

A Small Farmer's Practical Guide to

Food Safety

Contributors



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.



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.

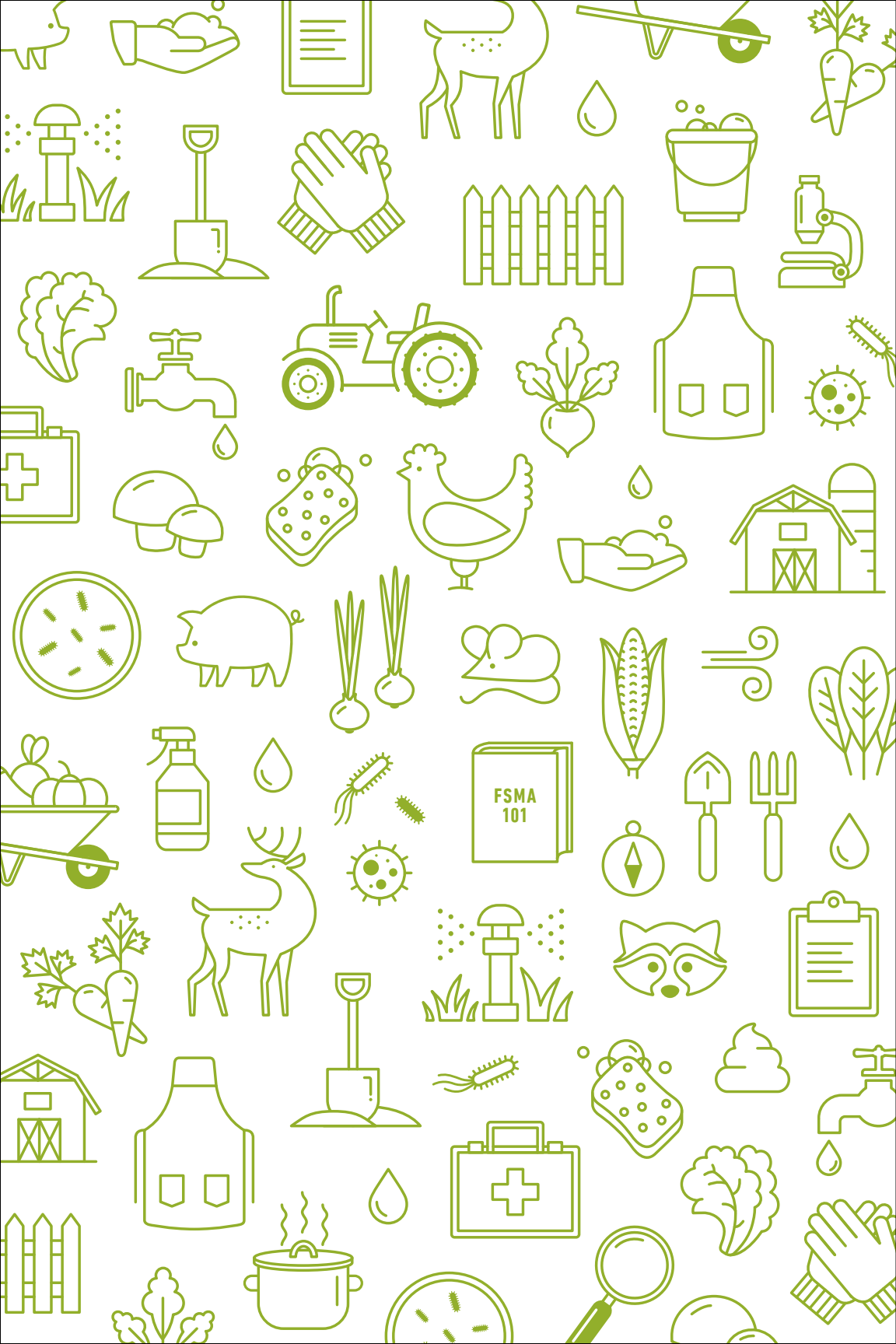


PSL LAW GROUP LLC

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 to 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..

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Introduction

IS THIS GUIDE FOR ME?

Hi there. We're Cara Fraver and Maggie Kaiser with the National Young Farmers Coalition. Over the past two and a half years, we have been lucky enough to travel around the country, helping young farmers to understand a bit about the Produce Safety Rule. Many of the over 1,500 farmers that we've trained are exempt from some parts of the rule because they run small farms that mostly sell locally. But even though these farmers are considered "Qualified Exempt" under the rule, they still wanted to learn about how they could improve food safety practices on their farms. Some of these small farmers are in the process of scaling up, and others are simply very focused on growing the healthiest food possible for their communities.

After spending eight hours learning about the ins and outs of the Food Safety Modernization Act and the Produce Safety Rule in our workshops, many of them asked, "Okay, now how do I put this into action on my farm?!" This guidebook is meant to answer that very question.

This guidebook and the accompanying online resource library are not exhaustive instructions on how to legally comply with the Produce Safety Rule, but are meant to equip growers with the basics to improve food safety on their farm: training agendas, template standard operating procedures (SOPs), specific options for wildlife management, suggestions for how to set up a washing station, and much more.

This guidebook is intended for direct marketing produce farmers who want to improve their produce safety practices. In the process of working on this guide, we collaborated with PSA trainer and attorney Jeni Lamb Rogers to assist us in reviewing legal requirements and helping us to represent them in this guide.

With her help we also created a more comprehensive, legally-focused version of this book for growers who need to have an inspection or want more specifics on the Produce Safety Rule requirements. We call this guide the “Deep Dive Guide” throughout this text and it is available at the Young Farmers website.

HOW TO READ THIS GUIDEBOOK

We have organized this guidebook to complement the trainings and materials developed by the Produce Safety Alliance (PSA), a government collaboration that is setting food safety best practices for produce growers. If you’ve attended a training, you received a very large binder with specifics on the rule. We have tried to include some of the language from the curriculum, as well as the “**MUST**” and “**should**” language of the rule itself.

The Produce Safety Rule uses the words “**MUST**” for requirements and “**should**” for practices they’d like to see. We’ve tried to keep those words throughout this guide for clarity. Additionally, we mention lots of practices that might help you reach the **shoulds** or **MUSTS** but that aren’t specifically required by the rule.

Throughout this book we’ll also mention many additional resources that you can find in our 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.

Throughout this book we will be referring to section numbers (§) of the Produce Safety Rule. We try to put the rules of the law in straightforward, simple language, but sometimes you might need to read the text of the law to answer a more detailed question. The 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>.



The following acronyms will appear in this guide. Here’s a quick list so that you can look up any that you aren’t familiar with!

BSAAO Biological Soil Amendment of Animal Origin *See page 54*

CFR The Code of Federal Regulations

CFU Colony Forming Units

CSA Community Supported Agriculture

EPA Environmental Protection Agency

FSMA Food Safety Modernization Act *See page 11*

GAPs Good Agricultural Practices

LGMA Leafy Greens Marketing Agreement

MWQP Microbial Water Quality Profile *See page 84*

NOP National Organic Program

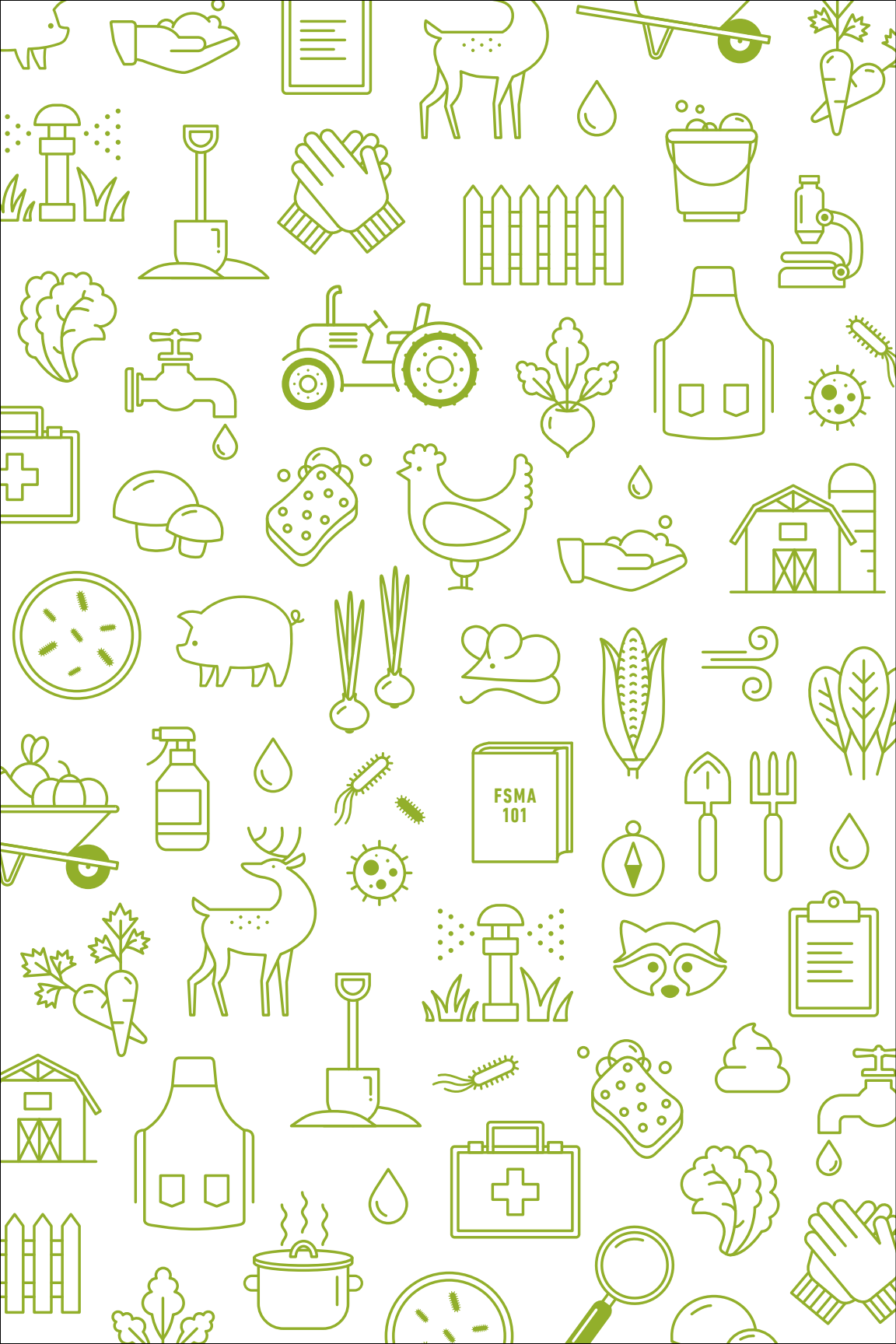
NFU National Farmers Union

OFRR On-Farm Readiness Review *See page 131*

PSR Produce Safety Rule *See page 11*

QEU Qualified End User *See page 21*

SOP Standard Operating Procedure *See page 32*



Chapter 1

The Food Safety Modernization Act and Its Produce Safety Rule

A SAFETY MEASURE FOR YOUR FARM

As a farmer, you're likely already striving to grow the healthiest food possible for your family, your community, and all the people you help to feed. Farmers think about growing produce that's flavorful, nutritious, and prioritizes environmental stewardship. But farmers also need to make sure that in the packing, processing, and delivery of our produce we do our best to safeguard against harmful bacteria and other pathogens.

Fruits and vegetables are often eaten raw so they don't go through a "kill step," like cooking, to eliminate harmful bacteria or other pathogens. There are many instances in the production of fruits and vegetables where contamination can occur: handling by humans; contact with wildlife; application of soil amendments containing manure; irrigation; contact with unclean surfaces or packaging facilities; and more.

You've likely heard about outbreaks of foodborne illness from contaminated produce. You can 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 your staff may encourage them to report, identify, understand, and care about foodborne illness outbreaks.

Produce safety isn't about eliminating all bacteria or creating a sterile working environment. In fact, our bodies contain more bacteria than human cells, and our bodies need bacteria to perform even the most basic bodily functions. Soil bacteria are instrumental in growing produce. 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, and it's also true that pathogenic bacteria can make people very sick.



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>.

1. 21 C.F.R. § 112.141.

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

Established in a 1975 Supreme Court case, *United States v. Park* (421 US 658), the Park Doctrine holds that a responsible party introducing food into interstate commerce is strictly liable for its safety. 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 on harvest days." 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 FOOD SAFETY MODERNIZATION ACT AND THE PRODUCE SAFETY RULE ARE A LEGAL REQUIREMENT

Food safety is not only important for the health of your customers, but it's also now a legal requirement. Federal law under FSMA requires all growers² to take food safety seriously and to comply with the rule, even if only by proving they are exempt.

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. There were previous laws and guidance for specific agricultural products, but FSMA directed FDA to develop mandatory requirements for growers,³ and covers the majority of the food value chain.⁴ Food that is imported into the U.S. needs to be grown and/or processed under these rules, too. In Chapter 2, we'll discuss who needs to be in full compliance. Our deep dive guide also features more details about inspections. Also note there is another rule that might apply to you if you process food, for example by creating a value-added product like fresh salsa, or even if you chop head lettuce into a salad mix. These activities are not covered under the Produce Safety Rule, but rather fall under the Preventive Controls Rule.

2. Growers of produce likely to be consumed raw and consumed off the farm. See 21 C.F.R. § 112.1.

3. 21 USC § 350h.

4. See, e.g. 21 U.S.C. §§ 350e & 350g and accompanying regulations promulgated there under, 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).

THE PRODUCE SAFETY RULE

Remember, FSMA's Produce Safety Rule is concerned with keeping pathogens off of produce.⁵ 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.

GOOD AGRICULTURAL PRACTICES VERSUS THE FSMA PRODUCE SAFETY RULE

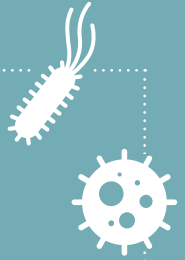
Many growers ask if the FSMA Produce Safety Rule is the same as Good Agricultural Practices (GAPs). Though they are different, the purpose of both programs is to address produce safety risks, and there are many similarities.

Unlike FSMA, which is now a requirement for many farms, GAPs are voluntary. Started in 2002, based largely on FDA's 1998 GAPs guidance, 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. GAPs are considered voluntary because farms can sell to plenty of customers who do not require GAPs audits (like through farmers markets, CSAs, etc.). That said, if your largest buyer requires a GAPs audit, it may not feel voluntary! Because they 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.

Many farms that sell through wholesale channels will need both a GAPs audit and will also be subject to Produce Safety Rule inspection. 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 the Produce Safety Rule so that growers who pass a Harmonized GAPs audit can be comfortable knowing they'll likely be in compliance for their FSMA inspection too.⁶

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

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




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.

