pressure regulators, backflow prevention devices, risers, and other parts to this map. You could simply add these irrigation system parts to your general farm map or create a separate map of your irrigation system.

INSPECT YOUR WATER SYSTEM

Each year, you **MUST** inspect the system and make sure that it is not compromised or could be contributing to food safety risks.²³³ This inspection includes looking at your water sources, water distribution systems, facilities, and equipment to identify any conditions that could cause contamination.²³⁴ You **MUST** consider:

1. The type of water source and its relative risk
2. How much control you have over that water source
3. Degree to which the water source is protected
4. Impacts from adjacent and nearby land use, such as the likelihood that water could become contaminated by another user before reaching your covered farm²³⁵

To prevent contamination, you **MUST** maintain the parts of the agricultural water distribution systems that are under your control.²³⁶ Walk the ponds, ditches, lakes, or

²³³ 21 C.F.R § 112.42(a).

²³⁴ 21 C.F.R. § 112.42(a).

²³⁵ 21 C.F.R. (§ 112.42(a).)

²³⁶ 21 C.F.R. §112.42(b).

other sources of surface water to look for damage to infrastructure, debris, and signs of animal activity. Check for:

- leaks
- drops in pressure
- freeze damage
- missing parts
- continued functionality of backflow prevention devices
- rodent damage or nests
- faulty sprinkler patterns
- well heads, caps, seals, and casings—be sure that they're intact, fully capped, and sloped correctly
- piping or pressure tanks
- treatment equipment
- exclusion of domesticated animals
- keeping the source free of debris, trash
- intake pipes
- inspect head gates
- screen and debris systems
- water measurement devices such as Parshall flumes. (In a ditch system, if you go from an open ditch to underground pipe, make sure drains in your pipes system are functioning in case the system needs to be flushed due to contamination.)

Additionally, you **MUST** inspect and implement measures to prevent pooling of water or contact between **covered produce** and pooled water.²³⁷ The Rule gives some examples of how to prevent that contact, like choosing to stake crops.²³⁸ If you have areas that you know are likely to experience pooling, for example a low spot that often ponds after a hard rain or the part of the beds closest to the flood gate or the area where you flush a media filter, you **MUST** take appropriate action to prevent contamination.

²³⁷ 21 C.F.R. §112.42(d).

²³⁸ 21 C.F.R. §(112.42(d).

FLOODING

Any produce that is touched by flood water cannot be harvested.

Flooding is when water from a stream, river, or lake jumps the banks and enters your field, potentially carrying waste, pathogens, and dangerous chemicals. Flooding is not when heavy rainfall accumulates in areas of your farm or when an irrigation mistake results in a big puddle. Because flood waters are not considered agricultural water since they're not intentionally applied, accidental exposure of produce to flood water isn't covered by the Agricultural Water provisions of the Produce Safety Rule. However, the FDA is pretty clear in other documents that if the harvestable portion of the crop is exposed to flood water it shouldn't enter the food supply.²³⁹

KEEP YOUR IRRIGATION WATER CLEAN!

- ✓ Fence your animals out of your agricultural water sources
- ✓ Maintain your well head ([Online: tip sheet](#))
- ✓ Install backflow prevention device, which is like a one-way valve to ensure that the water in your irrigation lines doesn't wash back to your well ([Online tip sheet](#))
- ✓ Keep manure or compost storage away from water sources
- ✓ Figure out what occurs upstream from your water source and how it could impact your produce safety: animal operations, garbage dumps, chemical plants, power plants, waste treatment plants
- ✓ Maintain sewage and septic systems. The Rule says that you **MUST** maintain sewage and septic systems and check them after potentially significant events like a flood or earthquake. Specifically, you **MUST** consider how sewage or septic systems could impact "**covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.**"²⁴⁰

²³⁹ FDA, Guidance for Industry: Evaluating the Safety of Flood-affected Food Crops for Human Consumption (Oct 2011) available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-evaluating-safety-flood-affected-food-crops-human-consumption>.

²⁴⁰ 21 C.F.R. § 112.131.

TEST YOUR WATER

Until the FDA begins enforcing this part of the Rule, if you are already testing your water as part of a third-party audit, keep testing. If you aren't testing yet, start testing. For surface water, the most useful test is probably a quantitative test—one that tells you exactly how much *E. coli* you have, not just that you have some level of bacterial activity. Find out and record the exact name of the type of test you get.

In the text of the Rule, you are directed to take multiple tests based on the type of source you use. This profile is called a **Microbial Water Quality Profile** and is abbreviated **MWQP**. The table below tells you how many tests you'll need to build an **MWQP** and over what period of time to obtain them depending on your source.

Type of water	Municipal water	Ground water, like a well	Surface water, like a stream, pond, open holding tanks, acequia, rainwater catchment, etc. where the water is open to the environment and springs, wells, or other sources that are impacted by surface water
How often it needs to be tested	Get a letter from the municipality that shows that the water has been tested and has no detectable <i>E. coli</i> (see page 88)	Four or more times during the growing season or over a year, to establish an initial water quality profile. After that profile is established, one new test a year and the oldest test rolls out of the profile until you have a four-year, four or more sample profile. ²⁴¹	20 or more times over two to four years, to establish a water quality profile. After that profile is established, at least five new tests a year and the oldest tests rolls out of the profile. ²⁴²

²⁴¹ 21 C.F.R. § 112.46 (b)(1)(i)(B) (establishing the number of tests); 21 C.F.R. § 112.46 (c) (establishing the roll off).

²⁴² 21 C.F.R. § 112.46 (b)(1)(i)(A) (establishing the number of tests); 21 C.F.R. § 112.46 (c) (establishing the roll off).

Assuming the Rule stays in its current form, the following table shows when you must begin and complete sampling for surface water used in the production of **covered produce under the finalized extension**.²⁴³ Moreover, the compliance date refers to the year in which you must begin testing your water.²⁴⁴ An inspector shouldn't request records about your water systems inspection, testing, or usage until your compliance date.

FARM BUSINESS SIZE		"Other"		"Small"		"Very Small"		"Not Subject"	
PRODUCE SALES (three year rolling average)		Over \$500,000		Between \$250,000 and \$500,000		Up To \$250,000		Under \$25,000 (adjusted for inflation)	
WATER SOURCE TYPE		Surface	Ground	Surface	Ground	Surface	Ground	Surface	Ground
SCHEDULE	BEGIN SAMPLING AND FOLLOWING WATER RULES	2022	2022	2023	2023	2024	2024	Not Required (but a good idea)	
	COMPLETE SAMPLING BY END OF SEASON	2025	2022	2026	2023	2027	2024		
	USE MWQP TO MAKE DECISIONS	2026	2023	2027	2024	2028	2025		

²⁴³ Water Extension, 84 Fed Reg. at 9708.

²⁴⁴ Water Extension, 84 Fed Reg. at 9711.

Because water, especially surface water, can vary in quality from month to month or even day to day, the current Rule requires growers to take a representative sample of their water²⁴⁵ and dictates a minimum number of samples to be tested based upon the risks presented by the type of water source.²⁴⁶ These tests, taken over a period of up to four years depending on source²⁴⁷ during each respective growing season and as close to the harvest as practicable,²⁴⁸ establish a baseline. So instead of asking for one test, FDA wants you to get a number of tests during the growing season, and for surface water over multiple years to paint a more nuanced picture of your water quality.

You can have a single test (or a few tests) that are above allowable levels and still have water that is usable. Once you've established a **Microbial Water Quality Profile**, you'll test your water during the growing season when you are using the water. The newest test contributes to your **MWQP** and the results of the oldest test falls away. You might be thinking that the costs of all of this water testing can add up. That could be true, especially if you have multiple water sources, like a pond, two wells, and an irrigation ditch. Extension services in some states offer food safety water testing to help farmers. Again, many of the water parts of this Rule are currently being reevaluated and the requirements on types and frequency of testing may change. For now, we strongly suggest testing to get some sense of the quality of your during the time when you're using the water. For more information about MWQPs and other aspects of water quality sampling please refer to the PSA fact sheet on the topic.²⁴⁹

USING MUNICIPAL WATER

If you use municipal or "city" water on your farm, your water source is probably low risk for pathogens. Typically states and often their departments of health are responsible for monitoring the quality of drinking water. The Safe Drinking Water Act requires community water systems to supply an Annual Consumer Confidence Report or Drinking Water Quality Report.²⁵⁰ If you need to be in compliance with the Rule, print out a copy of the annual Drinking Water Quality Report by searching here <https://ofmpub.epa.gov/apex/safewater/f?p=136:102:::::>. In some towns this report is mailed to residents. Often it is on the town website. In some locations you may need to call the town and ask for a copy. In some places they might not have this readily available but could provide you with a letter or "certificate of conformance" that shows that the water meets the standards of the Safe Water Drinking Act.

²⁴⁵ 21 C.F.R. § 112.46 (b)(1)(ii).

²⁴⁶ 21 C.F.R. §§ 112.46 (b)(1)(i)(A) & (B).

²⁴⁷ 21 C.F.R. § 112.46 (b)(1)(i)(A).

²⁴⁸ 21 C.F.R. § 112.46 (b)(1)(ii).

²⁴⁹ PSA, The Water Analysis Method Requirement in the FSMA Produce Safety Rule (updated April 2019) available at <https://producesafetyalliance.cornell.edu/sites/producesafetyalliance.cornell.edu/files/shared/documents/Water-Analysis.pdf>

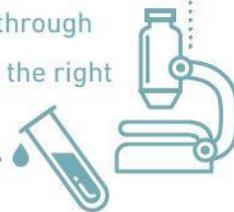
²⁵⁰ 40 C.F.R. § 141.155(a).

All of the currently approved tests look for generic *E. coli*. Generic *E. coli* is an indicator organism test, meaning that a positive test indicates that a certain quantity of *E. coli* is present, but does not necessarily mean that the water or produce it touches would make a person sick. A test could signify that a non-pathogenic form of *E. coli* is present or that a pathogenic form is present. Of course, there are other types of pathogens or parasites that might not be found when looking for generic *E. coli*, but FDA determined that generic *E. coli* is a good indicator of potential fecal contamination.²⁵¹ Many residential well tests might test for generic coliforms, which is even broader than generic *E. coli*.

Some growers feel intimidated by the task of conducting a water test, but we have found that it's easier than it might seem at first blush. Water tests should come with very clear instructions from the lab. Follow the instructions closely, including the amount of time you have to get the test to the lab.

