



Roots FSMA Guide for Hawai'i Growers



About Roots

This guide is a part of the Hawai'i Roots Food Safety Outreach Project.

The Roots Program is the food arm of Kokua Kalihi Valley, a community health center that serves residents of Kalihi Valley. We understand health in a holistic way and use food as a vehicle to connect to each other, to our cultures, and to the `āina, in order to heal and better our community.

Some of our projects include: a cultural food hub to support local growers and bring fresh produce to the Kalihi community; a cafe that serves `āina-to-table lunches; running EBT booths at 2 farmers markets in Kalihi; workdays at Ho`oulu `Āina and Mala O Kaluaopalena to teach others to grow food; technical assistance for our food hub partners; and much more. To find out more about what we do, please visit <http://rootskalihi.com>.

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Table of Contents

Introduction	1
What it is	1
What it's all about.....	1
The Produce Safety Rule	4
This guide will help you to	4
Who will the Produce Safety Rule apply to?.....	5
Full Exemption	5
Qualified Exemption	6
Produce Exemption.....	7
Deadlines (Compliance Dates)	8
Produce Safety Rule	9
1. Workers and Visitors.....	10
2. Soil Amendments	13
3. Animals.....	16
Rat Lungworm	18
4. Agricultural Water	19
5. Packing Area, Tools/Equipment, Transportation	24
Recordkeeping	25
Writing a Food Safety Plan.....	27
Appendix.....	29
Contact Info.....	30

Introduction

What it is

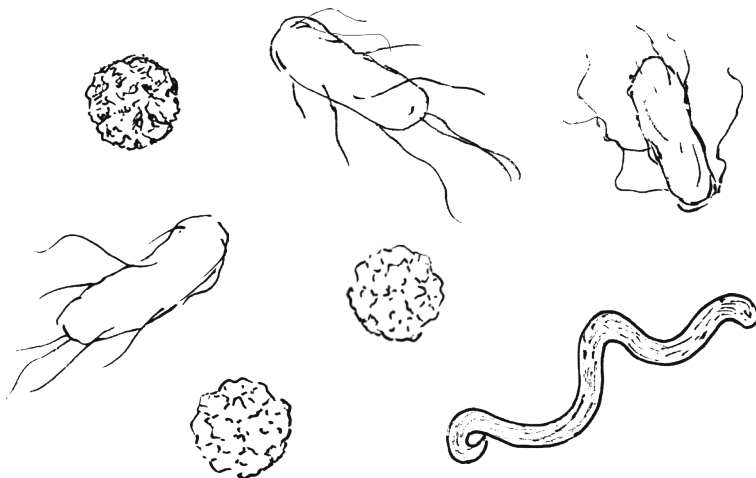
The Food Safety Modernization Act (FSMA) is the biggest update of the United States' food safety laws in 70 years.

What it's all about

When FSMA talks about food safety, it is mainly worried about this:

*We don't want people eating
the food we produce to get sick.*

(i.e. food poisoning/foodborne illness from salmonella, E. coli, stomach flu virus, parasites, etc).



Foodborne Illness Statistics

- Salmonella and norovirus (stomach flu) are most common.
- Sprouts are most risky. Leafy greens cause many outbreaks because a lot of it is eaten raw.
- In the US, <1000 foodborne illnesses a year from produce that was contaminated before it got to the store, restaurant, or home (out of 48 million foodborne illnesses overall).
- Many cases go unreported.

Recorded Foodborne Illness Examples in Hawaii (since about 1985)¹:

- 15 confirmed cases of rat lungworm disease on Maui and Big Island in 2017 (as of May 11)
- 1 outbreak (14 illnesses) of Salmonella from ogo grown in Kahuku (2016)
- 1 mac nut producer found contaminated with salmonella, but no reported illnesses (2015-16). Nuts sold "raw" (just dehydrated) not roasted like the typical product.
- 1 outbreak (8 illnesses) from contaminated lettuce traced to Kaua'i farm, likely due to runoff from neighboring cattle operation (2007)
- About 60 other cases of rat lungworm, mostly on Big Island
- 1 outbreak (38 illnesses) of Salmonella from local eggs
- Most outbreaks are from imported produce.

¹ See Appendix, page 30, for sources.

At Roots, we wanted to expand on the definition of food safety. We wanted to engage in a deep conversation about how we as a community define food safety, and what that means for a local, resilient, and sovereign food system in Hawai'i. We created space for this conversation in two ways.

1. We interviewed local businesses that buy produce about how they view food safety. Below is a summary of buyers' main concerns and how that might affect local farmers:

- Buyers are not too concerned about FSMA, since they believe that their own requirements are already more strict.
- Buyers will turn to stateside suppliers if local farms are unable to comply with FSMA.
- Most buyers will increase food safety requirements over the next 5 years because of market and customer pressure.
- Buyers do have some control/wiggle-room over how strictly they enforce their requirements. Large food distributors and processors are more strict, grocery stores vary more.
- Some buyers prefer suppliers show some form of food safety plan, policies, or product flow diagram.
- Most buyers do site visits, mainly look for: chemical storage, packing area design/sanitation, pests (rodents, insects, etc).
- When deciding on suppliers, buyers value: consistency and quality of produce (more than scale/volume); turnaround time for orders; legal risk (don't want food safety lawsuits, so pass it back along the supply chain).
- Some buyers have misperceptions about food safety: mixing up the produce quality (i.e. freshness/looks) with safety; mixing up recommended practices for food-processing facilities vs farms (ex: complete animal exclusion for food).

2. We held a pa`ina and invited people across O`ahu's food system from farmers to community activists to organizations to express and discuss what food safety means to them.



What does "safe" mean?

When you know where the food comes from and who grew it; when the land is healthy and people are healthy; a local food system where people are connected to one another.

What makes food unsafe?

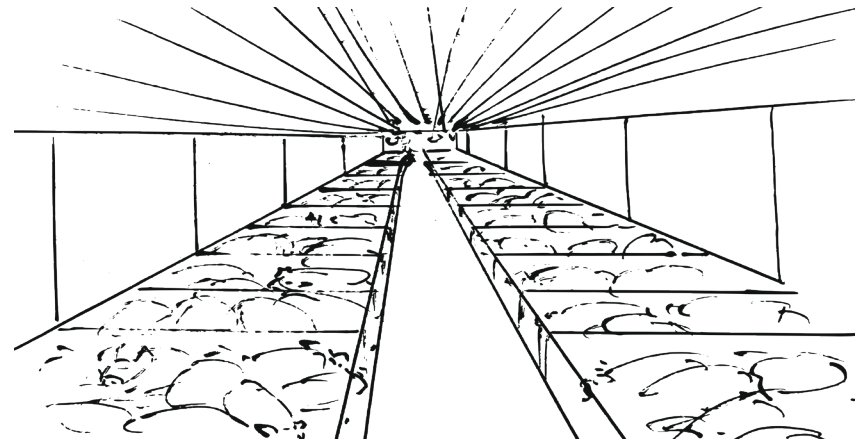
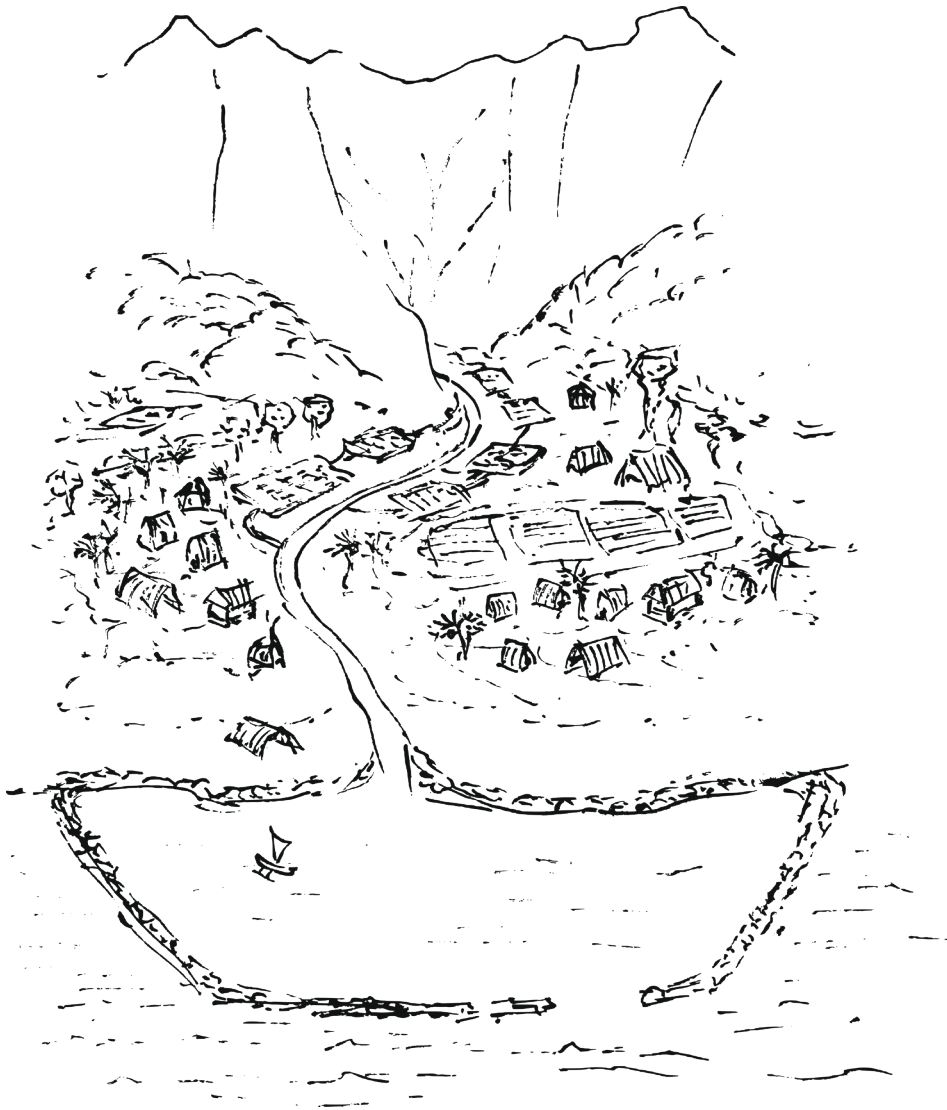
When farmers, sellers and consumer are disconnected from one another, food becomes unsafe; the industrial food system itself; pesticides, herbicides, and other chemicals.