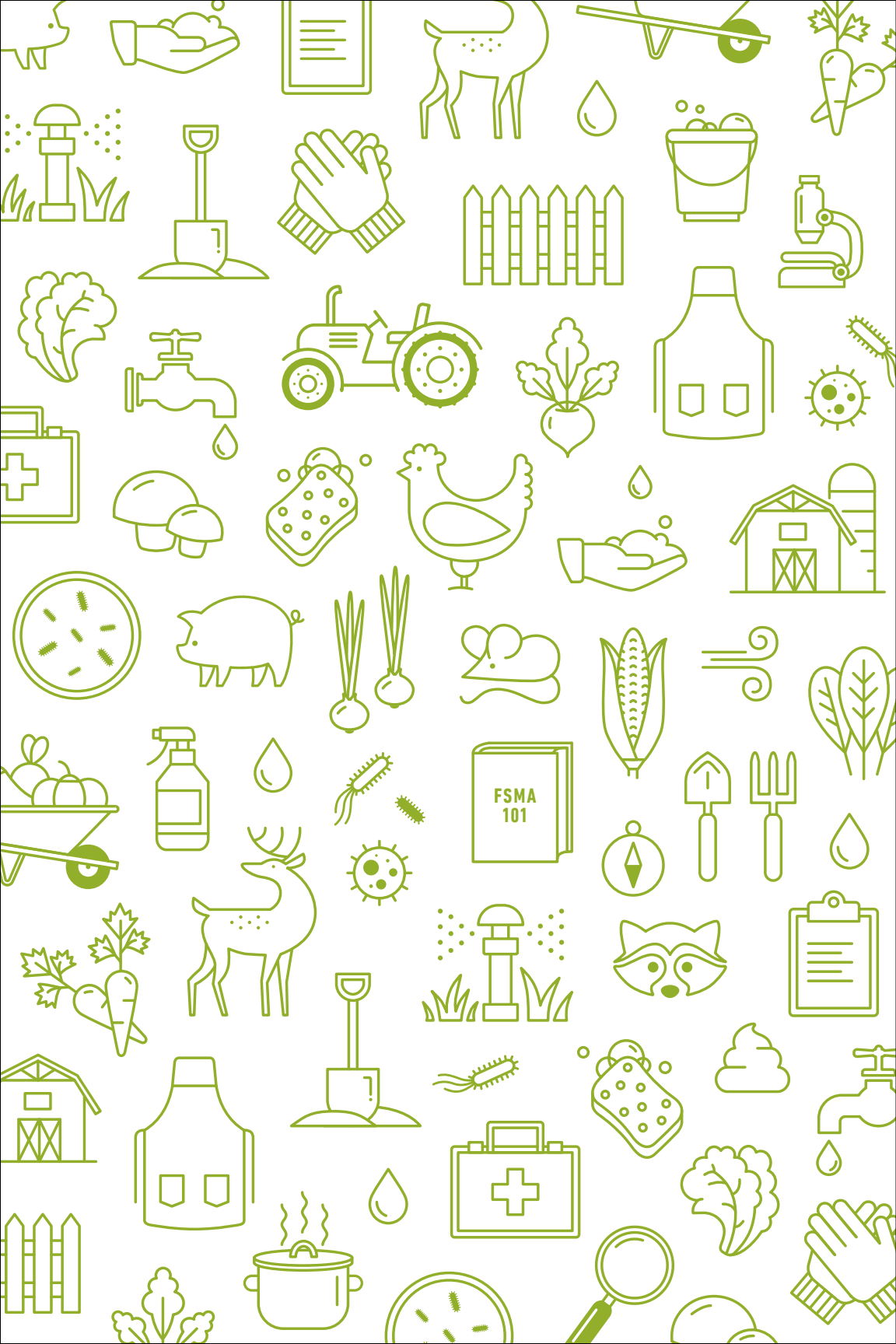
VIRUSES cannot reproduce outside of a host, so they're tough little critters who have evolved to make you sick with only a few cells. They usually travel from a sick person to a soon-to-be-sick person via poor post-toilet practices. They are hardy enough to withstand many hand sanitizers, but handwashing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

PARASITES can reproduce, but only 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.





Chapter 2

Coverage and Exemptions: Is My Farm Covered By the Produce Safety Rule?

WHO MUST FOLLOW THE PRODUCE SAFETY RULE?

Every produce grower needs to assess 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. All produce growers need to know how this law applies to their operation; if the farm meets one of the exemptions, however, the requirements are dramatically fewer. You will 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.

There are a lot of activities that are common on a farm, like growing, harvesting, packing, and holding produce. Sometimes you do those things on-farm and, in some cases, at another location. Under the rule, there are primary and secondary activity farms. We're imagining that most readers are primary activity farms, but if you have a food hub, aggregated CSA, or similar off-farm location where these activities occur, find out more about secondary activity farms and get detailed descriptions of packing, holding, or harvesting in our deeper dive guide.

COVERAGE AND EXEMPTIONS

Farms can be classified as Not Subject, Exempt, Qualified Exempt, or Covered. Farms that are Not Subject to the Produce Safety Rule because of what they grow, how or where their produce is consumed, or the overall amount of produce sales shouldn't expect 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.

Just because you're exempt or not covered, doesn't mean you should ignore food safety! Farms still have a responsibility to comply with all applicable requirements of the Federal Food, Drug & Cosmetic (FD&C) Act. We recommended that even farms that are not covered under the Rule implement food safety practices to ensure that their produce doesn't serve as a vector for foodborne illness.

NOT SUBJECT because what you grow does not fall under the rule:

- ➔ Not subject because it is not produce.
- ➔ Not subject because it is not a "raw agricultural commodity."
- ➔ Not subject because it's rarely consumed raw.

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.

NOT SUBJECT or **EXEMPT** based on where or how it is consumed:

- ➔ Not subject because it's only consumed on-farm (see more on page 23).
- ➔ Exempt because it goes through a kill step before being sold.

COVERED means you do not fall into the above categories and must comply. Sometimes we call these "covered farms" or farms that are fully covered.

What if I grow "covered" *and* "not covered" or "exempt" produce?

You might grow a combo 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, onions, carrots, beets, and radishes (you love roots!), some of which—sweet potatoes and beets—are considered "not covered" because they're rarely consumed raw and some—onions, carrots, and radishes—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.¹

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 surfaces and before the covered produce touches the surfaces.² This process is called a "clean break." For most highly diversified produce farms, we hear that growers choose to treat all produce as if it covered and we believe that's a best practice for smaller diversified farms.

1. 21 C.F.R. § 112.111(a).

2. 21 C.F.R. § 112.111(b).

Not Subject Based On What You Grow



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 is 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, BEANS (specifically great northern beans, kidney beans, lima beans, navy beans, and pinto beans), **BEETS** (garden beets—roots and tops—and sugar beets), **CASHEWS, SOUR CHERRIES, CHICKPEAS, COCOA 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.**³

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. Any produce that is not on the fairly limited list of "not covered produce" above qualifies as "covered produce." There are a few crops, specifically wine grapes, hops, pulse crops, and almonds that are in enforcement discretion, meaning that FDA is not prioritizing inspections of those crops.

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.

FOOD THAT IS NOT PRODUCE

Fruits and vegetables are obviously produce, but the rule extends to some crops that we might not think of as "produce," like mushrooms, peanuts, tree nuts, edible flowers, and medicinal herbs.⁴ The Rule does not cover non-produce, such as:

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)

Note that a crop is considered "produce" when the harvestable portion, like the flower that will produce the fruit, is present.⁵ Currently, the way that we—and other experts—interpret the Rule, for any fruiting crop, like apples, berries, beans, zucchini, tomatoes or many others, flowering is the moment that the produce is present.

PRODUCE THAT IS NOT A "RAW AGRICULTURAL COMMODITY"

Produce in its natural state is covered by the Produce Safety Rule until it is processed. Some types of processing that change produce from a "raw agricultural commodity" can include:⁶

JUICING, CUTTING (like chopping romaine heads into salad mix⁷), **CHOPPING** (like to sell melon cubes), **SPIRALIZING** (to create zucchini noodles), **GRINDING, COOKING, IRRADIATION**

Important Note: Washing; cooling; curing; or removing stems, husks, or roots when performed on a farm are considered to be harvesting activities⁸ and do not count as a process that would change produce from a raw agricultural commodity.

When produce changes from a raw agricultural commodity, it is no longer covered by the Produce Safety Rule and may be covered by another area of FSMA, namely the Preventive Controls for Human Food Rule, and/or another FDA regulation. Farms that are growing, harvesting, holding, and packing produce and processing produce (as listed above or even just simply bagging chopped salad mix) are called Mixed Type Facilities. See online resources for the Preventive Controls for Human Food Rule and the Deep Dive Guide.

Not Subject or Qualified Exempt 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 meet this qualified exemption, you have 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 2017, this figure was closer to \$548,654;⁹ and
2. A majority of the food sold over the last three years, by value, goes directly to a qualified end user.]

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.¹⁰

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.¹¹ 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.¹² In addition to a traditional restaurant, a bakery, food truck, or soup kitchen would count as a qualified end user.¹³

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.

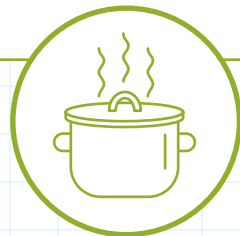
Not Subject or Processing Exemption Based On Where or How Produce Is Consumed

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, but not washing or freezing.¹⁴

For example, tomatoes that go to a sauce company, plums that go to a baby food manufacturer, or apples for hard cider are exempt. You may either sell the produce to a processor who carries out a kill step or you might do the processing on-farm.¹⁵ If you aren't processing the produce yourself, but selling to someone else who will, you'll need to develop some labeling and documentation practices to show your produce qualifies for this commercial processing or kill step exemption. If your farm is likely to use this type of exemption, check out the detailed recordkeeping requirements in our Deep Dive Guide. This recordkeeping requirement is also under enforcement discussion.

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* can survive freezing.



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.¹⁶ 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, even if the carrot farm is covered. 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.¹⁷



3. 21 C.F.R. § 112.2 (a)(1).

4. 21 C.F.R. §112.3 “produce.”

5. “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” 80 Fed. Reg. 44354, 74449 (hereinafter the “Preamble”) Comment 230 in the preamble to the Produce Safety Rule.

6. 21 C.F.R. § 117.3 manufacturing/processing definition.

7. Depending on the type of processing performed on the produce, the produce may actually fall under multiple FSMA regulations before it reaches the consumer. For example, romaine lettuce that is grown on a farm and then sold to a commercial processor for the creation of a salad mix would be subject to both the Produce Safety Rule and the Preventive Controls for Human Food Rule. The farm that grew the romaine would follow the Produce Safety Rule. The facility that chopped the romaine into bite size pieces for the salad mix would follow the Preventive Controls for Human Food Rule. However, the facility that is buying the romaine will care very much about the farm's compliance with the Produce Safety Rule.

8. 21 C.F.R. § 112.3 “harvesting.”

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

10. 21 C.F.R. § 112.5.

11. 21 C.F.R. § 112.3 “qualified end user.”

12. 21 C.F.R. § 1.227 “retail food establishment.”

13. 21 C.F.R. § 1.227 “restaurant.”

14. 21 C.F.R. § 112.2(b)(1)-(6).

15. 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. Additionally, those rules come with facility registration requirements at the federal and often local level.

16. 21 C.F.R. § 112(a)(2).

17. FDA, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry (Draft Guidance) (October 22, 2018), at 10 available at: <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM623178.pdf>.

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 that you will need to do to keep 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.¹⁸

PROVE YOU ARE EXEMPT BY BECOMING A RECORDKEEPING PRO

To prove your exemption, you **MUST** keep records that prove that you're exempt. All records **MUST** be kept according to the recordkeeping rules described in our deeper dive (mostly about how long you keep the records and such).¹⁹

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 tipsheet 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 page 21 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).
- To support this review, you'll need to have dated receipts.

Less Than \$25,000 In Annual Produce Sales Exclusion Records

The Rule isn't as specific about how farms in this category need to prove that they aren't subject, but they do say that they "expect a farm

18. 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).
19. 21 C.F.R. § 112.161.

to be able to demonstrate using existing sales records."²⁰ We advise using the Qualified Exemption Annual Review above.

Produce Exempt Due To Commercial Processing

Check out the detailed recordkeeping requirements in our deeper dive guide.

REQUIRED SIGNS AND LABELS FOR QUALIFIED EXEMPT GROWERS

If you are Qualified Exempt, you have one additional labeling requirement 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.²¹ 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.²² With online sales, you can include an electronic message with your farm name and address. If a label is required by the Federal Food, Drug, and Cosmetic Act, the label **MUST** have the name and address of the farm.²³ It doesn't need to be the physical address of your farm, if you have a separate business address or even a PO Box. This isn't likely to be too costly or imposing, and improving your labeling is also a great way to boost the branding of your farm!



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

20. Response to comment 122 in the Preamble.

21. 21 C.F.R. § 112.6(b)(1).

22. 21 C.F.R. § 112.6(b)(1).

23. A label is required when produce is sold in packaged form, meaning any container or wrapping in which the food is enclosed. See 21 U.S.C. § 343 (e).

24. (§ 112.115) Also, See FDA, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry (Draft Guidance), (Oct 22, 2018), at 88.

Know the Rule!

Is this farm covered?



Q 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.

A **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.

Q 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.

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

Q 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.

A **NOT SUBJECT!** These crops aren't covered by the Produce Safety Rule.

Q 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.