Finding a Water Testing Lab

Agricultural extension, state departments of agriculture or health, and other farm service providers are currently working to create a Google Map of labs with clear information about which tests they provide. (See Online Resource Library.) Until that map is live, you can contact your local extension agent for a recommendation of a lab in your area or ask other farmers or farm service providers. You'll want a lab that is as close as possible because most of the tests need to arrive at the lab within six hours. In order to be sure that you're getting the test that you need, you can provide the lab with the The Water Analysis Method Requirement in the FSMA Produce Safety Rule handout from the Produce Safety Alliance. Because this request is still quite new for many labs, there is a handout in our online resources library to help guide you through a conversation with your lab to be sure that you're getting the right



²⁵¹ See Preamble, 80 Fed. Reg. at 74449.

WHAT ARE YOU GOING TO DO WITH THE RESULTS?

As of the publication of this guidebook (2019), the FDA is re-evaluating the water quality criteria in the Produce Safety Rule. Under the current regulation, there are two numbers that you'll be looking at to evaluate your water quality. One is a *geometric mean (GM)*, which is a special type of average that helps you understand your "typical" amount of generic *E. coli*. The other number is a *Statistical Threshold Value (STV)* which shows the range in *E. coli* levels. This number is helpful because it gives growers using surface water a little bit of flexibility, in the case of a test that shows a small spike in *E. coli* levels without making all their water unusable. These two numbers together give a more nuanced picture of your water; they show what your *E. coli* levels are generally like, and what kinds of ranges you might see.

To have water that is suitable for a use where it is likely to come into contact with the harvestable part of the crop, you need to make sure it meets the following thresholds:

(1) the water must have 126 or fewer colony forming units (CFU) generic *E. coli* per 100 mL water using the geometric mean (GM)²⁵² AND

(2) the water must have 410 or fewer CFU generic *E. coli* per 100 mL water statistical threshold value (STV).²⁵³

Sometimes, growers get frustrated with these calculations – "why couldn't this just be a simple mean average?" However, the combination of these two calculations is actually a lot more forgiving than a simple mean average. Additionally, several universities have jumped in to make this process easier. Even through the Rule isn't final, if you have the data over a few years, you may want to experiment with one of the calculators below and understand what your water quality looks like.

There are a few tools to help growers understand their water tests:

- An Excel spreadsheet, created by the Western Center for Food Safety at UC Davis: wafs.ucdavis.edu/
- [Ag Water App](#) created by University of Arizona
- [Online Calculator](#), also created by University of Arizona
- Do you love math? Here's how to arrive at GM and STV with only a trusty [calculator](#)

If you don't have enough samples for a complete **MWQP** to experiment with calculating your GM or STV, then you might consider reviewing your results like a "stoplight chart"

²⁵² 21 C.F.R. § 112.44(b)(1).

²⁵³ 21 C.F.R. § 112.44(b)(2).

based on typical standards and guidelines from other specific commodity food safety rules and other water guidelines.²⁵⁴

- If your *E. coli* concentration is less than 100 CFU/100 mL, you are in the green zone and may continue using your water as is. In almost all agricultural water standards from other programs, like LGMA, the *E. coli* counts where farmers must take precautions or make changes to keep the produce safe are above 100 CFU/100 mL.
- If your *E. coli* concentration is between 100 and 500 CFU/100 mL you are in the yellow zone. Most of the *E. Coli* counts where farmers must take precautions or make changes to keep the produce safe are in this range. If you can, wait a few days to harvest, after irrigating or spraying, to give any pathogens that might have gotten onto the crop time to die off in the sunlight or take some of the steps below. (See page 83 for more discussion about die-off.)
- If your *E. coli* concentration is over 500 CFU/100 mL, you are in the red zone. You should not use this water directly on **covered produce** without treating it. In other types of regulated water, say recreational water or LGMA, if a water test came back with *E. coli* levels higher than 500, the water use would need to stop or actions, like the water treatment, would need to occur. Some changes you might consider are discussed in more depth in the next section.

ADDRESSING WATER PROBLEMS

If you get test results that are significantly out of your normal range, that's a smart time to reinspect your water system and make sure that there isn't an obvious problem. If there is an apparent issue, like a dead animal near your intake valve or a broken backflow protector, fix the issue, make a record of it, flush the system, and retest the water. If you have a well, you can shock your well and retest. That doesn't erase the record of the high *E. coli* results, but it helps you understand why you've gotten high tests results and to avoid continued risk of spreading illness. Being proactive is always useful!

There are other very important steps you can take to mitigate the risk that your irrigation or harvest water is going to spread contamination across the farm:

- **Choose another water source:** Water is a valuable resource and is in scarce supply in some parts of the country. Many farmers don't have alternative water sources, however, one of the options if you think your water is too risky is to find another water source. You could, for instance, switch from surface water to a well.

²⁵⁴ These suggestions are based not on FSMA but on other water quality guidelines. We're providing them because we understand that, if you are to begin testing now, you'll need some way of interpreting the results of the tests. These guidelines don't put you into or out of compliance currently, but they can help you understand the riskiness of your water source.

- **Change water application method:** Switching to a less risky method of irrigation, like drip, can lower risk. Note that if you use drip irrigation in a way that it isn't likely to touch covered produce and there is a problem, like a big tear in your drip lines, you SHOULD consider the food safety risk and have a plan to address that problem.
- **Shock your well:** Shocking your well with a disinfectant treatment is a common practice and there are lots of online resources for best practices. See [online resources for tips on shocking a well](#).
- **Stretch the time between applying water and harvest:** Because bacteria are likely to die off in a dry, sunny field, the Produce Safety Rule includes a specific calculation for stretching the time between applying water—like in spraying, frost protection, or irrigation—and harvest. This microbial die off rate is .5 log per day up to 4 days to achieve a calculated log reduction of your GM and STV to meet the above water quality criteria.²⁵⁵ You could also use an alternative microbial die-off rate instead of this one, provided you have adequate scientific data to support that your alternative would provide a similar level of public health protection.²⁵⁶ Some food safety experts believe the use of microbial die off rate promulgated by FDA is problematic, in part because it doesn't address the risk of dangerous water-borne parasites that wouldn't die off in those environments. Using this corrective measure would require that a covered farm would keep a record of when you apply water and when you harvest. If you're applying the water with a spray of some sort, you'll probably already be keeping a record of that, but if you're using this die-off option for irrigation water, you'll need to have a record of when you irrigated. Even if you water tested within the limits FDA included in the final rule, you can still leave time between applying water and harvest to improve food safety. Also, note that not all field conditions are the same. Pathogens will die faster in hot, dry, windy weather than they will on a humid, cloudy day.²⁵⁷ While some experts are reconsidering if this imperfect die-off period really makes produce safer, it is an affordable option for some growers.
- **Water treatment:** One of the ways FDA suggests that farmers can deal with agricultural water that has high levels of pathogens is to treat the water.²⁵⁸ There are a number of water treatment options that farmers use for irrigation water, such as chlorine, peroxyacetic acid, UV-light, or ozone. Any chemical that you're using MUST be labeled by the EPA for that use, and be regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). UV filters, which don't add a chemical, are registered as a pesticide device. They can be costly but might be the best choice for smaller growers.

²⁵⁵ 21 C.F.R. § 112.45 (b)(i)(A).

²⁵⁶ 21 C.F.R. § 112.49; 21 C.F.R. § 112.

²⁵⁷ Preamble, 80 Fed. Reg at 74416.

²⁵⁸ 21 C.F.R. § 112.43.

WELL WATER

Well water can remain quite stable and consistent and can be found to have no *E. coli*. If you're using the same well water for your postharvest rinsing, washing, and packing, you will need to have water with no generic *E. coli*. Currently the Rule only allows presence-absence tests for postharvest water, but, until FDA provides further clarification on the water section of the Rule or the Rule is being enforced for your operation, you could consider using a presence-absence test for any well water.

Production Water Record Keeping

REQUIRED

If the rule is implemented as written, these would be the required records. But, remember that no size grower is expected to comply at this time.

- Findings of the annual inspection of your water system²⁵⁹
- Documentation of all analytical tests on your agricultural water conducted to demonstrate your compliance with this section of the Rule²⁶⁰
 - In other words, all of your tests of your surface water or groundwater
- Or, if you are using municipal water, the annual certificate of conformance discussed in this section²⁶¹
- If you are using a water treatment method, the scientific substantiation showing that the water treatment method is appropriate²⁶²
- Documentation of the results of any water treatment you are using.²⁶³
- If you are trying to reduce risk by stretching the time between the application of water and harvest, scientific documentation you rely on for showing that interval is appropriate.²⁶⁴
- If you are trying to reduce risk by stretching the time between the application of water and harvest, you need to have a record of each to show that interval.²⁶⁵

SUGGESTED

- Copies of any water tests or municipal water testing results
- Records of when you do an irrigation system inspection and any results

²⁵⁹ 21 C.F.R. § 112.50(b)(1).

²⁶⁰ 21 C.F.R. § 112.50(b)(2).

²⁶¹ 21 C.F.R. § 112.50(b)(7).

²⁶² 21 C.F.R. § 112.50(b)(3).

²⁶³ 21 C.F.R. § 112.50(b)(6).

²⁶⁴ 21 C.F.R. § 112.50(b)(5).

²⁶⁵ 21 C.F.R. § 112.50(b)(6).

- Records of when you irrigate²⁶⁶
- Records to prove/support any corrective measures like using a UV filter or shocking your well

Production Water Standard Operating Procedures

- How to do an annual water system inspection, including what to check for
- How to take a water test

²⁶⁶ Don't worry, this is optional! But if you're stretching the time between water application and harvest, you'll want to document when you irrigate.



Chapter 8

Postharvest Water²⁷⁸

Postharvest water is used to rinse or cool produce, to clean harvest equipment and bins, to move produce (like fluming), to make ice, or to wash hands--any water that comes into contact with produce during or after harvest. Even a farm that doesn't use any water in harvesting will have some postharvest water because hand washing is required.

Like the Production Water Standards, FDA is reexamining postharvest water standards and, meanwhile, has extended the compliance date for testing and use of postharvest water.²⁶⁷ However, the standards for postharvest water haven't been very contentious, so this part of the rule might remain unchanged.

No matter how many precautions you take during production, produce grown outside will always carry some risk of contamination and postharvest water can take a little bit of bacteria that's on one leaf of spinach and spread it to an entire batch. The use of water in your postharvest activities is one way that an isolated problem can become a really large concern. You **MUST** manage postharvest water to prevent contamination of covered produce and food contact surfaces.²⁶⁸

Water that's used to wash produce is a little riskier than water that's used before harvest, because it definitely touches the edible part of the crop. Because of this increased risk, postharvest water needs to be a higher quality: no detectable generic *E. coli* per 100 mL. The concern about postharvest water is not only about the starting quality of the water, but also the way that the water can become contaminated during use—from contaminated produce, bins, hands, equipment, or other items—and spread that contamination throughout a load of produce.

Examples of postharvest water use include:

- Washing or rinsing produce
- Cooling produce
- Making ice
- Applying postharvest wax or fungicide
- Washing and sanitizing tools, equipment, bins, or food contact surfaces
- Hand washing²⁶⁹

²⁶⁷ FDA, Final Rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E, 84 Fed Reg. 9706, 9708.