How do we make food safe?

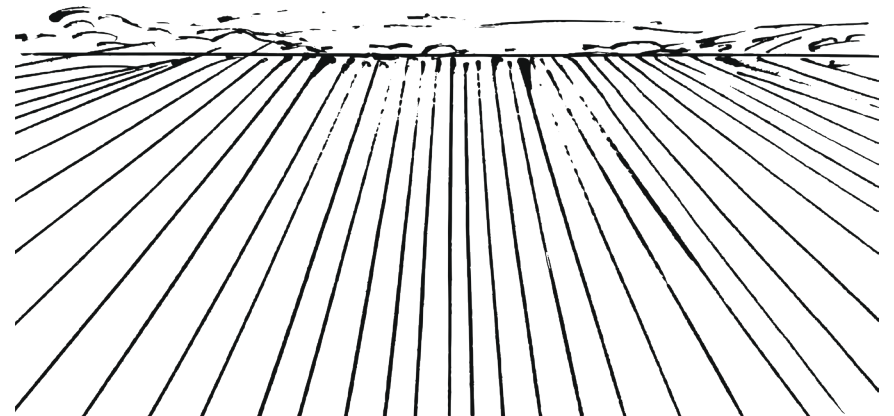
Build a local food system, build relationships with food growers and consumers, organize, elect people who are dedicated to this purpose.

What did we miss? What does food safety mean to you?

Our kupuna knew how to grow, forage, prepare, and preserve food (ex. fermentation) in ways that were in balance with natural cycles and systems. **What was pono also kept people safe** - balance in natural systems also kept pathogens in check.



On the other hand, our present-day industrialized food system, produces food on a large scale, in conditions that are out of balance with natural cycles and systems. Researches have argued these conditions allow certain pathogens to emerge, thrive, and spread more easily.²



FSMA's rules are built for these conditions—for factory farms and food processing plants—and can be difficult to adapt to the diversity of practices that small farms have developed to take care of their crops, soils, water, and communities.

Knowing this, **our intention is to help break down the federal regulations to make it clearer for small farmers in Hawai'i** and how they will specifically affect Hawai'i farmers.

The Produce Safety Rule

There are 7 primary rules included within FSMA. Hawai'i farmers mainly need to worry about the first one*:

1. **Produce Safety Rule**
2. Preventive Controls for Human Food
3. Preventive Controls for Animal Food
4. Foreign Supplier Verification Programs
5. Accreditation of Third-Party Auditors/Certification Bodies
6. Sanitary Transportation of Human and Animal Food
7. Prevention of Intentional Contamination/Adulteration

The Produce Safety Rule sets standards for growing, harvesting, packing, and holding produce (fruits and vegetables) that will be sold and eaten by other people.

Because FSMA is a law, these standards are also regulations that will be enforced most likely by Hawai'i Department of Health and Department of Agriculture.

This guide will help you...

1. Figure out if the Produce Safety Rule regulations apply to you (you could be exempt!).

If the rules do not apply to you, you won't be legally required to follow them, but it will be good to know what the standards and best practices are to prevent the spread of disease.*

2. Learn what the Produce Safety standards/regulations are.

These standards/regulations help you determine what you are already doing to prevent human disease from spreading, and what you can do to better.

3. Create a food safety plan.

Make sure your farm and practices follow the standards/regulations before the deadline, when they will start enforcing them (Compliance Dates, see page 8 for more info).

* Do I need to worry about the other rules?

If your farm does anything to **turn raw produce into a processed food** (cutting, cooking, canning, etc), you may also count as a "farm mixed-type facility" and **have to deal with Preventive Controls for Human Food**. Harvesting, packing, holding, ripening, drying/dehydrating raw produce does NOT count as processing. Farms can do these things WITHOUT having to deal with Preventive Controls.

* If you are exempt, you may still need to:

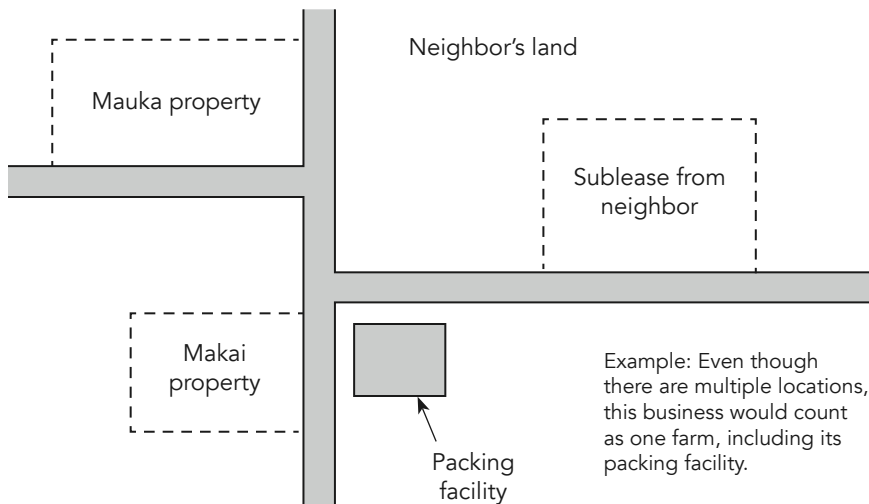
- Keep sales receipts and other records (verify exemption status).
- Label produce packaging with farm name and business address.
- Follow good practices (if outbreak traced to your farm, exemption withdrawn).

Who will the Produce Safety Rule apply to?

The Produce Safety Rule applies to any farm that grows or handles produce (fruits and vegetables) that will be sold to and eaten by other people.

What counts as a farm?

- Has to be under 1 management, can be multiple locations.
- Activities include growing, harvesting, packing, or holding crops.
- If you sell as a co-op, each member farm will be responsible for ensuring its own compliance with the Produce Safety Rule.
- For more information about what counts as a farm, see Appendix (page 29).



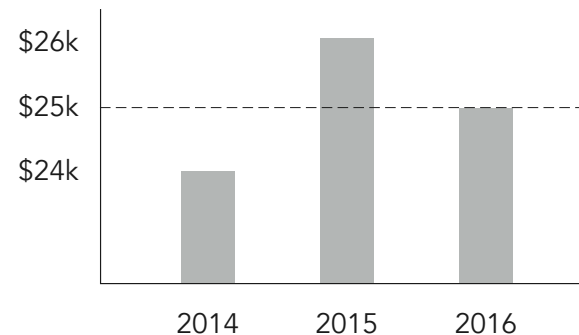
There are 3 types of exemptions:

- Full exemption*
- Qualified exemption
- Produce exemption*

Full Exemption*

You are fully exempt and the Produce Safety Rule does NOT apply to your entire farm if:

- you do NOT grow, harvest, pack, or hold produce
- OR - you sell **\$25,000** or less of **produce** per year (**average** of last 3 years, you will need to show documentation to prove this - ex. sales receipts)



Example:
This farm would be exempt even though one year is over \$25k, because the exemption looks at the **average** of the past 3 years.

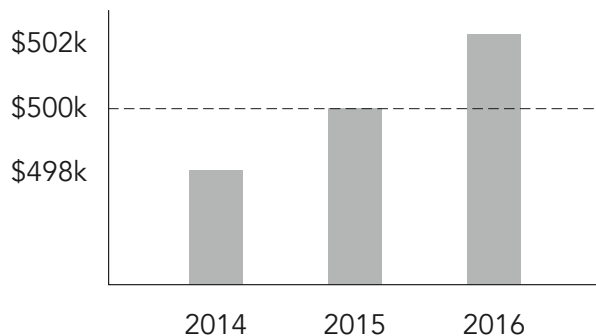
* "Full exemption" and "Produce exemption" are not official FSMA terms. They are terms we are using to make the exemptions easier to understand.