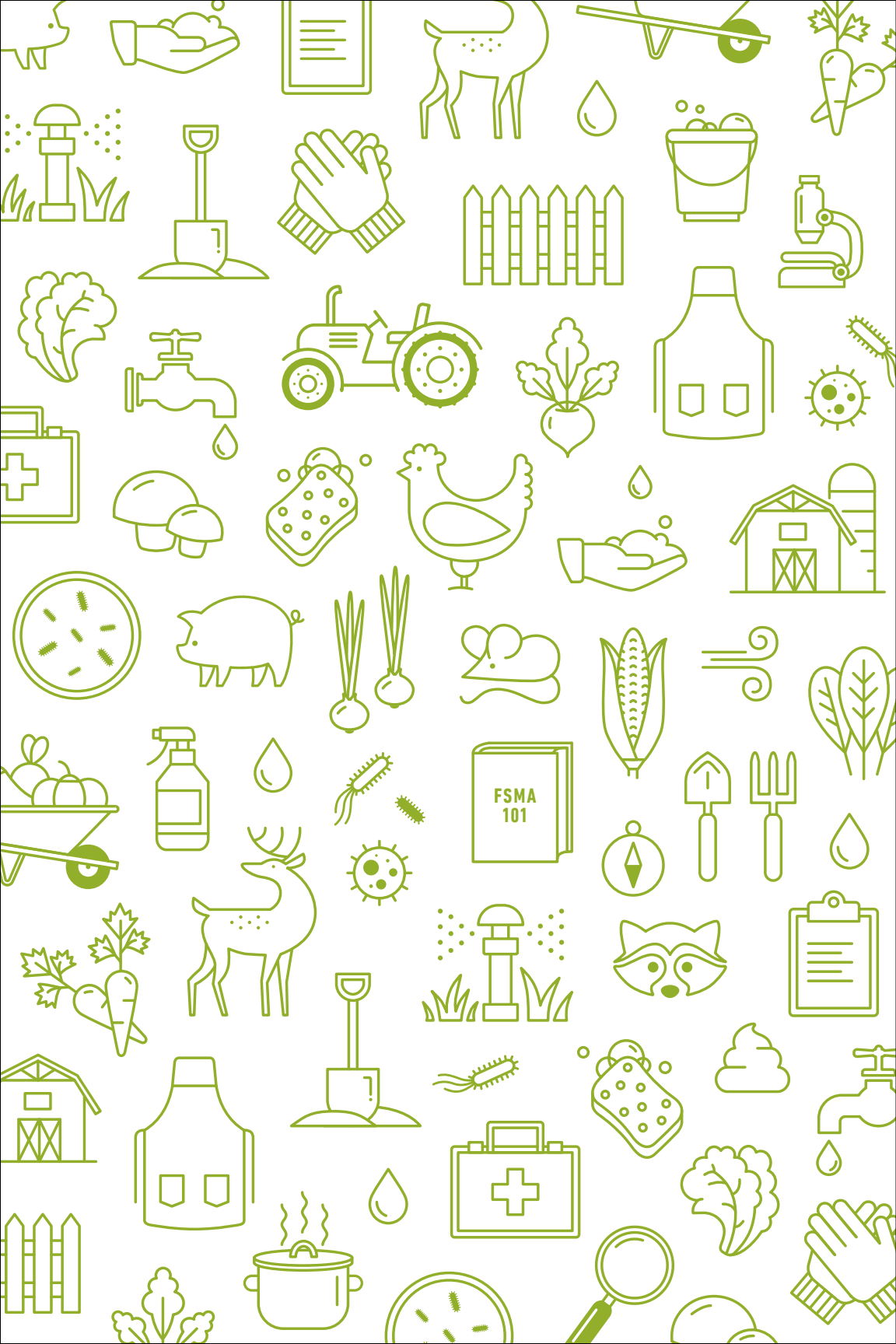
A **QUALIFIED EXEMPT!** This farm has less than \$500K in food sales and more than half of sales (40% + 40% = 80%) are direct to consumers at farmers markets and CSA distributions. The food hub is not a Qualified End User, but it's less than half of the farm's sales.

Q 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.

A **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.

Q 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.

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



Chapter 3

Where to Start with Food Safety on Your Farm

In this chapter we'll discuss the concepts and building blocks of creating produce safety 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

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 equivalent to the training approved by the FDA.¹ The Produce Safety Alliance Grower Training is one way to meet that 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 as low as \$25. To find a training visit: <https://producesafetyalliance.cornell.edu/training/grower-training-courses/upcoming-grower-trainings/>

The Produce Safety Alliance curriculum is currently the only workshop recognized by the FDA to meet the training requirement. The Rule allows for other curricula, also known as alternate curricula, to be developed that could also satisfy

1. 21 C.F.R. § 112.22(c).

the training requirements. We expect others in the coming years. Additionally, there are many workshops, basic or in-depth, that will help you learn more about growing food safely.

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 another way of growing healthy food for your community.

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 concern seriously. When an issue arises, address it swiftly and consider what improvements to the process or infrastructure could reduce challenges. For example, if your employee 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 to a U-pick operation or petting zoo.

RISK ASSESSMENT

There are a few phrases that we use often throughout this guidebook and that you might hear in trainings, on template records, or from inspecting agencies. 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.”² 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 everyday: 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 record).

Once you’ve identified potential risks, you’ll want to write down how you will fix any problem that might arise. For example, you **MUST** consider what corrective action you’ll take if you see poop in the field. You could figure that out ahead of time and write a Standard Operating Procedure (SOP) for what employees should do.

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. Even if you are a one-person farm, you might find that taking time to write out and post directions helps you see ways to improve the food safety or efficiency of a task. Also, it may be easier to use a written plan rather than to keep all of the steps in your head. SOPs are a critical food safety tool, but 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.

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

2. Produce Safety Alliance Grower Training Course, Version 1.1, © 2017.

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, or 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 recordkeeping 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 and others are just good practice. Here is a list of the required records:

Not-Subject

- Records to prove your produce sales

Qualified Exempt

- Qualified Exemption Annual Review Record

Covered

- Worker Training Record
- Water System Inspection Record
- Water Treatment Monitoring Record (if applicable)
- Agricultural Water Die-off Corrective Measures Record (if applicable)
- Compost Treatment Record (if applicable)
- Cleaning and Sanitizing Record

If your farm is fully covered by the Rule, your required records **MUST** include some specific info, like dates, times, signatures, and sometimes review by a supervisor. To learn more about those details, see our deeper dive document or Produce Safety Alliance's "Records Required by the FSMA Produce Safety Rule." Check out our Online Resource Library for templates.

Each section in this guidebook will have a list of required and recommended records. Records can be kept electronically (in something like Google Sheets or a temperature data logger), in photos (of dry erase board records or paper lists), or in hard copies of the paper records. Recordkeeping is most effective when it can be done close to the location of the activity. For example, a cooler temperature log is most useful near the thermometer in the cooler. Since required records **MUST** be kept for at least two years, make it a habit to record the year along with the day and month each time you make a record. This small detail can really reduce later confusion!

How to Write a Good SOP

INCLUDE:

- Name of author and a title (if they have one).
- Date written or revised.
- 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.
- Display 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 and protect them so you can bring them into the field or washing space.

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.

Sample SOP

Cleaning and Sanitizing Surfaces, Tools, and Equipment

Created by: Valeria Rodgers, Farm Owner and Manager
Date: 07/22/19
Revision: 1.4

PURPOSE AND WHY:

Describes how food contact surfaces, tools, and equipment are to be cleaned and sanitized so that they don't transmit pathogens.

WHO:

All farm owners, managers, employees, or volunteers.

RESPONSIBILITY:

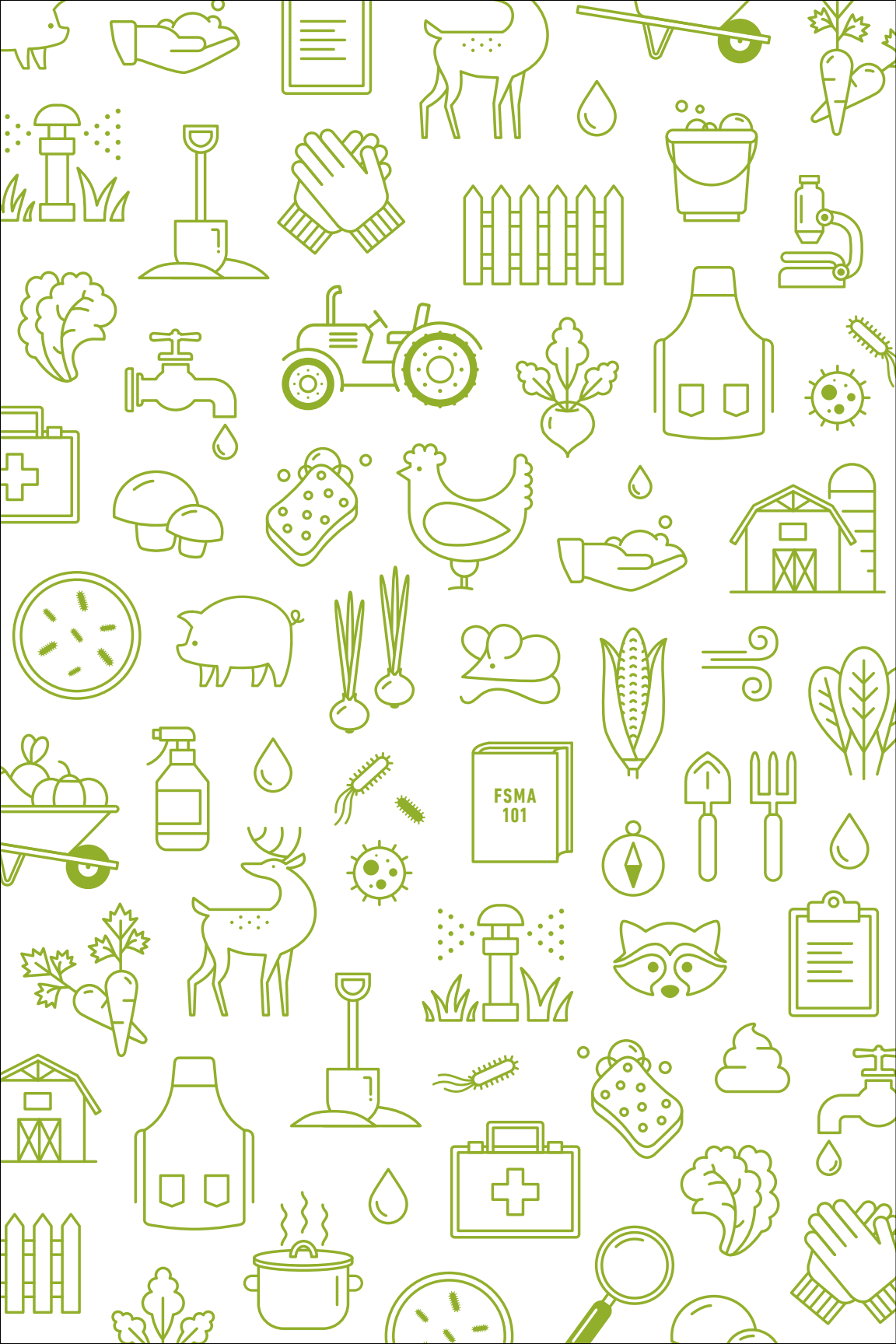
Workers are responsible for following the SOPs to properly clean and sanitize food contact surfaces. Farm owners and food safety managers are responsible for training the workers on proper technique, providing necessary resources such as tools, detergents and sanitizers, and making sure the cleaning and sanitizing steps are followed correctly.

MATERIALS OR TOOLS:

- **Simple Green Industrial** from blue spray bottle (Ratio **Simple Green** to water of 1:10: see SOP on mixing Simple Green if bottle is low)
[Sanitizer name, brand, and concentration]
- **Sanidate 5.0** from red spray bottle, (1.6 fl. oz. **Sanidate 5.0** to 5 gallons of potable water: see SOP on mixing Sanitizer if bottle is low)
[Detergent name, brand, and concentration (labeled for use on food contact surfaces)]
- Light blue tall cylinder container for dunking knives and scissors
[Container(s) as needed for mixing and using detergent(s) and sanitizer(s) or for washing tools]
- 7 inch blue scrub brush for tables, smaller round blue brushes for knives and scissors
[Brushes, sponges, or towels for scrubbing tools and equipment]
- Clean water (microbial equivalent to drinking water)

PROCEDURE:

- Brush the surface of tables, tubs, or tools and rinse with running water to remove visible dirt and debris.
- Apply the prepared **Simple Green** from the spray bottle (about 10 sprays on the stainless tables or tubs and one to each side of the knives) and scrub the surfaces until lather forms.
- Rinse the surface with clean water until all soap suds are rinsed off the table.
- Apply the **Sanidate 5.0** solution so that the entire surface is contacted (about 20 sprays on tables and dunk the tools in the Sanidate bucket.)
- Allow knives or scissors to soak for more than one minute. Remove and lay in rack to the right of the handwashing sink labeled "clean tools."
- Let the surface air dry.



Chapter 4

Worker Training, Health, and Hygiene

Workers contribute to your farm’s success and play a key role in ensuring the safety of your produce. Workers can be hired employees, interns, volunteers, or you and your family members—anyone who is touching food or surfaces that touch produce. Workers do not include visitors, who are not employed by the farm, but they can benefit from some training, too. Even if you are the sole operator of your farm, knowing how contamination spreads and doing your part to prevent it will help you get your produce to market safely. You can reduce the risk of an outbreak by educating everyone who works on the farm about food safety basics.

Key Concepts

Food Contact Surface: Any surface which directly contacts human food and surfaces where water could drain onto a surface that will touch food. (We’ll talk about this more in the chapter on postharvest handling.) This includes:

- The surfaces of equipment used in harvesting produce that contact produce, like knives, greens harvesters, conveyors, clippers.
- The surfaces of tables used for curing, culling, sorting, or packing lines.

1. 21 C.F.R. § 112.3.

- Food-packing materials, like bags, clamshells, berry containers, waxed boxes.
- Totes or bins used for harvesting, packing, holding.¹

Supervisor: Person with an adequate combination of training, experience, and education in food safety to supervise workers who handle or contact covered produce and/or perform particular functions under the Produce Safety Rule to satisfy its requirements.

Worker: We use the term “worker” in this chapter to refer to the people on your farm that handle or contact covered produce or food contact surfaces. This can mean family members, volunteers, contract or hired labor, temporary help, seasonal workers, or part time or full-time employees.²

Visitor: Any person, other than a worker, that enters your farm with your permission, whether they’re handling produce or not.³

FOOD SAFETY BOSS!

If your farm needs to be in full compliance with the Rule, you **MUST** identify a person or several people on the farm who are in charge of produce safety and your compliance.⁴ At least one of the supervisors must attend a training, as mentioned in previous chapters.⁵ They only need to attend the standardized curriculum course or an equivalent training one time. Even if you are a small Qualified Exempt farm—maybe just you and a partner—it can still be really useful to designate one of you as the “food safety captain.”

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 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

2. 21 C.F.R. § 112.21 (b).

3. 21 C.F.R. § 112.30 (b).

4. 21 C.F.R. § 112.22 (a).

5. 21 C.F.R. § 112.22 (b).

handle covered produce or food contact surfaces have the skills to do their jobs; have a supervisor who is capable of supervising and training; train workers upon hiring, at least annually, and in a way that they are capable of easily understanding; retrain workers if they’re not meeting food safety standards;⁶ and keep a supervisor-reviewed record of the training, including the date, topics, and people trained.⁷

Trainings **MUST** cover:

- The basics of food safety.
- The importance of personal hygiene.
- How to know if someone has an illness that could cause contamination.
- Any other requirements from the Produce Safety Rule that the employee needs to know to complete their job, such as rules around making compost, managing animals and their waste, cleaning and sanitizing.⁸

If your workers are also harvesting, the training **MUST** also cover:

- Knowing when not to harvest covered produce.
- How to inspect harvest containers and equipment to make sure they’re safe and clean.
- How to report or correct issues with harvest containers or equipment.⁹

6. 21 C.F.R. § 112.21 (d).

