

{Insert Logo Here}

{Insert Farm Name}
Farm Food Safety Plan

[Name of Food Safety Coordinator]

Food Safety Coordinator

[Farm Address]

[City, State, Zip]

[GPS Coordinates]

[Food Safety Coordinator phone number]

[email address]

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SECTION 1

FARM FOOD SAFETY PLAN

Farm Description

The farm is located at [add location address and GPS coordinates] and is a [insert brief description of farm]. [include a mission statement if you would like].

A written food safety policy is in place that outlines our commitment to food safety, in general terms, how it is implemented and how it is communicated to employees, and it is signed by the senior management.

[Attach maps here. Include maps of the farm, the packing house maps showing flow of product, and floor plan of other areas, including storage areas, employee break areas, and restrooms, Include location of mouse/rodent traps on building floor plans.]

Management

[Name of Food Safety Coordinator]

[Phone #]

[Email]

Self-audits or Farm Assessment

Our farm has completed the PSA “My Farm Assessment”. This assessment is reviewed and updated (as required) annually. A Copy of the assessments and updates are kept on file.

Documentation

Documents and records of procedures, standard operating procedures (SOPs), and policies are in place for meeting each of the food safety standards identified in the Farm Food Safety Plan. Records comply with prevailing regulations. Documentation is available for inspection and is maintained for a minimum of two years.

Traceability Procedures

Our farm utilizes a traceability system that allows us to trace products one step back (field) and one step forward (customer). The system is based on the Gregorian calendar date system for date harvested, field/location code, and product code. Ex.

052624010208: 052624 (date of harvest, May 26, 2024), 01 (field/location based on farm map), 02 (row location in correlation with field/location based on farm map), 08 (product code based on farm product coding system; can be found in Section 4: Traceability).

To test our traceability plan, we conduct a mock recall (Doc. 3.07). In the recall, a buyer is contacted and asked to identify a load received from our company. We ask how much of the product has been sold and how much they still have in inventory. This information is recorded in our mock recall form and kept on file Section 4.

(SOP 2.18, SOP 2.19)

Mock recall

To test our recall plan, we conduct a mock recall once a year, usually in [say which month]. In the mock recall, we contact one of our buyers and ask them to identify a shipment received from us. We ask how much of the product has been sold and how much they still have in inventory. This information is recorded on our Mock Recall Log (Doc. 3.07) and kept on file.

(SOP 2.20)

Company Health and Hygiene Policy

Training

All employees receive training when they start work on the farm and a refresher course at least once a year. Employees include those that work on the farm that plant, care for, harvest, scout pests, process, and pack fresh produce. Family workers are required to have the training too.

Training includes instruction on all company policies related to worker health and hygiene and (where appropriate) specialized training related to specific jobs as required by law (for example, pesticide applicator license or training). Contracted personnel whose activities can affect food safety are held to the same food safety standards as they would be as employees. All worker training is documented in the worker training log. (Doc: 3.01) (SOP 2.01)

Employee training is documented on the Employee Training Log (Doc. 3.01). Documentation of training includes employee's printed name and signature, description of training, written materials or video/DVD, date, and name of person doing the training.

Training is provided in the language of the employees.

Visitor Health and Hygiene Policy

Visitors are required to comply and sign a copy of the farm's Visitor Health and Hygiene policy which is filed in Section 5. Visitors are also required to sign a Hold Harmless which is filed in Section 5. The Visitor Health and Hygiene Policy is also on display at the entrance of the farm which is outlined on the farm map (site map location).

(SOP 2.23)

Handwashing and Toilet Facilities

Clean and well-maintained toilet and handwashing facilities are provided for all employees, visitors and customers. All toilet/restroom facilities are properly supplied with single-use towels. These facilities are checked on a [e.g. daily/every other day/weekly] basis. Restroom facilities are serviced and cleaned [write down how often—daily, weekly, on Tuesdays and Fridays, every other Wednesday.] Monitoring, restocking, and cleaning are documented on the Restroom Cleaning Logs (Doc. 3.02, completed logs are kept on file in Section 5).

Handwashing

Everyone must wash their hands before beginning work and returning to work after taking breaks, going to the restroom, eating, smoking, or otherwise compromising the sanitary nature of their hands. Signs in English and [list native languages of the employees and have signs in those languages] are posted in restrooms, eating areas, and smoking areas to instruct employees to wash their hands before beginning and returning to work.

Proper Handwashing Technique

All employees handling produce for processing or sale will use proper handwashing techniques before beginning work and after returning to work after taking breaks, going to the restroom, eating, smoking, or otherwise compromising the sanitary nature of their hands.

Proper handwashing techniques includes the following:

1. Wet hands with clean water (warm is preferred is available), apply soap, and work up a lather.
2. Rub hands together for at least 20 seconds
3. Clean under the nails and between the fingers.
4. Rub fingertips of each hand in suds on the palm of the opposite hand.
5. Rinse under clean, running water.
6. Dry hands with a single-use towel.

It is important to remember to wash hands after touching any potentially unsanitary surface. When possible, turn off the faucet with the single-use towel instead of directly with the hand when using a sink and faucet that is not automatic or knee- or foot-operated.

Do NOT use a paper towel more than once or share towels with others.

(SOP 2.02)

Toilets and Handwashing Facilities

Clean and well-maintained toilet and hand wash facilities are provided for all employees, visitors, and customers. Employees are instructed that used toilet tissue shall only be disposed of in the toilet. All toilet/restroom facilities are properly supplied with single-use towels. These facilities are checked on a daily basis. Restroom facilities are serviced and cleaned weekly. Monitoring, restocking, and cleaning are documented on the Restroom and Field Sanitation Logs (Doc. 3.02, completed logs are kept on file in Section 5).

The number, condition, and placement of field sanitation units comply with applicable state and/or federal regulations.

The field toilets are located away from the growing fields to avoid contamination by fecal material. Flush toilets and sinks located on the farm are on a municipal sewage line.

There are no municipal sewage treatment facilities or waste material landfills adjacent to the farm.

(SOP 2.03)

Injury and Illness Policies

First Aid Procedures

If someone is injured at the farm, either in the packinghouse or in the field, the first aid kits are available for use. The supplies are checked and updated [YOU decide and stick to it, e.g. MONTHLY, WEEKLY].

All workers are instructed during training to deal with injuries immediately. This includes any cuts, abrasions, or other injury that happens while working. Employees must notify the farm manager or their supervisor and fill out an accident report. If the injury is

critical or life threatening, employees are instructed to call 911 for proper care. (SOP 2.04)

Blood and Body Fluid

If blood or other bodily fluid should come in contact with produce or in the field, immediate action must be taken.

If a person is not able to immediately deal with the contamination due to injury, that person must mark the area if able and immediately notify the farm manager or his/her supervisor who will take appropriate action.

If an employee is injured in the field or packinghouse, the farm manager or supervisor--after assuring the employee's safety--will immediately inspect the area where the injury happened to make sure no blood or bodily fluids have contaminated the area.

If there is blood in the field, all contaminated surfaces will be removed to a plastic bag with a shovel or gloved hands and placed in a trash can. All affected soil will be shoveled up around and under the area and will be removed. All affected produce will be discarded as well as any packing materials. All actions will be documented in this FSP. (Cite SOP 2.04, SOP 2.05, SOP 2.22)

Illness

Any employee who is sick should notify the farm manager or his/her supervisor immediately and must not handle fresh produce. If an employee does not report his or her illness and is found to be sick by the farm manager or supervisor, the employee will be immediately dismissed from work and not allowed to return until they are symptom free.

These symptoms preclude an employee from working and handling fresh produce or food contact surfaces:

- Diarrhea
- Fever
- Vomiting
- Jaundice (when the whites of the eyes are yellowish and the skin has a yellowish tinge)
- Sore throat with fever
- Lesions containing pus (including boils or infected wounds, however small) on the hand, wrist, or any exposed body part

If an employee has any of the conditions listed above, these conditions will be recorded on the Illness/Injury Report Form. (Cite SOP 2.05)

Policy on Taking Breaks

Breaks that include smoking, eating, chewing gum or tobacco, or drinking (other than water), must be taken in areas away from fresh produce production and packing. In the packinghouse, there are designated break areas. Breaks in the field are taken in designated areas (not in production nor near harvestable crops). Short rest breaks are permitted in the field during production as long as workers are not smoking, eating, chewing gum or tobacco, or drinking (other than water).

All personal items must be stored in designated areas in the field, break room, and packinghouse. Under no circumstances will glass containers be allowed in the field or packinghouse. (Cite SOP 2.06)

Drinking Water Policy

Potable drinking water is provided and available for employees in the packinghouse and in the field. All employees are notified of this policy during training and instructed to notify their supervisors if water is not available or if disposable cups are not available. No glass is allowed.

(SOP 2.21)

Clothing, Jewelry, and Cell Phone Policy

Employees will wear clean clothing to work every day. When required, employees will wear appropriate supplied clothing including hats, hairnets, aprons, and disposable gloves.

No jewelry is permitted in the field, around machinery, packinghouse, or packing facility with the exception of a plain wedding band (no stones allowed) and wrist watches.

Cell phones are not allowed unless they are required for farm business. All cell phones will be stored in lockers or kept in a belt holster or pants pocket.

Racks and/or designated storage areas for worker belongings, protective clothing, and tools must be provided and not serve as a source of contamination.

Employee Food Safety and Security Empowerment

All employees are instructed to share information they observe regarding food safety and security. If employees see unusual individuals or situations, they should notify their

supervisors so they can evaluate the situation. If employees notice pests or other food safety issues, they are encouraged to share this information with their supervisors. Our company food safety policy includes all employees and is companywide.

Agricultural Chemicals/Plant Protection Products

Safety During Application of Chemicals

Only licensed individuals may apply regulated substances including plant protective sprays. Non-regulated chemicals may only be applied by trained individuals.

Pest Monitoring for Chemical Application Decisions

A licensed applicator is responsible for inspecting crops during critical periods to determine whether the pest population is likely to cause economic losses. If so, they will apply chemicals and pesticides according to IPM (Integrated Pest Management) standard at minimal rates.

Chemical Application and Recordkeeping

Agricultural chemicals will ONLY be applied by and disposed of by a licensed applicator who will use proper safety equipment. The water used with the chemicals will be safe. Records of applied chemicals will be kept in accordance with regulation, including date, chemical and trade name, EPA (Environmental Protection Agency) registration number, rate applied, weather conditions, stage of crop, target pest, area treated, and applicators name.

Chemical General Usage and Storage

Chemicals will be applied according to label directions, and at a lesser rate if possible. Rinsate and excess chemical material will be stored in a safe location and used according to the label. Chemical containers will be triple-rinsed and disposed of safely.

Chemicals will be stored in a separate, designated area that is locked. The storage box will be made of an impermeable material and will only be used for chemicals.

Water Quality Assessment

Irrigation Water and Water Used for Topical Sprays

Our farm tests water used for irrigation and mixing with topical sprays. Our water sources include municipal water. It is tested once per year and these records are kept on file. If any water test is outside our normal range, we do an observational review of

the water source area to see if there are any obvious problems or situations that can be mitigated. All reviews are documented, and any mitigation actions are documented in our water testing log.

Water tanks, such as those used for dust control, are cleaned at a sufficient frequency so as not to be a source of contamination.

(SOP 2.07)

Water Testing

Our farm has a written procedure for water testing during production and harvest season that includes:

- Frequency of sampling
- Who is collecting samples
- Where samples are collected
- How the samples are collected
- Acceptable hold time prior to lab delivery
- Type of test conducted
- Acceptance criteria

If water is from a municipal source, municipal testing will suffice. The frequency and point of sampling is determined based on the risk assessment and current industry standards for that commodity, if applicable. All water test results are kept on file for a minimum of two years.

Water System Description, Risk Assessment, and Management Plan

A water system description is included in the farm food safety plan

- Maps, photos, drawings, or other means to communicate water sources
- Locations of permanent water fixtures (wells, gates, valves, returns, etc.)
- Flow of water system (including holding systems, reservoirs, water for reuse)

Water systems are not cross connected with human or animal waste systems. The water delivery system shall be maintained so as not to serve as a source of contamination of produce, water supplies or equipment with pathogens, or to create an unsanitary condition.

A risk assessment of water sources has been performed on (ENTER DATE, LOCATION HERE). An annual risk assessment is conducted and logged in the FSP. (Doc. 3.06)

The risk assessment includes:

- Potential physical, chemical, and biological hazards
- Characteristics of the crop (above/below ground, etc.)
- Stage of the crop when water is applied
- Water application method

Our farm has a water management plan established to mitigate risk associated with the water system including:

- Preventative controls
- Monitoring and verification procedures
- Corrective action
- Documentation

If water is treated to meet microbiological criteria, the treatment is approved and effective for its intended use and is appropriately monitored. If post harvest handling is used to achieve microbial criteria, the farm maintains the documentation supporting its use. If the operation uses an alternative approach to regulatory microbiological testing, the operation has scientific data or information to support the alternative.

Farm Location and Land Management

There are no concerns about previous land use related to microbial contamination of crops. Cropland is not susceptible to flooding. If any land use history indicates a possibility of contamination of soil or cropland, please indicate measures that were taken to address the concern including test results from any soil samples that were tested.

An annual evaluation of land use and adjacent land must be conducted to document any risks associated with land, equipment, or structures.

Animals/Wildlife/Livestock and Manure Lagoons

Livestock

Crop production areas are not located near livestock production areas or manure

lagoons. Livestock are restricted from on-farm ponds and other sources of irrigation water. Our farm also restricts domestic animals access to food handling facilities.

Wildlife

Wildlife activity is monitored and deterred through fencing.