²⁶⁸ 21 C.F.R. §112.48 (a).

²⁶⁹ 21 C.F.R. § 112.44 (a).

Key Concepts

Single Pass Water: To understand your risks associated with postharvest water, it's helpful to imagine that there are two types of produce washing water. The first style is "single pass water," like you might see at a spray table, brusher washer, or barrel washer. In this scenario, the water sprays onto the produce and then immediately drains off, carrying dirt and pathogens with it—hopefully! Choose this type of washing technique if it's reasonable for your crop and systems.

Batch Water: Recirculated or batch water is water that is either recirculated through sprayers or in a dump tank. Water used like this could become contaminated with pathogens brought in on workers' hands, dirty produce, soil on a harvest tote, or in some other way. Once in the water, the pathogen is free to attach to many of the other pieces of produce in the dump tank. Batch water poses a higher risk for cross-contamination and FDA has previously acknowledged that using a sanitizer in batch water likely reduces risk.²⁷⁰ The Rule does not require that you use a sanitizer in batch water.²⁷¹ However, if you use batch water, you **MUST** have a schedule for changing the water.²⁷²

Biofilms: Communities of bacteria exude natural polymers to protect themselves and make them resistant to the harsher environments that would usually spell death for bacteria. One common example is plaque on our teeth.

Sanitizer: A product that kills or inactivates microorganisms. When talking about sanitizers in wash water, we like to say that they sanitize the water, but they don't sanitize the produce in the water.

Turbidity: The amount of sediment suspended in water that makes it cloudy.

Infiltration: When warm produce is placed in cooler water, we sometimes see a process called infiltration where the water is drawn into the fruit at the stem scar or other blemish on the fruit.

Food Contact Surface: Usually we think about the surfaces that are contacting our food, but we also need to think of the surfaces that are touching the water that is touching the food. So, consider food contact surfaces in your postharvest water system like:

- The surfaces of your equipment in which wash water is held or flows through that will contact produce, like the inside of tubs or sinks;
- Surfaces that will contact ice if it is being used to pre-cool any produce, like the inside of ice makers;
- Hoses, nozzles, and sprayers used to apply water;
- Any drains in your equipment (and what happens when that drain backs up);

²⁷⁰ See FDA, Guidance for Industry Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, (October 1998) at 16, available at: <https://www.fda.gov/media/117408/download>.

²⁷¹ See 21 C.F.R. §§ 112.45 (a)(1)-(2) (providing growers the option of re-inspecting, making changes, and remeasuring if water does not meet or treating the water if water does not meet the no detectable generic *E. coli* standard).

²⁷² 21 C.F.R. § 112.48(a).

- The surface of a packing line; and
- The inside of totes used for harvest, packing, holding.²⁷³

INSPECT THE SYSTEM ANNUALLY AND BEFORE EACH USE

You **MUST** inspect your postharvest water system at the beginning of the growing season, and at least once annually.²⁷⁴ This inspection **MUST** include all parts of your water distribution system that are under your control, including regularly inspecting all the equipment used in your system and making sure that it is appropriately stored when not in use to prevent the introduction of hazards to **covered produce** or **food contact surfaces**.²⁷⁵ You can add the parts of this water system, like drains and hoses, to the map of your pack station.

Remember from Chapter 2 that FDA considers “washing” to be a harvesting activity.²⁷⁶ As such, you must train your workers to inspect the equipment used for washing to ensure that it is functioning properly, clean, and maintained so that it will not contaminate covered produce and how to either correct problems or report them to a supervisor.²⁷⁷ Seams on food contact surfaces of equipment and tools **MUST** be either smoothly bonded or maintained to minimize the accumulation of dirt, filth, food particles, and organic material.²⁷⁸ Consider repairing or replacing these parts and/or surfaces which are food contact surfaces, or you **MUST** take care cleaning (and sanitizing) these areas, as appropriate, before you use your system.²⁷⁹ Please note that FDA is not exercising enforcement discretion nor has it delayed compliance dates with respect to either this training requirement or the equipment requirements part of the Rule.

A good way to do ensure that this inspection is being done is to highlight key **food contact surfaces** in your washing system, like sinks and hoses, and then create a checklist for an inspection before use. That way, you can confirm that everything is still in good working condition before you get started. Due to the build-up of dirt and/or sediment which can conceal the true condition of your equipment, you may find that the best time to inspect a system is after cleaning, but before any sanitizing activities. Cracked or broken seals, rough welds, and scraped surfaces might be a reality of well-used and well-loved equipment, but such surfaces may be very difficult to clean and sanitize fully and can create a harborage area for pathogens.

²⁷³ 21 C.F.R. § 112.3 “food contact surface”.

²⁷⁴ 21 C.F.R. § 112.42(a).

²⁷⁵ 21 C.F.R. § 112.42(b).

²⁷⁶ 21 C.F.R. § 112.3

²⁷⁷ 21 C.F.R. § 112.22(b)(1).

²⁷⁸ 21 C.F.R. § 112.123(c).

²⁷⁹ 21 C.F.R. § 112.123(c).

START WITH NO E. COLI IN YOUR POSTHARVEST WATER

Postharvest water **MUST** be free of generic *E. coli* when you start using it.²⁸⁰ You **MUST** not use untreated surface water for postharvest uses, including hand washing, cleaning produce, making ice, or washing **food contact surfaces**.²⁸¹ Municipal water sources should be free of *E. coli*. A PSA handout on water testing details the seven quantitative tests and the seven presence/absence water tests that the FDA was allowing growers to use to test well water for use as postharvest water.²⁸² Since the compliance dates have since been extended in this area or you may be qualified exempt, at this point, any test for *E. coli* should help you know that your water is usable.²⁸³ If you haven't tested your well water or haven't tested it in a long time, get a test! See page [80](#) for info on finding and communicating with a laboratory. If you get a test and it comes back positive for *E. coli*, you **MUST** stop using it and take a corrective measure like shocking the well, treating the water, or changing your water source.²⁸⁴

USE SANITIZER

Using sanitizer when washing produce isn't required, but it is recommended. Even with **single pass water**, where the risk of cross-contamination is lower, sanitizer can reduce the buildup of **biofilms**. **Biofilms**, once present, can be really difficult to remove, so trying to keep them from establishing is key. **Sanitizers** are especially recommended in **batch water**.

Many folks think that **sanitizer** cleans microorganisms off of the produce itself. It does not. Rather, when a piece of produce with bacteria enters the water and some bacteria comes off, the **sanitizer** is able to attach to that bacteria cell, ensuring that it won't attach to another piece of produce. In that way, the **sanitizer** is reducing the risk of cross-contamination. The **sanitizer** doesn't just bond to bacteria, though. It will attach to all kinds of things in the water, so high levels of sediment (meaning your water has high turbidity) will tie up the **sanitizer**. Temperature and pH will also affect the efficacy of the **sanitizer**. (See [online resources here](#) for how to choose a **sanitizer** or monitor wash water.)

²⁸⁰ 21 C.F.R. § 112.44 (a).

²⁸¹ 21 C.F.R. §§ 112.44 (a)(2)-(4).

²⁸² PSA, The Water Analysis Method Requirement in the FSMA Produce Safety Rule (updated April 2019) available at:
<https://producesafetyalliance.cornell.edu/sites/producesafetyalliance.cornell.edu/files/shared/documents/Water-Analysis.pdf>

²⁸³ PSA, The Water Analysis Method Requirement in the FSMA Produce Safety Rule (updated April 2019) available at:
<https://producesafetyalliance.cornell.edu/sites/producesafetyalliance.cornell.edu/files/shared/documents/Water-Analysis.pdf>

²⁸⁴ 21 C.F.R § 112. 45 (a).

If you use **sanitizer** in your wash water, you'll have a few additional **MUSTS**:

1. Choose a **sanitizer** and method that is labeled for the right use (for example, in produce wash water) and only use it according to that label.²⁸⁵
2. Monitor the **sanitizer** during use, to be sure that there is still enough “free” **sanitizer** in the water to be effective. You can usually buy test strips from the **sanitizer** supplier. Check the label of your **sanitizer** for instructions on monitoring.²⁸⁶
3. Use the **sanitizer** in a way that keeps the water safe during use, for example, by monitoring it and adding more if necessary.²⁸⁷
4. Calibrate, maintain, and provide enough instruments for monitoring wash water or **sanitizer**, for example pH strips, sanitizer strips, thermometers, or oxidation reduction potential (ORP) monitors.²⁸⁸

CHANGE WATER FREQUENTLY

It seems obvious that changing your wash water frequently could reduce cross contamination. For wash water that will be recirculated (**batch water**), you **MUST** establish and follow a schedule to change the water to maintain its safety.²⁸⁹ For all postharvest water, you **MUST** visually monitor the quality of the water.²⁹⁰

Strongly consider making a clear rule for workers addressing when to change wash water based on **turbidity**. For example, you could use a line or visual marker on your tank—when **workers** can no longer see that line or the drain plug in the sink or some other existing feature, that might be a practical and useful indicator. Another tool might be to use a modified Secchi disk at the bottom of a vase of water (see [online resource](#)). These simple, cheap measures give you a clear way to help workers know exactly when to change water. This is a helpful place for an SOP.

Double or Triple Wash

Although not required by the Rule, FDA has previously noted that a multiple step washing system may reduce risk. This can be helpful because you can get most of the soil off in the first washes so that you don't tie up the **sanitizers** in the later rinses.²⁹¹

²⁸⁵ 21 C.F.R § 112.43 (a)(1).

²⁸⁶ 21 C.F.R §112.43 (c).

²⁸⁷ 21 C.F.R §§112.43 (a)(2).

²⁸⁸ 21 C.F.R §§112.124(a)-(c).

²⁸⁹ 21 C.F.R. § 112.48 (b).

²⁹⁰ 21 C.F.R. § 112.48 (b).

²⁹¹ See FDA, Guidance for Industry Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, (October 1998) available at: <https://www.fda.gov/media/117408/download>.

WHAT IS SOMETHING GOES WRONG?

In addition to testing your water and finding out that the water contains *E. coli*, there may be some other instances when you believe that your water isn't safe to use and must make a corrective action. You have an ongoing responsibility to identify and correct conditions that put covered produce or food contact surfaces at risk for contamination.²⁹² For example, if your water looks or smells odd, if you find a dead mouse in your **batch water**, or if you drop a hose in a puddle that is very close to a drain, you will want to take steps to make sure that the safety of the produce isn't compromised.