7. 21 C.F.R. § 112.30 (b).

8. 21 C.F.R. § 112.22 (a).

9. 21 C.F.R. § 112.22 (b).

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 it's risky. Share info about how and where bacteria grows quickly. The more the workers understand, the more they can evaluate risks on their own.

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. If you're chatting with your team at the beginning of the harvest day and cover some food safety activities, make a note about the topic of the training, who attended, and when it happened. Stick that into your food safety binder, make sure a supervisor reviews, signs, and dates the record within a reasonable time (if you aren't the supervisor), and it can count as a "worker training."

SICK WORKERS

Sick or injured workers **MUST** not contact covered produce or food contact surfaces. Workers **MUST** also let their supervisor know if they're sick.¹⁰

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 employees to a job that does not involve produce or food contact surfaces. However, if an ill employee on "desk duty" doesn't properly wash their hands and then touches a door knob that another employee who is working with produce that day uses, pathogens could ultimately be transferred to produce. Workers who handle covered produce **MUST** be trained to recognize symptoms of illnesses that pose a risk of contamination and how contamination spreads.¹¹ 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.









10. 21 C.F.R. § 112.31.

11. 21 C.F.R. § 112.22 (a)(2).

HYGIENE

Anyone who is handling covered produce or food contact surfaces on the farm **MUST** follow good hygiene practices,¹² but what does that mean, specifically?

Good Hygiene Practices:

- Wear clean clothing at work.
- 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.
- Gum and tobacco can only be used in designated areas (The Chewing Zone—just kidding!).
- Eat in designated areas and only on breaks.
- Wash hands:
 -  After using the toilet.
 -  Before starting or returning to work.
 -  Before and after eating and smoking.¹³
 -  Before putting on gloves.
 -  After touching animals or animal waste.
 -  Any other time they may become contaminated.

12. 21 C.F.R. § 112.32; 112.33.

13. 21 C.F.R. § 112.32 (b)(3)(vi). Also Tobacco Mosaic Virus! Lots of farmers don't allow workers to smoke or chew tobacco on the farm due to the potential impact on tomatoes.

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.

Clean Clothes Every Day

Though it may be your inclination to skip a shower or wear the same unwashed work pants all week to reduce laundry tasks, it is important to shower regularly and 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 Gear

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. 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.¹⁴ Watches and rings with stones or etching are generally considered hard to clean and sanitize because they have little crevices where pathogens can hide out. Smooth bands are easier to clean. Earrings and other face jewelry isn't so risky from a microbial angle, but could fall out and be a physical hazard.

14. 21 C.F.R. § 112.32 (b)(5).

Snacking

Workers **MUST** not eat, chew gum, or use tobacco while in areas where covered produce is grown, handled, harvested or packed.¹⁵ 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. Try to incorporate this taste testing into a pre-harvest walk instead of during harvest and help your workers understand the risk of eating while handling produce.

Cell phones

Cell phones are obviously incredibly useful, but 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 and wash your hands after touching your phone.

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

15. 21 C.F.R. § 112.32(b)(6).

HANDWASHING

Handwashing 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. 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 handwashing 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.¹⁶

Hand sanitizers **MUST** not be used as a replacement for handwashing.¹⁷

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.



16. 21 C.F.R. § 112.32 (b)(3).

17. 21 C.F.R. § 112.130 (d).

FACILITIES



Handwashing Stations

Handwashing facilities **MUST** be stocked with soap, clean running water (see chapter 8 for rules about postharvest water), a way to dry hands that is single-use, like paper towels, single use towels, or a hand dryer, and a trash can for those paper towels. Also, you **MUST** provide a way to dispose of wastewater that isn't likely to contaminate covered produce. If your sinks aren't plumbed to septic or sewers, use buckets or other containers that will not leak under the handwashing stations to capture used water and empty them regularly in an area that will not contaminate covered produce or food contact surfaces.

There are many designs for building your handwashing 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.



Bathrooms

You **MUST** provide toilets that are accessible to the growing, harvesting, packing, and holding areas. The handwashing station **MUST** be near the toilet.¹⁸

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 port-a-lav, or an outhouse. The Rule isn't specific about where the restrooms should be, but the Occupational Safety & Health Administration (OSHA) requires that there be at least one toilet and one handwashing facility per 20 workers,¹⁹ that the toilets be within a ¼ mile of the where workers are working, and that the toilet and wash station **MUST** be in close proximity to one another,²⁰ when 11 or more employees are working on a given day.²¹

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

You **MUST** keep the toilets clean, stocked with toilet paper, and

maintained so that waste from the toilets doesn't contaminate covered produce, food contact surfaces, agricultural water sources, or water distribution systems.

Make sure the bathroom can be easily cleaned and do so on a regular schedule. Be clear with workers that they should put soiled toilet paper in the toilet, not in garbage cans.²² 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, port-a-potties, and waste water from handwashing stations **MUST** be handled safely so that it doesn't contaminate produce. 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 an 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. Situate your covered produce fields and areas for covered activities well away from the leach field.



Break Areas

Since workers on a farm **MUST** not eat, chew gum, or use tobacco while in areas where covered produce is grown, handled, harvested or packed, you should provide a specific break area.²³ 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 an 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.

18. 21 C.F.R. § 112.129 (c).

19. 29 C.F.R. § 1928.110(c)(2)(i).

20. 29 C.F.R. § 1928.110(c)(2)(iii). The federal regulation only permits driving to a restroom when the terrain prohibits the location of facilities as described.

21. 29 C.F.R. § 1928.110(a).

22. Signs are available on youngfarmers.org.

23. 21 C.F.R. § 112.32 (b)(6).



Drinking

Workers **MUST** not eat while doing a covered activity, but workers can drink in designated areas. One suggestion for creating a “designated area” is to have water (or another beverage) at the end of the row where workers are harvesting. Provide your workers potable water. Don’t allow workers to share cups, so you can provide single use cups or they can bring reusable water bottles. 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 Band-Aid.

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 Band-Aid 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.²⁴ 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 be a liability. Let them know which areas of the farm they are allowed to visit, including where the toilets and handwashing stations are located. Provide instructions on how to wash their hands, following the same steps as outlined for workers (on page 45). 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 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, and to keep pets at home.

24. 21 C.F.R. § 112.33 (a) & (b).

Records for Worker Training, Health, and Hygiene

REQUIRED:

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

SUGGESTED:

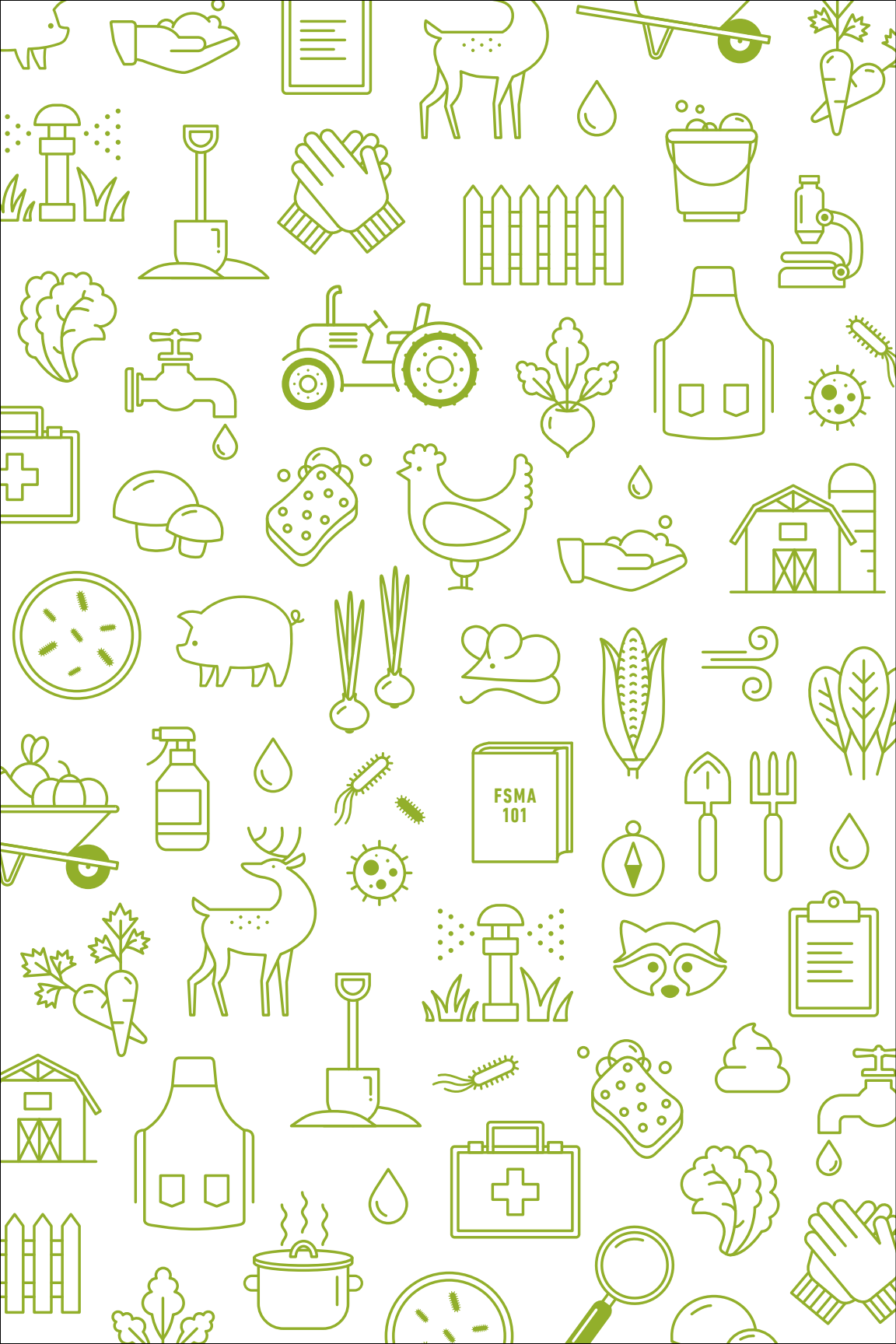
- Monitoring and restocking of toilet and handwashing facilities
- Worker illness and injury reporting
- Restocking of first aid kits
- Worker attendance

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.

²⁵ 21 C.F.R. § 112.30(b).



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. The Produce Safety Rule only regulates biological soil amendments of animal origin.¹ Synthetic soil amendments can be dangerous, too, but their risks are rarely from human pathogens. As a reminder, the Rule requirements related to sprouts are not the focus of this guide. Find out more about making sprouts safer through the Sprout Safety Alliance.

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

1. 21 C.F.R. § 112.51.

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).^{2,3}

Biological Soil Amendment: Any soil amendment containing biological materials, alone or in combination. Includes: stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings.⁴

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.⁵ 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,

2. 21 C.F.R. § 112.3.

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

4. 21 C.F.R. § 112.3.

5. 21 C.F.R. § 112.3.

restaurants, retail operations, or other sources where the food has been served to a consumer.⁶

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.⁷ Examples could be compost-based, manure-based, plant-based, fish emulsion, or biodynamic preparations.

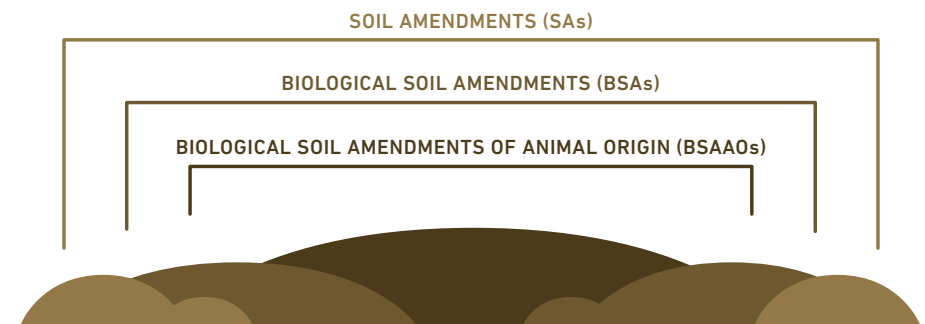
Agricultural Tea Additive: Nutrient source (such as molasses, yeast extract, or algal powder) added to agricultural tea to increase microbial biomass.⁸

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.⁹

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



6. 21 C.F.R. §112.3.


7. 21 C.F.R. § 112.3.

8. 21 C.F.R. § 112.3.

9. 21 C.F.R. § 112.3.

UNDERSTANDING RISK

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

 AMOUNT OF RISK	Type of Amendment	Covered by Rule?
L E S S R I S K Y	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 67 for more on agricultural teas.	Yes, called Treated BSAAO.
M O R E R I S K Y	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. ¹⁰

10. 21 C.F.R. § 112.53.

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. While the Produce Safety Rule focuses on the control of microbiological hazards, FDA has other mechanisms (outside of FSMA) for controlling chemical hazards.

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. 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 is usually considered low risk from a microbiological perspective.

TREATED OR UNTREATED?

Under the Rule, there are two types of BSAAO, treated and untreated. Whether the amendment is treated or not determines 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.”¹¹ If you’re making compost tea (here usually called agricultural tea) it is considered treated if the compost is treated and no additives are used during the brewing process. Also, the water you use to make the tea **MUST** to be free from detectable generic *E. coli*.

All BSAAOs **MUST** be handled to minimize contamination with covered produce.¹² If the treated BSAAOs becomes contaminated after treatment, it **MUST** be considered an untreated BSAAO.¹⁴

This could happen if your treated BSAAO is mixed with an untreated BSAAO, if an agricultural tea contains an agricultural tea additive (like molasses), and/or you have any reason to think that it was contaminated.

11. 21 C.F.R. §112.51 (a).

12. 21 C.F.R. § 112.52 (b).

13. 21 C.F.R. § 112.52 (b).

14. 21 C.F.R. § 112.51 (b)(1)-(5).

UNTREATED BSAAOS

Requirements for Storage and Handling of Untreated BSAAOs:

- If you own the animal, you **should** control its poop! You **should** 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.¹⁵
- You **should** consider and minimize runoff to prevent raw manure from potentially contaminating covered produce, agricultural water, or areas where covered activities are performed.¹⁶ The concept of runoff will be discussed in more detail in the following chapter.
- You **should** 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.¹⁷
- You **should** keep raw manure or untreated BSAAOs from contaminating any treated BSAAOs.¹⁸ So, say you have a few compost 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.