Qualified Exemption

(only has labeling requirements)

There is also a “qualified exemption” which is different than an full exemption. You can get a qualified exemption if:

1. Your **total food sales** (not just produce; includes animal/meat products, prepared food, etc.) is **less than \$500k per year** (3 year average)



Example:
This farm would be exempt for 2017 even though the previous year was over \$500k, because the exemption looks at the **average** of the past 3 years.

AND

2. Majority of that food is sold directly to:
 - The person who will eat it
 - Restaurant or retail food establishments in Hawai'i

Requirements for Qualified Exemption

If you get a “qualified exemption,” you will NOT be legally required to follow the *other* regulations in the Produce Safety Rule.

But you will need to have:

- **Labels** on produce packaging with **name of farm** where produce was grown and **complete business address** (street address/PO Box, city, state, zip).
 - You do NOT have to start labeling/packaging each unit of produce, if you don't already.
 - “Produce packaging” can be the box you send to retailers, but if you do package individual units, have farm name/address on it.
 - Farm Name/Address can be on the invoice you give with the produce to the retailer (but label the box also to be safe)
- **A sign at point of sale** showing **name of farm** where produce was grown and **complete business address** (street address/PO Box, city, state, zip), or in an electronic notice for Internet sales.
- All sales receipts must show: name/address of farm, date, item(s) sold, amount, price.
- Records (ex. sales receipts and taxes filed) proving that you are eligible (see above section).
- **Written statement each year** saying you checked your records to make sure you still are eligible for a qualified exemption, dated and signed.

Produce Exemption

If you don't meet the requirement for the other 2 exemptions, check if any of your produce is exempt. **You will need to check for each type of produce** (i.e. if you grow kalo, `uala, and mai`a, you will need to check for each one).

The Produce Safety Rule does NOT apply to a *specific produce type* if:

- It is for personal use or will be eaten on the farm.
- It will go to another business that will process it with a "kill step" (ex. cooking).

You will have to submit documentation (see right side of this page for required documentation)

- It is not raw when you sell it.
If you process the produce yourself in any way, including chopping, you might have to worry about Preventive Controls. Farms are allowed to dry or dehydrate without worrying about Preventive Controls.
- It is one of the following:
asparagus; black beans, great northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets (roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; water chestnuts.
- It is a grain.
(i.e. barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat)
- It is an oilseed.
(i.e. cotton seed, flax seed, rapeseed, soybean, sunflower seed)

All other produce NOT meeting the above will be subject to Produce Safety Rule regulations.

Note: Sprouts are covered by the Produce Safety Rule, but have their own regulations. The regulations for sprouts will NOT be covered in this guide. Please see the Sprouts Safety Alliance website for more information - <https://www.ifsh.iit.edu/ssa>

Documentation required for commercial processing exemption for produce:

1. A document stating the following disclosure:
"not processed to adequately reduce the presence of microorganisms of public health significance"
(use these words exactly), given with your produce **to the business that will process it**.
2. Annual written assurance from the business that will process your produce, saying one of the following:
 - The business that will process your produce has "established and is following procedures that adequately reduce the presence of microorganisms of public health significance"
(use these words exactly) and **what those procedures are**.
 - OR - one of *their* customers (ie. a business further down the distribution chain) will perform the processing step.

The above documents need to:

- Have name and business address of each person, date, signature.
- If handwritten, be readable and in pen (can also be electronic, or printed).
- Be kept for 2 years.

* "Produce exemption" is not an official FSMA terms. We are using it to make the exemptions easier to understand.

Deadlines (Compliance Dates)

Compliance Dates For:	Very Small Business (>\$25k-250k)	Small Business (>\$250k-500k)	All other Businesses (>\$500k)
Sprouts	1/28/19	1/26/18	1/26/17
All Other Covered Produce	1/27/20	1/28/19	1/26/18
Agricultural Water	1/26/22	1/26/21	1/27/20
Qualified Exemption Labeling Requirement	1/1/20		N/A
Start Keeping Records to Prove a Qualified Exemption	1/26/16		N/A

* Above business size categories are based on the average annual produce sales over the past 3 years

** Businesses that make less than \$25k of produce sales a year are exempt from the Produce Safety Rule. (See Exemptions section, page 5).

Notes:

Produce Safety Rule

The Standards/Regulations

Foodborne pathogens (bacteria, viruses, or other microbes that can cause disease, and are carried by food) spread through fluids or through direct contact.

There are 5 main sources on a farm that can spread pathogens to produce. We have split the Produce Safety Rule into sections, based on these main sources.

In each section, we will list:

- **Produce Safety Rule requirements**
(indicated by this kind of bullet)
- **Best practices**
NOT required by the Produce Safety Rule, but good to do (indicated by this kind of bullet)

The following sections talk about each of these sources, and how to prevent spreading disease.



1. Workers and Visitors



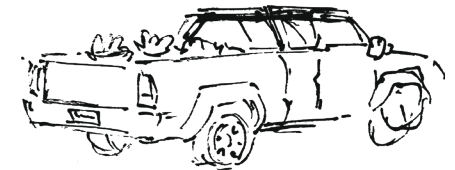
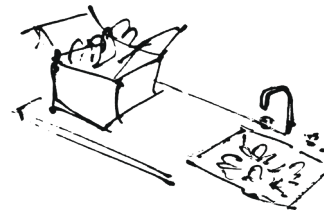
2. Soil Amendments



3. Animals



4. Agricultural Water



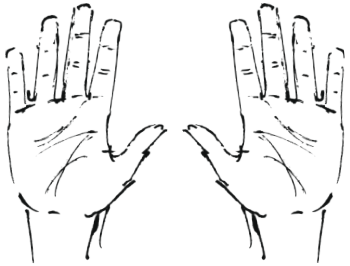
5. Equipment, Packing Area,
Transportation

1. Workers and Visitors

How People Spread Pathogens

Foodborne pathogens can live in poop, saliva, mucus, blood, other body fluids of infected people. Sometimes people don't feel sick, but are infected and carrying pathogens without knowing it. Even people who are not infected can spread pathogens if they touch something that is contaminated (has pathogens on it) and touch something else.

Ways people can spread pathogens:



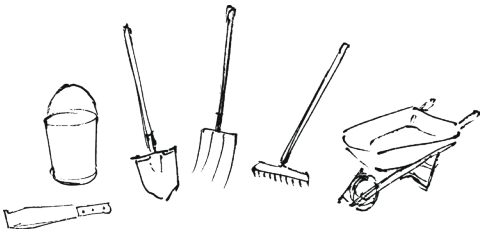
Hands

Not washing after going to the bathroom, eating, smoking, etc.



Air

Sneezing, coughing.



Tools/equipment

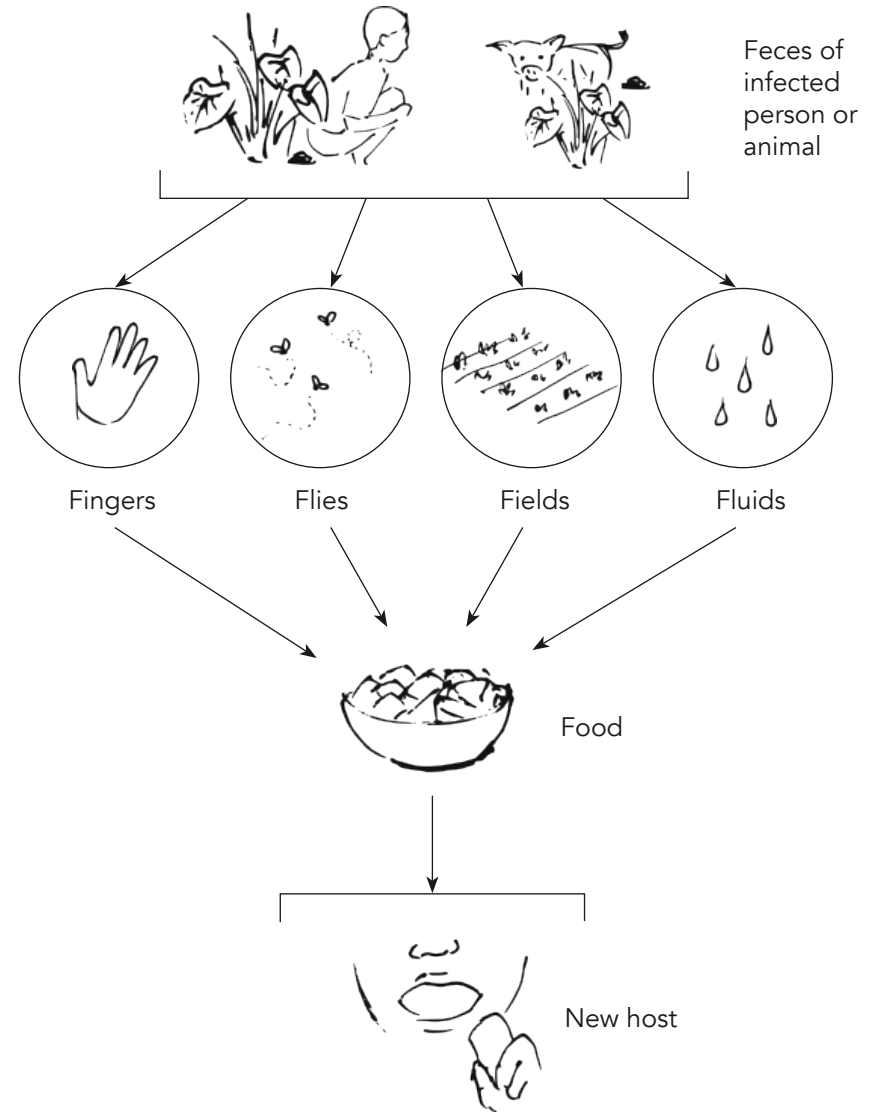
Picks up pathogens from hands or manure.