AVOID INFILTRATION

When warm produce is placed in cooler water, we sometimes see a process called **infiltration** where the water is drawn into the fruit at the stem scar, other blemish on the fruit, or pores on the surface of the produce. Pathogens in wash water can enter produce as the warm produce pulls in the cooler water. FDA cited to studies that observed **infiltration** in apples, oranges, tomatoes, and mangoes during the rulemaking.²⁹³ Infiltration is particularly likely to occur in crops like melons, peppers, and spinach as well. The longer the produce is in the water and the deeper it is in the water; the more likely **infiltration** is to occur. The likelihood also increases as the difference between the temperature of the produce and the water increases, however some studies have demonstrated infiltration can occur when there is zero degree temperature difference.²⁹⁴

This is a complicated issue and we want to emphasize it a bit. The Rule says that you **MUST** monitor and maintain a water temperature that is appropriate for the **covered produce** and the time and depth of submersion to minimize the potential for **infiltration**.²⁹⁵ We know that this is tricky, because farmers are often, perhaps usually, using water that is at least 10 degrees colder than the produce. In some parts of the country where the mornings aren't very cool, it would be difficult to avoid such a temperature differential. Also, farmers often use that cooler water to chill and "crisp up" greens that need high humidity. This is a part of the Rule where you should do some individual research-- or call your produce safety extension agent -- to understand the particular risk of infiltration for your crops given the design of your system.

- To *avoid infiltration*, you could:
 - Not wash produce prone to **infiltration**. Especially with tomatoes, peppers, and cantaloupe, consider whether the small amount of dirt on them is worth the risk.

²⁹² 21 C.F.R. § 112.42 (b).

²⁹³ Preamble, 80 Fed. Reg. at 74459.

²⁹⁴ Preamble, 80 Fed. Reg. at 74460.

²⁹⁵ 21 C.F.R. § 112.48(c).

- Spray off **infiltration**-prone produce rather than dunking
- To *reduce* the likelihood of **infiltration**, you could:
 - Use **sanitizer** in the wash water
 - Pre-cool the **covered produce** so that the **covered produce** is less than 10 degrees warmer than the water (you could just stick it in the cooler while you wash other items, or you could look into forced air cooling) (see [online resources](#))
 - Reduce the amount of time the produce is in the water
 - Use wider, shallower tanks to prevent produce from being deeply submerged

You can read more about [infiltration here](#).

CONSIDER YOUR WATER'S LIFECYCLE

When the water you're using to rinse or cool your produce leaves your washing and packing space, where does it go? Consider this question, as it could carry pathogens that could contaminate nearby fields. Used water from washing and cooling produce or handwashing **MUST** be properly disposed of so as not to become a source of contamination to **covered produce** or **food contact surfaces** or your **agricultural water** sources.²⁹⁶ If workers are walking through puddles created from washing, they could carry pathogens to other parts of the farm. Additionally, if you've used a **sanitizer**, there may be other applicable federal, state, or local regulations regarding how you discharge your water. French drains, drainage pipes, or simple ditches can help move water away from a wash area without creating dangerous (and unsightly) mud puddles.

DON'T WASH THINGS THAT DON'T NEED IT

Some growers are required to provide a very well washed product to their buyers. However, if there are types of produce that you can avoid washing, don't wash! Introducing water into the system can not only spread types of bacteria that make humans sick, they can also spread plant pathogens that cause decay. Especially reconsider washing any produce that is prone to **infiltration**.

²⁹⁶ 21 C.F.R. § § 112.132 & 112.133.

Postharvest Water Record Keeping

- **REQUIRED**

- Annual inspection of your postharvest water distribution system²⁹⁷
- Water test results or municipal water record²⁹⁸ A **supervisor** must review, sign, and date each record within a reasonable time after the record is created.²⁹⁹
- If you treat water, you must keep monitoring records³⁰⁰
- Documentation of any corrective actions you take, including re-inspection of your water system, corrections made, and measures taken to verify compliance or records of water treatment and monitoring³⁰¹ A **supervisor** must review, sign, and date each record within a reasonable time after the record is created.³⁰²

- **SUGGESTED**

- If you use **batch water**, you could keep a record of when water was changed to show you have established and followed a schedule for changing recirculated water³⁰³

Postharvest Water Standard Operating Procedures

EXAMPLE SOPs

- How to sample **postharvest water**
- How to inspect the **postharvest water** distribution system
- How to add **sanitizer** and monitor batch water
 - Checking for pH
 - Checking for turbidity
 - Checking for temperature
- How to change wash water
- Steps taken to reduce infiltration
 - Monitoring temperature of water and produce
 - Precooling

²⁹⁷ 21 C.F.R. §112.50(b)(1).

²⁹⁸ 21 C.F.R. §§ 112.50 (b)(2) & 112.161(b).

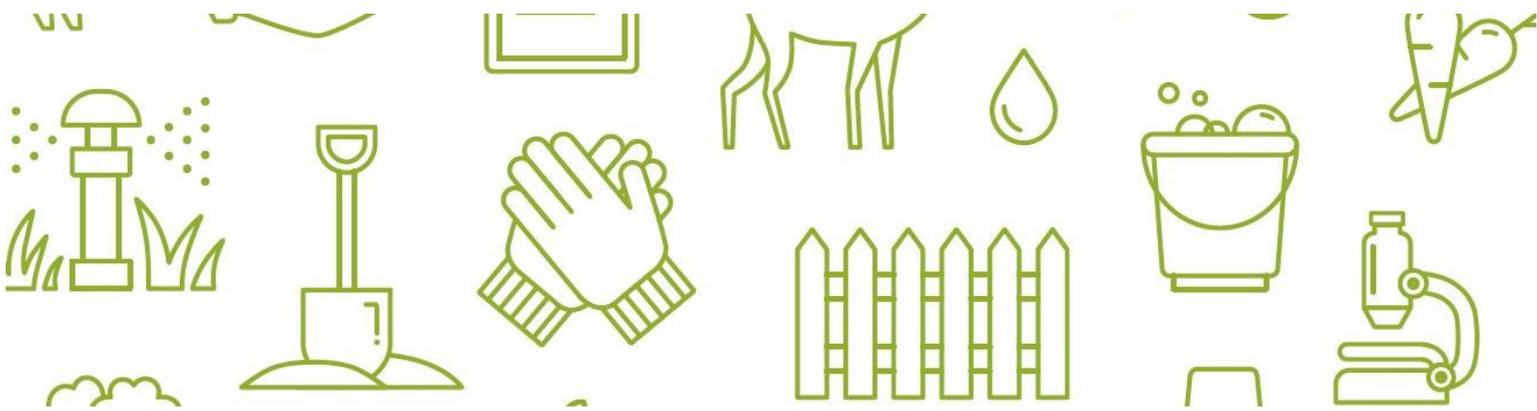
²⁹⁹ (§ 112.161(b))

³⁰⁰ 21 C.F.R. §§ 112.50(b)(4) & § 112.161(b).

³⁰¹ 21 C.F.R. § 112.50(b)(6).

³⁰² (§ 112.161(b))

³⁰³ I know that many of you are changing your water very frequently, sometimes with each crop. This kind of recommendation might not work for your farm but might be useful for a larger farm.



Chapter 9

Harvest and Postharvest Handling

Postharvest activities like packing and washing can introduce bacteria or viruses to produce just before it leaves your farm. Harvest containers, workers' hands, tables, knives, washing or processing equipment, floors, packing materials, coolers, vehicles, and market setups can harbor pathogens if they are not cleaned, sanitized, and maintained. Taking the time to establish a cleaning schedule will help prevent pathogens from contaminating your produce.

Many of the practices around harvest and postharvest will be very important to clearly teach your workers. We've created some worker training agendas in our [online resource library](#). Workers who harvest **MUST** be trained to:

- Know when not to harvest produce, like if it is “dropped covered produce” or if it's contaminated by animals;
- Inspect harvest containers and equipment to be sure that it's clean and working correctly; and
- How to address any of the problems above or how to contact a supervisor.³⁰⁴

Key Concepts

Clean break: A halt in production when all **food contact surfaces** are fully cleaned and sanitized before restarting production. **Clean breaks** can help limit the amount of produce subject to a recall if you have a problem with contamination. **Clean breaks** can also help establish **lots**. Read more about lots on page 117.

Cleaning: Cleaning and sanitizing are two distinctive steps. Cleaning is physically removing dirt from a surface, typically with the use of water and soap or another surfactant and a brush, rag, or other abrasive surface to lift away debris and dirt.

Dropped covered produce: This is **covered produce** that drops to the ground before harvest. **Dropped covered produce** does not include root crops that grow underground

³⁰⁴ 21 C.F.R. § 112.22 (b).

(such as carrots), crops that grow on the ground (such as cantaloupe) or produce that is intentionally dropped to the ground as part of harvesting (such as almonds).”³⁰⁵

Sanitizing is a process performed after cleaning wherein a clean surface is treated to kill microorganisms. You can’t sanitize a dirty surface. Picture rubbing hand sanitizer on soil covered hands; it doesn’t seem helpful, does it?³⁰⁶

GOOD PRACTICES FOR HARVEST

Fully Distinguish Between Covered and Non-Covered Produce

We talked a little about how farms that grow non-covered and **covered produce** will want to treat those two kinds of crops on page 15. When it comes to harvest and postharvest, there are a few additional considerations. If you treat **covered produce** and non-covered produce differently but you use the same packing space, you **MUST** clean and sanitize all food contact surfaces between the non-covered and **covered produce**.³⁰⁷ The cleaning and sanitizing process should also be verified by at least a detailed visual inspection to ensure that it was appropriately performed. Depending on the risks of the activities undertaken, and scale of the operation, some growers will incorporate some routine environmental swabbing to verify that the cleaning process is effective. Commonly, verification testing will be through ATP, which tests for actively growing microorganisms. This process of cleaning, sanitizing, and verification is called a “clean break.” Obviously, if the verification process identifies an issue, the area must be recleaned and sanitized.

For example, say you grow a lot of beets and treat them differently than **covered produce**, such as using a non-tested irrigation water source. You harvest the beets into bins and run them through your washing line. Before using the bins or washing line for carrots, you must fully clean and sanitize all of the equipment that was used for the beets. Similarly, you’d want to be sure that workers washed their hands, knives, or any other harvest tools between harvesting non-covered produce and **covered produce**.

Covered Produce and Soil Contact

While harvesting, your main obligation is to handle produce in a way to protect against contamination.³⁰⁸ There are a few steps you can take to reduce risk. One way to do this is to minimize soil contact with covered produce to the extent practicable. The Rule has some built in protections for this. Specifically, the Rule requires that you don’t distribute **dropped covered produce**, meaning any type of **covered produce** that falls on the ground before harvest. The definition does not include crops that grow in or on the ground, like roots or un-trellised cucumbers. It also doesn’t cover crops that are

³⁰⁵ 21 C.F.R. § 112.114.

³⁰⁶ 21 C.F.R. § 112.3.

³⁰⁷ 21 C.F.R. § 112.111(b).