15. 21 C.F.R. § 112.134 (a).

16. 21 C.F.R. § 112.52 (a).

17. 21 C.F.R. § 112.52 (a.)

28. 21 C.F.R. § 112.52 (b).

Good Practices for Handling Untreated BSAAOs:

- Keep equipment and tools for untreated BSAAOs and other tasks separate. For smaller farms, where shovels are used in compost or 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 untreated BSAAO 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 soil amendments.
- 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 BSAAOs 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** exclude animals from your raw manure and compost piles through fencing or other means, because animals can spread contamination quickly if they have access to other areas of the farm and because if they poop in the compost pile enough, they can contaminate it and then you'll need to treat the pile like an untreated BSAAO.

Application Timing and Methods for Untreated BSAAOs:

- FDA is still researching and discussing how long farmers should or **MUST** wait between application of untreated BSAAO and harvest, and expect it will be a few years before they have a final statement. For now, the FDA is comfortable with the National Organic Program (NOP) standards.¹⁹
- 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 BSAAOs should be treated like raw manure) if the edible part of the produce touches the soil, like lettuce, spinach, and melons.²⁰ If the edible part of the crop is unlikely to have direct contact with the soil or soil particles—like trellised 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.²¹

19. "Comfortable with" wasn't clear enough? Read more on this in the Preamble: 80 Fed. Reg. 74354, 74463.

20. 7 C.F.R. § 205.203(c)(iii).

21. 7 C.F.R. § 205.203(c)(iii).



Examples of Untreated BSAAOs:

Raw manure²²

"Aged" or "stacked" manure²³

Untreated slurry²⁴

Agricultural tea made from untreated manure²⁵

Agricultural tea that uses a nutritive additive (like molasses, yeast extract, or algal powder) because they may feed and promote harmful bacteria²⁶

Agricultural tea made with untreated surface water²⁷

Compost that hasn't been processed with a validated process²⁸

Vermipost²⁹

Treated soil amendments that have been mixed with untreated soil amendments³⁰

Treated soil amendments that have been contaminated after treatment, such as through significant pest activity or animal intrusion³¹

22. 21 C.F.R. § 112.51(b)(1).

23. 21 C.F.R. § 112.51(b)(1).

24. 21 C.F.R. § 112.51(b)(1).

25. 21 C.F.R. § 112.51(b)(1).

26. 21 C.F.R. § 112.51(b)(5).

27. 21 C.F.R. § 112.51 (a) and (b)(1).

28. 21 C.F.R. § 112.51(b)(1).

29. 21 C.F.R. § 112.51(b)(1).

30. 21 C.F.R. § 112.51(b)(3) & 112.52(c).

31. 21 C.F.R. § 112.51(b)(2).

TREATED BSAAOS

To comply with the application restrictions associated with treated BSAAO in the Rule, treated BSAAOs **MUST** be processed according to a scientifically valid controlled physical, chemical, or biological process (or combination of such processes) validated to one of two microbial standards.³² The first “validated process” creates a soil amendment that meets the more stringent standards and can be applied without restriction. The other “validated process,” which includes both static and turned composting created using the methods on pages 64 ad 65, creates a soil amendment that **MUST** only be applied in a way that minimizes contact with covered produce. We cover this a bit more in the deeper dive version of this guidebook.

Applying Treated BSAAO

Compost can be applied in a manner that minimizes potential contact with covered produce during and after application, but what practically does that mean? The answer depends on lots of factors, but here are potential risks you should consider:

- The type of treated BSAAO: composted BSAAOs or heavily processed BSAAOs like blood meal.
- 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. (underground, low growing or stem fruits).
- 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 rain.³³

Once you've thought this through, write out your rationale, and, if you need to be in compliance, keep records of steps you're taking to reduce risk.



32. 21 C.F.R. § 112.54.

33. FDA, Draft Guidance Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry (Oct 22, 2018) at 67-68.



Examples of Treated BSAAOs:

Compost
(created with validated process)

Pelleted chicken manure

Fish emulsion

Bone meal

Feather meal

Blood meal

Documentation From Seller

If you buy treated BSAAOs from a supplier and apply it as the Rule suggests for treated BSAAOs, you **MUST** have annual documentation, such as a letter or “certificate of conformance,” that says that a scientifically validated process porcess was used, to which standard the BSAAO was treated, that the process was monitored, and that the treated BSAAO was handled, conveyed, and stored in a manner and in a location that minimizes its risk of contamination from untreated BSAAOs.³⁴ The Rule doesn't require any records if a treated BSAAO is handled, conveyed, stored and applied as the Rule suggests for raw manure.

34. 21 C.F.R. § 112.56 & 112.60 (a) and (b).

MAKING COMPOST: MUSTS for Making Treated BSAAOs 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. It is also how you change an Untreated BSAAO to a Treated BSAAO. 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. Specific temperatures contribute to the decomposition and are the main way in which pathogens are reduced.

The Rule recognizes two specific composting techniques that have been validated to the standard for application in a manner that minimizes the potential for contact with covered produce during and after application.³⁵ These validated processes are:

1. AERATED STATIC COMPOSTING

- Aerobic, maintaining oxygenated conditions at a minimum 131°F (55°C) for three consecutive days.
- 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.”³⁶

2. TURNED COMPOSTING

- Aerobic, maintaining oxygenated conditions at a minimum of 131°F (55°C) for 15 days (possibly not consecutive days).
- Minimum five turnings.
- 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.”³⁷

You may also follow other scientifically valid, controlled composting processes or validated processes.³⁸ 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 in the rule and the deeper dive guide. 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 either of the standards set out above.

Farmers following one of the two methods above 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).³⁹ 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.⁴⁰



Compost is **NOT** a piled and forgotten stack of rotting vegetables or animal manure in the back of a field. “Passive” piles like that may be used, but **MUST** be treated as if they were raw manure or untreated BSAAOs, as described above.

35. 21 C.F.R. § 112.55 (b).

36. 21 C.F.R. § 112.54 (b) and 112.3.

37. 21 C.F.R. § 112.54 (b) and 112.3

38. 21 C.F.R. § 112.54.

39. 21 C.F.R. § 112.60 (b) (2).

40. 21 C.F.R. § 112.56 (a)(2).

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 in this rule, this kind of compost doesn't reach the temperature levels required by the Produce Safety Rule. That means you would 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. In fact, it very explicitly says that it doesn't cover food grown in fully enclosed buildings or with fish. 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.

Biosolids (Humanure)

You **MUST** not use untreated human waste to grow covered produce (see definition of covered produce on page 18). There are types of biosolids available that have been treated in accordance with the Environmental Protection Agency (EPA) requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements for growing covered produce, for example Milorganite. For most purposes, "40 CFR part 503, subpart D, limits application for land growing covered produce to Class A biosolids." With any use of biosolids, you'll want to consider heavy metals and 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."⁴¹ Bottom line, if you have a composting toilet, be safe and don't use it on any food crops!

41. <https://www.epa.gov/biosolids/frequent-questions-about-biosolids>.

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 this Rule.

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 tea but has a few requirements. If you make an agricultural tea from an BSAAO that is processed in accordance with the standards above and you use water that doesn't have detectable general *E. coli*, you can use it like you would use the compost. 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 and then held it for more than an hour, you need to treat it like raw manure. Meaning, you have to have a 120- or 90-day interval to harvest. 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.

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.⁴² (See example online).
- For on-farm composting to create a treated BSAAO, you must keep time, temperature, and turning records as applicable to show you followed a validated process.⁴³ (See templates online). A supervisor must review, sign, and date these records within a reasonable time after they are generated.⁴⁴
- Worker training for handling of untreated BSAAOs on your farm.⁴⁵
- Worker training for composting and recordkeeping, if applicable, including the names of the workers, the topics covered and the date.⁴⁶

SUGGESTED:

- 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 you comply.
- 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 BSSAOs.
- How to make an agricultural tea using a validated method.
- How to make a pre-consumer vegetative waste agricultural tea.
- How to clean equipment after spreading BSSAOs.

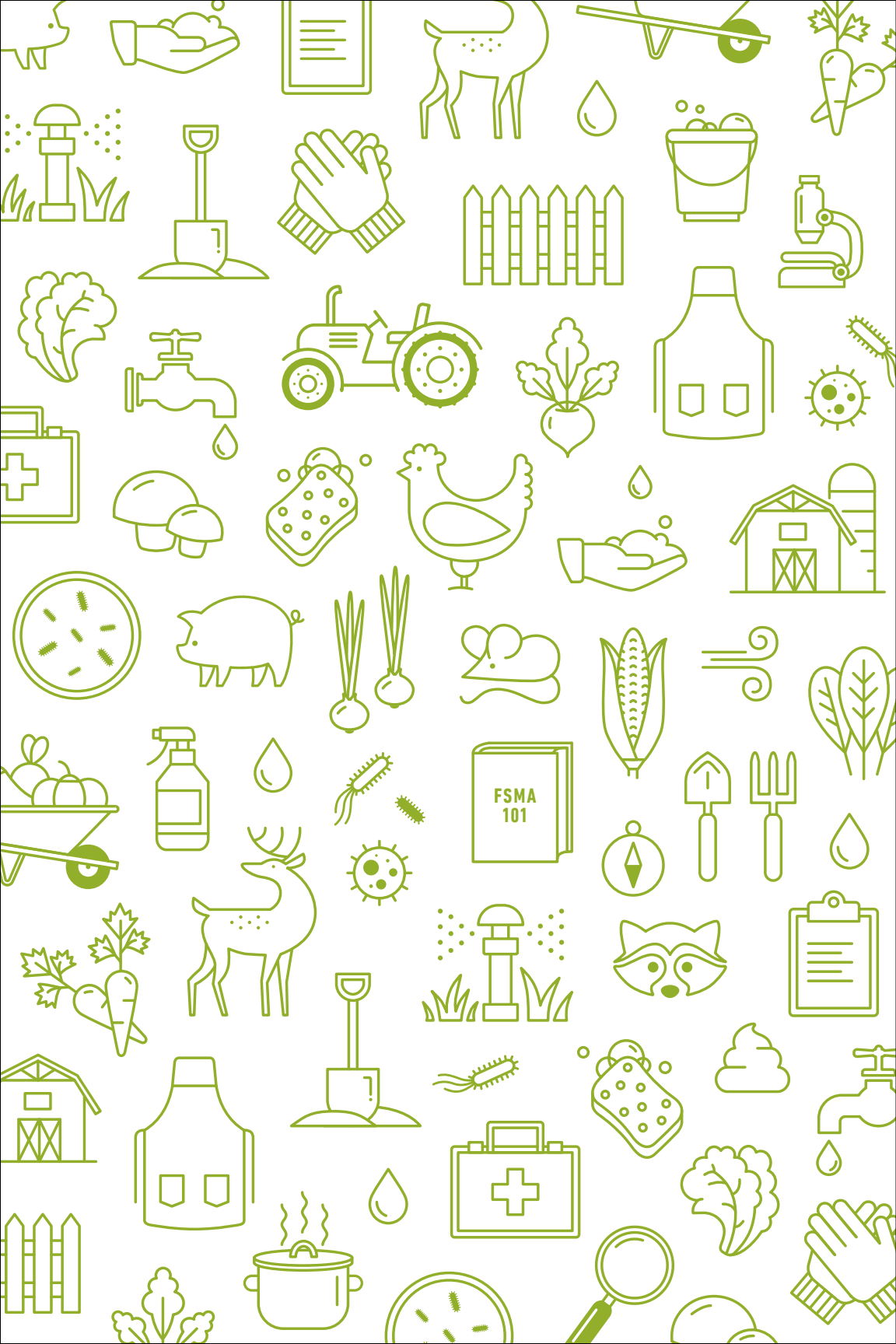
42. 21 C.F.R. § 112.60 (b)(1)(i)-(ii).

43. 21 C.F.R. § 112.60 (b)(2).

44. 21 C.F.R. § 112.161 (b).

45. 21 C.F.R. § 112.21.

46. 21 C.F.R. § 112.21.



Chapter 6

Animals and Adjacent Land

Animals—like wildlife, livestock, working animals, or pets—can carry and spread human pathogens through their feces. Therefore, your 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 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,¹ 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.²

1. 21 C.F.R. § 112.22(b)(1).

2. 21 C.F.R. § 112.83 (a) the requirement to assess 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) and (2).

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 manure piles or grazing areas, 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.

No-Harvest Buffer Zone: A defined distance around an identified risk—like poop or other signs 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-Planting 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-Planting 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? Do you live near a chemical plant? If so, are you on their emergency call list?



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 stored in the past? Did your neighbors use their property for any residential or commercial purposes?



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 could 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?

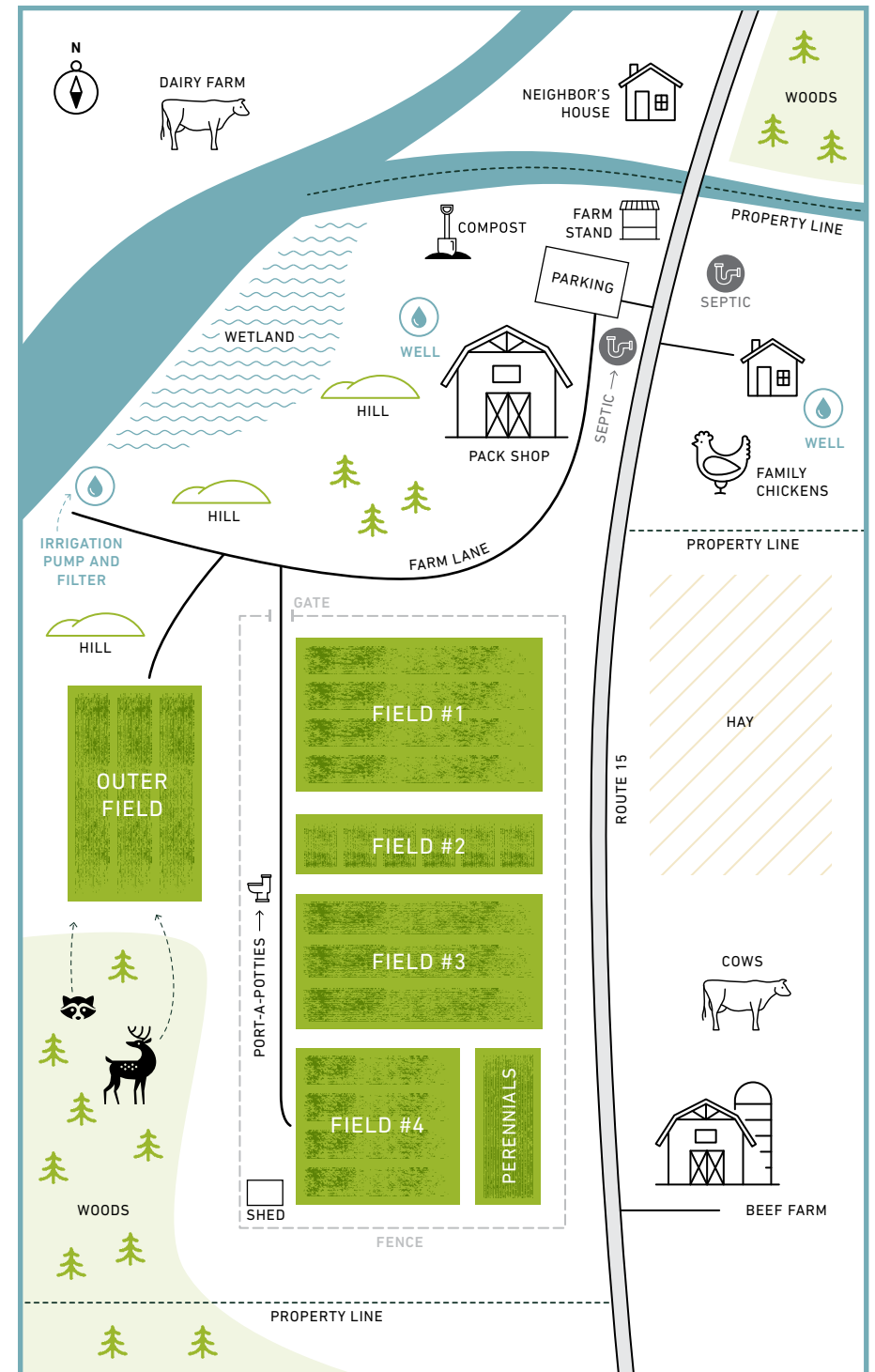


Animal Population Density Do you know how many deer live near your farm? Does one wild hog or twelve ravage your cantaloupe field? Do you need to set up trail cameras or get a scat identification guide to help you identify the animals or the scope of the problem?