Clothes, Shoes, Gloves

What you're wearing picks up something that has pathogens in it (ex. animal poop).

Poop is the most common way foodborne pathogens are spread on a farm.³



Farms and workers can take action to prevent pathogens from spreading. The Produce Safety Rule tells what the FDA requires farms and workers to do.

Farm Kuleana

Under the Produce Safety rule, each farm is REQUIRED to:

- Give food safety training:
 - To any worker who handles or touches produce.
 - To anyone who supervises people who touch produce.
 - When people are first hired and at least once a year after.
 - (See right side of this page for what training should include.)
- Keep a record of who was trained, the date they were trained, and topics that were covered.
- Have at least one supervisor from the farm complete an FDA recognized food safety training.
 - One FDA recognized training is: Produce Safety Alliance Grower Training Course, <https://producesafetyalliance.cornell.edu/training/grower-training-courses>
 - If that person leaves the farm, another person on the farm will have to do the training.
- Provide toilets close to growing area, and toilet paper. Make sure toilets are working and cleaned regularly.
- Provide somewhere to wash hands with running water, soap (hand sanitizers don't count), and a way to dry hands (can't be a reusable towel).
- Inform visitors of the food safety policies (that the farm determines) + where toilets and sinks are.
- Tell workers to notify supervisor if sick.
- Make sure sick workers do not contaminate covered produce or food contact surfaces (assign to different job or send home).

Trainings for workers are required to include:

- Food Safety 101
Principles of food safety and food hygiene (how to prevent spreading foodborne illnesses at every point of process from production to consumption - growing, harvesting, processing, storage, distribution, transportation and preparation).
- The importance of health and personal hygiene for all workers and visitors.
- How to recognize symptoms of foodborne illnesses (food poisoning).
 - Most common: nausea, vomiting, or diarrhea
 - Can also happen: fever, bloating, gas, stomach cramps, headache
- The Produce Safety Rule standards that have to do with the worker's job.

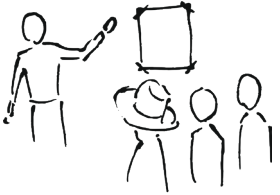
Not under Produce Safety Rule, but is required by Occupational Safety and Health Administration (OSHA):

- Provide drinking water to workers.
- Provide first aid kit.

These aren't the only practices for food safety around workers and visitors. What are you doing that wasn't mentioned? If you can kōkua your fellow farmers by sharing what you know, that can do even more to keep our communities healthy.

Worker Kuleana

Under the Produce Safety rule, workers are REQUIRED to:



- Attend training provided by the farm, when:
 - First hired
 - Once/year after that
 - If issues need to be addressed



- Wash hands:
 - Before starting work.
 - Before putting on gloves.
 - After using the toilet.
 - After breaks.
 - ASAP after touching animals, animal poop, or other material that comes from animals.
 - Any other time you might have touched something that has pathogens.

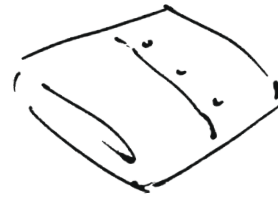


- Avoid touching non-working animals (like pets).

- Maintain "personal cleanliness" (shower/bath, brush teeth, wear clean clothes, etc).
- Make sure gloves clean and intact, if used.
- Remove or cover hand jewelry that cannot be easily cleaned.
- NOT eat, chew gum, or use tobacco near produce, whether growing or packing area (drinks allowed).

Best Practices for Workers

Workers should:



- Wear clean clothes, do NOT go near produce if wearing clothes or boots that have been near animals or poop.

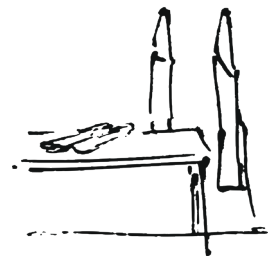


- Tell supervisor if sick.

- Poop and pee in toilets only, definitely NOT where produce is growing.



- Throw used toilet paper in toilets only, NOT floor or garbage.



- Take off aprons, gloves, etc before using bathroom.

2. Soil Amendments

What are soil amendments?

Anything added to the soil to improve plant growth or improve soil functions, such as ability to hold water.

- Examples: fertilizers, compost, manure, perlite, bone meal, yard trimmings, natural mulch, bokashi, etc.

This also includes agricultural tea, a water extract of biological materials.

- Examples: compost tea, bokashi tea, or fermented amendments used in Korean Natural Farming (i.e. fermented plant/fruit juice, effective microorganisms, etc)

The Produce Safety Rule has regulations 2 types of soil amendments only:

1. Human waste - poop and pee
2. "Biological soil amendments of animal origin" i.e. manure and anything else added to the soil that comes from animals (bone meal, blood meal, feather meal, fish emulsion, worm castings, etc).

What kinds of soil amendments do you use? If you do NOT use any of the regulated soil amendments (or plan on using them in the future), you can probably skip this section.

There are 4 things farmers can* to do, to make sure disease doesn't spread through soil amendments. We will talk about each of these things in more detail in the sections below.

1. Don't use human waste.
2. Treat raw manure to reduce pathogens.
3. If using raw or untreated manure, apply to fields that are NOT planted with produce.
4. After applying manure, wait as long as possible before harvesting produce.



Poop from humans or animals is the biggest spreader of foodborne pathogens.

* These are best practices, not Produce Safety Rule requirements. A specific list of requirements is listed on page 15.

** Any standards that mentions "manure" in this section, also apply to any other soil amendments that come from animals **

1. Human Waste

Do NOT use human waste (poop, pee, etc). Produce Safety Rule lists one exception (sewage sludge biosolids with requirements) if you really want to...

2. Treat raw manure to reduce pathogens

What counts as treating?

- Composting:
 - Minimum of 131°F (55°C) for 15 days
 - Minimum 5 turnings
 - Followed by curing
- Other scientifically valid, controlled processes
- For agricultural teas (see pg 13 for definition):
 - If contains material of animal origin, those materials have been treated
 - Water used in the ag tea is NOT untreated surface water AND has no detectable generic *E.coli*

* Note: FDA will not require you to have your treated soil amendments tested, but will look at your process documentation.

What counts as untreated?

A soil amendment of animal origin is untreated if it:

- Hasn't gone through process listed above. (Aged manure counts as untreated, even if it has been sitting for years.)
- Becomes contaminated after treatment.
- Is combined with untreated manure.
- For agricultural teas:
 - Contains untreated material of animal origin.
 - Contains untreated surface water or water with detectable generic *E.coli*.
 - Contains material of animal origin (whether treated or untreated) AND also an agricultural tea additive (a nutrient source added to increase microbial biomass - i.e. molasses, yeast extract, algal powder, etc).

3. If using raw or untreated manure, apply to fields that are NOT planted with produce.

(See "Best Practices" on page 15 for more tips on how/when to apply.)



4. How Long to Wait Before Harvesting (Application Interval)

After applying manure, it is best to **wait as long as possible before harvesting** - so plants can fully use nutrients and if there are pathogens they are more likely to die off.

For **untreated** manure, the application interval has not yet been determined, but will soon. The National Organic Program suggests farmers wait:

- 120 days before harvesting if edible part of produce touches soil.
- OR - 90 days if edible part does not touch soil (these are recommendations and not a temporary requirement of FSMA).

There is a 0 day application interval (you are not required to wait before harvesting) for soil amendment that comes from animals if:

- It has been treated.
- It is untreated but does NOT touch harvestable or edible portion of produce while you apply it and any time after.