³⁰⁸ 21 C.F.R. § 112.113.

supposed to fall to the ground during harvest, like almonds.³⁰⁹ The Rule doesn't specifically say that if you drop a box of covered produce after harvesting that you shouldn't distribute that, but we believe you should avoid distributing those crops, too, as they could be damaged. Other parts of the Rule require that you **MUST** avoid, as much as you can, contact between soil and the cut surfaces of harvested produce.³¹⁰ Clear ways of putting this into effect are still being debated. For now, minimize contact between soil and food as much as you can. To comply with this part of the Rule, you might need to change some of your harvest activities to ensure that harvested produce goes directly into clean totes.

Since you **MUST** minimize contact between soil and the cut surfaces of produce, when you stack harvest bins or totes, especially if they do not have lids, you'll want to watch for soil on the bottom of the bins that could touch produce in the bin below it. To further minimize risk, you could choose to keep harvest totes off the ground or the soil, like by using a tote under the one into which you're harvesting. Other growers reduce risk by using one type of container for harvesting and a different type or different color for produce that has been washed.

Larger growers use conveyors, wagons, or tractor mounted surfaces where harvesters can place produce directly instead of putting it down in the field. This is a good food safety practice and is more efficient! A smaller scale version of this could be a wheeled cart full of totes that can straddle the bed. Keep in mind that wheels can track contamination a long way, and you should ensure that if you are using a cart with wheels you are avoiding spreading contamination from one part of the field to another.

GOOD PRACTICES FOR POSTHARVEST

Master Your Product Flow, Organization, and Design of the Space

Lots of different types of packing spaces are allowed: enclosed, open, partially enclosed, and field packing. The Rule doesn't describe or require any kind of building, you just need to keep your space as clean and pest-free as possible.

When thinking about the layout, cleanability, and flow of your space, there are a few things to consider. The Rule requires that you have or make "sufficient space for placement of equipment and storage of materials."³¹¹ We barely know any farmers who feel like they have all the space they need, but consider this a legal mandate to instate that old adage, "A place for everything and everything in its place." While you're organizing and tidying your spaces, keep in mind that you ideally want space between the walls and storage so that you can monitor for pests. Especially consider where you store packaging materials. Space is necessary to make sure that you can properly store,

³⁰⁹ 21 C.F.R. § 112.114

³¹⁰ 21 C.F.R. § 112.113.

³¹¹ 21 C.F.R. §§ 112.126 (a)(1)(i).

clean, and sanitize your equipment. It is hard to clean something when it is jammed against a wall, or to monitor for pest activity. A recommendation is to place any storage racks, washing and packing equipment like brusher washers or packing lines at least 18 inches from the wall.

The Rule requires that you “reduce the potential for contamination of **covered produce, food contact surfaces** or packaging materials... through separation of operations in which contamination is likely to occur by one or more of the following: location, time, partition, enclosed systems, or other effective means.”³¹² So how are you supposed to do that? Keep **covered produce** handling areas distinctly separate from where you work on the tractor, mix chemicals or sprays, seed flats, or other non-postharvest steps. Storage of pesticides, fertilizers, fuel, paint, or other chemicals SHOULD also be physically separate from the areas where you wash and hold produce (though you could adopt another effective means of separation).

There are countless ways that you can improve the food safety in the space where you wash, pack, or hold produce. The best place to begin is to map your space. Imagine how product flows through the space. Organize the area so that tools and materials that you need are stored right where you use them and not scattered throughout the space. You can trace the paths that the produce or workers move using a spaghetti diagram. Minimizing crisscrossing paths is more efficient and can reduce cross-contamination. Ideally, the route of dirty produce and the route of clean produce shouldn't cross.

It's required that you have handwashing facilities that are near to the toilets in packing and holding areas.³¹³ If the toilets aren't close to your washing and packing area, you should consider putting a handwashing station nearer to ensure that, if a worker touches something dirty, sneezes, or ties their shoes, they can easily clean their hands

Physical Hazards

Most of the Produce Safety Rule is about contamination from pathogens, but like separate chemical storage, there are some physical dangers you should consider. Using sleeves and light guards can keep glass light bulbs from shattering onto produce or into packing and storage areas. Monitor equipment to be sure that bearings, plastic, or other hazards are not contaminating your produce.

Floors and Drains

Bacteria can grow in puddles of water left on the floor. *Listeria*, especially, is very happy to grow in drains, inside coolers, and can be transmitted by condensation. For that reason and others, minimize puddles. You can do this by avoiding over-spray, using catch basins which can be easily dumped and cleaned, or even using a broom or floor squeegee if you have concrete. If drains back up, this could be a significant food safety risk as workers can track these microorganisms around the farm. Keeping floors clean

³¹² 21 C.F.R. § 112.126)

³¹³ 21 C.F.R. § 112.129(c).

can help keep your drains from backing up. You **MUST** manage condensation and puddling on the floors, if there is a chance that it could contaminate **covered produce**.³¹⁴

Consider the Lifecycle of Postharvest Water

Run off from wash water should be considered. If your water doesn't go down an enclosed drain but rather drains away from your washing area over gravel, dirt, or concrete, you should take precautions to be sure that workers, equipment, and other vehicles don't walk or drive through that water, potentially tracking contamination around the farm. Ideally it wouldn't drain back into your irrigation water, either. If you use sanitizers in your water, you will need to follow the label for disposing of that washing water.

Keep your Packing Area Clean and Tidy

Keeping your packing space clean and tidy is a great first step. In all areas where you conduct covered activities you **MUST** dispose of trash, litter, cull piles, and other waste to minimize the potential for attracting or harboring pests and to protect **covered produce**.³¹⁵

You might consider having separate bins for produce, pre-consumer vegetative waste (see Chapter 5) , and trash. Don't use the same bins for produce as for culls, if possible. Label the bins clearly. Take out the trash and culls at the end of each packing day, or more frequently as needed. Consider lids for the culls bins and trash cans and have enough bins and trash cans to prevent overflow.

Pest Control: Rats, Mice, Stray Cats, Birds, and More!

You **MUST** take precautions to protect **covered produce, food contact surfaces,** and food packing materials from pests and animals.³¹⁶ That is easy to write but hard to do. All packing areas **SHOULD** have a pest management plan to exclude or eliminate pests from packing and storage areas.

³¹⁴ 21 C.F.R. §§ 112.126 (b) (1) & (2)

³¹⁵ 21 C.F.R. §§ 112.132 (a)& (b).

³¹⁶ See 21 C.F.R. §§ 112.128 (a)-(c). For a fully enclosed building, you **MUST** take measures to exclude pests. If it's partially enclosed, you **MUST** take measures to prevent them from becoming established. Take home message, keep out the pests!

Keeping pests at bay in the pack room

- Close doors to keep out birds and other pests, adding a self-closing spring if that's helpful.
- Keep windows and window screens in good repair.
- Cut the grass and don't plant or allow bushes to grow right next to buildings.
- Don't let all your farm stuff (you know, old equipment, tomato stakes, row cover, sand bags, balled up drip tape, unused bins, and plain old junk) keep you from being able to keep the area around your buildings tidy.
- Inside buildings, leave an 18-inch space between equipment or stored pallets and the wall so that you can monitor for pests.
- Create a map of rodent traps and check them frequently.
- Do not use bait inside a building, but you can use baited traps outside.
- Sweep up food waste and remove cull bins daily.
- Store grains, seeds, cover crop seed, pet food, or other attractive foods in a separate building and/or in closed bins that reduce rodents.
- Fill up holes in the building as much as possible. Some people find steel wool useful for filling holes because mice and rats don't like to chew through it.
- Put up netting below rafters or spikes in the rafters to prevent birds from roosting.
- In open buildings, cover any **covered produce**, stored harvest totes, food packaging materials, or **food contact surfaces** so that birds don't poop on them

Cleaning and Sanitizing

When possible, the four steps of cleaning and sanitizing *should* be completed to keep reusable harvest containers, tools, grading tables, and packing equipment clean and to reduce the presence of microorganisms.

- ① Remove dirt and debris from the surface.
- ② Apply water and detergent and scrub the surface. Detergents need to be food safe and appropriate for the type of soil: fat, carbs, or proteins. The scrubbing action is important for breaking up biofilms.
- ③ Rinse the surface with clean water, removing all the detergent and soil. Use water with no detectable generic *E. coli*/100mL.
- ④ Apply a sanitizer approved for use on food contact surfaces. You may need to rinse the surface, depending on the type of sanitizer. Read the label thoroughly. Let the surface air-dry.

Be Smart About Surfaces

You **MUST** prevent contamination of **food contact surfaces**, including the drains on equipment.³¹⁷ The definition of **food contact surfaces** is on page 45, but remember you **MUST** consider surfaces (like walls, ceilings, fixtures, ducts or pipes) that might drip, leak, or splash onto food or food contact surfaces.³¹⁸ If condensation is dripping off a cold water line above your packing area, that pipe or hose should be considered a **food contact surface**.³¹⁹ That means that you should be cleaning overhead fixtures to prevent the buildup of **biofilms**.³²⁰ Also, think about what workers lean on or touch while handling with produce postharvest. Since their hands are **food contact surfaces**, the equipment, knobs, hoses, and handles that they're touching during washing and packing could be sources of contamination.³²¹

Growers are adapting to the new Produce Safety Rule, which says that equipment and tools **MUST** be adequately designed, constructed, placed, stored, and maintained to enable them to be adequately cleaned and properly maintained.³²² At the same time, equipment suppliers are hustling to create better, safer food handling equipment. We know that as farmers, you're working with what you have and might not have the funds to upgrade to brand new surfaces. That said, food contact surfaces should be non-

³¹⁷ 21 C.F.R. § 112.126 (b).

³¹⁸ 21 C.F.R. § 112.126 (b).

³¹⁹ 21 C.F.R § 112.3 "food contact surface."

³²⁰ Preamble, 80 Fed. Reg. at 74493.

³²¹ 21 C.F.R §112.3 "food contact surface."

³²² 21 C.F.R § 112.123

absorbent, durable, able to withstand corrosion, and able to be easily cleaned and sanitized.

Considerations for packhouse surfaces:

- Select materials for harvest containers, tables, and washing or packing equipment that are easy to clean and sanitize.
- Many farms may have old or wooden equipment that is harder to clean. The law doesn't forbid using wooden bins. Keep them as clean as you can and air-dry wood after washing and sanitizing.
- Avoid foam, carpet, and other absorbent materials.
- Make sure you have easy access to the equipment and the space around it and can remove or access brushes, rollers, nozzles, etc. for cleaning and sanitizing.
- You MUST pay attention to the welded areas on equipment and clean them carefully. These areas, especially on an imperfect weld, are a place for bacteria to hide.³²³
- Any oils and lubricants for harvesting or washing equipment which may have incidental contact with food MUST be food grade.³²⁴

Are You Cleaning and Sanitizing?