Inspection of fences and fields includes the following:

- Walking the fence line, observing any places where the fence may be compromised or in need of repair. All repairs are noted in the fence maintenance log.
- Making sure there are no weaknesses or places where animals are clearly entering and exiting the fields.
- Checking to see if any part of the fence needs to be re-baited for deer.
- Visually inspecting the fields from the outside to see if there are any noticeable signs of animal presence. If animal presence is noted, affected sections of the field will be documented and not harvested for an appropriate amount of time.

Rodent and Pest Control

There is a written procedure regarding the policy for rodent control in packaging areas and storage facilities on the farm. This policy includes a 4 step prevention program:

1. Elimination of harborage
2. Rodent-proofing structures
3. Elimination of food and water
4. Killing rodents

(SOP 2.08)

Soil Assessment

Soil Amendments

A risk assessment is conducted for the soil amendments used on our farm. This includes their preparation, application, and proper storage.

Manure

Raw manure is applied at least 90/120 days before harvest (for crops not in contact with the soil versus crops in contact with the soil, respectively) and applications are documented in the Manure Application record. All manure is stored in areas away from crop production areas.

All composted manure and treated biosolids are stored in a way that minimizes the risks of recontamination.

Composted manure is also applied. Records are maintained as to the type of composting (passive or active), composting time, temperature of pile (if active), and microbial testing reports for active treatment.

Compost piles are covered to reduce the chance of runoff, leaching, wind spread, or recontamination. If composted manure or treated biosolids are purchased, documentation of analysis reports are received for each shipment and kept with the manure records.

(SOP 2.09, Doc. 3.14, Doc. 3.27)

Composting Practices

Manure compost is turned frequently to maintain proper oxygen and moisture levels, and to ensure that the entire amount of material is heated properly to destroy pathogens and weed seeds. The temperature is maintained at over 131 degrees Fahrenheit for 15 days to destroy pathogens and weed seeds. During this time, the pile is turned to maintain proper oxygenation and to make certain the entire pile is exposed to the high temperatures. Appropriate records are kept confirming compost procedures are followed.

(Doc. 3.27)

Field Traceability

Production areas are identified by [NAME or CODE]. See the farm map.

Field Harvest and Field Packing Activities

Harvesting

A pre-harvest assessment is performed on our farm. In our assessment we look for signs of physical, chemical, or biological contamination of the crop, including, but not limited to:

- Animal fecal material or signs of animal activity
- Glass, metal, or other debris that may pose a physical hazard
- Signs of chemical contamination, including gasoline, other fuel, or agricultural chemicals

Mechanically harvested products are inspected to remove foreign objects such as glass,

metal, rocks, or other dangerous material. Workers also are trained not to harvest decayed or contaminated produce. The pre-harvest assessment record is located in Section (Doc. 3.21)

Harvesting Tools, Containers, and Carts

If an object comes into contact with produce it must be cleaned, in good working condition, and sanitized or disinfected. This includes, but is not limited to, hands, harvesting equipment (knives, etc.), harvesting totes and boxes, transportation equipment. Equipment cleaning and sanitizing operations shall be conducted away from the product and other equipment to reduce the potential for contamination. (SOP 2.12)

Harvesting Totes, Containers, Packaging

Our farm has a written policy regarding storage and handling of product-contact containers. Any containers not in use will be stored in a clean and secure location. (SOP 2.12)

Harvesting Tools

Any tool, such as a knife, used to harvest produce will be cleaned and disinfected before use each day and as frequently as reasonably necessary to protect the produce from contamination. (SOP 2.13)

Broken Glass

No glass containers are allowed in the field or packing house. Any broken glass will be placed in a cardboard box that is sealed and placed in a secure trash can. (SOP 2.14)

Vehicles in the Production Fields

Transporting produce from the field to storage or processing

Any product that is being moved from the field to the processing and storage house will be covered. Any vehicle or means of moving the harvesting totes to the processing house will be clean and in good repair. All vehicles will be inspected for the following prior to entering the fields:

- Interior and exterior cleanliness
- No broken or cracked plastic or glass windows, fixture, covers, or other parts
- No dripping oil, anti-freeze, petroleum product, automotive lubricant, or other fluid

Gas and Petroleum Spills or Leaks

Vehicles, equipment, and tools are controlled so as not to be a source of chemical hazards. Our farm has a written procedure to address the spills and leaks (fuel, oil, hydraulic fluids) which might occur during equipment operation in the field. Spill/leak procedure is located in Section 2. (SOP 2.15)

Procedure For Handling A Septic Or Sanitation Hazard In The Field

Sanitation facilities that have been tipped over or are in any way not available for use will be noted immediately and dealt with in a manner that prevents contamination of the produce. In the case of a sanitation unit spilling or any other septic leakage occurring in or near field boundaries, the following clean-up steps will be performed:

1. Any affected produce is immediately disposed of in a covered waste bin.
2. The contaminated area will be marked off with caution tape or string.
3. Signs in appropriate languages will be posted at the perimeter prohibiting entry to the contaminated area.
4. People and animals will be kept out until the area is sufficiently decontaminated.
5. Any solid waste still resting on the surface will be collected, shoveled up, and removed to the waste bin.
6. Any affected permanent structures will be hosed off and disinfected with a dilute bleach solution.
7. The sanitation unit will be cleaned up and replaced by the company providing the units and maintenance services.
8. The spillage event and corrective actions will be written down in the field sanitation log and kept in our records.

(Cite SOP 2.15)

Packinghouse Facility

The Packing and Storage House will be accessed by authorized personnel only.

Before being packed, the product is stored [where] and protected from contamination during the staging period by [write down how the product is protected].

Packing and Storage House Sanitation

There are several operating procedures outlining the cleaning, sanitation, and maintenance of the packing and storage house. This includes the containers used for harvest, and storage, the storage of these containers and equipment, and the cleaning and sanitation of the packing house itself, and the organization of produce in the packing house. (SOP 2.12, SOP 2.16)

Procedure For Handling A Septic Or Sanitation Hazard In The Packinghouse

Packinghouse toilets are located away from the packing area. All restrooms have floor drains to control any toilet overflow or sanitation leak. These drains go to a private septic system that is properly maintained to prevent direct or indirect product contamination. The farm sewage treatment system/septic system is functioning properly and there is no evidence of leaking or runoff.

Washing and Packing Line

There are several standard operating procedures outlining the washing and packing lines in regard to the way product is transported from the field to the storage packing facility and how this product is inspected and controlled. (SOP 2.11, SOP 2.17)

The water used in the packing, cooling and rinsing of fresh fruits and vegetables is potable. Municipal water tests are obtained yearly, and farm wells are tested twice yearly and kept with the Water Source Testing Log (Section 5, Doc. 3.06). We do not use surface water from ponds, lakes, streams, ditches, or canals in the packinghouse. Backflow devices are installed to prevent contamination of clean water. Water test records are filed in Section 5.

The temperature of the water in [dump tanks, flumes, wash tanks, sinks, basins etc.] is monitored [hourly] [automatically or with a standard thermometer]. The water temperature is not more than 10 degrees Fahrenheit cooler than the produce. Dump tank water is changed [insert how often here] and water sanitizer [say what the sanitizer product is] levels are maintained at [insert levels here] and documented on the Water Sanitizer Log (Doc. 3.23, Section 5).

Food contact surfaces, dump tanks, flumes, and wash basins are kept in good condition and cleaned and sanitized before use each day and as needed and documented on the Packinghouse and Washing Line Cleaning Log (Doc. 3.20, Section 5).

Product flow zones are protected from sources of contamination. [describe how it's protected. **Remember:** Assess your risks and work to reduce the risks. If you have a roof with rafters, you will need to keep birds from roosting in the rafters by using nets, predator decoys, or other methods. If flies are an issue, use fans to keep them away. If you pack under a tent or other temporary permanent structure, keep the area clear and control dust and dry dirt from blowing. If your open air packing is under a tree, you need to prevent birds from dropping their droppings on your produce.].

Ice Management

Ice making machines are sanitized on a regular schedule [Say what the schedule is]. When purchased, the supplier will supply a copy of the sanitization log and water quality

tests for ice production. This documentation is kept with our water logs. All ice hauled to a separate location is transported in a closed truck or in covered bins. No ice will be transported in wood containers.

Food Grade Lubricants

Only food grade lubricants are used on packing and other equipment that comes in contact with produce. We commonly use [say what you use] and the MSDS (Manufacturer's Safety Data Sheet) is kept on file and posted in the packinghouse.

Packinghouse Worker Health and Hygiene Policy

Employees will wear clean clothing to work every day.

When required, employees will wear appropriate supplied clothing including hats, hairnets, aprons, and disposable gloves.

No jewelry is allowed in the packinghouse, or packing facility with the exception of a plain wedding band (no stones allowed).

Employee areas including lunch and break areas are located [say where, note areas on map, can't be in the packing area] and are kept clean. Under no circumstances will glass containers be allowed in the packinghouse.

Packinghouse General Housekeeping

The packing and storage facilities are cleaned on a regular basis, including cleaning and sanitizing of food contact surfaces. Light bulbs are protected from breakage by either being in sleeves, covered, or are made of shatterproof material. Pipes, ducts, fans and ceilings are kept clean. At the end of each day, packing areas are dry swept. The washing, grading, sorting, and packing lines are cleaned and sanitized as well. A thorough cleaning, including floor drains, will happen on a weekly basis or as needed and this will be recorded on the Packinghouse and Washing Line Cleaning Log (Doc. 3.20, Section 5).

Sanitation chemicals have their own storage area separate from the processing line and are marked on the building map (Section 4, Farm Map).

Areas outside the packinghouse are well-maintained [say how, well-mowed or gravel]. They are free of debris that could harbor pests and free of standing water. Garbage cans/dumpsters are covered and located away from packinghouse entrances.

Glass

No glass containers are allowed in the packing house. All light bulbs are shatter proof or are shielded with shatter proof sleeves or covers.

Policy For Produce That Hits The Floor

If produce falls or is dropped to the floor it may not be picked up and put back on the packing line. And dropped produce should remain on the floor. Produce culls will be cleaned from the floor regularly. Produce will be swept or pushed away from the packing line and shoveled into the clearly marked vegetable waste bins. Employees will wash their hands before returning to the packing line. The produce in the waste bin will be emptied at the end of the day, or sooner, and taken to [e.g. the compost pile, disposed of in the dumpster].

Packing containers

All containers used for packing are new or sanitized containers. Records of cleaning are kept on the Harvest Tool and Container Cleaning Log (Doc. 3.11, Doc. 3.12, Section 5). Packing containers are covered and stored [say where you are storing them]. Pallets and containers are kept in good condition; if broken they are disposed of.

Rodent and Pest Control

Farm buildings, packinghouses, and storage areas are inevitably subject to animal and pest infiltration. Special attention will be paid to the processing and storage facility due to the permeability of the structure. If this permeability becomes a pest problem, a plan to deal with the cracks and holes will be developed at that time.

Traps are placed throughout the operation and their location is identified on a map (Section 4, Farm Map). Traps are checked daily and records are kept of the daily checks as well as any pests that are found in the traps on the Pest Control log (SOP 2.08, Section 2) (Doc. 3.13, Doc. 3.15, Section 5). We NEVER use bait inside the packinghouse.

All walls, doors, and windows are inspected. All windows are screened. Any holes are repaired to prevent pest and/or bird entrance into the buildings. Employees are trained to report any signs of infestation in the field or processing and storage areas.

If we hire an exterminator or pest control company, they will monitor the buildings on a [say how often] basis. All traps will be checked and documented [say how often] by the farm manager. A service report from pest control company will be provided or updated [say how often]. If a change in conditions develops, the monitoring company will be

contacted immediately.

Storage and Transportation

Storage area housekeeping

Storage areas are kept clean and tidy. The general housekeeping policy for the storage area general housekeeping is the same as for the packinghouse areas, as is the pest and rodent control program

Storage coolers

Storage cooler temperatures will be checked and logged [how many] time(s) per day. Problems will be addressed immediately. Multiple thermometers are used to assure correct temperatures.

Before using coolers for the season, we check for holes, cracks, or any other openings that rodents or insects could use to get in the cooler.

The cooler will also be cleaned on a monthly basis or sooner if needed. This cleaning will be recorded in the Storage Cooler Cleaning Log (Doc. 3.20) and kept on file for one year.

Vehicles for Produce Transportation to Market

All delivery trucks and vehicles used to transport produce to market are inspected for odors and signs of unsanitary conditions before loading. If a vehicle is found to be unsanitary, it will be cleaned and sanitized before produce is loaded. All records of inspections and cleaning will be kept on the Delivery Vehicle Cleaning and Inspection Log (Doc. 3.18, Doc. 3.22, Section 5). All shipments will be documented on the Transportation Log.

Equipment used to carry animal products or other potentially hazardous items including carcasses, manure, or pesticides will not be used. Any contracted truck operators will be asked to state the last load that was hauled in the vehicle and provide a cleaning schedule and temperature log for the vehicle before loading, as well as a log of previous loads.

Invoices and shipping manifests will be kept on file for the period of one year. Proper transport temperatures will be maintained and printed on manifests to ensure the quality and safety of the product. Produce will be loaded carefully so that risk of damage will be minimized. Only employees who are trained in loading produce out of the storage cooler and onto trucks will be allowed to do so.