Requirements for Soil Amendments

Under the Produce Safety Rule, you are REQUIRED to:

- Keep manure away from:
 - Produce
 - Surfaces that food will touch
 - Water sources
 - Other soil amendments
- Keep treated manure away from untreated manure.
- Handle or store treated manure as if untreated if you think it's been contaminated.
- If using untreated manure, apply in a way that doesn't touch produce when you apply it, and will touch produce as little as possible afterwards.
- Keep records for manure you receive from someone else or for your process of treating it (time, temperature, turnings).
- **Train workers who will handle manure.**
- Handle table waste (leftovers) and restaurant waste in the same way as raw manure (it can be contaminated from saliva or touching hands and counts as "biological soil amendment of animal origin").
- Handle wastes that animals have touched in the same way as raw manure.

Best Practices for Soil Amendments

It is good if you:

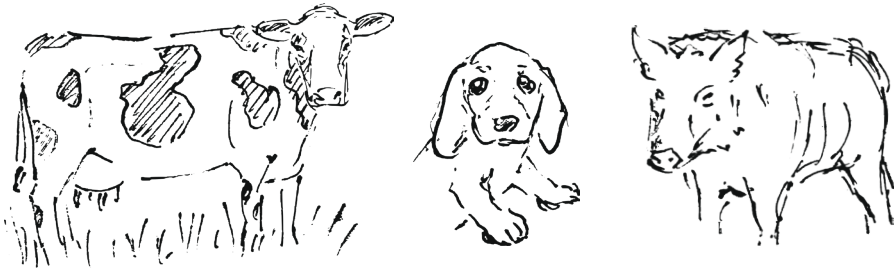
- Keep compost piles covered.
- Keep animals (pets and wildlife) away from compost piles.
- Store manure away from busy areas.
- Leave a buffer area when applying so manure doesn't go into nearby fields.
- Think of other market options in case manure does touch produce (ex. instead of selling raw produce directly to consumer, sell it to a business that will cook it. If you take this option, you will need some documentation. See "Produce Exemption" section, page 7).
- Set aside tools that will only be used for untreated manure.
- If a tool that touched untreated manure will be used in the field, make sure it is clean.
- Do NOT spread manure in high winds.
- Do NOT apply manure when ground is saturated, to reduce runoff.
- Do NOT side-dress (apply manure after crop is established) with raw manure.

** Reminder: any standard that mentions "manure" in this section, also applies to any other soil amendments that come from animals. **

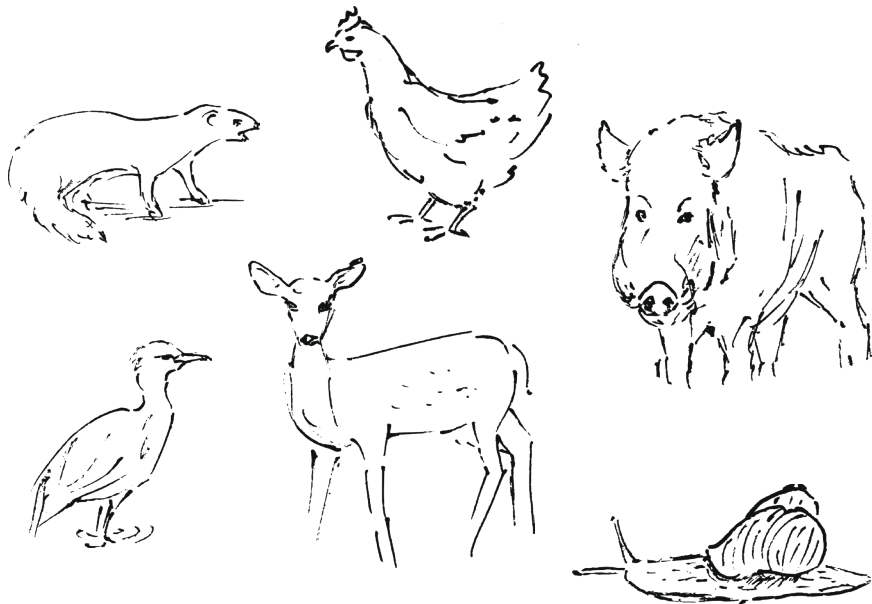
3. Animals

Animal poop and pee can contain pathogens that make people sick. If it touches produce and we eat it, it can make us sick. This includes:

- Domestic animals (pets, livestock, working animals) - since close to humans, more likely to carry pathogens.



- Wildlife (ex. mongoose, deer, wild boar, birds, snails, slugs; note: Hawai'i is different because lots of wild cats and chickens here, which is considered domestic in other places.)



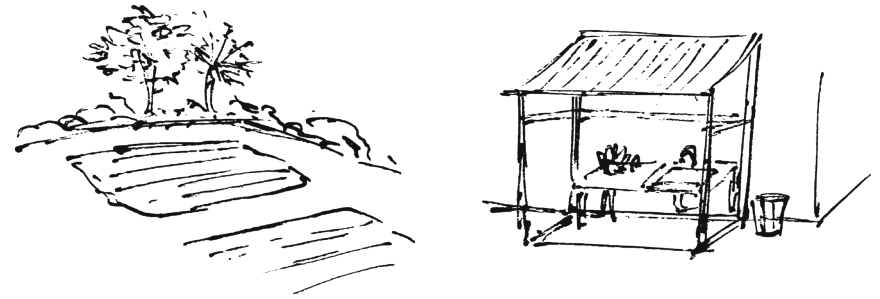
It's not possible to completely keep all animals out, so instead, the Produce Safety Rule **REQUIRES** you to:

- Keep watch for animals and signs of contamination (listed on page 17).
- Decide if still can harvest, don't harvest if you think it's contaminated.
- Definitely **do NOT harvest if there is poop on it.**
- If you accidentally drop produce, don't sell or give it to anyone outside the farm.

You don't have to do this for produce that grows in or on the ground (ex. kalo, `uala, kabocha, etc), or if bringing it to the ground is a part of harvesting.

You are **REQUIRED** to do the above for:

- **Outdoor areas or partially enclosed buildings**
Where you are growing or handling produce, if there's a chance animals will pass through.



You do **NOT** have to do it for:

- Fully-enclosed buildings
- Fish used in aquaculture operations

The following sections will help you identify signs of contamination from animals and what to do if you see them.

What to Watch Out For (Signs of Contamination)

- Animals passing through or tracks
- Animal poop left in the area
- Signs of animals messing with crops (trampling, rooting, feeding)
- Poop runoff to water source (could be from compost, manure storage, or neighbor farm) - good to look at this before planting

What to Do If There is Poop

If you see poop in the field, you can:

- Leave it, and don't harvest around it, mark area with flags (could spread).
- Bury it, make sure wash/sanitize hands and tools after.
- Sell produce to a business that will process the produce with a "kill step" (ex. cook it).

What are some effective methods that you use to deter wildlife? What wildlife are you having trouble with and need ideas for?

Best Practices

Good to do:

- "Co-management"
(Term that Produce Safety Alliance uses) keep food safe from poop in a way that also protects soil, water, air, and wildlife. Pros and cons for each practice, talk with others (local NRCS or Extension office, other farmers) to see what's best for you.
 - Example: hedgerow vegetation - supports pollinators and beneficial insects, but could attract other animals to come
- No pets in growing areas.
- **Train workers** to spot signs of animals and contamination and what to do if there is.
- Do NOT use bare ground buffers - leads to soil erosion and makes it easier for pathogens to spread through runoff.

If you take action to try to keep wildlife out, don't go crazy with the killing and destroying.

- You are NOT required to keep animals out of growing areas, destroy animal habitat, clear farm borders.
- Animal presence doesn't automatically mean crops contaminated.
- Wildlife can be good - (ex. animals that keep rodents in check).
- Do NOT clear river and stream banks (aka "riparian areas") - can actually make it easier for pathogens to spread.
- Produce Safety Rule REQUIREMENT: do NOT touch endangered species

Rat Lungworm

Overview

- Rat lungworm is a parasite that causes nerve and brain damage in humans.
- People get rat lungworm from eating a slug/snail or part of one. Not many of the worms are in the slime.
- For more information about rat lungworm see appendix.

How to prevent Rat Lungworm from spreading on the farm:

- Keep growing areas tidy - remove logs, planks of wood that snails/slugs like to hide under.
- Trap/remove slugs and snails:
 - Avoid squashing slugs/snails or applying contact-kill pesticides on crops. Killing a slug can release the worms, which can live freely in water for several weeks.
 - Slug/snail traps - put out shallow tins of beer (tuna fish can sized), slugs/snails are attracted to the beer and will drown or use commercial pesticide/bait (the active ingredient "iron phosphate" is safe to use around pets; "metaldehyde" is not).
 - Go at night and collect/kill them - wear gloves, use tongs. Throw slugs into a 15% salt solution after collecting to kill both the slug and the parasites.
- Trap and remove rats.
- Don't leave pet food/livestock feed outside or where it will attract rats, snails, or slugs.
- Feed animals away from growing area.