Fecal Contamination In Production Areas Do your workers often report fecal contamination in one field? What kind of animal does it come from?

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.

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

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. Maintaining 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 or riparian buffers can filter water and slow the movement of pathogens from animal habitats to harvest areas. Allowing grass strips between hedgerows and fields can also allow trees in hedgerows to thrive without providing roosts directly above produce fields.

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, 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."^{3,4} Steps that you take to deter wildlife must comply with the Endangered Species Act and with applicable state and local laws.

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, evidence of 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 Greens Marketing Agreement (LGMA) recommends that you do not

3. 21 C.F.R. § 112.84.

4. You **MUST** comply with the Endangered Species Act at all times.

harvest produce within a five-foot radius of the contamination, unless you can take some sort of remedial action that can adequately control the contamination (see the LGMA Food Safety Guidelines in our online resource library). 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.

Additional corrective actions 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 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. 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.⁵ 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:

5. 21 C.F.R. § 112.32 (b) (2).

- 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 handwashing 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.
- 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

Working 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. 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.⁶ Guard or guide dogs may be 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. Note that only dogs are permitted as guard 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.

6. 21 C.F.R. § 112.127 (a).

Records for Animals and Adjacent Land

REQUIRED:

- Worker training, including knowing when produce cannot be harvested⁷ and understanding the risks of animals on-farm⁸

SUGGESTED:

- Pre-Planting Land 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 using of nuisance permits

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

7. 21 C.F.R. § 112.22 (b)(1).
8. 21 C.F.R. § 112.32 (b)(1)(2).

trying to understand how to mitigate risk, we want to give you some clear and precise tips. We have left the "MUSTs" in this chapter since they're still in the Rule, but understand that growers have extra time to comply and some MUSTs might change. Remember that the water rules for sprouts are stricter and sprout growers already need to be in compliance (see page 10 about sprouts). The water rules discussed in this chapter are for non-sprouts!

Because the water parts of the Rule are being re-examined, FDA announced that they would not be enforcing the water sections until 2022 at the earliest. So growers who need to be in full compliance have lots of extra time to prepare.

Key Concepts

Production Water: Water that is going to touch the harvestable portion of non-sprout covered produce during growing activities, which starts at flowering. Some examples are irrigation, fertigation, application of fungicide or insecticide sprays, dust abatement, or frost protection.

Postharvest Water: Water that is used during harvest or postharvest, for fluming, washing, waxing, hand-washing, and more.

Microbial Water Quality Profile (MWQP): 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.

Using Municipal Water

If you use municipal or "city" water on your farm, your water source is quite safe. The city or town where you live tests that water to be sure that it is safe for drinking. If you need to be in compliance with the Rule, print out a copy of the annual Drinking Water Quality Report. 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.



UNDERSTANDING PRODUCTION WATER RISKS

Risks From Water Sources

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 pathogens. Since each source of water has a different level of risk, they require different strategies for testing, described on the chart on page 89.

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)

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. Drip irrigation, usually considered least risky, could have more risk if applied to covered root crops where the water is likely to touch the harvestable portion.

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

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.¹ This inspection includes looking at your water sources, water distribution systems, facilities, and equipment to identify any conditions that could cause contamination.² You **MUST** consider:

- The type of water source and its relative risk.
- What control you have over that water source.
- How protected is the water source.
- Impacts from adjacent and nearby land use, like the likelihood that water could become contaminated by another user before reaching your covered farm.

To prevent contamination you **MUST** maintain the parts of the agricultural water distribution systems that are under your control.³ Walk the ponds, ditches, lakes, or 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, like fences.
- Keeping the water source free of debris, trash.

1. 21 C.F.R. § 112.42(a).

2. 21 C.F.R. § 112.42(a).

3. 21 C.F.R. § 112.42(b).

- Filters.
- 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.⁴ The Rule gives some examples of how to prevent that contact, like choosing to stake crops. 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** consider these from a food safety perspective.

KEEP YOUR IRRIGATION WATER CLEAN!

- Fence your animals out of your agricultural water sources.
- Maintain your well head (See Online Resource Library for tipsheet).
- 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 (See Online Resource Library for tipsheet).
- 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."⁵

4. 21 C.F.R. § 112.42(d).

5. 21 C.F.R. § 112.131.

TEST YOUR WATER

Until you are required to be in compliance with this part of the Rule, if you are already testing your water as a part of a third-party audit, or GAPs, keep testing. If you aren't testing yet, start testing. For surface water, the most useful test is a quantitative test—one that tells you exactly how much *E. coli* you have, not just that you have some. And find out and record the exact name of the type of test you get.

The table on the next page describes timing of sampling requirements for agricultural water used in production of non-sprout covered produce. For more information about MWQP and other aspects of water quality sampling please refer to the PSA fact sheet on the topic. All of the rules in subpart E (agricultural water) other than those provisions related to sprouts are not being enforced until at least 2022.

Because water, especially surface water, can vary in quality from month to month or even day to day, in the current Rule, FDA described exactly how and how frequently growers should test their water. These water tests, taken over four

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		

*this chart is for water used on non-sprout produce only

years, could establish a baseline. So instead of asking for one test, they want you to get a number of tests during the growing season over a few years to paint a longer, more nuanced picture of your water quality.

In the text of the Rule, this four-year water profile is sometimes called a Microbial Water Quality Profile and is abbreviated MWQP. You can have a single test (or a few tests) that are above allowable levels and still have water that is usable, because the FDA wants you to have multiple tests to establish this broader picture. Once you've established the MWQP, you'll test your water during the growing season. The newest test contributes to your water profile and the results of the oldest test fall 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 getting some sense of the quality of your water via testing during the time when you're using the water.

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 create a profile for each.

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)
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 84).	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.	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 roll out of the profile.

All of the currently approved tests look for generic *E. coli*. Generic *E. coli* is an indicator organism, 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, however, testing for specific pathogenic strains of *E. coli* is not always practical. Of course, there are other types of pathogens or parasites that would not be found when looking for generic *E. coli*, but FDA determined that generic *E. coli* is a good indicator of potential contamination. 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.

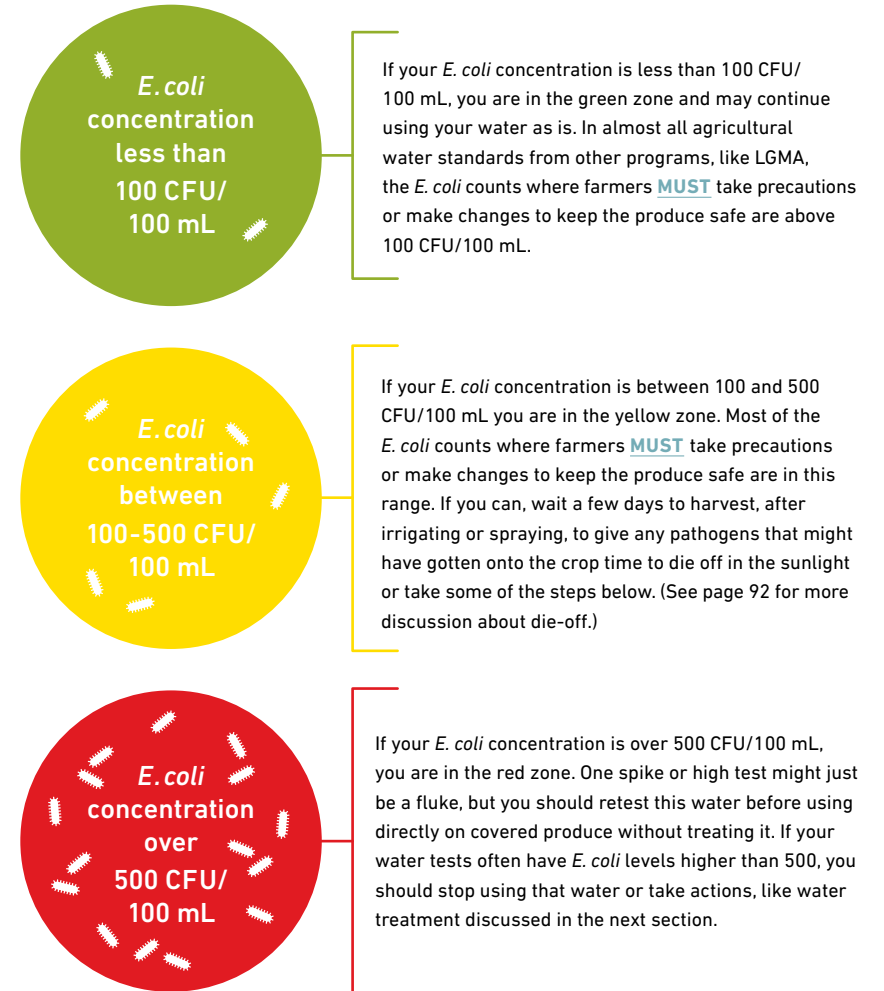
Finding a Water Testing Lab

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 test.



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. Until the requirements are known, consider thinking of the results like a "stoplight chart" based on typical standards and guidelines from other specific commodity food safety rules and other water guidelines.⁶



6. 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. If you want to read more about the more complicated numbers that are currently in the rule, you can read our deeper dive document or the Produce Safety Alliance's tipsheet on water testing calculations. Both are in our online resource library.

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 test 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.

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 our online resources library for tips on shocking your well.

Stretch the Time Between Applying Water and Harvest

Because bacteria is likely to die off in a dry, sunny field, the Produce Safety Rule suggests specific methods for stretching the time between applying water—like in spraying, frost protection, or irrigation—and harvest. Many food safety experts believe this suggestion 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 a covered farm to keep a record of when you apply water and when you harvest. If you're applying the water with a foliar 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 your water tests are within the limits FDA has proposed, 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. While many 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. There are a number of water treatment options that farmers use for irrigation water, such as chlorine, peroxyacetic acid, UV-light, ozone, or more. Any treatment that you're using **MUST** be used as defined by federal, state, tribal, and local regulations. EPA registers and labels antimicrobials (like chemical sanitizers) for use and they are regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). In a strange twist, there are many chemicals labeled for controlling plant pathogens in irrigation water and there are many labeled for use in postharvest water. But as of the date of publication, we didn't know of any technically labeled to control human pathogens in irrigation water. That said, farmers are clamoring for the products they use to become legally labeled and we expect to see changes soon. 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. We expect the industry to catch up with the needs of growers fairly quickly.

BEST PRACTICES WHEN QUALIFIED EXEMPT OR EXEMPT

If you are Not Subject, Exempt, or Qualified Exempt, you aren't required to do this testing, even once the Rule is finalized. We strongly recommend getting some initial tests and knowing a little more about the *E. coli* in your water. While it's a scary step to find how much *E. coli* is in your only source of much needed water, it is also reckless not to know. If you're using municipal water, getting the notification from your municipality is free and often quite easy. If you're using well water, a simple yearly presence/absence test can help you know if your well is remaining clean. Testing surface water is also a very smart tactic and can help you understand what changes you might need to make in coming years. Or perhaps your surface water is quite low in *E. coli* and now you can sleep better at night!

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. The FDA is very clear that if produce is exposed to flood water, it shouldn't enter the food supply. See our Online Resource Library for tipsheets.

Production Water Record Keeping

REQUIRED:

- As this part of the Rule is being re-evaluated and ag water compliance dates for non-sprout covered produce have been extended, no records are currently required

SUGGESTED:

- Copies of any water tests or municipal water testing results
- Records of when you do an irrigation system inspection and any results
- Records of when you irrigate⁷
- 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

⁷ 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.

Examples of postharvest water use:

- Washing or rinsing produce
- Cooling produce
- Making ice
- Applying postharvest wax or fungicide
- Washing and sanitizing tools, equipment, bins, or food contact surfaces
- Handwashing⁴

As a reminder, the Rule requirements related to sprouts are not the focus of this guide. Find out more about making sprouts safe through the Sprout Safety Alliance.

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 or sink. 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 because the same water touches lots of produce and using a sanitizer in batch water can reduce that risk. If you use batch water and need to be in compliance with the rule, you **MUST** have a schedule for changing the water.

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.

4. 21 C.F.R. § 112.44 (a).

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: Any surface which directly contacts human food and those surfaces from which drainage occurs onto the food or a surface that will typically contact food during normal operations. 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);
 - The surface of a packing line; and
 - The inside of totes used for harvest, packing, holding.⁵
-

INSPECT THE SYSTEM

You **MUST** inspect your postharvest water system at the beginning of the growing season, and at least once annually. 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.⁶ You can add the parts of this water system, like drains and hoses, to the map of your pack station.

It is good practice to simply visually inspect the equipment—like hoses, drains, tubs, and spray nozzles—before each time that you use it. A good way to do this 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

5. 21 C.F.R. § 112.3.