SECTION 1

FARM FOOD SAFETY PLAN

Section 2: **Standard Operating Procedures and Policies**

Section 3: Record Logs

Section 4: Traceability

Section 5: Supporting Documentation

**Section 6:
Appendix**

Section 7:

FSMA

This material is based upon work supported by the National Institute of Food and Agriculture, U.S. Department of Agriculture, through the Northeast Sustainable Agriculture Research and Education program under subaward number [insert your project number here ONE24-453-AWD00001359

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.01

Title: **Conducting a Sanitation and Worker Protection Training Using an Oral Checklist**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

1. In the event of training needed but video training/other materials are not available, the food safety coordinator may conduct an oral training using a checklist of sanitation and worker protection items to be covered.
2. Someone (foreman, worker) is available if translation is needed for Hispanic workers.
3. Workers will sign in using Doc 3.01 to confirm attendance during training sessions.
4. The sanitation portion of the training shall include the following items:
 - a. Potable drinking water sources- bottled and coolers
 - b. Proper handwashing procedures
 - c. Sanitary facility (PortaJohn) usage
 - d. Hand Wash station usage
 - e. Notify if soap, tissue, or towels are needed
 - f. Handwashing required before entering or reentering the production field after using restroom breaks, smoking, eating, handling, or disposing of trash.
 - g. No food items to be taken into the field/ No glass containers
 - h. Glove and hair net policy if required
 - i. No personal items or non-produce items stored in harvest containers
 - j. Jewelry policy
 - k. Sickness policy related to handling produce
 - l. Contaminated produce policy related to cuts or bodily fluids
 - m. First aid for cuts, abrasions, and injuries and location of first aid supplies
5. The worker protection portion shall include the following:
 - a. Posted information related to sprayed fields and re-entry
 - b. What to do if you suspect pesticide poisoning
 - c. Emergency phone numbers
 - d. Personal protective equipment available and location

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.02

Title: **Proper Handwashing Techniques for Employees and Visitors**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

1. Turn on and allow water to wet the hands and wrists
2. Use a soap bar or liquid soap and apply it to the hands
3. Rub hands vigorously together for 15-20 seconds
4. Scrub hands thoroughly including back of hands, between the fingers, around cuticles and under the wrists
5. Under a stream of running water, rinse the hands well
6. Dry the hands with a clean towel (do not reuse) or disposable paper towel.
7. If using a public restroom, a paper towel should be used to turn the faucet off.
8. Dispose of the towel in the proper receptacle.

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.03

Title: **Toilet, Restroom, and Field Sanitation Unit Policy and Cleaning Procedures**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

1. A basin container, or outlet with an adequate supply of potable water, soap, and single-use towels are provided for each toilet facility
2. Each station has a sign, written in a language(s) that all employees can understand that reminds them when and how to wash their hands
3. One toilet facility and one hand washing facility is provided for each twenty (20) employees
4. Toilet and hand washing facilities are accessible and located in close proximity to each other and within a one-quarter-mile walk of each hand laborer's place of work in the field. Where due to terrain or it is not feasible to locate facilities as required above, the facilities are located at the point closest to vehicular access and workers are provided reasonable access throughout the day
5. Toilet facilities are adequately ventilated, appropriately screened, have self-closing doors that can be closed and loathed rom the inside and are constructed to insure privacy
6. Where employees who perform field work for a period of three (3) hours or less (including transportation time to and from the field) during the day, toilet and hand washing facilities are available at alternative sites.
7. Toilet and handwashing facilities are regularly maintained and supplied as necessary to keep them clean, sanitary, and functional
 - a. Wash walls from top to bottom, as needed
 - b. Sanitize toilets, urinals, doorknobs, and any other surface inside the unit
 - c. Fill paper products and soap dispensers
 - d. Move trash to the dumpster
 - e. Record initials and date of cleaning on the 'Service Record" sheet when the unit is serviced
 - f. Brushes and any other cleaning utensils used to clean the restrooms must be identified for use and stored separately from brushes, or any other cleaning utensil used to clean the equipment, utensils, etc.
8. Water for drinking and handwashing is continuously supplied
9. If a major spill or leak of field sanitation units or toilet facilities occurs, access to the facility and the affected area around it is blocked off until clean up occurs.

The facility cannot be used by workers until a supervisor has inspected the site for cleanliness.

10. Facilities are cleaned and maintained times per week during the production/harvest season.

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.04

Title: **First Aid for Cuts and Abrasions**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

1. A first aid kit is properly identified with signage and located where all employees have access to its contents
2. If you obtain a wound or cut while working, you need to **stop working immediately**
3. Contact your supervisor and have it attended to
4. Here are the main steps for dealing with cuts on you body:
 - a. Cleanse the area thoroughly with soap and warm water, carefully washing away and dirt
 - b. Apply direct pressure to the wound until bleeding stops
 - c. Apply antibacterial ointment to sterile bandages
 - d. Put sterile bandages on wounds and secure them with tape
 - e. If the cut is deep, get to a doctor as quickly as possible
5. How here are the main steps for dealing with abrasions:
 - a. Wash thoroughly with soap and warm water
 - b. If it bleeds or oozes, bandage it to protect it from infection
6. Attending a cut or abrasion fast will help prevent infection. However, sometimes an infection can still occur; here are the main signs to look for:
 - a. Swelling
 - b. Redness
 - c. Pain
 - d. May cause fever
 - e. Presence of pus
 - f. If a wound is infected, or you just think it might be, get additional medical attention right away
 - g. Record all incidents of cuts or abrasion on the Illness/Injury Reporting Log (3.03)

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.05

Title: **Policy for Reporting Illness or Injury**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

1. Any worker who becomes ill while working in production or harvest areas must report the condition to the foreman or supervisor
2. If the illness requires medical attention, the foreman or supervisor should seek either emergency attention or regular medical attention for the worker
3. If there is an episode of blood or body fluid involved, be sure to follow procedures (SOP 2.22) for cleaning and isolating contaminated products
4. If the worker wants to and is able to continue work, they should be moved to a non-production/handling area and assigned other types of tasks in order to avoid contaminating any produce or production area
5. Record the illness episode on the Illness/Injury Log (3.03)

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.06

Title: **Rules for Smoking, Eating, and Breaks**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

1. No tobacco use is allowed on (Farm Name), except in designated areas.
2. This farm has a designated lunch and break time period
3. Employees are responsible for bringing their own food in coolers or they are allowed to leave the farm during the lunch time period to go to purchase lunch
4. No food or drinks except water in plastic or metal containers are allowed to be consumed in production or product handling areas
5. No glass containers are allowed in any produce areas of the farm
6. A break room is available for workers to use during lunch or breaks.

This Room contains:

- a. Tables and chairs
- b. Water cooler
- c. Restroom facility that includes handwashing
- d. **All employees must wash hands before returning to work or production areas**

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.07

Title: **Sanitation of Crop Spray Water Including a Chlorination Rate Table**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

1. Determine the source of water to be used for spraying
2. Well or municipal water sources will use the 5ppm recommendation from the Chlorination Table on this SOP. Pond, stream, or reservoir will use the 10ppm recommendation
3. Wear required personal protective equipment as directed from the pesticide label that you are using
4. Pre-fill $\frac{1}{4}$ of the spray tank with clean water
5. Mix into the tank the appropriate amount of chlorine bleach according to the Chlorination Table
6. Continue to fill the tank until $\frac{1}{2}$ full then proceed to mix in crop protectants according to requirements
7. Finish filling the spray tank to the top and prepare to move to the field

CHLORINATION OF CROP SPRAY WATER

Chlorination Table for Spray Water

Gallons of Mix	5.25% Bleach Solution		6% Bleach Solution		10% Bleach Solution	
	5 ppm	10 ppm	5 ppm	10 ppm	5 ppm	10 ppm
1	0.5 cc	0.8 cc	0.3 cc	0.6 cc	0.2 cc	0.4 cc
2	0.8 cc	1.1 cc	0.6 cc	1.2 cc	0.4 cc	0.8 cc
3	1.1 cc	2.2 cc	1 cc	2 cc	0.6 cc	1.2 cc
4	1.5 cc	3 cc	1.2 cc	2.4 cc	0.8 cc	1.6 cc
5	1.8 cc	3.6 cc	1.6 cc	3.2 cc	1 cc	2 cc
10	3.6 cc	7.2 cc	3.2 cc	6.4 cc	2 cc	4 cc
15	5.4 cc	10.8 cc	4.8 cc	9.6 cc	3 cc	6 cc

25	9 cc	18 cc	8 cc	16 cc	5 cc	10 cc
50	0.6 fl oz	1.2 fl oz	0.5 fl oz	1.1 fl oz	0.33 fl oz	0.67 fl oz
100	1.2 fl oz	2.4 fl oz	1.1 fl oz	2.2 fl oz	0.67 fl oz	1.3 fl oz
250	3 fl oz	6.1 fl oz	2.7 fl oz	5.4 fl oz	1.6 fl oz	3.2 fl oz
500	6.1 fl oz	12.2 fl oz	5.4 fl oz	10.7 fl oz	3.2 fl oz	6.4 fl oz
1000	12.2 fl oz	24.4 fl oz	10.7 fl oz	21.4 fl oz	6.4 fl oz	12.8 fl oz

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.08

Title: **Policy for Rodent Control in Farm Work Areas and Storage**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

1. Our farm's rodent control program is considered to be an ongoing process
2. We will practice a 6 step prevention program:
 1. Elimination of harborage
 - a. All stacked or stored materials including product, packaging, and other materials will be kept on pallets or equivalent
 - b. When possible, stored materials including stored products will be stored no closer that 18 inches from adjacent walls
 - c. Vegetation, rubbish, and ornamental plants around structures will be reduced as much as possible
 - d. Any spaces under building will be blocked off and burrows filled in
 2. Rodent-proofing structures
 - a. Any opening that is considered a possible entry (greater than $\frac{3}{8}$ - $\frac{1}{2}$ inch) will be closed up
 - b. This includes sealing around pipes and floor drains
 - c. Areas where recurring burrowing has occurred, will be sealed with sheet metal or concrete
 3. Elimination of food and water
 - a. Daily facility cleaning procedures shall be followed and documented (Doc. 3.13)
 - b. No foods should be left in worker break rooms unless they are kept in a sealed container or refrigerator
 - c. All culls or 'grade outs' shall be removed from building on a daily basis and placed in closed containers away from production or storage areas
 4. Killing rodents
 - a. All rodenticides will be used according to the label directions
 - b. Rodenticides will be used in enclosed tamper-proof bait stations placed out of the building (no farther than 50' from the perimeter of such buildings). No rodenticides will be used inside storage facilities or coolers when produce is present
 - c. Bait stations will be placed so that they are located on both sides of outside corners

- d. Traps will be used inside of building and coolers when needed
- 5. During harvest season when product is being cooled or stored, monitoring of traps and bait stations shall be done weekly and recorded in the Pest and Rodent Control Log (Doc. 3.13)
- 6. The rodent control program will follow policy Doc. 2.08

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.09

Title: **Proper Use/Disposal of Farm Based Manures or Biosolids**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

Option One

1. No manures are to be used on any production fields for this farm

Option Two

1. Non-food crop production areas such as hay or pasture are the only areas to be utilized for spreading manure
2. These areas are chosen so that they are not in close proximity to any food crop production areas

Option Three

1. Any or all manure that may be applied is utilized during planting of fall cover crops, i.e. rye, wheat, etc
2. Manure is applied and cultivated into soil seed bed
3. Fall cover crops are seeded and grown to capture nutrients and allow decomposition of organic materials
4. The green manure is turned under and cultivated in the spring
5. This allows for 180+ days before planting or harvest of any food product

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.10

Title: **Handling/Disposition of Contaminated Produce**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

1. Produce contamination occurring during harvest or packing will be addressed immediately when this occurs
2. When produce is exposed to bodily fluids related to accident or illness:
 - a. Stop work immediately
 - b. Attend to injured or sick workers
 - c. Isolate all produce involved in the immediate vicinity
 - d. Remove this produce to a bin, trailer, or facility designated for culled produce
 - e. This product is not to enter the packing/processing line again
 - f. Clean all affected areas as directed in SOP 2.22
3. When produce is mechanically damaged during harvest, packing, or processing
 - a. Stop work immediately
 - b. Pull all damaged products from the harvest, packing, or processing operation
 - c. Dispose of product by depositing in designated culled produce areas
 - d. Remove damaged containers to the trash area so they are not reused again
 - e. Clean area or equipment to avoid future accidents or injuries
 - f. This product is not to enter the packing/processing line again

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.11

Title: **Policy for Field Inspection and Quality Control of Harvested Product in the Field**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

In order to assure the utmost quality and cleanliness of field harvested and packed product, routine and random inspections must take place.