Tips for preventing Rat Lungworm disease, for consumers (share with your customers):

- **Cooking food is the safest** way to kill the parasites (and other foodborne pathogens). Recommended temperature of 165°F.
- Best way to clean produce is to use **running water** and rubbing produce, which physically knocks off slugs/snails. Dipping/dunking produce is NOT as effective.
 - Take more time with curly leafy vegetables, wash leaves individually.
 - Baby slugs/snails can be 1/4th inch long and translucent.
 - Do not squash a snail/slug that you find. This can release the nematodes, which can live freely in water for several weeks.
 - If you find a slug or snail, remove that section of the produce and throw it into a 15% salt solution to kill both the slug and the parasites.
- Adding chemicals, sanitizers, hydrogen peroxide, salt water, vinegar, etc to water is NOT any more effective at knocking slugs/snails off. Sanitizers are also NOT proven to completely kill parasites.
- Keep food covered, especially if eating outside.
- Don't leave food or pet food outside (which will attract rats, slugs, and snails).
- Don't drink from the hose.

4. Agricultural Water

The Produce Safety Rule has a specific definition for “agricultural water”. When it talks about agricultural water, it means water used on “covered produce” (produce that is covered by the rule) AND will touch:

- The harvestable or edible portion of the crop
- Surfaces that produce will contact (i.e. during washing or packing)

This means that a source of water you are using will NOT be subject to the Produce Safety Rule water requirements IF:

- It is being used for exempt produce ONLY.
- OR - It will NOT touch the harvestable or edible portion of the crop.
(ex. drip irrigation on fruit tree, but be careful - if equipment breaks can spray on crop)

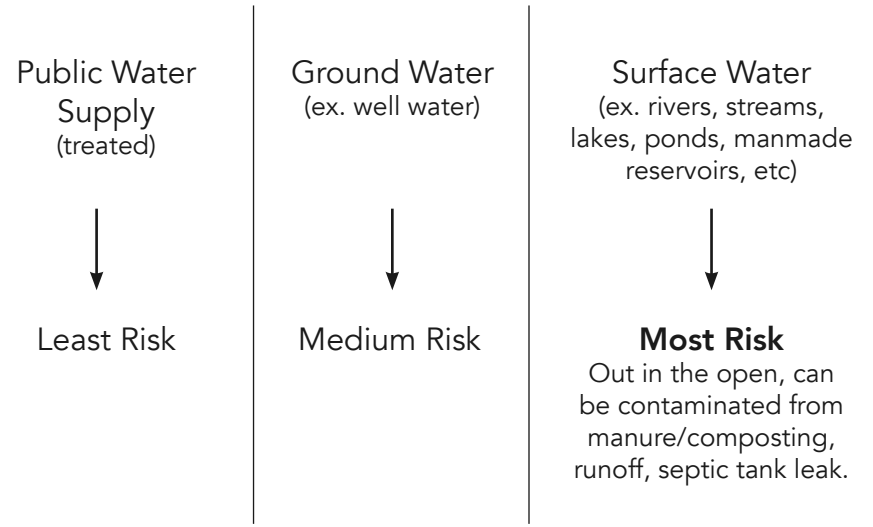
There are two different kinds of agricultural water:

1. Production Water - any water used during growing
2. Postharvest Water - any water used during or after harvest

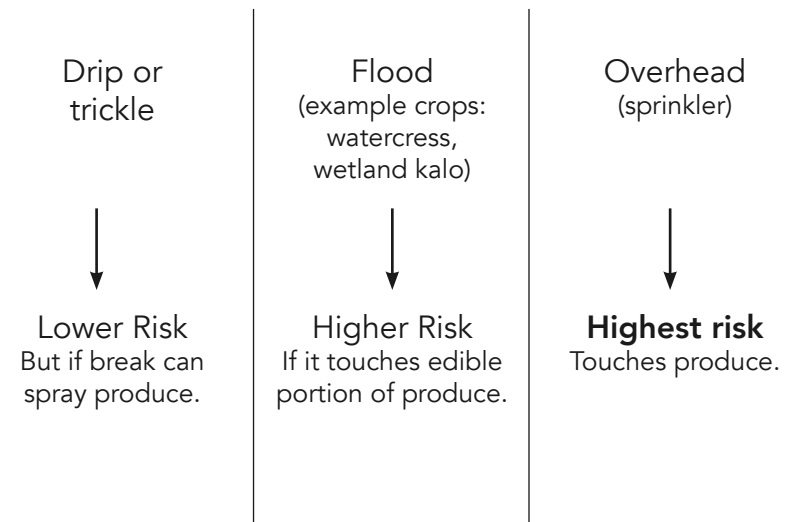
The Produce Safety Rule testing requirements are different for each (see the last part in this section for testing requirements for agricultural water).

Production Water

Pathogens spread easily through water. The Produce Safety Rule is mainly concerned about probability that poop from animals will get into the water - depends on source:



And whether that water will touch harvestable portion of crop. This depends on type of irrigation:



Requirements for Production Water

Under the Produce Safety Rule, you are REQUIRED to:

- Keep water free of debris, trash, domesticated animals.
- Inspect water sources and distribution systems once a year.
- Make sure your water is under the set limits for generic E. coli (see page 22 for testing requirements).
- Do NOT use untreated surface water for sprouts.

Best Practices for Production Water

Surface Water



- Look out for runoff sources and avoid planting produce downhill from runoff sources. (ex. manure or compost piles, livestock feeding area, etc).

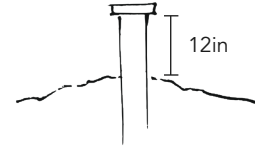


- Pay attention to how your neighbors are using their land, especially activities upstream (are they a source of runoff?).



- Use ditches and berms to control runoff.

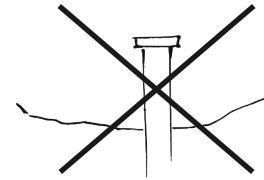
Ground Water



- Make sure well is well-constructed and in good condition (i.e. not too shallow, no cracks, etc).



- Make sure septic system is at least 100 ft from wellhead.



- Make sure well is capped, elevated, and land slopes down away from wellhead (so runoff doesn't go in as easily).



- Install backflow devices.

All

- Map out your water sources, for your own protection.
- Inspect your distribution systems.
- Get water tested if you think there is a problem.

Postharvest Water

Postharvest water is **any water that is used during harvest, washing, cooling and packing** - it includes water used for cooling, making ice, washing hands, cleaning surfaces, etc.

Postharvest water can become contaminated from touching something else that is contaminated - could be worker's hand, a container, equipment, etc. There is no way to know if water is contaminated with foodborne pathogens unless you test it or someone gets sick. If postharvest water is contaminated, you could be spreading pathogens to a lot of people and not know it. Below are tips to keep pathogens from spreading too much, in case your water is contaminated and you don't know it.

Produce Safety Rule requirements for postharvest water:

- Make sure there is no detectable E. coli in 100 mL of agricultural water (see page 22 for Agricultural Water testing requirements).
- Do NOT use untreated surface water for:
 - Anything that will touch produce during or after harvest (including making ice that might touch produce).
 - Anything that will touch a surface (container, table, etc) that produce will touch (aka "food contact surface").
 - Washing hands during/after harvest.
- Water from public water supply that is held in open containers outside counts as untreated surface water.
- Keep track of when water gets cloudy.
- If using recirculated or batch water, must set a schedule for changing water.
- Keep track of water temperature.

Best Practices for Postharvest Water:

- **Do NOT use untreated surface water for washing produce**, or doing anything else that will touch the produce.
- Running water is better than dipping/batch washing for washing produce.
- If batch washing, change water often, especially when it gets cloudy (set a limit for how cloudy and how often to change).
- Make sure temperature of water is less than 10°F different than produce.
- Watch out for produce, esp. fruit, whose skin breaks easily (ex. Tomatoes, mangoes, etc.) Can become contaminated on the inside (aka "infiltration").
- If using sanitizers (not required, but can help with preventing spread of pathogens):
 - See Appendix, page 29, for list of approved sanitizers (there are organic options; **bleach is NOT acceptable**).
 - Sanitizers are meant for *preventing the spread* of pathogens, not a guaranteed way of killing them.
 - Read the label! Make sure it is safe for washing produce, safe for your workers, and the environment.
 - Test pH of water (pH can affect effectiveness of certain sanitizers).
 - Make sure temperature of water is appropriate for the sanitizer.
 - Used water should go down a drain or into a catch basin, NOT outside.
 - Using a sanitizer counts as treating the water, so certain records are required (see "Required Records for Agricultural Water" on page 23).

Testing Requirements for Agricultural Water (for both Production and Postharvest Water)

Note: FDA is currently reviewing the water testing requirements, and the requirements may change.

Number of Tests

The Produce Safety Rule has different requirements depending on what type of water source you use:

Source Type	At First	Later On
Ground Water	4+ times during growing season OR over 1 year	1 time during growing season
Surface Water*	20+ times over 2 to 4 years	5 times each year
Public Water Supply	NO testing required if you have documentation (current water supply certificate from water utility, treatment plant, or lab)	

* For Surface Water:

- Must test each water source.
- Water samples must be representative of farm's use.
- Water samples must be collected as close to (but before) harvest as possible.