6. 21 C.F.R. § 112.42(a).

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. Consider repairing or replacing these parts and/or surfaces, or taking extra care cleaning and sanitizing these areas before you use your system.

START WITH NO *E. COLI* IN YOUR POSTHARVEST WATER

Postharvest water **MUST** be free of generic *E. coli* per 100 mL of water when you start using it. You **MUST** not use untreated surface water for postharvest use like handwashing, cleaning produce, making ice, or washing food contact surfaces. Municipal water sources should be free of *E. coli*. A PSA handout on water testing lists the seven quantitative tests and the seven presence/absence tests (presence/absence is allowed to test well water for use as postharvest water) that the FDA considers equal to the one test named in the Rule. Since compliance dates are extended in this area and since you may be Qualified Exempt, any test for *E. coli* should help you know that your water is usable. If you haven't tested your well water or haven't tested it in a long time, get a test! See page 90 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.

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, but not required, 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 pathogens enters the water and some pathogens come off, the sanitizer is able to inactivate that pathogen, 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 pathogens, though. It will attach to all kinds of things in the water, so high levels of sediment (also called high turbidity) will tie up the sanitizer. Temperature and pH will also affect the efficacy of the sanitizer. (See Online Resource Library for how to choose a sanitizer or monitor wash water.)

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

- 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.⁷
- 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.⁸
- Use the sanitizer in a way that keeps the water safe during use, for example, by monitoring it and adding more if necessary.⁹
- Calibrate, maintain, and provide enough instruments for monitoring wash water or sanitizer, for example pH strips, sanitizer strips, thermometers, or oxidation reduction potential monitors.¹⁰

7. 21 C.F.R. § 112.43 (a)(1).

8. 21 C.F.R. § 112.43 (c).

9. 21 C.F.R. § 112.43 (a)(2).

10. 21 C.F.R. § 112.124(a)-(c).

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.¹¹ A farm can simply have a set schedule for changing water, which might work for some crops or conditions. Additionally, for all postharvest water, you **MUST** visually monitor the quality of the water.¹²

Strongly consider making a clear rule for workers addressing when to change wash water based on turbidity or on a schedule. 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 employees know exactly when to change water. This is a helpful place for an SOP.

WHAT IF SOMETHING GOES WRONG?

In addition to testing your water and finding out there is *E. coli*, there may be some other instances when you believe that your water isn't safe to use and take a corrective action. 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, you will want to take steps to make sure that the safety of the produce isn't compromised.

11. 21 C.F.R. § 112.48 (b).
12. 21 C.F.R. § 112.48 (b).

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. The preamble to the Rule discusses the risk of infiltration in apples, oranges, tomatoes, and mangos, but other sources also list melons, peppers, and spinach.^{13,14} 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: water that is just ten degrees colder than the produce can cause infiltration.

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 operation to minimize the potential for infiltration.¹⁵ 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.

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.
- 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 Resource Library.)
- Reduce the amount of time the produce is in the water.
- Use wider, shallower tanks to prevent produce from being deeply submerged.

You can find factsheets about infiltration in our Online Resource Library

13. Response to comment 253 in the Preamble.

14. <https://ag.umass.edu/vegetable/fact-sheets/infiltration>.

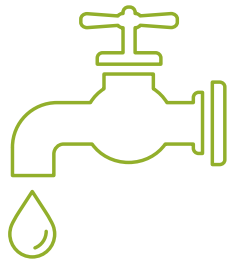
15. 21 C.F.R. § 112.48(c).

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.¹⁶ 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 pathogens that make humans sick, they can also spread plant pathogens that cause decay. Especially reconsider washing any produce that is prone to infiltration, like melons or tomatoes.



16. 21 C.F.R. § 112.132 & 112.133.

Postharvest Water Record Keeping

REQUIRED:

- As this part of the Rule is being re-evaluated and ag water compliance dates for non-sprout covered produce have been extended, no records are currently required

SUGGESTED:

- Annual inspection of your postharvest water distribution system¹⁷
- Water test results or municipal water record¹⁸
- If you treat water, you must keep monitoring records¹⁹
- 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 monitoring²⁰
- If you use batch water, a record of when water was changed to show you have established and followed a schedule for changing recirculated water²¹

Postharvest Water SOPs

EXAMPLE SOPs:

- How to sample postharvest water
- How to inspect the postharvest water distribution system
- How to add sanitizer and monitor batch water for pH, turbidity, and temperature
- How to change wash water
- Steps taken to reduce infiltration by monitoring temperature of water and produce and precooling

17. 21 C.F.R. § 112.50(b)(1).

18. 21 C.F.R. § 112.50 (b)(2)) & 112.161(b).

19. 21 C.F.R. § 112.50(b)(4)) & 112.161(b).

20. 21 C.F.R. § 112.50(b)(6).

21. We 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.

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 help establish lots. Read more about lots on page 128.

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 cleanser 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 (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).²

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?³

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 17. 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 handling the non-covered and covered produce.⁴ For example, say you grow a lot of beets and treat them differently than covered produce, such as using a non-tested irrigation water

2. 21 C.F.R. § 112.114.
3. 21 C.F.R. § 112.3.
4. 21 C.F.R. § 112.111(b).

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, there are a few steps you can take to keep produce clean. First, parts of the Rule require that you **MUST** avoid, as much as you can, contact between soil and the cut surfaces of harvested produce.⁵ Also, the Rule requires that you don't harvest dropped covered produce, meaning any type of covered produce that shouldn't touch the ground during harvest. This excludes produce that drops to the ground as part of harvest (like almonds).⁶ Clear rules around this 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. In addition to being a good food safety practice, this 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.

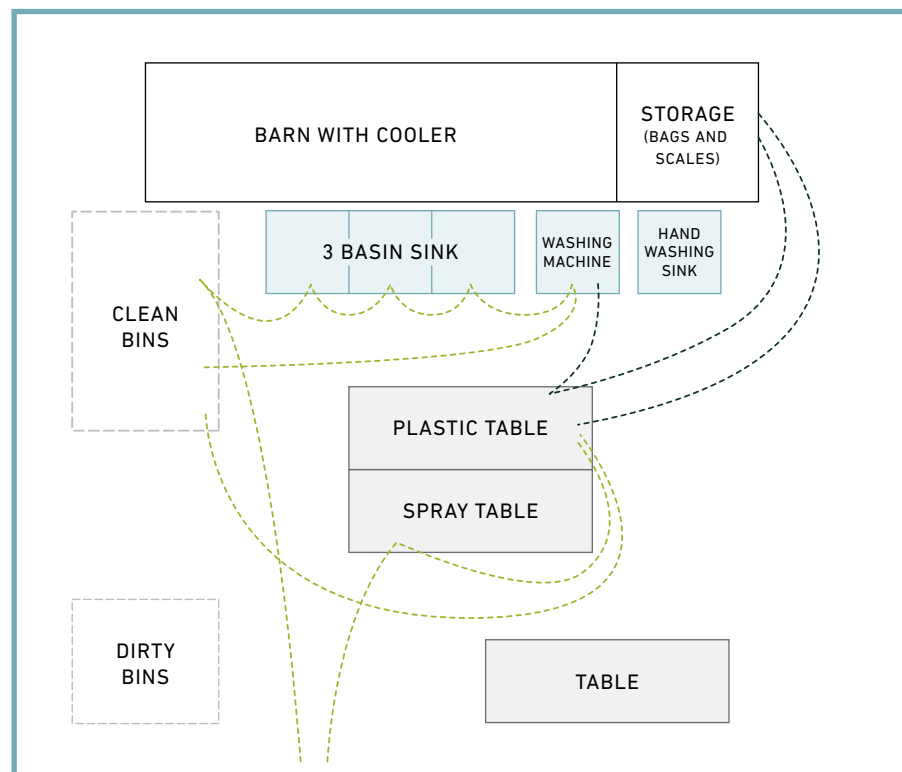
5. 21 C.F.R. § 112.113.
6. 21 C.F.R. § 112.114.

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 considering 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."⁷ 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 space, 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



7. 21 C.F.R. § 112.126 (a)(1)(i).

that you can properly store, clean, and sanitize your equipment. It is hard to clean something when it is jammed against a wall. A recommendation is to place any storage shelves or 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."⁸ 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, fuel, paint, or other chemicals **should** also be separate from the areas where you wash and hold produce.

There are countless ways that you can improve food safety in the space where you wash or pack 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 (see page 110). Minimizing criss-crossing paths is more efficient and can reduce cross-contamination. Ideally, the route of dirty produce and the route of clean produce shouldn't cross.

You'll need handwashing facilities near the toilets or portapotties. 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

8. 21 C.F.R. § 112.126.

happy to grow in drains, inside coolers, and can be transmitted by condensation. For that reason and others, try to minimize puddles, by minimizing over-spray, using catch basins which can be easily cleaned, or even using a broom or floor squeegee if you have concrete. A backed-up drain, could be a significant food safety risk as workers can track microorganisms from the puddles around the farm. Keeping floors free from debris can help keep your drains clear. You should manage condensation and puddling on the floors in your cooler as well.

Consider 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 vehicles don't walk or drive through that water, potentially tracking contamination around the farm. It **should** not 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 Room Clean and Tidy

Keeping your packing space clean and tidy is a great first step. 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.⁹

You might consider having separate bins for produce, compost, and trash. Don't use the same bins for produce as for culls, if possible. Label the compost and trash bins clearly. Take out the trash and compost at the end of each packing day, or more frequently as needed. Consider lids for the trash cans and have enough trash cans.

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.¹⁰ 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.

9. 21 C.F.R. § 112.132 (a)(b).

10. 21 C.F.R. § 112.128. 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. Add 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.

Be Smart About Surfaces

You **MUST** prevent contamination of food contact surfaces, including the drains on equipment. The definition of food contact surfaces is on page 99, but remember you should also consider other surfaces that might drip, leak, or splash onto food or food contact surfaces. If condensation is dripping off a cold water line above your packing area, that pipe or hose should be considered a food contact surface. That means that you should be cleaning overhead fixtures to prevent the buildup of biofilms.¹¹ Also, think about what workers lean on or touch while dealing with produce in this area. 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.

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.¹² 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-toxic, non-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 Rule 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. Ensure welded areas are smooth and clean them carefully. These areas, especially on an imperfect weld, are a place for pathogens to hide.
- Any oils and lubricants for harvesting or washing equipment **should** be food grade.

11. 21 C.F.R. § 112.126(b) and Response to Comment 352 in the Preamble of the Rule.
12. 21 C.F.R. § 112.123.

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 pathogens and cause them to fly everywhere. This can potentially cause additional contamination. Food safety experts suggest only using power washers outside or far from food contact surfaces.

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 so that they won't get contaminated. Ideally, harvest bins would be stored under cover, separately from dirty bins, and off the floor. Workers **MUST** inspect bins before using them to be sure that they're clean. 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.

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.

Are You Cleaning and Sanitizing:

- Harvest knives, scissors, clippers
- Table tops
- Workers' hands (didn't you read Chapter XXX?)
- 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.



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. 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.¹³ 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**

13. 21 C.F.R. § 112.126 (b)(2).

be accurate, calibrated, and maintained.¹⁴ The job of monitoring your cold storage is a good one for a WiFi enabled system.

Food Safe Containers

According to the Produce Safety Rule, you **MUST** only use new, single-use containers or cleaned, reusable containers to pack produce. In order to reduce waste and costs, some farmers use liners in reused boxes or berry containers. Sadly, this creates more plastic waste. We see some 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 chapter 8 on postharvest water 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 between types of uses, and make sure to inspect it before harvesting or loading in produce. If you hire someone else to transport your produce, inspect their vehicle for debris or unusual odors. (Is it really clean or did they just spray air freshener?)

Safety Data Sheets

Safety Data Sheets (SDS), documents about chemicals, dangerous substances, and how to handle these materials provided by the manufacturer of the chemical, **should** be on site or easily accessible in case of a medical emergency.

14. 21 C.F.R. § 112.124(a)-(c).

Harvest and Postharvest Records

REQUIRED:

- Training logs for workers¹⁵
- Logs of cleaning and sanitizing of tools, equipment, and containers used for harvesting, packing, and holding activities¹⁶

SUGGESTED:

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

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

¹⁶ 21 C.F.R. § 112.40 (b).

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 OUTLINE¹

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.



1. Adapted from UP Food Exchange, PSA, Penn State.

Food Safety Plan Outline

1. **Farm name and address**
2. **Farm description** (potentially pulled from your business plan if you have one)
3. **Name and contact info for farm food safety manager** (which may be the farm owner)
4. **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**
 - Handwashing
 - 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 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 you irrigate and what kinds of water sources you use
 - Source of water for crop sprays

(Outline continued on next page.)

- Where the water for your washing and packing space comes from
- Harvest Practices: include description of tools, containers, vehicles
 - Rules about what workers are trained to look for (poop, glass, debris, contamination), also no dropped or rotten produce
 - Methods of making sure tools, containers and vehicles are clean
- Postharvest handling description of space, practices, tools, and rules
 - Buildings and uses: how it is designed and maintained: Floors, drains, walls, ceilings, doors, coolers, storage, pipes and water management, lighting, equipment
 - Animal and pest management
 - Buildings and uses
 - Harvest and packaging containers
 - Equipment, including maintenance and cleaning
 - Cleaners and lubricants used
 - Ice use
 - Transportation
 - Sanitizers
 - Temperature control
 - Wash water schedule

5. Documentation in an appendix:

- Farm Map(s)
 - Production fields
 - High Tunnels
 - Barns
 - Buildings and uses
 - Manure or compost storage areas
 - Livestock/dairy pastures and facilities
 - 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 Land Assessment (see page 73)
- Pre-harvest risk assessment
- Compost turnings and temperature
- Compost tests or Certificate of Conformance (see page XXX)
- Pest control
- Wellhead inspection
- Cooler temperature log
- Corrective Actions you've taken when problems arose
- Agricultural water test results
- 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, especially:
 - Handwashing
 - Cleaning and sanitizing of different food contact surfaces
 - Cleaning your harvest or market vehicle
- Worker training agenda(s) and attendance records

6. Emergency contact information for farmers or food safety boss

7. Supplier and buyer information and contact numbers

- Compost
- Soil amendments
- Packing/packaging materials

8. Traceability program and results of previous traceability exercises

9. Recall plan (see online Model Recall Plan from University of MD)

- Name and phone numbers for food safety manager on your farm
- Contact of FDA Regional Recall Coordinator
- Phone numbers for various sales channels- farmers markets, restaurants, wholesalers, anyone you'd need to call if you wanted to recall a load of produce
- Script for making these difficult calls

10. Contact info for contracted service

- Port-o-potties
- Transportation

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. Your traceability program follows your 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 harvesting and labeling produce that will leave the farm. Again, having a traceability program is not a requirement of the Rule.