Routine inspections shall include:

1. Checking to assure that workers are following acceptable clothing and equipment (gloves/hairnets, etc.) requirements
2. Sanitary facilities and handwash are available to workers
3. To further protect the produce from contamination during harvest, the crew will regularly inspect the harvested produce. Any foreign object (glass, metal, rocks, or other matter not the harvested crop) will be removed
4. Workers are instructed and expected to report such foreign matter contamination to their supervisors
5. Any damaged or culled produce that is discarded is placed in an appropriate location
6. Excess soil must be removed from product before packing
7. The product should be reasonably clean when harvested if it is to go into a future washline process
8. Any harvest containers and packing boxes stored at the site are done so as not to contaminate harvested products
9. All packing containers are new and not re-used
10. Harvest product has been marked correctly for traceability
11. All harvested produce is kept from contact with ground surfaces
12. A percentage of closed boxes of finished product are opened in the field for re-inspection
13. Finished product is transported, stored and cooled appropriately for the type of product being harvested

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.12

Title: **Maintenance and Cleaning of Harvest Containers, Lugs, or Totes**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

1. All harvest containers are inspected for damage and repaired before being used in the field. Un-repairable containers are taken out of use and disposed of by crushing, burning, or taken to disposal facilities
2. Harvest containers are inspected on a weekly basis
3. A cleaning/sanitation schedule is followed after each product is harvested or at the end of each daily shift whichever occurs most often
4. Procedure:
 - a. Harvest containers are flushed with a potable water source
 - b. Water added to harvest containers has added detergent to dissolve field soil
 - c. Containers are agitated as they travel back to the field for the next harvest
 - d. All harvested product then goes through a chlorinated washline before final packaging
 - e. Cleaned and sanitized containers are only used for harvest of produce. No non produce items will be stored in harvest containers
 - f. Employees are instructed to not use containers to store personal items such as clothing or lunches
 - g. Cleaned harvest containers and new boxes are either stored in a clean sealed area or stacked on pallets and covered with plastic until used. All harvest containers- old or new- are washed and sanitized at the beginning of each production season

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.13

Title: **Cleaning and Sanitizing Hand Harvest Equipment**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

1. Examine the cognition of all harvest tools, containers, crates, and pallets at the start of the season and at scheduled intervals during the season
2. Discard any hand tools or harvest equipment if they cannot be properly cleaned or repaired
3. Tools where handles are taped for maintenance purposes should be discarded because of concealed cracks/crevices where bacteria cannot be removed
4. Tools used for harvest of fresh produce should be designated for this purpose only and not used for any other purpose
5. Keep all harvest tools and equipment that comes in contact with fresh produce as clean as is practical
6. Cleaning and sanitation should be followed for the following items:
 - a. Knives and cutting tools will be dipped in sanitizer (Chlorine, Hydrogen Peroxide, or Iodine) located at hand wash stations each time that hands are washed before re-entering the harvest field. (This solution will be emptied at the end of the shift and replaced at the beginning of each day.)
 - b. Knives and cutting tools will be washed with soap and potable water at the end of each harvest day
 - c. Sheaths for knives or harvest tools can cause cross contamination and therefore, should not be used unless constructed of a material that can be cleaned regularly
 - d. Boots, gloves, and aprons should be inspected at the end of each workday
 - e. They should be washed with soapy water, rinsed, and hung to dry overnight
7. When purchasing knives or cutting equipment to be used for harvesting, preferred materials should include handles made of materials other than wood; an metal parts of stainless steel if possible
8. Do not use tools for harvest that have been used for maintenance or mixing of other materials

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.14

Title: **Glass Breakage/Contamination Clean UP**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

1. When broken glass/brittle plastic is/are found anywhere in the area, put a HOLD on all activities (Anyone can do this)
2. Conduct a thorough inspection of all open, uncovered products, packing materials, etc. in the immediate area
3. Immediately inform the Foreman or Supervisor
4. Wear protective disposable gloves
5. Remove large pieces of glass or brittle plastic by hand and place in the garbage bin
6. Sweep up the rest of the glass/brittle plastic shards in the area
7. Wash all affected areas thoroughly with water or with a dap wipe-all
8. Area must be checked by Foreman or Supervisor before resuming work in the area
9. Return cleaning equipment and dispose of protective equipment
10. Wash hands before returning to work

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.15

Title: **Spill or Leak Response Plan**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

1. Any sanitary facility used by workers on the farm should be located away from any primary production area
2. If a major spill or leak of field sanitation units or toilet facilities occurs, access to the facility and the affected area around it is blocked off until it can be inspected
3. All affected areas around the facility should be properly cleaned
4. Have available either equipment (tractor with loader) to move soil or materials (filled sacks or bales of hay or straw) to help to contain the spill
5. The area will be secured and contaminated soil will be removed from the affected area and properly disposed of
6. Before reusing, check the facility for leaks or cracks and have it serviced by the contractor

The facility cannot be used by workers until a supervisor has inspected the site for cleanliness and approves the clean-up activities

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.16

Title: **Selecting and Storing Packaging Materials**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

1. At no time will any product-contact container or packaging material come in contact with the ground/floor or walls, a pallet should be used as a buffer at all times to prevent contact with the floor of the facility, and workers are instructed when using mechanized transportation not to come into contact with the walls of any area of the facility
2. Plastic, collapsible bins are built with a pallet-like bottom which raises the product portion of the bin off of the ground
3. Procedures for Storage of Packaging Materials:
 - a. As shipments of new containers and packaging materials are received, each pallet will be individually wrapped to ensure contaminants are restricted from contact with the containers
 - b. All containers and packaging materials are stored in an enclosed location to prohibit contamination. Space is left between the stored materials to leave room for cleaning and inspection
 - c. As pallets of containers or packaging are opened, the remainder of the pallet will be rewrapped to prevent contamination
 - d. Product-contact containers in use in the Grading/Packing/Cooling area will be covered when not in use, and all packaging materials in use will be closed up when not in use to prevent contamination
4. Inspection of Packaging Materials and Pallets:
 - a. Visual inspection of all boxes, bins, packing materials, and pallets will be done by market staff and contract employees before use
 - b. Any broken packaging or pallet will be discarded
 - c. If any foreign materials are present, the packaging or pallet may be properly cleaned and sanitized; but these products must be properly dried before use

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.17

Title: **Moving Harvested Product from Field to Storage/Packing Facility**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

1. All produce will be harvested into clean plastic harvest containers for washing/grading or new boxes/containers in the case of field packing products
2. All finished containers or harvest containers shall be labeled to assure traceability from the field
3. Filled containers, finished boxes or marketable units shall be loaded onto trucks or trailers with cleaned surface as per policy (Doc. 2.12, Doc. 2.13, Doc. 3.11, Doc. 3.12, Doc. 3.22) for cleaning equipment
4. The method of transport shall have either a permanent cover or temporary cover available while moving from field to storage
5. Temperature sensitive product will be uncovered once it arrives at storage/packing facility if there is a permanent covered facility to house such vehicles
6. No product will be parked under any area where it may be contaminated from bird, tree dropping or dust from roadways
7. Products requiring cooling or refrigeration will be transferred to these areas within one half hour of arrival at the storage facility

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.18

Title: **Product Traceability Plan**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

1. All products produced by the farm will be assigned a traceability code (Lot number) based on harvest date, field number/location, and product/crop code. (SOP 2.19)
2. Lot numbers with inventory will be recorded on crop production/disposition sheets (pick ticket, invoice, etc) as product is harvested from the field
3. Harvested products will be tagged, stamped or labeled by the marketing unit (example: bin, box, pallet, bag, etc) with the assigned lot number
4. All product is invoiced as it is shipped from the farm
5. Invoices include farm name and information, buyer name and information, inventory amounts transferred/exchanged, corresponding lot numbers, and chain of custody signature acceptance with date
6. Invoice should be signed or initialed and dated by the customer (receiving party) when product is delivered
7. All unused/unsold inventory is accounted for (production/disposition sheet) including quantity, date, and method of disposal
8. An annual "Mock Recall" shall be performed during the [redacted] full week of crop production each growing season (SOP 2.20)

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.19

Title: **Assigning Traceback Codes on the Farm**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

1. Traceback codes will be assigned to all commercial crops produced on the farm
2. The code will include (1) the date harvested, (2) location number and (3) product/crop code
3. The following protocol will be followed in assigning traceback codes (lot number):
'On **date & year**, I harvested **location number** from **crop code**.'
4. The four digit date will be assigned using the Gregorian calendar format
5. The harvest year will be the last two digits of the current year
6. A two digit number will be assigned to both production fields and rows under the management of the grower (These numbers will be posted in the field.)
7. The crop code will be a two digit number assigned by the grower based on crops grown
8. The assigned traceback code (lot number) will be set up as follows: 000000-0000-00
9. The traceback code (lot number) will follow that crop from time of harvest through final disposition from the farm
10. All products will carry the assigned traceback code (lot number) on boxes, pallets, or designated harvest containers and will be recorded on crop production/disposition sheets and invoices

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.20

Title: **Conducting a Mock Recall**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

1. In order to test this farm's traceability system, a mock recall will be conducted during the first full week of harvest
2. A lot number from the crop production/disposition sheet or invoice will be randomly selected from Section 4
3. The product will be traced from the field through the disposition of the total inventory to all buyers. (Direct Marketed products will be designated as such and will not go further.)
4. This activity will be recorded on form (3.07)
5. A call to each buyer will be made by the grower asking the status of the selected lot number. The buyer will verbally give the status
6. How much is still in inventory at their site?
7. How much has been distributed to retailers or other?
8. The grower will then request written confirmation of the information received related to the status of the product
9. The written confirmation will be maintained by the grower (Section 4)

Random Inspections shall include:

1. Observations as to availability of sanitary facilities and handwash
2. An additional random inspection of a closed box of finished product is conducted
3. Observation and inspection of transportation and storage of finished products is noted

All quality control inspections are documented and stored in Section 5

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.21

Title: **Policy for Potable Water Used for Drinking and Handwashing**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

1. All potable water sources must have been tested annually to maintain quality and freedom from pathogenic bacteria
2. A municipal water source is considered potable and a test from the municipality shall be kept on record
3. The water test must be done by an accredited laboratory
4. Results must indicate absence of both E. coli. And total fecal coliform to be acceptable for drinking or handwashing
5. If hand wash stations are used where potable water is not available, the water will be shocked with household chlorine bleach (free for fragrances and additives) at a rate of $\frac{1}{8}$ teaspoon per gallon of water. Let treated water stand for 30 minutes before using.
6. If hand wash stations are contracted through a private contractor, the grower will request a confirmation of the test and source of contractor's water. This confirmation will be kept on record.

STANDARD OPERATING PROCEDURE

(Farm Name)

Doc. No. 2.22

Title: **Cleaning Food Contact Surfaces Exposed to Bodily Fluids**

Effective Date: (00-00-0000)

Reviewed by: (Food Safety Coordinator Name, Date 00-00-0000)

1. If you obtain a wound, cut, or have a nosebleed while working, stop working immediately and contact your supervisor to get first aid or medical attention
2. Immediately stop all activities in the area where contamination has taken place
3. Wear protective disposable gloves
4. Discard all product that has come into contact with any blood
5. Move any contaminated product containers or transport equipment to the area to be washed and disinfected
6. Ventilate the room well prior to using chlorine products
7. Soak up any fluid using disposable paper towels
 - a. Cover area with towels soaked in 10,000ppm (1%) of available chlorine (e.g. Milton)
 - b. Marke the container of mixture as a 1:10 Disinfectant Solution of Chlorine Bleach (This is 1 part chlorine to 9 parts water, put water in container first then add chlorine)
 - c. Leave for at least 2 minutes
 - d. Remove used cleaning materials to refuse container
 - e. Clean area with hot water and detergent
 - f. Dry area using disposable paper towels
 - g. Dispose of protective clothing and wash hands

[Farm Name]

Visitor Health and Hygiene Policy

At [Farm Name], the health and safety of our visitors, staff, and the environment are our top priority. We ask that all visitors follow these health and hygiene guidelines to help ensure a safe and enjoyable experience for everyone.

1. General Health and Safety

- **Do Not Visit if Unwell:** If you are feeling unwell or have symptoms of illness (e.g., fever, cough, nausea), please refrain from visiting the farm. If you are exhibiting any signs of illness, we encourage you to reschedule your visit.
- **Personal Responsibility:** Please be mindful of your own health and well-being while visiting, and take necessary precautions to ensure your safety.

2. Hygiene Standards

- **Handwashing and Sanitization:** Visitors are encouraged to wash their hands after touching farm equipment, surfaces, or participating in activities. Hand sanitizing stations are available throughout the farm for your convenience.
- **Cleanliness:** We ask all visitors to maintain good personal hygiene during their visit and to help keep the farm clean by disposing of waste responsibly.

3. Visitor Guidelines

- **Supervision:** All visitors, including children, must be supervised at all times while on the farm. We ask parents or guardians to take full responsibility for the safety of minors in their care.
- **Proper Footwear and Clothing:** For safety and comfort, please wear closed-toed shoes (e.g., boots, sturdy sneakers) while on the farm. We recommend wearing weather-appropriate clothing that you don't mind getting dirty, as farm conditions can be muddy or dusty.

4. Animal Areas

- **Animal Interaction:** Please follow all signage and staff instructions when in or around animal areas. Do not approach, feed, or attempt to interact with animals unless explicitly allowed by staff.
- **Respect Boundaries:** For your safety, avoid entering animal enclosures or petting areas unless supervised.

5. Food and Drink

- **Eating Areas:** Food and beverages are to be consumed in designated picnic or eating areas. Visitors are not permitted to eat or drink in fields, barns, or animal areas.
- **No Harvesting or Eating Raw Products:** Visitors are not allowed to pick or eat any crops, fruits, or vegetables from the field unless otherwise indicated by farm staff. Any produce purchased in the farm shop or market is for consumption only after it has been properly washed and prepared.

6. No Outside Pets

- **Service Animals Only:** To ensure the safety and comfort of all visitors, pets are not permitted on the farm, with the exception of service animals. Please ensure your service animal is under control at all times.

7. Waste Management

- **Trash Disposal:** Please dispose of all trash, including food wrappers and personal items, in the designated bins. Help us maintain the cleanliness of the farm by using the trash and recycling bins provided throughout the property.
- **Environmental Care:** Do not leave litter or items in fields, gardens, or common areas. Respect the natural environment by minimizing waste and keeping the farm clean.

8. Safety and Emergency Procedures

- **In Case of Emergency:** In the event of an emergency, please notify a farm staff member immediately. Emergency contact numbers and procedures are posted at key locations around the farm.
- **First Aid:** A first aid kit is available at the main entrance, and staff are trained to assist with basic first aid if necessary.

9. Visitor Responsibility

- **Follow Farm Staff Instructions:** Please follow all instructions given by farm staff and any signage posted throughout the property. These guidelines are in place to ensure the safety of everyone.
- **Respect the Environment:** Visitors are encouraged to treat the farm and its resources with respect. Do not damage plants, structures, or other property. Help us maintain a positive and safe experience for everyone by being courteous and considerate.