The series of tests will be will be your "Microbial Water Quality Profile." If your water changes, you will have to start the entire process over again.

How to Test

- You will need to test your water for **E. coli**.
- Find an accredited lab, certified by state environmental agency or third party accreditor. (See Appendix, page 29, for a list of food and water testing labs in Hawai'i.)
- Make sure lab can analyze the kind of water you need tested (i.e. surface water, agricultural water, etc). Some only test drinking water.
- Make sure lab can do a "**quantitative analysis using EPA Method 1603 (modified mTEC)**" or equivalent.
- Make sure lab provides instructions for how to collect and deliver the water sample.
- Costs \$30-50.

Do You Pass?

For **Production Water**:

- Using test results, you will need to calculate the Geometric Mean (GM) and Statistical Threshold Values (STV) using the test results you receive from the lab.
Tools for calculating here: <http://wcfs.ucdavis.edu/> (Western Center for Food Safety, UC Davis)
- Requirements need to pass:
 - Geometric Mean (GM): 126 or less colony forming units (CFU) generic E. coli per 100 mL water
 - Statistical Threshold Value (STV): 410 or less CFU E. coli per 100 mL water

For **Postharvest Water**:

- NO detectable generic E.coli in 100mL water sample

Testing Requirements for Agricultural Water (continued)

What Happens If You Don't Pass

For Production Water, you are REQUIRED to:

- Stop using the water ASAP (no later than the following year).
- OR - Do one of these "corrective measures"*:
 - Wait before harvest (must calculate "time interval").
 - After harvest, store for a certain amount of time (must calculate "time interval").
 - Re-inspect water system, identify problems, make necessary changes.
 - Treat water. (no specific type of treatment stated in Produce Safety Rule. Water just has to meet the passing requirement after treatment.)

For Postharvest Water, you are REQUIRED to:

- Stop using the water for postharvest activities immediately.
- Before using water again, do one of the following "corrective measures":
 - Re-inspect water system, identify problems, make necessary changes.
 - Treat water. (No specific type of treatment stated in Produce Safety Rule. Water just has to meet the passing requirement after treatment.)

Required Records for Agricultural Water:

- Findings of your agricultural water inspection at beginning of growing season.
- Results of all testing done.
- If you take any "corrective measures" for agricultural water that doesn't pass the E. coli test (ie. treating water or applying time interval before harvesting):
 - Documentation of "corrective measure" taken.
 - Proof that the method you are using is safe and will kill E. coli so that there it is not detectable in 100 mL of water.
 - Results of "corrective measure" taken (from further testing).

* More details for these "corrective measures" will be provided at an FDA certified training.

5. Packing Area, Tools/ Equipment, Transportation

Packing Area

The packing area is where produce is washed and packed, whether indoors or outdoors.

Produce Safety Rule requirements for packing areas:

- Keep produce that is exempt separate from produce that will be regulated under the Produce Safety Rule.
- Clean and sanitize any surfaces that will touch the produce before using.
- If using re-usable packaging, make sure it is cleanable. Clean before re-using or use clean liner.
- Check for / avoid condensation or drip (especially from walls, ceiling, cooling equipment, pipes over packing area).
- Try to keep out animals (mice, rats, birds, pets, etc.) - tips on the right side of this page.
- **Train workers about these practices.**

Best Practices for Packing Areas:

- Keep produce handling area separate from other parts of farm (ex. animal area, equipment repair/ storage, compost area, etc).
- Sweep, empty trash every day, clean up spills immediately.
- Avoid standing water.
- Food contact surface should be non-toxic, non-absorbent, durable, easy to clean.
- Store produce in covered area, off of floor.

Cleaning and Sanitizing

Cleaning and sanitizing are NOT the same:

- Cleaning = removing dirt from surface
- Sanitizing = treating cleaned surface to kill microorganisms (sanitizing won't work if there is still dirt on it)

4 steps for cleaning and sanitizing food contact surfaces (any surface that food/produce will touch):

1. Remove dirt (can use brush, air, or water, don't use high pressure washers or air compressors)
2. Apply detergent and scrub (make sure detergent is safe - approved for using on food contact surfaces)
3. Rinse with clean water
4. Apply sanitizer, rinse with water if necessary* (look on label), let air dry.

*If organic operation, certifier might require rinse after sanitizer applied.

Tips for Keeping Out Animals (Pest Management)

- Check for holes and cracks in walls, doors, windows. Repair if you find any.
- Use nets/spikes to deter birds.
- Keep doors and windows closed as much as possible.
- If grass around packing area, keep it trimmed.
- Take out trash at least once a day, more if necessary.
- Keep produce covered.
- Don't use bait inside packing area.

Tools / Equipment

Tools/equipment you need to worry about:

- Any tool or equipment that will touch produce at any time.
- (Examples: knives, harvesting equipment, cooling equipment, containers, packing material, transport vehicles, etc)

Produce Safety Rule requirements for tools/equipment:

- Equipment and tools have to be able to be cleaned. If can't clean it, don't use it.
- Keep your tools/equipment clean (including build up in the seams).
- Keep tool/equipment storage area clean.
- Store tools/equipment where pests can't get to easily.
- **Train workers about these practices.**

Best practices:

- Write down a schedule for cleaning tools.
- Keep a log of when tools are cleaned, have folks initial when they clean.
- See right side of this page for link to template log.

Transportation

Produce Safety Rule requirement for transportation:

- Clean vehicle before transporting produce.

Good to do:

- If vehicle also used to transport animals or compost, clean and sanitize before transporting produce.
- Add a clean liner on the floor.

Recordkeeping

Recordkeeping helps you keep track of everything that's going on at your farm and makes it easier to deal with regulations.

Tips for Recordkeeping

- Keep recordkeeping materials where the task is done.
- Set recordkeeping schedules.
- Review records to identify trends/problems over time.
- You don't have to create your own log sheet from scratch. **Here are 50 template logs and SOPs** (standard operating procedures) you can use: <http://gaps.cornell.edu/educational-materials/decision-trees/log-sheets-sops>

Sample Worker Training Log

Name of farm: _____ Date: _____
 Trainer: _____ Training time: _____
 Location: _____

Training materials: Please attach any written materials and provide an outline of the training topics discussed. Also reference any relevant SOPs or sections of your farm food safety plan that apply.

Employee Name (please print)	Employee Signature
1. _____	_____
2. _____	_____
3. _____	_____
4. _____	_____
5. _____	_____
6. _____	_____
7. _____	_____
8. _____	_____
9. _____	_____
10. _____	_____
11. _____	_____
12. _____	_____
13. _____	_____
14. _____	_____

Reviewed by: _____ Title: _____ Date: _____

Sample Restroom Monitoring and Cleaning Log

Name of farm: _____

Please see the food safety plan for detailed first aid kit monitoring procedures.

Date	Restroom # or location	Checked (✓)	Cleaned (✓)	Supplies filled/actions completed	Comments (e.g. special maintenance required)	Initials
4/20/13	#3	✓	✓	Cleaned the inside and emptied trash	None	EAB

Reviewed by: _____ Title: _____ Date: _____

Visitor Log

Information on food safety procedures for visitors.

Purpose of visit	Host (initials)	Read visitor policy (yes or no)

On-Farm Decision Tree Project: Worker Health, Hygiene, and Training—v14 07/16/2014
 E.A. Bhn, M.A. Schermann, A.L. Wszelaki, G.L. Wall, and S.K. Amundson, 2014 www.gaps.cornell.edu

Required Format and Storage of Records

Required records should have:

- Name and address of farm.
- Name of task / Location of where it was done (specific growing area, packing shed, etc).
- Description of what was done/measured/observed.
- Any materials relevant to the task.
- Date and time the task was completed.
- Space for a signature of the person responsible for the food safety plan .

Required records need to be:

- **Created at the time task is performed (not later).**
- Readable, in pen if using written log.
- Signed or initialed by person who did the task.
- Kept for 2 years.

Other notes on required records:

- Can be handwritten or electronic.
- If already using these types of records for other purposes, can use them for FSMA, don't need to duplicate.
- Records can be stored off-site, as long as they can be retrieved and made available and accessible to FDA within 24 hours of request by FDA for inspection and copying.
- Electronic records are considered to be 'on-site' if they can be accessed from the farm via computer or other devices.