Information for harvest or packing logs:

- 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: what amendments applied, when irrigated, etc.

Information for labels or invoice:

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

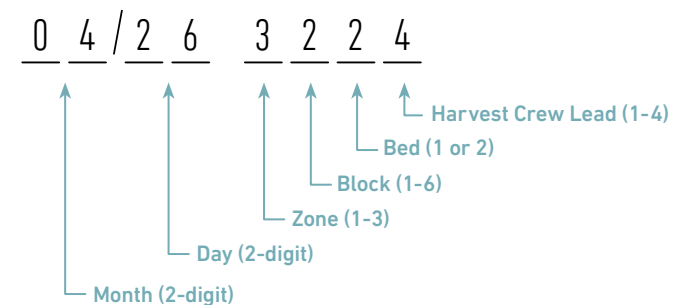
LOT CODES

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, Arkansas creates their lot code. Lot numbers are generated using the following template at the time of harvest:



Being able to trace your produce 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.

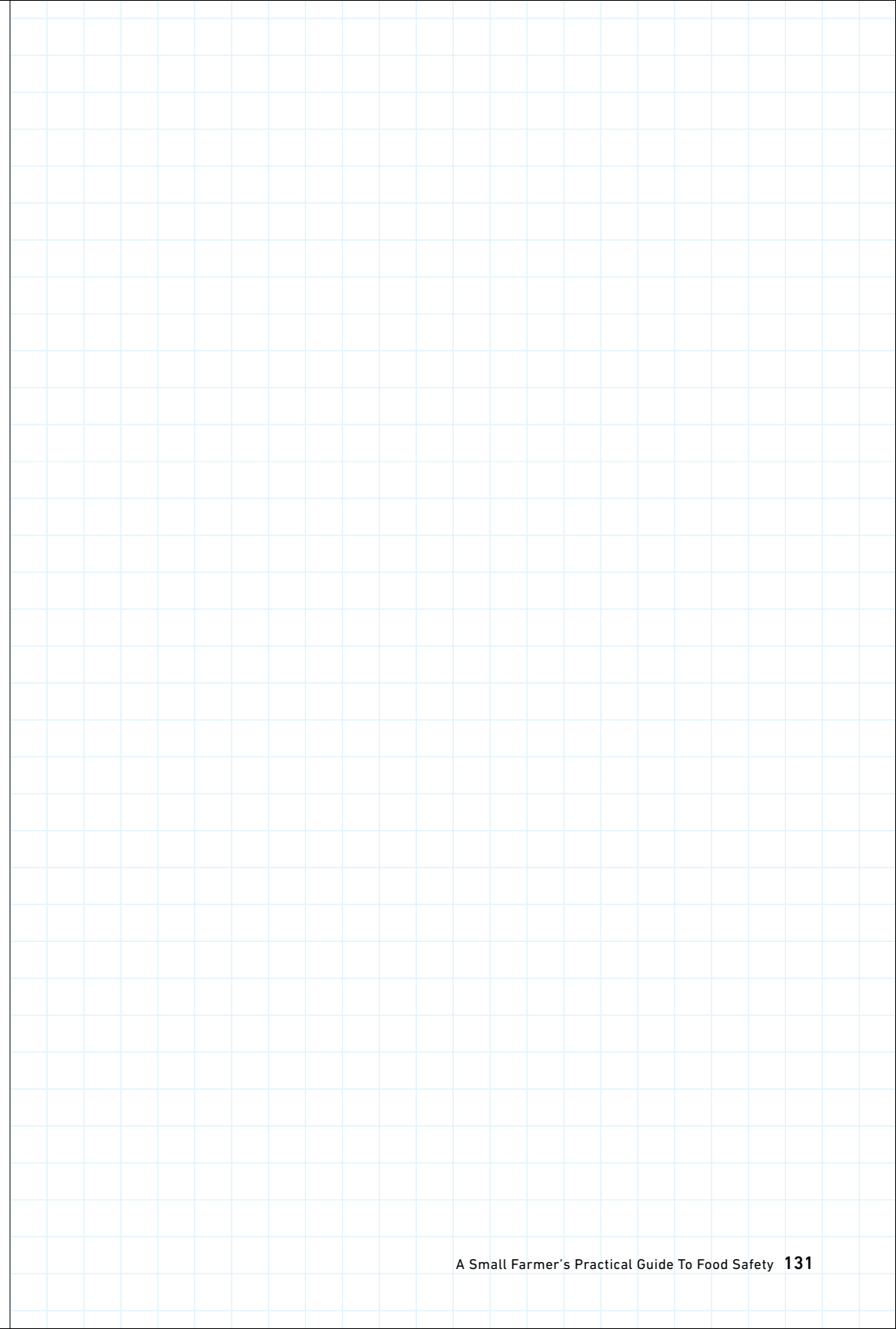
CLEAN BREAKS

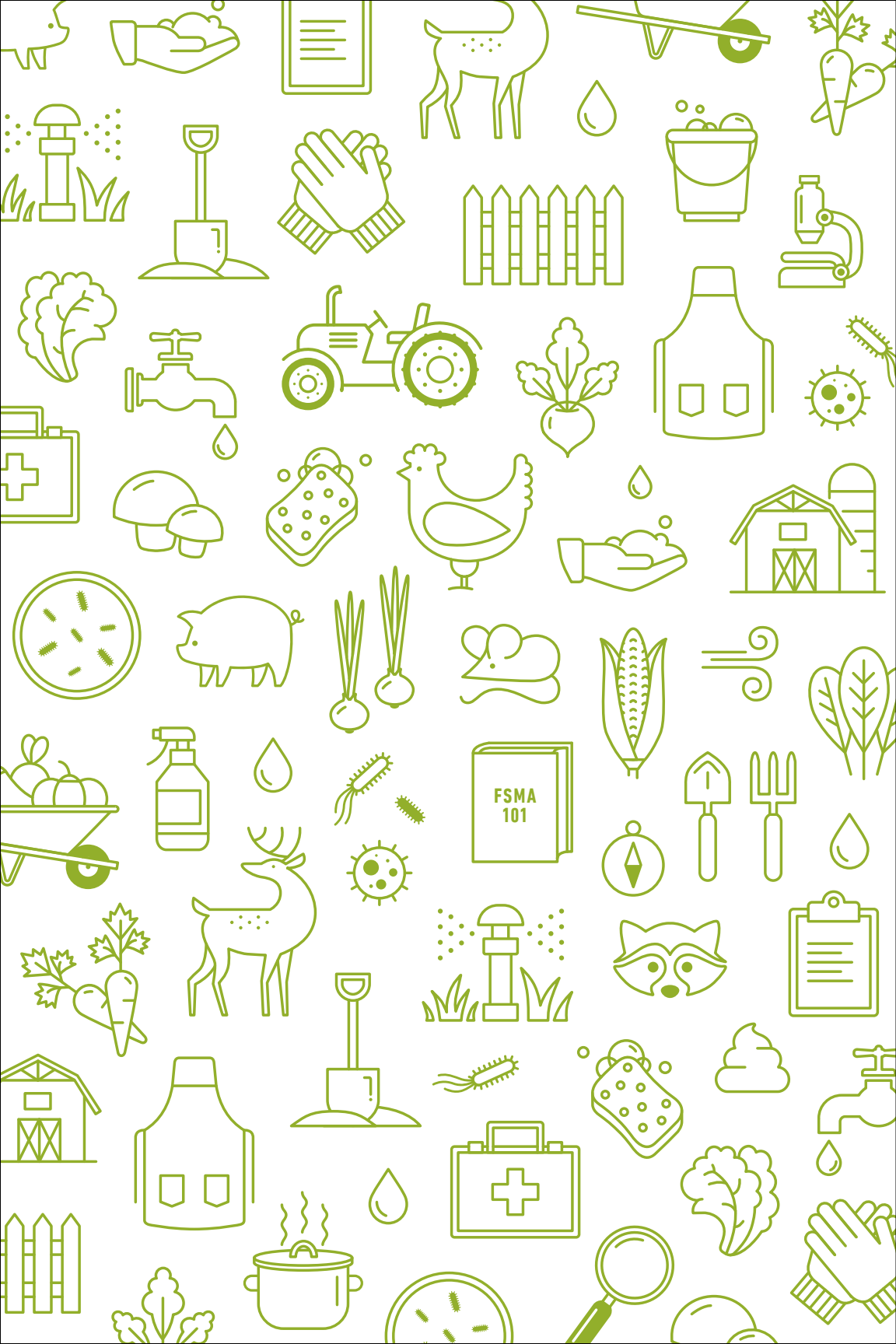
You can establish a clean break after taking the steps to clean and sanitize food contact surfaces (see page 115). This helps limit the amount of produce subject to a recall or withdrawal should you have a problem with contamination.

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 our online resource library for more lot info.

RECALL PLAN

We hope that you never have a recall! However, you might want to 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. The University of Maryland has a Model Recall Plan.





Chapter 11

Final Thoughts

WHAT CAN YOU DO TO LEARN MORE?

We've said it before, but we'll say it again: take a training to learn more! There are lots of trainings available about GAPs or the Produce Safety Rule. Check the Produce Safety Alliance website or with your local extension office. Or contact us!

ON-FARM READINESS REVIEWS

Many states are offering On-Farm Readiness Reviews (OFRRs). These are educational visits by a team of inspectors and extension educators. The aim of these visits is to help your specific farm see what you could change to make your produce safer, prior to having a Produce Safety Rule inspection. During these visits, the inspectors and extension educators will ask questions, walk around the farm with you, and check out your operation and teach you in a conversational way. At the end, they'll provide you with some areas for improvement. The OFRRs are meant to help covered farms feel fully educated before inspection; if you are Not Subject or Qualified Exempt, you **should** check with your extension to see if your state offers OFRRs for farms like yours.

If an "egregious condition" is noticed during an OFRR, the state department of agriculture or other regulatory body could take action to make sure that the situation is fixed, the contaminated produce doesn't enter the marketplace, or sold produce is recalled if necessary. This clause worries some growers, but FDA and state agencies have insisted that they would only take action in "egregious" situations where serious food safety violations are occurring.

For privacy reasons, the teams conducting the OFRR *should* not take any pictures, nor leave the farm with any notes. The OFRRs are meant to be a tool to help farmers understand how they would fare during an inspection. There isn't a charge for the OFRR and they are completely voluntary.

FARM INVENTORIES

Because there hasn't been a reason for state agencies to know about farm incomes before, there isn't a clear list of farms that will need to be inspected. Some farms might seem really large but be Qualified Exempt or others might make an ample income from a small but intensively cultivated space. So, in order for state agencies to know how many farms they're going to need to inspect, they're trying to do an inventory of farms. This inventory is an important first step and can even impact how much funding a state receives to hire inspectors or educators. This inventory isn't mandatory, but we suggest sharing your sales numbers to make the process go smoothly.

WHAT TO DO WHEN THE INSPECTOR CALLS?

If you are Qualified Exempt, you should not receive an inspection. Likely, the state agency in charge of inspections will contact you at some point. Because you'll be keeping great annual records, like a Qualified Exemption Annual Review, to prove your exemption (Right?! for a refresher, see page 24), you can happily offer to show or send those records to your state inspection agency.

If you're feeling nervous about this, you could say something like this, "Thanks for calling. We're aware of the Produce Safety Rule and its requirements, and have determined that we're Qualified Exempt, and so we shouldn't need an inspection. I can show you or send you my annual financial review that will prove my qualified exemption. Where should I send it?"

You could add, "So you know, we've attended a Produce Safety Alliance training and take food safety very seriously, and stay abreast of current issues to improve our practices. I'm happy to be on your newsletter list so we can be updated on upcoming events or announcements." Remember, inspectors are people too, and tasked with a big job. They appreciate it when you are informed and sincere, but there is no need to volunteer information you aren't required to provide.

In some states (and depending on what agency is doing your inspection), those records could be subject to a state sunshine act and/or the the Federal Freedom of Information Act, in which case an interested person could file a request for that record and the state or federal agency may be required to disclose it. If you're uncomfortable about that, you can request that the inspector comes to the farm and to review your Qualified Exemption Annual Review record in person, but

the inspector still should not tour the farm. There's also exceptions to protect documents from disclosure under state and Federal law, and we briefly cover these in the Deep Dive Guide.

WHAT ABOUT INSPECTIONS?

States agencies will also play a role in the enforcement of the Produce Safety Rule. In most states, a state or territory government food agency—likely the department of agriculture or department of health—will inspect covered farms to be sure that they're in compliance. In some states or territories, the FDA will conduct produce safety inspections. Understand who is providing inspections in your state by checking out our Online Resource Library.

In some states, inspections will start for the largest farms, ones that sell more than \$500,000 in produce, in Spring of 2019. Inspections will be tiered, with the largest farms scheduled to be inspected first. (See the Deep Dive Guide for timing).

In most cases, the inspectors will call at least five days ahead of time and schedule an inspection. There will be an initial interview, a walkthrough of the farm, a review of required records, and an exit interview. For covered farms, these inspections can last more than a day. As we've written this guidebook to be about general produce safety for mostly Qualified Exempt farms, we'll point you toward the Deep Dive Guide if you want to learn more about inspections.

IF YOU AREN'T REQUIRED TO HAVE AN INSPECTION BUT WANT ONE

You might want a FSMA Produce Safety Rule inspection right now. Perhaps you're Qualified Exempt and aren't going to have an inspection but you've worked really hard on your food safety practices and want some signs that your farm would pass. Or you might be fully covered and required to be inspected, but your state is slower in implementation and your buyer is requesting some sign that you're ready to meet the Produce Safety Rule requirements. In these cases, you could request a Harmonized GAPs audit. Harmonized GAPs, which is a type of GAPs audit that is a little more stringent than some other GAPs audits, has been brought into alignment with FSMA's Produce Safety Rule. This means that, if you can pass the Harmonized GAPs audit, you should also pass the FSMA inspection (see Chapter 1). For 2019, the USDA is subsidizing 100% cost of Harmonized GAPs audits in 16 states so that growers who are being asked to "pass FSMA" by a buyer, can request these audits.

Conclusion

Thanks for reading! If you're reading this, you've made it through the entire *A Small Farmer's Practical Guide to Food Safety*! Thanks for your attention. We're hopeful that you've gleaned some tips, ideas, and strategies that you can use to start improving food safety on your farm. Please explore our online resource library at youngfarmers.org/foodsafety. And feel free to reach out to the National Young Farmers Coalition's business services team if you have any questions, concerns, frustrations, or resources that you'd like to share with us. Our email is services@youngfarmers.org. Speaking with farmers about food safety practices is one of our favorite parts of this job.

Disclaimer

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