Acknowledgment

By visiting [Farm Name], you agree to abide by this Visitor Health and Hygiene Policy. Your cooperation is essential in helping us maintain a safe, clean, and enjoyable environment for all.

If you have any questions or need further information, please speak with a staff member during your visit.

Contact Information:

For inquiries or further assistance, please contact us at:

[Farm Contact Details]

[Phone Number]

[Email Address]

(Farm Name)

Doc. 3.01

Worker Sanitation and Worker Protection Training Log

Date: _____ Location: _____

Trainer: _____ Training Time: _____

Training material (Please attach any written materials to this log with a staple): Please see the food safety plan for overall Worker Training procedures.

Employee Name (please print)

Employee Signature

1. _____

2. _____

3. _____

4. _____

5. _____

6. _____

7. _____

8. _____

9. _____

10. _____

Reviewed by: _____ **Title:** _____ **Date:** _____

(Farm Name)

Doc. 3.03

Illness/Injury Reporting Log

Please see the food safety plan for overall illness/injury reporting procedures.

Date	Name of Employee	Injury sustained/illness reported	Action taken (ice applied, bandaged, sent to hospital, etc)	Did employee return to work: (yes or not)	Initials

Reviewed by: _____ Title: _____ Date: _____

(Farm Name)

Doc. 3.04

First Aid Kit Monitoring Log

Please see the food safety plan for overall First Aid Kit Monitoring.

Date	Location of First Aid Kit or #	Date checked and stocked	If restocked, list added items here (band aids, ointment, etc)	Initials

Reviewed by: _____ Title: _____ Date: _____

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Reviewed by: _____ Title: _____ Date: _____

(Farm Name)

Doc. 3.06

Water Testing Log

Please see the food safety plan for overall information on surface water testing. Save any document providing information on test methods and test results from your laboratory.

Date	Surface water location/name	Laboratory	Results	Corrective action if necessary	Initials

Reviewed by: _____ Title: _____ Date: _____

(Farm Name)

Doc. 3.07

Traceability and Mock Recall Exercise

Date: _____

Conducted by: _____

Lot #: _____

Product traced: _____

Please see the food safety plan for overall traceback procedures.

Step Backward				
Harvest Date	Harvester	Packing Date	Packer	Shipping Date

Step Forward		
Customer(s) Contacted	Amount of product remaining from original shipment at customer's location	Disposition of product which could not be recalled

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Reviewed by: _____ Title: _____ Date: _____

(Farm Name)

Doc. 3.08

Visitor Log

Please see the food safety plan for overall information on food safety procedures for visitors.

Date	Enter Time	Visitor Name	Host	Exit Time

Reviewed by: _____ Title: _____ Date: _____

(Farm Name)

Doc. 3.09

Waiver of Liability and Assumption of Risk Agreement

Waiver

In consideration of my voluntarily working/entering the premises, property at (insert address), I for myself, personal representative or assigns, do hereby release, waive, discharge, and covenant not to sue the business (insert business name) or the business owner (insert name), it's trustee, directors, officer, employees, and agents from liability from any and all claims including negligence resulting in personal injury, accidents or illnesses (including death) and property loss arising from time on premises.

Assumption of Risk

The property at (insert address) carries with it certain inherent risks that cannot be eliminated regardless of the care taken to avoid injuries. I have read the previous paragraph and I know and understand and appreciate these and other risks inherent in the activity in which I am participating. I hereby assert that my participation is voluntary and that I knowingly assume all such risks.

Indemnification and Hold Harmless

I also agree to indemnify and hold harmless the business (insert business name) and the owner (insert name), its trustees, directors, officers, employees and agents from any and all claims, actions, suits, costs, expenses, damages and liabilities including attorney fees as a result of this activity on these premises.

Severability

The undersigned further expressly agrees that the forgoing waiver and assumption of risk agreement is intended to be as broad and inclusive as is permitted by the law of the State of West Virginia and that if any portion thereof is held invalid, it is agreed that the balance shall, notwithstanding, continue in full legal force and effect.

Acknowledgement of Understanding

I have read this waiver of liability, assumption or risk, and indemnity agreement, and fully understand its terms. I acknowledge that I am signing the agreement freely and voluntarily, and intend by my signature to be complete and unconditional release of all liability to the greatest extent allowed by law.

Signature of Participant

Date

[Farm Name]

Doc. 3.10

Visitor Health and Hygiene Policy

At [Farm Name], the health and safety of our visitors, staff, and the environment are our top priority. We ask that all visitors follow these health and hygiene guidelines to help ensure a safe and enjoyable experience for everyone.

1. General Health and Safety

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- **Handwashing and Sanitization:** Visitors are encouraged to wash their hands after touching farm equipment, surfaces, or participating in activities. Hand sanitizing stations are available throughout the farm for your convenience.
- **Cleanliness:** We ask all visitors to maintain good personal hygiene during their visit and to help keep the farm clean by disposing of waste responsibly.

3. Visitor Guidelines

- **Supervision:** All visitors, including children, must be supervised at all times while on the farm. We ask parents or guardians to take full responsibility for the safety of minors in their care.
- **Proper Footwear and Clothing:** For safety and comfort, please wear closed-toed shoes (e.g., boots, sturdy sneakers) while on the farm. We recommend wearing weather-appropriate clothing that you don't mind getting dirty, as farm conditions can be muddy or dusty.

4. Animal Areas

- **Animal Interaction:** Please follow all signage and staff instructions when in or around animal areas. Do not approach, feed, or attempt to interact with animals unless explicitly allowed by staff.
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- **Eating Areas:** Food and beverages are to be consumed in designated picnic or eating areas. Visitors are not permitted to eat or drink in fields, barns, or animal areas.
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- **Service Animals Only:** To ensure the safety and comfort of all visitors, pets are not permitted on the farm, with the exception of service animals. Please ensure your service animal is under control at all times.

7. Waste Management

- **Trash Disposal:** Please dispose of all trash, including food wrappers and personal items, in the designated bins. Help us maintain the cleanliness of the farm by using the trash and recycling bins provided throughout the property.
- **Environmental Care:** Do not leave litter or items in fields, gardens, or common areas. Respect the natural environment by minimizing waste and keeping the farm clean.

8. Safety and Emergency Procedures

- **In Case of Emergency:** In the event of an emergency, please notify a farm staff member immediately. Emergency contact numbers and procedures are posted at key locations around the farm.
- **First Aid:** A first aid kit is available at the main entrance, and staff are trained to assist with basic first aid if necessary.

9. Visitor Responsibility

- **Follow Farm Staff Instructions:** Please follow all instructions given by farm staff and any signage posted throughout the property. These guidelines are in place to ensure the safety of everyone.
- **Respect the Environment:** Visitors are encouraged to treat the farm and its resources with respect. Do not damage plants, structures, or other property. Help us maintain a positive and safe experience for everyone by being courteous and considerate.

Acknowledgment

By visiting [Farm Name], you agree to abide by this Visitor Health and Hygiene Policy. Your cooperation is essential in helping us maintain a safe, clean, and enjoyable environment for all.

If you have any questions or need further information, please speak with a staff member during your visit.

Contact Information:

For inquiries or further assistance, please contact us at:

[Farm Contact Details]

[Phone Number]

[Email Address]

By signing below, I am stating that I have read and agree to the terms of this policy.

Signature _____ Date _____

(Farm Name)

Doc. 3.11

Harvest Container Cleaning Log

Date	Type of Container	Cleaned (Y/N)	Sanitized (Y/N)	Disinfectant Product Used	Initials

Reviewed by: _____ Title: _____ Date: _____

(Farm Name)

Doc. 3.12

Hand Harvest Equipment Cleaning Log

Date	Item(s)	Inspected	Cleaned	Sanitized	Initials

Reviewed by: _____ Title: _____ Date: _____

(Farm Name)

Doc. 3.13

Domestic and Wildlife Monitoring Log Including Pest/Rodent Control

Please see the food safety plan for overall Pest/Rodent control procedures. Field monitoring may be documented using a calendar. Be specific about when you monitor and document.

Company Used * or Self	Date of Service or Action Taken	Type of Pest	Type of Control **	Location of Traps	Traps Checked (date)	Checked by (name)	Disposal means

*If using a company for service, attach a report or receipt of service for each of their visits.

**List type of control methods used such as exclusion, traps, poison, repellants, etc.

Reviewed by: _____ Title: _____ Date: _____

(Farm Name)

Doc. 3.14

Manure Treatment and Storage Log

Please see the food safety plan for overall manure application procedures.

Date	Collected From	Stored (Y/N)	Enclosed (Y/N)	Incorporated (Y/N)	If so, Crop planted (type and date)	Crop harvested (type and date)	Initials

Reviewed by: _____ Title: _____ Date: _____

(Farm Name)

Doc. 3.15

Weekly Rodent Station Report

Station Number & Location	Activity (Y/N)	Add Bait (Y/N)	Empty Trap (Y/N)	Notes

Instructions

1. Inspect all traps and record findings weekly.
2. Wear disposable gloves when inspecting, emptying, and re-baiting rodent stations.
3. Remove any debris or carcasses to outside container when finished.
4. **Wash hands immediately at completion.**

L=Left, R=Right, F=Front, B=Back, C=Corner, Ctr=Container, Shwr=Shower

Date: _____ Inspected by: _____

(Farm Name)

Doc. 3.16

Buyer Contact List

Buyer Company Name	Name of Contact Person	Contact Address	Contact Telephone Number

Reviewed by: Date: _____

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Reviewed by: _____ **Date:** _____

(Farm Name)

Doc. 3.19

Equipment Tools and Utensils List

Tool	Description	Use	Storage Location

Reviewed by: _____ Date: _____

Reviewed by: _____ **Title:** _____ **Date:** _____

(Farm Name)

Doc. 3.21

Pre-Harvest Risk Assessment	Inspection date (mm/dd/yr) : _____ Conducted by: _____		
	Yes*	Correction Actions if Necessary	Yes (after correction made)
<p>* A check mark in the Yes column means that each of the items below is under control and therefore does not represent a threat to the safety of the harvested crop. All risks must be checked Yes before harvesting can begin.</p>			
Harvesters and Handlers			
Workers have been trained on personal hygiene and practices that can contribute to contamination			
Workers have been checked for compliance with hygiene policies.			
Field and Perimeter			
There are no farm animals or wildlife present in the field.			
There are no signs of animal droppings or other recent animal activity in the field			
There are no signs of recent flooding from nearby creeks, streams, and rivers or overflowing manure storage tanks and septic systems.			
Hand Washing and Toilet Facilities			
Toilet facilities are available, accessible, and adequate in number.			
Toilet facilities are clean and equipped with hand washing stations.			
Hand washing stations are adequately supplied.			
Portable toilet facilities are located far enough away from production areas that they cannot become a source of contamination.			

<p>Grey water from portable hand washing stations is diverted away from production areas.</p>			
<p>Produce Contact Containers, Packing Materials, Equipment, and Tools</p>			
<p>Harvest containers were stored in a manner that prevents contamination prior to use.</p>			
<p>Harvest containers have been cleaned according to the policy stated in the food safety plan.</p>			
<p>Harvest containers have been inspected to be free from splinters, exposed nails, or signs of contamination.</p>			
<p>Equipment and tools have been cleaned according to the policy stated in the food safety plan.</p>			

(Farm Name)

Doc. 3.22

Truck Log

Date	Time	Trucking Company	Trailer Number	Driver's Name	Trailer's Last Load	Truck clean (Y/N)	If no, state problem (e.g. odor, debris)	Corrective Action	Truck temp at Loading	Initials

Reviewed by: _____ Date: _____

Reviewed by: _____ **Date:** _____

(Farm Name)

Doc. 3.24

Product/Crop Code

Product/Crop	Code
Ex. Tomatoes	01

(Farm Name)

Doc. 3.28

Location Code

Field	Code
Ex. Field 1	01
Row	Code
Ex. Row 1	01
Tunnel/Greenhouse	Code
Ex. Tunnel 1	08 (starts after last field number)

*Reference Farm Map

*Ex. 0101 (Field 1, Row 1), 0801 (Tunnel 1, Row 1)

(Farm Name)

Doc. 3.27

On-Farm Compost Process Log

Farm Name:	
Composting Method:	
Date Started:	
Date Completed:	
Agriculture System:	

Use this log if you produce on-farm compost. Record all input materials and your composting method including date started, turning dates, and the temperatures maintained. Use this log per composting cycle. You can add additional rows to the table below by clicking the "+" button between cells.

Date	Pile #	Temperature(s) in F	Turned? (Yes or No)	Notes
Example: 10/1/2022	1	132	Yes	Materials were leaves, manure, and woody materials.

Use the table below to estimate the volume or tonnage of compost spread on fields. This log represents compost spread during a specific year. You can add rows to the table below if more than one field/APN is included in your project.

Average Compost Weight or Volume per Truck load:	
# of Truck Loads applied to field(s): (add rows if more than one field)	
Total Estimated Weight in Tons/Cubic Volume applied to all fields:	

Signature:			
Title:		Date:	

By signing this process log, you certify materials have originated from your operation to be included in the on-farm compost, and a similar amount of materials has been returned back to your operation. You also certify that the estimated tonnage above is accurate and meets HSP Grant requirements. CDFA requires a process log, lab analysis stating C:N (within 6 months of application), and 3-5 geotagged pictures to be submitted at time of reimbursement.