Required Recordkeeping

- Worker trainings: date of training, topics covered, and individual(s) trained.
- Date and method of cleaning and sanitizing of equipment used in covered harvesting, packing, or holding activities.
- Soil Amendments: the type and source of soil amendment used, when it was applied, how much was applied, handling and sanitation practices used that reduce risks, any analysis or testing that was done.
- If composting on your farm: Key factors in the composting process must be documented. These may include the following steps depending on the process used: time, temperatures, turnings, other processing steps.
- If getting soil amendment from third party, documentation should be kept of:
 - The name and address of the supplier.
 - What soil amendments were purchased.
 - The date and amount purchased.
 - Lot information, if available.
 - Get this documentation from your supplier once a year:
 - To ensure the supplier has used scientifically validated treatment processes and monitoring during the production of the treated amendment (including compost).
 - To ensure proper handling requirements have been met.
- Water quality testing, water management activities.
 - Findings of your agricultural water inspection at beginning of growing season.
 - Results of all testing done.
 - If you take any "corrective measures" for agricultural water that doesn't pass the E. coli test (ie. treating water or applying time interval):
 - Documentation of "corrective measure" taken.
 - Proof that the method you are using is safe and will kill E. coli so that it is not detectable in 100 mL of water.
 - Results of "corrective measure" taken (from further testing).

Good to Record

Choose what is most important for you:

- Facility monitoring, including cleaning and stocking toilet and handwashing facilities as well as maintaining first aid kits
- Worker illness and injury reporting
- Pre-plant land assessments (more info in “Writing a Food Safety Plan” section)
- Monitoring for animal activity
- Actions taken to reduce the risks related to animal intrusion into crop (domesticated animals and wildlife)
- Pre-harvest risk assessments (more info in “Writing a Food Safety Plan” section)
- Intrusion and contamination events
- All corrective actions taken
- Pest management
- Building maintenance and monitoring
- Worker training on sanitation SOPs
- Packing area and cold storage cleaning and monitoring
- Vehicle cleaning and inspections prior to loading
- How much sanitizer is being used, how the sanitizer responds to different organic loads and types of produce, and even how well the equipment and system is functioning to keep water safe

Writing a Food Safety Plan

A food safety plan is not required, but makes it easier when you have to deal with:

- Buyer questions/requirements (see page 2)
- Third party audits
- Food safety regulations

Tips before you start:

- **There are lots of templates online that you can use.**
(Ex: http://manoa.hawaii.edu/ctahr/farmfoodsafety/wp-content/uploads/2016/06/Model-Food-Safety-Plan_blank-copy-FR.docx)
- Write what you do, NOT what you hope to do.

A Food Safety Plan:

- Describes risks you identify
- Actions to address those risks
- Describes your practices, SOPs

Parts of a Food Safety Plan:

- Farm name + address
- Farm description (produce grown, farm size, etc.)
- Name + contact info for farm food safety manager
- Risk assessment of practices and environmental conditions on your farm that impact food safety
- Practices to reduce food safety risks
- Records that document practices
- Can also include:

Farm maps, farm policies, SOPs, training records, agricultural water test results, emergency contact info, supplier/buyer info, traceability and recall plans, contact info for contracted services

Steps for Writing a Food Safety Plan

1. Choose a food safety person (required by FSMA).

- This should be someone who has authority to make changes on the farm, who is willing to be the contact person for auditors, leading trainings.

2. Assess risks.

- Part 1:
 - Go through each of the sections (Workers/Visitors, Soil Amendments, Animals, Agricultural Water, Tools/Packing Area/Transportation).
 - Write down practices or situations on your farm that could be making it easier for pathogens to spread.
 - Make sure to consider each type of produce, set up of the farm, and how neighbors are using their land.
- Part 2 - Produce Flow:
 - Map the flow of produce from the field through the packing area, including storage and loading onto transportation vehicles.
 - Identify all surfaces that contact the produce as well as where incoming produce from the field and washed/packed produce might cross paths in the packing area or cooler.
 - Think about the steps with the biggest risks (where pathogens can be introduced, where they can grow) and identify ways to control spread of pathogens

3. Rank risks.

- Biggest risks:
 - Risks that can lead to whole crop contamination (i.e. overhead irrigation with poor quality water on day before harvest)
 - New/changed farm practices (i.e. hiring new people, changing process, retrofitting equipment, changing suppliers, etc.)

4. Develop practices to reduce risks.

- Use the Roots Food Safety guide or material from an official FDA certified training (i.e. Produce Safety Alliance) to help you decide what to do.
- Develop standard operating procedures (SOPs). SOPs could be developed for:
 - Monitoring for pests
 - Preparing cleaning and sanitizing solutions
 - Cleaning and sanitizing produce washing lines
 - Cleaning and monitoring cold storage areas
 - Inspecting trucks prior to loading fresh produce
 - Cleaning vehicles used to transport fresh produce
- Know what resources are needed, create a list of tasks, designate someone to be in charge of each task.

5. Document and revise.

- Record what you are doing.
- Update plan once a year, or whenever something changes.

Appendix

What counts as a farm?

For more information about what counts as a farm under the Produce Safety Rule, see: <http://sustainableagriculture.net/blog/fda-farm-definition-guidances/>

Resources on Rat Lungworm Disease/Prevention

- <http://manoa.hawaii.edu/ctahr/farmfoodsafety/rat-lungworm/>
 - <https://www.ctahr.hawaii.edu/oc/freepubs/pdf/FST-35.pdf>
 - http://health.hawaii.gov/docd/disease_listing/rat-lungworm-angiostrongyliasis/
 - <http://www.civilbeat.org/2017/04/video-the-creepy-collaboration-that-creates-rat-lungworm/>
-

Farming and Protecting Native Habitats/Animals

- Article: "Native Wildlife Habitat and Farming: Yes, They are Compatible" <https://www.ctahr.hawaii.edu/sustainag/news/articles/V5-Koob-wildlife.pdf>
 - Toward Sustainable Agriculture: A Guide for Hawai'i's Farmers (on page 18) https://www.ctahr.hawaii.edu/sustainag/NewFarmer/downloads/TSA_guide.pdf
-

Templates

- Food Safety Plan template - http://manoa.hawaii.edu/ctahr/farmfoodsafety/wp-content/uploads/2016/06/Model-Food-Safety-Plan_blank-copy-FR.docx
- SOPs and logs - <http://gaps.cornell.edu/educational-materials/decision-trees/log-sheets-sops>

List of Approved Sanitizers:

- <https://ag.purdue.edu/hla/fruitveg/Presentations/SanitizersApprovedforWashorProcessWatertwopagesAJD.pdf>

List of Approved Organic Sanitizers:

- <https://www.ams.usda.gov/sites/default/files/media/8%20Cleaners%20and%20Sanitizers%20FINAL%20RGK%20V2.pdf>
-

Food & Water Testing Laboratories in Hawai'i

(This list is from UH CTAHR Cooperative Extension Services.)

- Hawai'i Island
 - Microbiology Consulting Services, LLC
73-4159 Ka'ao Okace, Kailua Kona, HI 96740
Phone: (808) 345-6549
 - Pololei Labs
120 Pauahi St, Hilo, HI 96720
Phone: (808) 938-0560
- O'ahu
 - Analytical Services, LLC
3586 Kumu Place, Honolulu, HI 96822
Phone: (808) 358-0414
 - Food Quality Lab
3375 Koapaka St, Honolulu, HI 96819
Phone: (808) 839-9444
- Maui (county) - no on-island private labs
- Kaula'i - no on-island private labs

¹ Sources for Hawai'i Foodborne Illness Examples (page 1):

- 2017 Rat Lungworm outbreak
 - <http://www.staradvertiser.com/2017/05/11/breaking-news/confirmed-rat-lungworm-case-brings-total-to-15-for-hawaii/>
 - <http://www.hawaiinewsnow.com/story/35410315/fresh-case-of-rat-lungworm-disease-reported-on-hawaii-island>
- 2016 Salmonella outbreak - ogo
 - <http://www.staradvertiser.com/2016/11/10/breaking-news/oahu-salmonella-cases-prompt-times-to-stop-using-limu-in-poke/>
- 2015-6 Salmonella outbreak - macadamia nuts
 - <http://www.foodsafetynews.com/2016/02/recalls-pose-challenge-to-hawaiis-macadamia-nut-crop/#.WHf4FZJjoac>
- 2007 E. coli outbreak - lettuce
 - <http://the.honoluluadvertiser.com/article/2007/Aug/10/In/hawaii708100363.html>
 - <http://the.honoluluadvertiser.com/article/2007/Aug/10/In/hawaii708100364.html>

If you have unanswered questions about FSMA or food safety, please feel free to contact the following experts:

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² Source for emergence of certain pathogens from industrialized food system (page 3):

Otter, Chris. 2015. "Toxic Foodways: Agro-Food Systems, Emerging Foodborne Pathogens, and Evolutionary History." *Environmental History* 20 (4): 751–64. http://www.academia.edu/16053402/Toxic_Foodways_Agro-Food_Systems_Emerging_Foodborne_Pathogens_and_Evolutionary_History

³ Adapted from "F-diagram" by: UNICEF Philippines and Luis Gatmaitan / 2014 / Gilbert F. Lavidés (page 10)

- <https://www.flickr.com/photos/gtzecosan/17125224489/in/set-72157648282032913>