- ✓ Harvest knives, scissors, clippers
- ✓ Table tops
- ✓ Workers' hands
- ✓ Bins
- ✓ Wash tubs or sinks
- ✓ Handles
- ✓ Graders and grading tables, conveyors, belts, brushes, rollers
- ✓ Harvesting equipment like mechanical harvesters or conveyors
- ✓ Coolers
- ✓ Ice makers
- ✓ Strip curtains that hang down at the entrance to your cooler and may drag over bins of produce

You are able to set the schedule for cleaning or sanitizing these items; the Produce Safety Rule isn't prescriptive about a timeline. You must clean and sanitize (as appropriate) frequently enough to prevent contamination of covered produce.³²⁵

³²³ 21 C.F.R. § 112.123 (c).

³²⁴ 21 C.F.R. § 178.3570.

³²⁵ 21 C.F.R. § 112.123(d)(1).

Concerns about Pressure Washers

Cleaning with pressure washers is intensely satisfying and can be a great way to get something clean in a hurry, however, the strong spray of a pressure washer can aerosolize bacteria and cause them to fly everywhere. This can potentially cause additional contamination. Food safety experts suggest using power washers outside or far from food contact surfaces.³²⁶

Bin and Tote Washing

The Produce Safety Rule doesn't say how often you need to clean or sanitize your totes, but you **MUST** store cleaned bins in a way that they won't get contaminated.³²⁷ Ideally, harvest bins would be stored under cover and off the floor. Workers **MUST** inspect bins before using them to be sure that they're clean.³²⁸ You may wish to write an SOP for the cleaning, inspection, sanitation, and storage of bins. Choosing harvest bins with lids or tops seems to minimize the potential for cross-contamination from soil, other bins, or condensation drip. Plus, some growers find that a closed tote keeps the produce from drying out, especially if you use a CoolBot for cold storage.

Cold storage

Coolers and other cold storage areas **SHOULD** have a cleaning and sanitizing schedule. Like other places in this rule, the schedule isn't prescribed, but depends on your use. In addition, you **MUST** manage or scout for pests in your cold storage space.³²⁹ Bear in mind that *listeria monocytogenes* is particularly able to withstand cooler temperatures, and can establish **biofilms** in coolers that can be particularly difficult to remove.

Cooling units like air conditioners or condensers, **MUST** be monitored to make sure they are not dripping or forming condensation within the cooler in a manner that could risk contaminating covered produce.³³⁰ Condensate pans **SHOULD** be sloped and drained out of the room or directly to a drain, not onto the floor. The Produce Safety Rule doesn't talk much about the temperatures inside your cooler, but you know that you want to maintain ideal temperatures for product quality as well as food safety. Your thermometers **MUST** be accurate and maintained.³³¹ The job of monitoring your cold storage is a good one for a Wi-Fi enabled system.

³²⁶ E. Owens, *Listeria Monocytogenes* Intervention and Control: Sanitation Best Practices, Produce Marketing Association Resource Files available at: <https://www.pma.com/-/media/pma-files/food-safety/listeria/lm-control-workshop/miami-feb-2018/owens-sanitation-best-practices-25-jan-2018.pdf?la=en>

³²⁷ 21 C.F.R. § 112.123(d)(1).

³²⁸ 21 C.F.R. § 112.123(d)(1).

³²⁹ 21 C.F.R. §(§ 112. 128 (a).

³³⁰ 21 C.F.R. §112.126 (b)(2).

³³¹ 21 C.F.R. §112.124(a)-(c).

Food Safe Containers

According to the Produce Safety Rule, you **MUST** only use new, single-use containers or cleaned, reusable containers to pack produce.³³² In order to reduce waste and costs, some farmers use liners in reused boxes or berry containers. Many growers have expressed concern about the additional plastic waste this could create; biodegradable liners and bags are permitted. We see other growers moving toward reusable cleanable containers.

Ice

If you use ice, it should be stored in clean containers in a clean area. If you make ice on-farm, a schedule should be set to clean and sanitize ice machines and ice storage. See page [86](#) for water quality requirements for ice. If you use ice directly on produce, consider how water dripping from one bin to another bin below can carry microorganisms with it.

Farm Vehicles

Ideally a vehicle that transports produce **SHOULD** only be used to transport produce, not goats, soil amendments, gas cans, or row cover. However, that might be difficult to achieve on a smaller farm. It's easy to see how a dirty truck might cause contamination. If you're using a vehicle for many purposes, you **MUST** clean it before you use it to transport produce, and make sure to inspect it before harvesting or loading in produce.³³³ If you hire someone else to transport your produce, inspect their vehicle for debris or unusual odors.

Safety Data Sheets

Although not a requirement of the Produce Safety Rule, OSHA requires that Safety Data Sheets (SDS), documents about chemicals, dangerous substances, and how to handle these materials provided by the manufacturer of the chemical, must be on site or easily accessible to employees.³³⁴

Harvest and Postharvest Records

REQUIRED

- Training logs for workers³³⁵
- Logs of cleaning and sanitizing of tools, equipment, and containers used for harvesting, packing, and holding activities³³⁶

SUGGESTED

- Pest management
- Building maintenance and monitoring
- Cooler temperature log

³³² 21 C.F.R. § 112.116.

³³³ 21 C.F.R. § 112.115.

³³⁴ 29 C.F.R. § 1910.1200 (g)(8).

³³⁵ 21 C.F.R. § 112.22 (b)(2) & (b)(3).

³³⁶ 21 C.F.R. § 112.40 (b).

- Worker training on sanitation SOPs
- Packing area and cold storage cleaning and monitoring
- Vehicle cleaning and inspections prior to loading

Harvest and Postharvest Standard Operating Procedures

SUGGESTED

- Monitoring for pests
- Preparing cleaning and sanitizing solutions
- Cleaning and sanitizing produce washing equipment and tables
- Cleaning and monitoring cold storage areas
- Inspecting trucks prior to loading fresh produce
- Cleaning vehicles used to transport fresh produce
- Cleaning and sanitizing harvest bins/totes



Chapter 10

Farm Food Safety Plan

You made it to Chapter 10! Hopefully you feel more confident that you can identify produce safety risks on your farm and make some concrete changes to reduce those risks. If you're wondering how to organize those new changes/policies/records, this chapter is for you. Even for farms that need to be in full compliance with the Produce Safety Rule, a farm food safety plan is NOT a requirement.

HOW DO I WRITE A FOOD SAFETY PLAN?

After reading through this guidebook or going to a Produce Safety Rule training, you may feel overwhelmed by the amount of recordkeeping, SOPs, policies, and monitoring logs. While a farm food safety plan isn't required under the Produce Safety Rule, it can be a great way to organize your various records and practices. As you've learned, improving produce safety on your farm is a process of assessing and addressing risks, and a farm food safety plan can help you outline the practices that will reduce your risks. This could be as easy as buying a three-ring binder and adding each new document or practice as you create it. A farm food safety plan does not have to be fancy but it does have to reflect *your* farm—you don't want to borrow a neighbor's food safety plan or include things that you're not doing or aren't quite ready to do. Treat it as a living document, a plan that is constantly evolving as your farm grows, changes, and improves.

Having a farm food safety plan may also give you a marketing edge. It can show buyers that you are taking steps on your farm to address and prevent potential food safety risks, especially if you are not ready for or unable to get GAP certified. It is a way for you to organize your thoughts so you are prepared to discuss food safety on your farm, the trainings you attended, and the practices you have implemented to grow healthier, cleaner, and fresher produce.

This may especially be the case if you want to participate in the Farm to School program. The USDA does not require farms to be GAP certified to sell to schools, but more and more schools are taking into consideration the safety of the produce they are providing children. Your farm food safety plan can be a way to show schools that you are also taking produce safety seriously.

FARM FOOD SAFETY PLAN OUTLINE

We tried to make this outline as comprehensive as possible, but not all sections may pertain to your farm. Only talk about the things that you do! In some examples of farm food safety plans we've seen, the farmers write out descriptions of their practices but then provide associated documentation in the appendix of the plan.

If you are planning to apply for GAP certification, you can follow the GAP Audit checklist in writing your farm food safety plan so that an auditor can easily follow along.

Food Safety Plan Outline

- Farm name and address
- Farm description. This could be pulled from your business plan if you have one.
 - Crops grown
 - Farm size
- Name and contact info for farm food safety manager (which may be the farm owner)
- Risk assessment and practices to reduce food safety risks in the following areas:
 - Workers and the rules that you share with them
 - Training plans
 - Sick policies
 - Clothing/jewelry/cell phone policies
 - Break areas and rules about eating/tobacco/gum
 - Rules about when to wash hands
 - Facilities
 - Hand washing
 - Toilet/Restrooms/Field Sanitation Units
 - Visitor policies
 - Soil amendments: describe the types you use, where you store them, anything about how they are made or where you buy them, when you apply them
 - Raw manure
 - Other amendments of animal origin
 - Compost tea
 - Wildlife, domesticated animals, and livestock
 - Where domestic animals live and what you do to keep them from impacting the crop spaces
 - How do you manage the waste from livestock
 - Rules you have about pre-harvest assessments
 - What are workers supposed to do if they see poop
 - Adjacent land use
 - Agricultural water (production and postharvest uses)
 - Describe your water source
 - How do you irrigate and what kinds of water sources do you use?
 - Water for crop sprays

- Where does the water for your washing and packing space come from?
 - Field Harvesting
 - Tools and equipment used
 - Postharvest handling
 - Tools and equipment used
 - Cleaning and sanitation methods
- Documentation in an appendix
 - Farm Map(s)
 - Production fields
 - High Tunnels
 - Barns
 - Buildings and uses
 - Manure storage areas
 - Compost
 - Livestock/dairy pastures and facilities
 - Active wells and wellheads
 - Surface water sources
 - Adjacent land use
 - Portable bathrooms
 - Sewage/septic system
 - Direction of drainage
 - Possible flooding areas
 - Roads
 - Crop Plan (that shows what you grow)
 - Records that document practices
 - Pre-planting risk assessment
 - Pre-harvest risk assessment
 - Compost turnings and temperature
 - Compost tests or Certificate of Conformance
 - Pest control
 - Wellhead inspection
 - Cooler temperature log
 - Wash water temperature and turbidity monitoring
 - Corrective Actions
 - Agricultural water tests
 - When, where, and by what method the sample was taken
 - Actual results for the sample tested
 - Analysis and reviews of agricultural water quality
 - If you calculated an STV and GM or
 - Used a stoplight method
 - Farm policies- if you have these written out, like in an employee manual, put that in the appendix
 - Worker Hygiene

- Visitor
 - Blood and bodily fluids
 - Illness
 - Injury
 - SOPs- Any SOPs can be kept in this appendix
 - Hand washing
 - Cleaning and sanitizing of different food contact surfaces
 - Cleaning your harvest or market vehicle
 - Worker training agenda(s) and attendance records
- Emergency contact information
- Supplier and buyer information
 - Compost
 - Soil amendments
 - Packing materials
 - Packaging materials
- Traceability program
- Recall plan (see below)
- Contact info for contracted services
 - Port-o-potties
 - Transportation
 - Chemical consultants
 - Equipment suppliers

TRACEABILITY

In addition to creating a food safety plan, a grower might want to create a traceability program. Traceability is the ability to track a food product through the production and distribution system. This means identifying where the produce came from, including inputs—so this may be the field where it was grown and any amendments or irrigation that happened there—and where it went, or who bought it. Most farm traceability programs follow the produce one step forward and one step backward. Should you be unlucky enough to experience a recall, a traceability program should help you identify where and when produce was harvested and to whom that produce was sold. This requires keeping records when growing, harvesting, and labeling produce that will leave the farm.