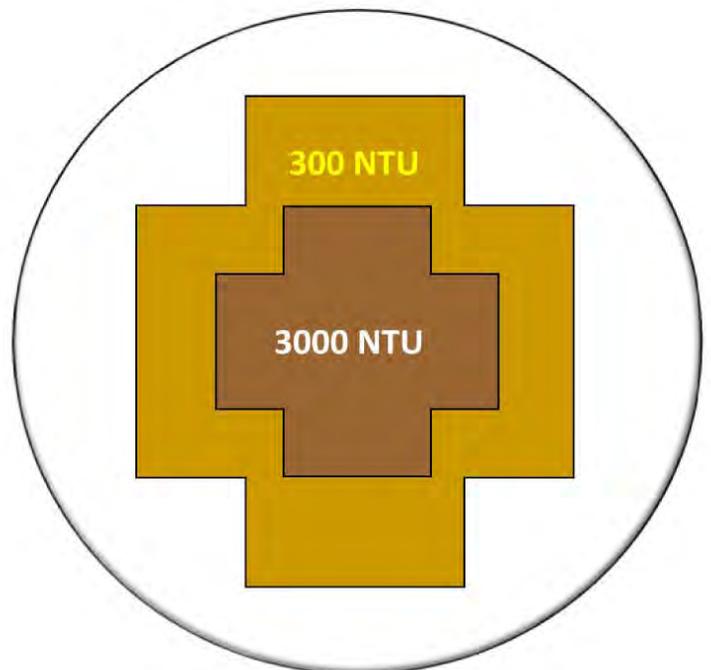
Handling Turbidity in Postharvest Wash Water

Turbidity in postharvest wash water is one of three major factors that need to be monitored to ensure effectiveness of sanitizer in wash water. Along with the wrong pH and inadequate free sanitizer, excessive turbidity may hamper efforts to effectively maintain sanitary postharvest wash water. Excessively turbid water can be from either from organic sources (plant particles and “juices”) or inorganic sources (soil). Excessive turbidity will consume the fast-acting oxidizers and interfere with testing of sanitizer levels, making it ineffective. In addition, the Food Safety Modernization Act (FSMA) requires growers to monitor turbidity in postharvest wash water.

Turbidity is a measure of the clarity of water. In lakes and streams, environmental scientists use a tool called a Secchi disk to measure turbidity. The disk itself has a high contrast pattern on it, divided in quarters and colored alternating black and white. The disk is dropped into a water body and lowered into the water until the scientist can't see the pattern. The depth is recorded and it is used as a comparison with other water bodies.

A similar process has been devised for postharvest wash water by Dr. Trevor Suslow of University of California-Davis. The disk below can be placed at the bottom of a clear polycarbonate cylinder that is at least 18 inches deep. The cylinder is then filled with wash water from the wash tank, flume, or other use. If the outer cross (labeled 300 NTU) is unable to be seen, it is time to change the wash water on account of excessive turbidity.

Whenever performing food safety procedures, it is important to have a Standard Operating Procedure in a food safety manual that outlines how the procedure is to be performed. As with any monitoring on farm, a record should exist that the activity actually took place. On the back of this document is a sample Standard Operating Procedure for measuring turbidity using the modified Secchi disk. It is left to the grower to create a record sheet for the activity.





Title: Turbidity Monitoring

Effective Date:

Developed by: Phil Tocco, Michigan State University; adapted from Trevor Suslow, UC Davis

Reviewed by: _____ GAP Coordinator, Date: _____

1.0 Purpose

Turbidity should be monitored to control the effects of turbidity on sanitizer effectiveness.

2.0 Scope

This SOP covers all produce that contacts the wash water being monitored.

3.0 References

This SOP is designed to support compliance with the FSMA Produce Safety rule §112.48 (b)

4.0 Definitions

Secchi disk: a tool to qualitatively determine the level of turbidity in a quantity of water.

5.0 Responsibility

_____ is responsible for carrying out this SOP.

(Fill in the appropriate name)

6.0 Procedures

1. At least hourly (flume) or after each load (batch), whichever interval is shorter, test water for turbidity
2. Using a clean container or bucket, fill a clear polycarbonate container to a depth of 18”.
3. View the modified Secchi disk through the water and polycarbonate container.
4. When the outer cross of the Secchi disk becomes difficult to see, change the wash water.
5. Record results on a record sheet.
6. Discard water in the monitoring container, and rinse it with clean tap water.

7.0 Verification procedures

_____ will intermittently verify the procedure being performed.

(Food Safety Coordinator)

8.0 Records

The results of each monitoring event will be recorded on the appropriate record sheet.

Food Safety for Flooded Farms

In the aftermath of flooding, fruit and vegetable crops may pose a food safety risk.

These catastrophic events can have a lingering and potentially hazardous impact on public health. Crops and other food commodities exposed to flood waters can be considered adulterated and not suitable for human consumption or animal feed. The U.S. Food and Drug Administration (FDA), as well as Universities and Extension Programs across the country, have provided guidance on how to handle manage flood crops, keeping food safety in mind.

Assessing the Risk

Before cleaning up or destroying crops in flooded fields, check with your crop insurance and/or their local Farm Services Agency (FSA) representatives regarding exact documentation to certify losses, procedures for initiating claims, and possible financial assistance.

Several questions should be answered in order to assess the safety of flood covered or damaged crops. The first assessments should involve determining the extent of flooding, what type of contaminants could be in the flood water, and what types of crops are being affected.

Types of Flooding

There are two types of flooding. The first is more typical and occurs after a heavy downpour when fields become saturated and water pools on the soil surface. This type of flooding can reduce yields and even kill plants, but usually will not result in contamination of produce with human pathogens. The second type of flooding is more severe and occurs when water or runoff from surface waters such as rivers, lakes, or streams overflow and run into fields. Flood waters, as described in the second definition, are likely to contain chemical and biological contaminants that may be harmful to the health of humans and animals.



Keith McCall—Photo Courtesy of the National Resource Conservation Service.

Sources of Contamination

There are two primary types of contamination that are of concern for food crops. Not only are these contaminants a concern for human health, they can also be harmful if fed to livestock.

Microbial Contamination

1. Pathogens may include bacteria, parasites, and viruses.
2. Sources of microbial contamination might come from upstream farms, rural septic systems, overflow from industrial sewage systems, and raw manure or feces.

Chemical Contamination

- Chemical contaminants may include heavy metals, petroleum products, pesticides, or other agricultural chemicals.
- Sources of chemical contamination will vary greatly depending on the severity of flood, proximity to operations using chemicals, or runoff from roadways.

Determining Whether Your Crop Is 'Safe'

If the edible portion of the crop has been exposed:

Unfortunately, if the edible portion of a crop has been exposed to flood waters, it is considered adulterated by the U.S. Food and Drug Administration and should not enter human food channels. There is no practical method to recondition the edible portion of a crop to provide reasonable assurance of human food safety.

If the crop comes in proximity to or is exposed to a lesser degree:

Crops near flooded areas or those that were flooded without the edible part of the plant coming in contact with the flood water (such as sweet corn or staked tomatoes) need to be evaluated on a case by case basis. These crops as well as those in which the edible portion develops after flood waters recede are not automatically deemed adulterated.

1. Is the edible part of the plant developing and if so, how far above the flood water was it?
2. Is there any evidence that floodwater splashed up onto edible portion of the crop? Floodwater almost certainly contains some pathogens and/or chemicals.
3. If feeding to livestock, was the crop exposed to prolonged periods of moisture and stress that could promote fungal growth or molds that could produce mycotoxins?

Additional Concerns and Considerations

- Place markers at the high water line so you can identify the areas where crops were in contact with flood waters.
- Leave a 30 foot buffer between flooded areas of fields and adjacent areas to be harvested for human consumption; this is to accommodate a generous turn-around distance for equipment to prevent contact with flooded soil and avoid cross-contamination of non-flooded ground.
- Workers should wear protective clothing such as rubber boots and rubber gloves when working in fields that were flooded. Protective clothing should be discarded or thoroughly cleaned after working in flooded areas.
- If your well head was submerged, re-test your well water to make sure that only safe, potable water comes into direct contact with produce.
- Allow at least 60 days to elapse between flooding and planting of the next human food crop. In absence of known or suspected biological or chemical contaminants in flood waters (such as sewage discharge or run-off from industrial sites) you can replant after 60 days.
- Organic growers should contact their certifier to discuss damage to the crop. Flood waters might contain residues of prohibited substances.

Recommended Resources

FDA Notice for Floods, Hurricanes, and Power Outages: <http://www.fda.gov/Food/FoodDefense/Emergencies/FloodsHurricanesPowerOutages/ucm112723.htm>

FDA Definition of Adulterated Food:

<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/FDCAActChapterIVFood/ucm107527.htm>

The Questions on Salvaging Flooded Crops, John E. Rushing, Ph.D. North Carolina State University. Department of Food Science, FSE 91-21.

<http://www.ces.ncsu.edu/depts/foodsci/ext/pubs/salvagingfloodedcrops.PDF>

Impact of Flooding on Organic Food and Fields, Jim Riddle - Organic Outreach Coordinator, University of Minnesota.

http://swroc.cfans.umn.edu/prod/groups/cfans/@pub/@cfans/@swroc/documents/asset/cfans_asset_229667.pdf

Produce Safety Alliance

web: <http://producesafetyalliance.cornell.edu>

How to build a field hand washing station in 10 easy steps for under \$20

Michele Schermann, University of Minnesota Agricultural Health and Safety Program

Jill Randerson, Kidzibits, Inc.

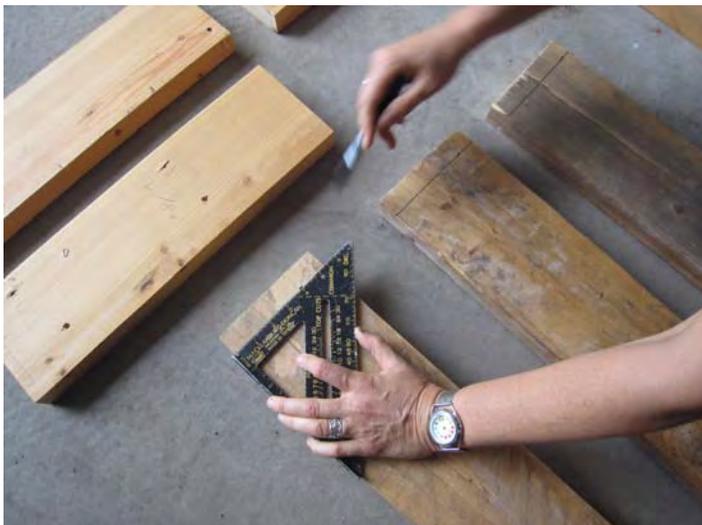
Field handwashing stations can be rented from the sanitation companies or you can purchase field handwashing stations from various sources. They are easy to build with a few purchased, found and salvaged materials.

1. Get some wood. Make the sides.



For this stand, we used 4 - 36" 2x6
4 - 18" 2x6" for the sides of the stand. We decided a stand 36" high would be good for handwashing. You can choose any height you wish.

2. Square off the ends and cut them to the right sizes for your space and what you need.



Materials list.

1. **Water container** -- the blue container holds 5 gallons of water and has an open/close valve. Available at big-box home hardware store in the camping section. \$9.99
2. **Soap.**
3. **Trash can** with a lid so paper towels don't blow around in the wind. We used an old rag container found in the barn.
4. **Water catching bucket** (5 gallon bucket)
5. **Dishpan.** Another found item, is the "drawer" under the water container and holds single use paper towels. You can use whatever you want for this. Doesn't need to be a dishpan.
6. **Wood** (salvaged). 2x6's, 2x4's, and plywood for the top, sized to fit.
7. 60 2.5" screws.
8. **Bungee cord**



This is how the sides will look. They aren't screwed together yet. At this point we decided to use the dishpan as the drawer because we had one and wouldn't need to purchase anything else. The top cross piece was placed slightly below the very top to create a lip for the dishpan "drawer" to slide on.
←



3. Screw the crosspieces in place. We used 2.5" screws, 4 on each end (16 total per side, 32 for both sides). We drilled holes before we drilled the screws.



Here you can better see how we placed the top cross piece down from the top to be the dishpan drawer slide.

Now we have our sides built.



4. Figure out how wide to cut the width-wise crosspieces. Placing our dishpan on the “drawer slides” we measured and determined that crosspieces of 14.5” would work. We cut 4- 14” pieces of wood. This time we used 2x4s.



5. Screw the bottom widthwise crosspieces onto the other crosspieces. You could also turn them the other direction and screw them into the side pieces. With the crosspieces turned flat, they make a bigger flat area in case you want to put something on those pieces.

6. Screw the top widthwise crosspieces in place. Notice that these are turned up and down (vs flat like the bottom pieces) and screwed through the side supports. They are low enough so that the dishpan drawer fits in the remaining space.



7. Next, cut a scrap of plywood, old countertop, or some other flat material (not glass) to fit the top of the stand.



8. Screw the top in place



9. Install your dishpan drawer. That is where you will have the single use hand towels.

Bungee cord a 5 gallon drinking container on the top. Supply soap. (see photo on the first page if you forgot what this looks like)

10. Get the rest of the parts together. Put a bucket underneath the spigot of the water container to catch the water. You might want to put a rock in the bottom of the bucket if you are in a windy area. Have a trash can handy for the used towels. One with a lid will keep the used towels from flying all over the place.

Final notes

This is just an idea plan. You can make this any size you want and with any materials. You could change the boards and install a paper towel dispenser under the top, or you could mount a paper towel roll holder on the side. If you do that, you will need to remember to remove it when it rains so you don't get all your paper towels wet. If you really want to be fancy, you could cover the top of the stand with a vinyl covering so that it will say dry and won't the plywood won't warp. Cut vinyl (oilcloth) slightly bigger and staple on to the bottom side of the top.

Of course this thing won't last forever, but for a seasonal handwashing station in the field it works very well. Remember to use clean potable water for handwashing, not rain water or other water.

2011. Developed by the University of Minnesota Agricultural Health and Safety Program team. Funding through a partnership between the MN Fruit and Veg Growers Association and the USDA-Risk Management Agency.

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Did you wash your hands?

Stop the spread of germs and be healthy.



WET

Wet hands under warm water.



WASH

Wash hands with soap for 20 seconds.



RINSE

Rinse under warm water.



DRY

Dry hands. Turn off water with paper towel.

Qualified Exemption Review *Template*

Name and address of farm: _____

Date: _____

Sales receipts or records reflecting **total food** sales over the previous 3 years:

Year 1 (Sales year: _____) \$ _____

Year 2 (Sales year: _____) \$ _____

Year 3 (Sales year: _____) \$ _____

Average total food sales \$ _____

Total food sales to qualified end users (E.g. consumers, or grocery stores and restaurants within 275 miles or within the same state or Indian reservation) \$ _____

\$ _____ ÷ \$ _____ x 100 = _____ %

Sales to qualified end users	Average sales	Percent sales to qualified end users
------------------------------	---------------	--------------------------------------

*Sales receipts must also be retained to support this record.

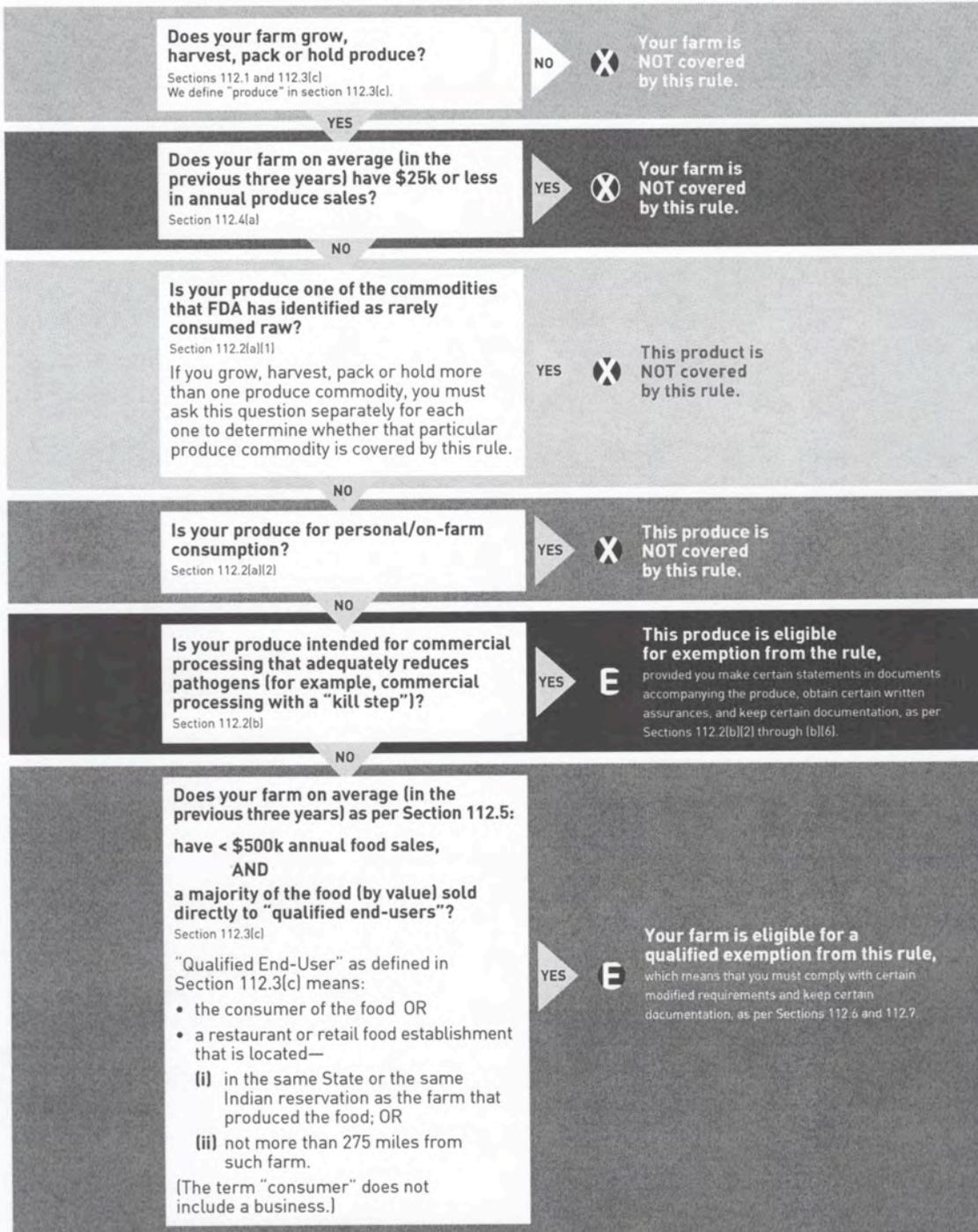
Reviewed by: _____ Title: _____ Date: _____

FSMA PSR Reference § 112.7(b) Confidential Record

STANDARDS FOR PRODUCE SAFETY

Coverage and Exemptions/Exclusions for 21 PART 112

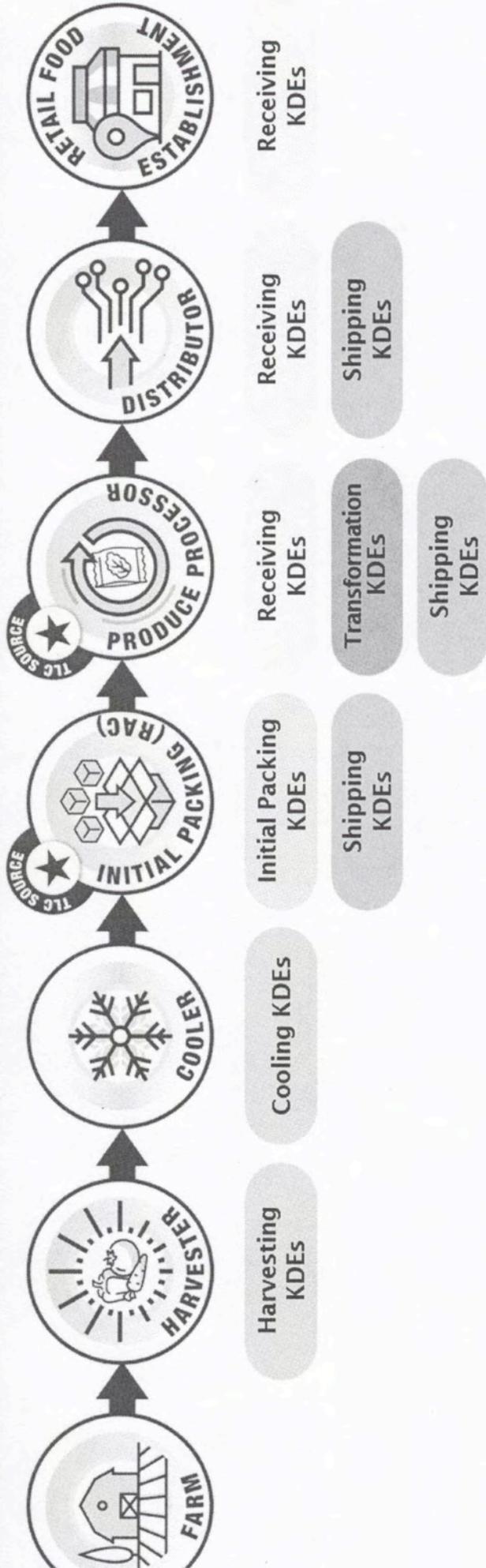
The Preventive Controls for Human Food rule clarified the definition of a farm to cover two types of farm operations, primary production farms and secondary activities farms. The same definition is used in the Produce Safety rule (section 112.3(c)). Below are basic criteria that determine whether an operation that meets the definition of "farm" is subject to the produce rule.



YOU ARE COVERED BY THIS RULE.

Supply Chain Example: Cucumbers

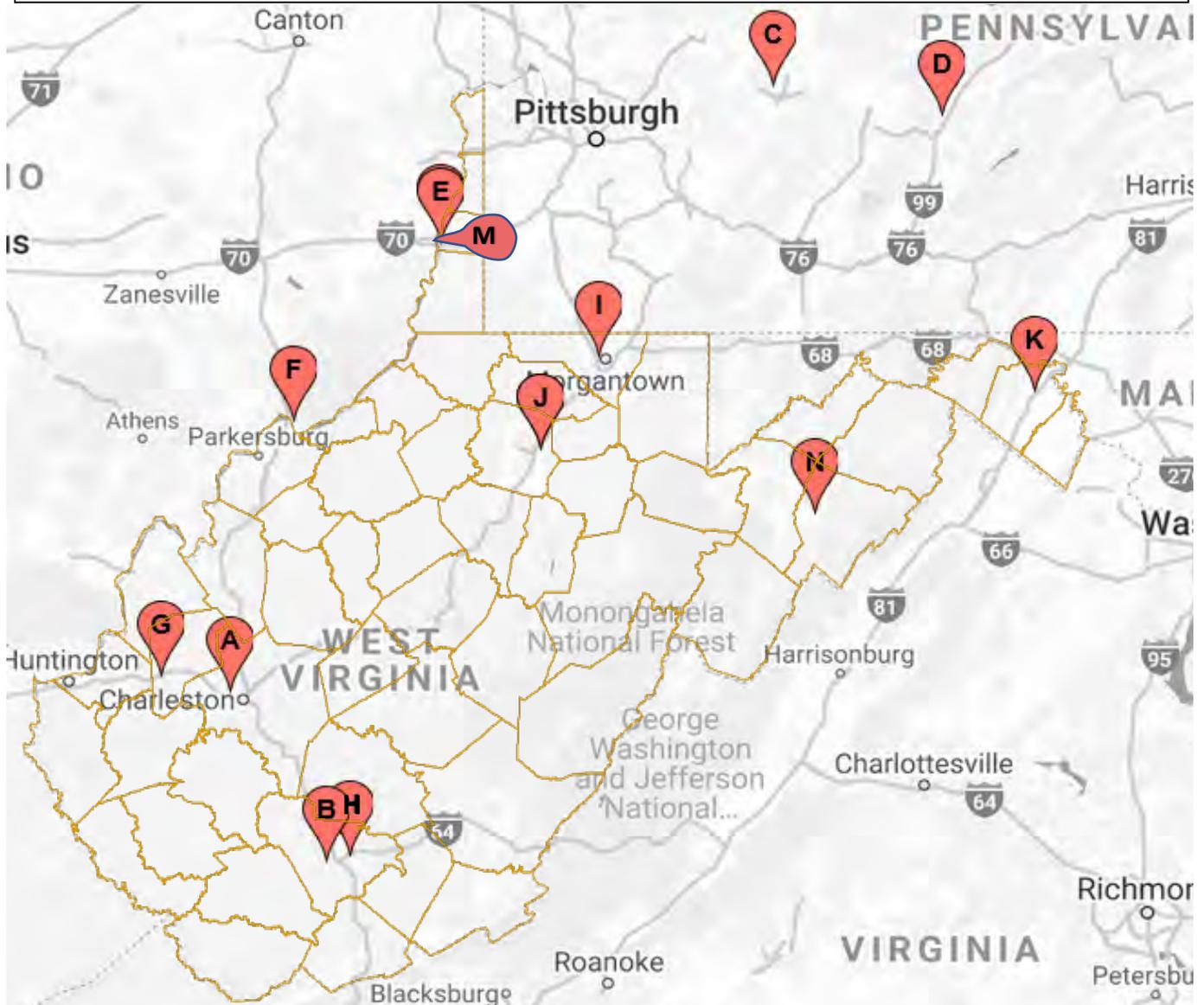
Traceability Plan





WV Water Quality Testing Laboratories for Produce Growers Biologicals: Total coliform and e-coli count

Farms covered under the Food Safety Management Act (FSMA) Produce Safety Rule must test their agricultural water using methods approved by the FDA, § 112.151(a). This list will help you locate a lab near you with the capability to perform one of the approved test methods. Please inquire for costs, requirements, and to confirm tests meet latest FSMA guidelines before ordering. Labs are listed in alphabetical order and no one lab is recommended over any other. For the latest updates please visit: <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>



Funding for this statement, publication, press release, etc. was made possible, in part, by the Food and Drug Administration through grant PAR-16-137. The views expressed in written materials or publication and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government.



WV Water Quality Testing Laboratories for Produce Growers

Biologicals: Total coliform and e-coli count

A

ALS ENVIRONMENTAL- SOUTH CHARLESTON

[147 11th Avenue](#)
[South Charleston, WV 25303](#)

Testing Capability: Ag Water
Lab Phone: [\(304\) 356-3168](#)

B

ANALABS, Inc.

[PO Box 1235](#)
[Crab Orchard, WV 25827](#)

Testing Capability: Ag Water
Lab Phone: [\(304\) 255-4821](#)

C

Environmental Service Laboratories, Inc

[1803 Philadelphia St.](#)
[Indiana, PA 15701](#)

Testing Capability: Ag Water
Lab Phone: [\(724\) 463-8378](#)

D

Fairway Laboratories, Inc.

[PO Box 1925](#)
[Altoona, PA 16603](#)

Testing Capability: Potable and Ag Water
Lab Phone: [\(814\) 946-4306](#)

E

Industrial Lab Analysis

[65 36th St.](#)
[Wheeling, WV 26003](#)

Testing Capability: Ag Water
Lab Phone: [\(304\) 233-5595](#)

F

Microbac Laboratories - Ohio Valley Division

[158 Starlite Dr](#)
[Marietta, OH 45750](#)

Testing Capability: Ag Water
Lab Phone: [\(740\) 373-4071](#)

G

PACE Analytical Services Inc.