Information for harvest log:

- Item, like the type of crop or variety
- Field or block or bed it was harvested from
- Quantity harvested
- Date
- Identification of who harvested and/or packed, if you have different crews
- Other unique identifying information: when and what amendments applied, when irrigated, etc.

Information for label or invoice:

- Farm name
- Farm address
- Item (i.e. Butternut, or Bok Choi, or Brandywine tomatoes)
- Quantity
- Delivery or harvest date
- Lot number or code, if you use one

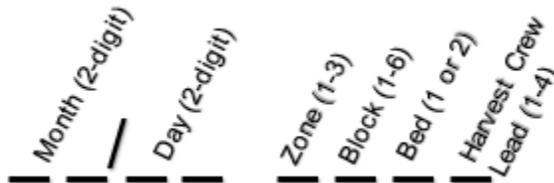
LOT CODES

Some farmers utilize a lot numbering system to create unique identifying information to define and follow a distinct portion of the crop. A lot is a distinct and limited portion of the crop that can be grouped and identified. This system is unique to your farm and may, for example, include all of the cucumbers harvested on the same day from the same field or block. Based on the specific information you choose to collect at time of harvest, you can assign letters or numbers to create your own unique code.

Field level: workers label each case as it comes in from the field with the following:

- Farm name
- Product name
- Unit size
- Lot number, see the template below, which includes harvest date, field location, and crew name

As an example of a lot code, here's how Heifer Ranch in Perryville, AR creates their lot code. Lot numbers are generated using the following template at the time of harvest:



Being able to trace your produce one step forward and one step back has other benefits besides trying to minimize foodborne illness. It can also help you keep track of the amount of each crop sold and follow the quality, helping your farm business run more smoothly. Sometimes growers are concerned that a lot code that clearly indicates a date in this manner may be a deterrent to the consumer if they perceive that the product isn't fresh. An alternative to a 2-digit day and month is to use a Julian Calendar date.

If your produce is moving through a packhouse, you may wish to also include information about the shift during which the produce was washed and packed, though you could also record this information in a packhouse log.

CLEAN BREAKS

- You can establish a **clean break** after taking the steps to clean and sanitize food contact surfaces, and by performing a verification activity, such as visual inspection or swabbing to verify that the clean break has occurred. This can help limit the amount of produce subject to recall or withdrawal should you have a problem with contamination.
- **Clean breaks** can also help you establish lots to trace your produce once it leaves your farm. Lots can be determined by date, grower, variety, field, buyer, or other information that makes sense for your operation, and they must be flanked by a **clean break** to keep them separate from other lots. See [online resources](#) for more lot info.
- If you cannot perform a full clean break between every lot of produce in your pack house, you should carefully record exactly which lots of produce were packed during a single shift and clearly record when clean breaks occur in your packhouse. The longer you go between clean breaks, the more product you put at risk. You also are providing more time for the build-up microbiological organisms on equipment.

RECALL PLAN

We hope that you never have a recall! However, you should have a plan in place in the event that you or an agency identifies a safety issue and you need to recall produce that you've sold. A good recall plan is tailored to your operation and location (there are different FDA regional recall coordinators who should serve as your point of contact depending on where you are located).

A recall plan should include contacts (email and phone number) for:

- ✓ Your internal team for investigating a potential recall
- ✓ The FDA regional recall coordinator for your region
- ✓ Each of your customers (when possible)
- ✓ Local media outlets
- ✓ Outside legal counsel (if you have it)

A recall plan should include procedures for the following:

- Conducting a mock recall,
- conducting a root cause investigation to understand what product might be affected,
- communicating with your workers,
- notifying your insurer,
- notifying the FDA,
- communicating with your customers,

- drafting a press release and managing consumer and customer perceptions,
- performing effectiveness checks, and
- quarantining and eventually disposing of recalled or potentially affected produce by an appropriate method.

The University of Maryland has a Model Recall Plan to get you started with that process, and United Fresh hosts a recall ready workshop every few years.



Chapter 11

Inspections

WHAT ABOUT PRODUCE SAFETY RULE INSPECTIONS?

States and FDA will each play a role in the enforcement of the Produce Safety Rule. In most states, cooperative extension and/or a state or territory government food agency—likely the department of agriculture or department of health—will educate farmers about the Produce Safety Rule and, later, a member of a state agency (often with FDA credentials) will inspect covered farms to evaluate whether the farm is in compliance. In some states or territories, the FDA will educate growers and conduct Produce Safety Rule inspections. In a few other states, cooperative extension and/or state agencies will educate growers, but the state agencies will leave Produce Safety Rule inspections to the FDA. Understand who is providing education and inspections in your state here.

We haven't talked about them in a while, but keep in mind that if you are a Farm Mixed-Type Facility subject to one or more other rules in addition to the Produce Safety Rule, you will likely be subject to additional FDA inspection and inspection by additional state agencies, and that additional regulations and responsibilities apply with respect to those routine regulatory inspections.

In some states, inspections will start for the largest farms — ones that sell more than \$500,000 in produce — began in Spring of 2019. Inspections will be tiered, with the largest farms, by sales, scheduled to be inspected first. The figures below reflect total produce sales – including covered and not covered produce.

Business Size in Produce Sales	Anticipated Inspection Commencement
More than \$500,000 in produce sales*	Spring 2019 ³³⁷
More than \$250,000, but not more than \$500,000 in produce sales*	Spring 2020 ³³⁸
More than \$25,000, but not more than \$250,000 in produce sales*	To be determined

*based on a rolling three-year average of produce sales, including covered produce and not covered produce, adjusted for inflation (See Chapter 2)

³³⁷ FDA, Produce Safety Inspections, (Feb. 7, 2019)

<https://www.fda.gov/ICECI/Inspections/ucm627767.htm>.

³³⁸ *Id.*

SCHEDULING THE INSPECTION

The inspector will call ahead of time to schedule an inspection with the person in charge of the operation, and will typically expect to perform the inspection within five business days of that initial contact.³³⁹ If the person in charge of the operation is not the food safety captain (see Chapter 4) you should try to make the food safety captain available for this phone call, as the inspector will explain the flow of the inspection, what the inspection will cover, and what records may be reviewed.³⁴⁰ This is all information that the food safety captain should be aware of to put the best foot forward on the day of the inspection. Additionally, the inspector will ask about biosecurity practices, hazards, safety protocols and practices inspectors will need be aware of to prepare for before visiting your farm.³⁴¹ For example, if you require personal protective equipment, such as steel toe boots because of heavy equipment being used on the farm in certain areas, you should inform the inspector of that policy on that initial phone call.

During that initial call, the inspector may also work with you to determine if you are covered by the Produce Safety Rule. Some states may have produce grower registries, and have conversations about whether your farm is subject to the Produce Safety Rule at the time of registration. For example, if you're Qualified Exempt, you may need to present records to show the inspector the documents that prove that exemption at that time. We have a script for that in the short form guide.³⁴²

You should also know that inspectors also have the right to conduct unannounced (surprise) inspections, and may do so if a farm has had produce safety issues in the past and such issues have not been corrected, the inspector is performing a follow-up inspection to determine whether necessary changes have been made, the farm is being unresponsive (no contact within 5 business days after contact attempts have been made or is unwilling to schedule an inspection), or there is a complaint associated with the farm, recall, or outbreak investigation.³⁴³ However, if FDA intends to go onto a farm for produce safety purposes, FDA will invite the state to conduct a joint FDA-state inspection or investigation.³⁴⁴

FLOW OF THE INSPECTION

On the day of an inspection, upon arrival the inspector will ask to speak to the owner or person in charge, and the inspector will introduce himself or herself with their name,

³³⁹ FDA, FDA Fact Sheet, Produce Safety Rule (21 CFR 112) "What to Expect of a Regulatory Inspection" Informational Handout for Farmers, (Feb. 7, 2019).

³⁴⁰ *Id.*

³⁴¹ *Id.*

³⁴² Page XXX

³⁴³ *Id.*

³⁴⁴ FDA, Produce Safety Dispute Mitigation and Resolution Procedures, Doc # FMd-152 (Effective Jan 31, 2019), at 4,

<https://www.fda.gov/downloads/ICECI/Inspections/FieldManagementDirectives/UCM630608.pdf>

title, and agency, inform you of the reason for the inspection, and show you their identification.³⁴⁵

Depending on whether the state or the FDA conducts an inspection, the inspector or investigator may provide a written Notice of Inspection or similar form.³⁴⁶ You should become familiar with whether such a form will be provided in your state, and if so what a copy of this form looks like and how to review this form and ensure that all of your farm information is reported accurately. The inspector will then do an initial interview, a walk-through of the farm, may request and review required records, and conduct an exit interview.³⁴⁷

Because the inspection is scheduled ahead of time, you should have both the person in charge and your food safety captain available to meet with the inspector upon his/or her arrival. You will want to be sure that the food safety captain is available to meet with the inspector during the scheduled farm inspection, and available to escort the inspector around the farm during the entire duration of the inspection.³⁴⁸ We also recommend that you have an additional person that is familiar with the farm's food safety practices accompany the food safety captain to be able to take notes of what happens during the inspection. These notes will serve as a helpful reference to you in the event that you need to prepare a written response to any regulatory observations, and to implement any corrective or preventive actions. You can take notes in a way that makes you comfortable – if you can carry a laptop and type while observing, that's great. Many farms and food companies will simply have someone use a clipboard and take handwritten notes.

INITIAL INTERVIEW

Once you have reviewed the inspector's credentials and any notice of inspection, you should escort the inspector to a place where you can have the Initial Interview. Typically, this will be a clean conference room or a neat office. There should not be any documents or written material stored in the room, and preferably the room should not look out over the production or packing area.

During the Initial Interview, the inspector will describe the reason or scope of the inspection, and will ask you about the organizational structure of the farm (who is in charge of what), activities that are happening on the farm currently, and that may be

³⁴⁵ FDA, FDA Fact Sheet, Produce Safety Rule (21 CFR 112) "What to Expect of a Regulatory Inspection" Informational Handout for Farmers, (Feb. 7, 2019).

³⁴⁶ *Id.*

³⁴⁷ *Id.*

³⁴⁸ *See id.*

performed the day(s) of the inspection.³⁴⁹ The length of an inspection will depend on the size of the farm and activities happening on the farm.³⁵⁰

This is also an appropriate time to explain to the inspector the policies you have for food safety for visitors to your farm, including telling them where the restrooms and handwashing stations are located, to communicate expectations for handwashing and appropriate attire before visiting different locations on your farm, and to explain that you will accompany them at all times during the inspection. Explaining these policies before you walk out into your operation will help to ensure the safety of your produce, the inspector's safety, and to minimize disruption to your activities and make the inspection. It may be easiest to put these policies in writing, so that you don't forget anything and can stay organized when talking to the inspector.

If your farm has a confidentiality policy addressing photography by visitors and regulatory agencies, this is also the appropriate time to inform the inspector of that policy and the documentation to support it. FDA does not have specific statutory authority to take photographs on farm operations, though investigators in food facilities will typically cite to several cases to argue that they have such authority and may take photographs.³⁵¹ However, if you have a state inspector, state laws may permit the inspector to take photographs on your farm, so you should have any policy developed or reviewed by appropriate experienced food regulatory legal counsel. Declining FDA photography may be characterized by some investigators as a refusal to permit inspection (a violation of the Federal Food, Drug, and Cosmetic Act) or if you have a state inspector could actually violate state law, so you should seek legal guidance about developing appropriate policies for your farm.

WALK-THROUGH ON THE FARM

Next, the person most knowledgeable about your farm's food safety practices should escort the inspector through the activities you discussed in the initial interview. If you have multiple activities ongoing, you should plan a route that minimizes food safety risk. For example, it may make sense to visit the packing house or holding area, green house, and then the production area, rather than the other way around to avoid tracking from the field into the pack house.

During the walk through, the inspector will take notes, and has the authority to take samples from your farm.³⁵² These samples may be actual samples of produce, packaging, labeling, wash water or production water, or environmental samples, such as

³⁴⁹ *Id.*

³⁵⁰ *Id.*

³⁵¹ *See Dow Chemical v. United States*, 476 U.S. 227 (1986); *United States of America v. Acri Wholesale Grocery Company, A Corporation, and JOSEPH D. ACRI and ANTHONY ACRI, Individuals*, 409 F. Supp. 529. (S.D IA 1976).

³⁵² *Id.*

swabbing for pathogens on your packing line. In the event that the inspector takes samples, you can request that the FDA or inspector take a duplicate sample, which you can then hold it under conditions to preserve its integrity if an issue later arises. If you have a person of appropriate training and experience on your staff, you may wish to take your own samples with your own instruments. If environmental samples are being taken, your food safety captain may wish to ask about the method being used to take the sample, whether the method used is an FDA approved method, what instruments are being used, and when those instruments were last calibrated. The note taker should record all of this information, and appropriately label all samples with the time and location from which they were taken, and ensure that they are appropriately held to preserve their integrity.

Inspectors may also take photographs, unless you successfully object to photography using an appropriate policy.

During the walk-through phase of the inspection, if the inspector sees something that is a risk or potential violation, they may identify that behavior or issue as a risk or potential violation.³⁵³ Inspectors are also supposed to explain what they are looking at and why throughout the inspection. If the inspector identifies a regulatory concern, the inspector should discuss it with you, explain the reasons for each concern, and the public health significance. Your note taker should record these observations and the explanations provided by the inspector.

If you can make a change immediately to correct a risk identified by an inspector, such as refilling the soap at a soap dispenser or having a worker wash their hands between an activity that could introduce a safety risk and a covered activity, you should make such correction and ensure that the inspector documents it. Some issues will not be readily fixable – and if that is the case, you can simply acknowledge the observation, and have your note taker record it and revisit it during the exit interview discussion. As you are evaluating whether to make a correction during the walk-through, consider the potential food safety risk presented by the observation, the likelihood the observation is actually a violation of the Produce Safety Rule, and to what extent a correction would disrupt ongoing activities on the farm.

Inspectors may also use the time during the walk through to ask about activities and practices used that are not currently happening at the farm, and occur during different parts of the growing season. The food safety captain should listen carefully to the question, and answer the question asked without volunteering more information than necessary.

If, at any time, there is an “egregious condition” that the inspector determines to create an immediate public health risk, like a porta-potty tipped over into a vegetable field, the

³⁵³ *Id.*

inspector may request more immediate corrective action, including requiring produce be held or destroyed or (eventually) requesting recall of produce, if deemed necessary.

If the inspector requests to review your records, we suggest that you escort them back to the same location as you held the Initial Interview. It is important for you to understand what records you are required to keep under the Produce Safety Rule, because these are the only records that an inspector is legally entitled to review.

Inspectors may request records that they are not legally entitled to access. It is your responsibility to know which records the agency is entitled to access, and to supply the appropriate records within 24 hours.³⁵⁴

For example, an inspector not supposed to ask for your farm food safety plan, because keeping a food safety plan is not a requirement of FSMA's Produce Safety Rule. If you do keep required records under the Produce Safety Rule as part of your overall food safety plan and in combination with records that are *not* required, you should consider having a way to mark what records are required so that those required records can be easily identified and provided to the inspector upon request under the pressure of an inspection situation. You may wish to do this by having a list of required records tailored to your farm reflecting the actual records you keep, and using a legend or symbol at the top of each form you use for a required record. You should be able to supply all the required records for the prior two years. Your note taker should record all records requested by the inspector, what records were given to the inspector, what records the inspector copied, and any observations the inspector shares verbally about your records.

Records requested and copied by the FDA are subject to the Federal Freedom of Information Act ("FOIA"), which means that the FDA must disclose these records upon an appropriately filed request to the federal government.³⁵⁵ For example, a valid request might be made by a journalist or an attorney pursuing a legal action against your farm. In states where inspections are being conducted by a state department of agriculture or state department of health, there may also be a state act requiring the disclosure of records upon a valid request. However, there are exceptions under federal law and some exceptions under state law that allow you to claim protection over certain documents, and particularly those containing trade secrets or confidential commercial information. An appropriately experienced regulatory attorney may help you determine what documents over which you may be able to request the protection of your trade secrets or confidential commercial information, and how to label your documents to protect them from disclosure under state or federal law.

³⁵⁴ 21 C.F.R. § 112.166

³⁵⁵ 21 C.F.R. § 112.167.

EXIT INTERVIEW

After the farm walk through and any record review are completed, the inspector will hold an Exit Interview. During this Exit Interview, the inspector will cover any regulatory concerns and findings. Because this meeting has legal implications for the person in charge, or owner, that person should plan to attend the Exit Interview for the inspection.³⁵⁶ If the inspector identified any regulatory concerns that were not capable of being immediately corrected, the inspector will work with you to identify a reasonable time frame to implement preventive measures and corrective actions.³⁵⁷ Importantly, if you do not understand a regulatory concern or finding described by the inspector during this meeting, you should ask the inspector to clarify their concern and explain their legal justification for the concern under the Produce Safety Rule. If you are not sure that the inspector is applying the rule correctly to your farm, it is perfectly appropriate to ask them to seek clarification from a supervisor on a particular issue.

During the inspection, the inspector will probably be using a Produce Farm Inspection Observations Form ([FDA 4056](#)). If your inspection is performed by the FDA, you will receive one of these forms at the conclusion of the inspection, regardless of whether the inspector identified any non-compliance issues. Before issuing an FDA 4056 with reportable observations to a farm, FDA inspectors are required to have that form reviewed by produce safety compliance staff and/or supervisors to ensure that observations are documented consistently with current agency policy.³⁵⁸ States have the freedom to develop their own procedures for review. If this form is used, you should review the completed form carefully to ensure that your information is correctly reported (such as your name, farm name, contact information, crops observed) and that any reportable observations and corrective actions made or intended to be made are reported accurately on this form.

After the Exit Interview, your notetaker should organize your notes and you should hold a meeting with your inspection team to discuss the implementation of any corrective or preventive actions, things that went well during the inspection, and things you would do differently and summarize the note taker's notes from the inspection into a written report.

If the agency notes items that should be corrected and requests a written response, that should be an immediate priority after the inspection.

PRACTICAL GUIDANCE

³⁵⁶ FDA, FDA Fact Sheet, Produce Safety Rule (21 CFR 112) “What to Expect of a Regulatory Inspection” Informational Handout for Farmers, (Feb. 7, 2019).

³⁵⁷ *Id.*

³⁵⁸ FDA, Produce Safety Inspections, <https://www.fda.gov/ICECI/Inspections/ucm627767.htm>.

Remember that your first inspection will likely be a new experience for your workers as well. It is a good idea to meet with your workers ahead of time to explain to them what to expect when a state or FDA inspector comes to your farm, and why it matters. Keeping your workers informed about what to expect during an inspection helps to build a culture of food safety on your farm by allowing your workers to feel bought into your food safety practices. Additionally, meeting with your workers will help both you and your workers feel more relaxed the day of the inspection so your workers can focus on following your food safety practices when an inspector is on the farm. Finally, sharing the results of your inspection with your workers is another way to continue to build your food safety culture. Sharing the outcome and lessons learned from the inspection the inspection with your workers can help them continue to learn how to improve food safety practices and feel bought into why they are important.

There is a lot to remember during an inspection of your farm by the FDA or your state inspector, and you should strongly consider developing an Inspection Policy or Inspection Manual to help you plan for that inspection. An Inspection Policy or Inspection Manual can help you feel comfortable with the flow of the inspection, and can include checklists to help you with questions to ask if samples are taken your farm and what records you are required to disclose. You should also include your policies with respect to photography, disclosure of your confidential information, and marking of documents to protect from FOIA disclosure. An attorney with appropriate experience in FDA regulatory compliance can help you draft this kind of policy or manual. Several years before the development of FDA's inspection policy, the Produce Marketing Association developed this [Regulatory Inspection Manual](#) for produce growers. It is targeted at larger operations and discusses different forms (such as the FDA Form 482 and the FDA Form 483 which are used with facilities and not farms), but you may find the information provided useful as you think about developing your own manual, and consider whether you wish to retain legal counsel to help with that.

PARTING THOUGHTS

We know that the conversation around food safety has changed dramatically in the last decade. Some of the practices that we learned years ago would be viewed as unsafe now. Some of the record keeping, planning, and prospects of multiple inspections and audits can seem daunting to small farmers who already feel overstretched. Growers are already doing many things right, because of food safety concerns, produce quality concerns, environmental concerns, or just because it seems like the best way to farm. We hope that this guide has given you some ideas of how to improve the food safety on your farm.