[5 Weather Ridge Dr.](#)
[Hurricane, WV 25526](#)

Testing Capability: Ag Water
Lab Phone: [\(304\) 757-8954](#)

H

PACE Analytical Services Inc.

[PO Box 286](#)
[Beaver, WV 25813](#)

Testing Capability: Potable and Ag Water
Lab Address2: 225 Industrial Park Rd
Lab Phone: [\(800\) 999-0105](#)

I

PACE Analytical Services Inc.

[16 Commerce Drive](#)
[Westover, WV 26501](#)

Testing Capability: Potable and Ag Water
Lab Phone: [\(304\) 241-5861](#)

J

Reliance Laboratories

[PO Box 4657](#)
[Bridgeport, WV 26330](#)

Testing Capability: Potable and Ag Water
Lab Phone: [\(304\) 842-5285](#)

K

Reliance Laboratories

[25 Crimson Circle](#)
[Martinsburg, WV 25401](#)

Testing Capability: Potable and Ag Water
Lab Phone: [\(304\) 596-2084](#)

L

Sturm Environmental Services

[PO Box 650](#)
[Bridgeport, WV 26330](#)

Testing Capability: Potable and Ag Water
Lab Address2: Brushy Fork Rd
Lab Phone: [\(304\) 623-6549](#)

M

Tra-Det, Inc.

[PO Box 2019](#)
[Wheeling, WV 26003](#)

Testing Capability: Potable and Ag Water
Lab Phone: [\(304\) 233-9060](#)

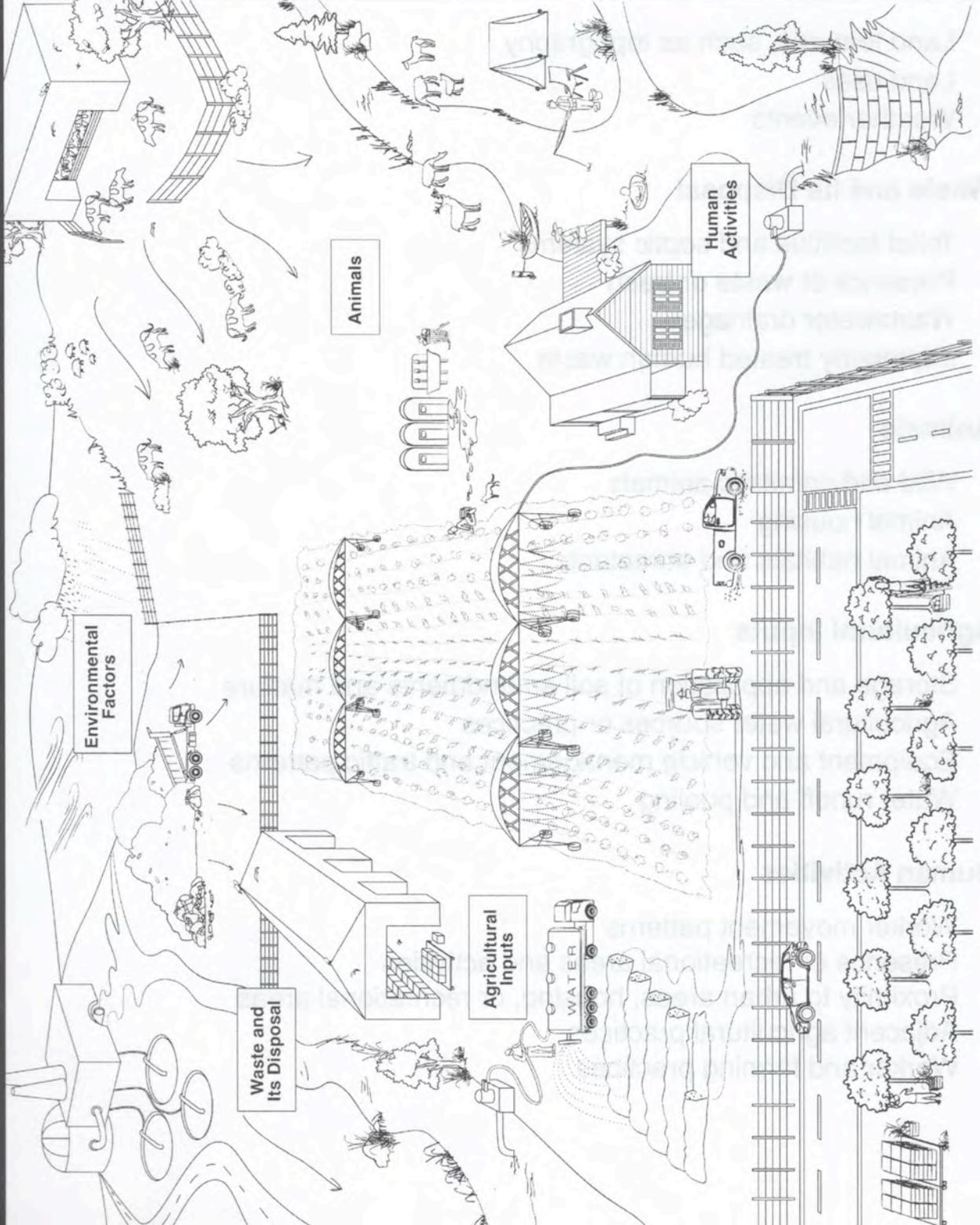
N

WVDA Nutrient Management & Water Quality Lab

[60B Industrial Park Rd](#)
[Moorefield, WV 26836](#)

Testing Capability: Ag Water
Lab Phone: [\(304\) 538-2397](#)

WHAT CONTAMINATION SOURCES CAN IMPACT A PRODUCE FARM?



Potential sources or routes of contamination on farms and adjacent and nearby land can include:

Environmental Factors

- Land features, such as topography
- Land uses
- Weather events

Waste and Its Disposal

- Toilet facilities and septic systems
- Presence of waste or trash
- Wastewater drainage
- Improperly treated human waste

Animals

- Wild and domestic animals
- Animal housing
- Animal habitats and attractants

Agricultural Inputs

- Storage and application of soil amendments and manure
- Agricultural water sources or practices
- Equipment and vehicle management and traffic patterns
- Water runoff and pooling

Human Activities

- Worker movement patterns
- Presence of recreational areas and activities
- Proximity to urban areas, housing or recreational areas
- Adjacent agricultural practices
- Worker and farming practices

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West Virginia Department of Agriculture

Kent A. Leonhardt, Commissioner
Joseph L. Hatton, Deputy Commissioner



Agritourism State Fire Code and Building Code Exemption Application

Date of Request:

Business Name:

Business Contact Name:

County:

Physical Address:

Mailing Address (if different):

Phone Number:

Email Address:

The following questions only pertain to the part of the business in which you are requesting the code exemption for buildings or structures used primarily for agricultural purposes including agritourism purposes.

1. What provision/s of the State Fire Code or Building Code are you requesting exemption for? Please explain.

2. Does the business provide an agritourism activity as defined in WV Code below? (circle one) YES NO

"Agritourism" activity means any lawful activity carried out on a farm or ranch that allows members of the general public for recreational, entertainment, or educational purposes to view or enjoy rural activities.

3. Is the agritourism activity carried out on a working farm or ranch as defined in WV Code below? (circle one) YES NO

"Farm" or "ranch" means an area of land used for the production, cultivation, growing, harvesting, or processing of agricultural products.

4. If you answered YES to #2, please describe your farm or ranch. If you answered NO please write N/A.

5. Are the buildings or structures utilized primarily for agricultural purposes? (circle one) YES NO

6. If you answered YES to #5, please explain the agricultural purposes and percentage or frequency of use. If you answered NO, please write N/A.

7. What is the business model?

8. What is the principal product and/or service?

9. Specify the size/scale of operation (# of acres, building size, building occupancy)?

10. Number of livestock and type of livestock if applicable? Please state N/A if not application.

11. Has the county assessors valuation been filed and approved? (circle one) YES NO

a) If YES, please attach a copy.

12. Is an IRS Schedule F filed? (circle one) YES NO

13. Have you completed a farm assessment form? (circle one) YES NO

14. Please attach any supporting documents that you would like to include about your agritourism activity and/or farm or ranch (flyers, pamphlets, pictures, etc.).

Business Owner/Operator Signature

Date

PLEASE RETURN APPLICATION AND ATTACHMENTS TO: agexemptions@wvda.us

For WVDA Use Only

Date Request Received: _____

Was site visit completed? YES NO

Site Visit Completed by (WVDA Employee Signature):

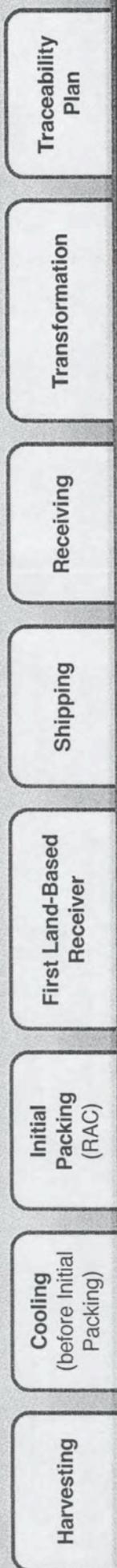
Date of Site Visit: _____

address: 217 Gus R. Douglass Lane, Charleston, WV 25312
telephone: 304-558-3550 • fax: 304-558-2203

www.agriculture.wv.gov

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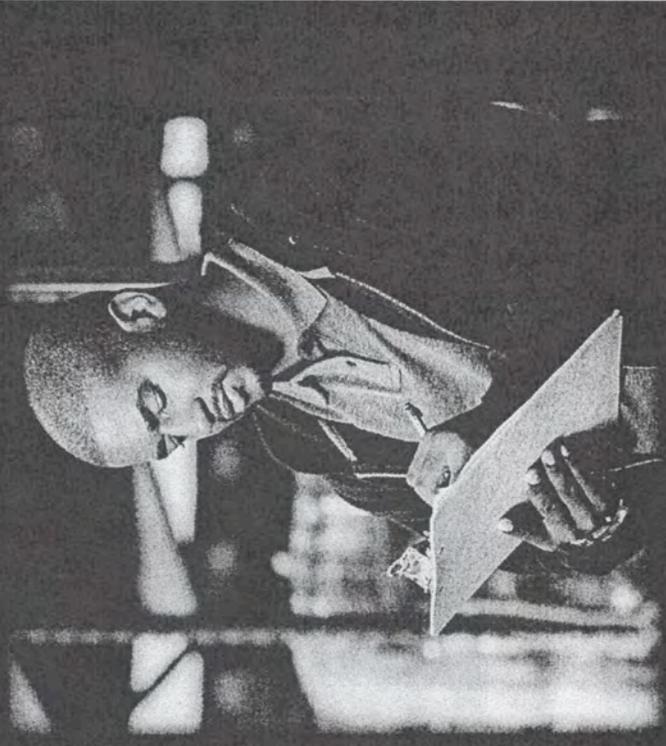
Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)



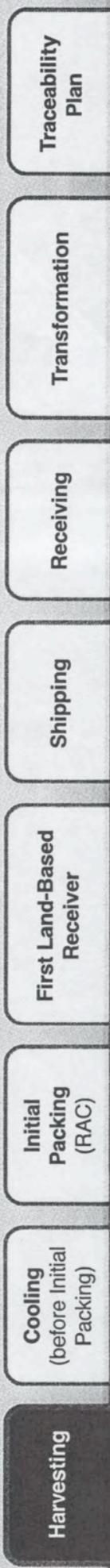
The Food Traceability Rule requires persons who manufacture, process, pack, or hold foods on the Food Traceability List (FTL) to maintain and provide to their supply chain partners specific information (key data elements or KDEs) for certain critical tracking events (CTEs) in the food's supply chain. This framework forms the foundation for effective and efficient tracing and clearly communicates the information that FDA needs to perform such tracing.

The information that firms must keep and send forward under the rule varies depending on the type of supply chain activities they perform with respect to an FTL food, from harvesting or production of the food through processing, distribution, and receipt at retail or other point of service. Central to the proposed requirements is the assignment, recording, and sharing of traceability lot codes for FTL foods, as well as linking these lot codes to other information identifying the foods as they move through the supply chain.

Graphics on the subsequent pages provide readers with a list of KDEs required for each CTE performed.



Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)



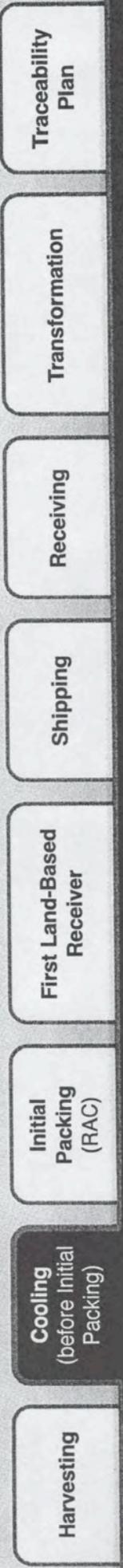
Harvesting KDEs (Raw agricultural commodities (RACs) not obtained from a fishing vessel)

- Location description for the immediate subsequent recipient (other than a transporter) of the food
- Commodity and, if applicable, variety of the food
- Quantity and unit of measure of the food
- Location description for the farm where the food was harvested
- For produce:
 - Name of the field or other growing area from which the food was harvested (must correspond to the name used by the grower), or
 - Other information identifying the harvest location at least as precisely as field or growing area name
- For aquacultured food:
 - Name of the container (e.g., pond, tank, cage) from which the food was harvested (must correspond to the container name used by the aquaculture farmer), or
 - Other information identifying the harvest location at least as precisely as the container name
- Date of harvesting
- Reference document type and reference document number

Provide to the Initial Packer

- Business name
- Phone number
- Harvesting KDEs (except the reference document type and reference document number)

Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)

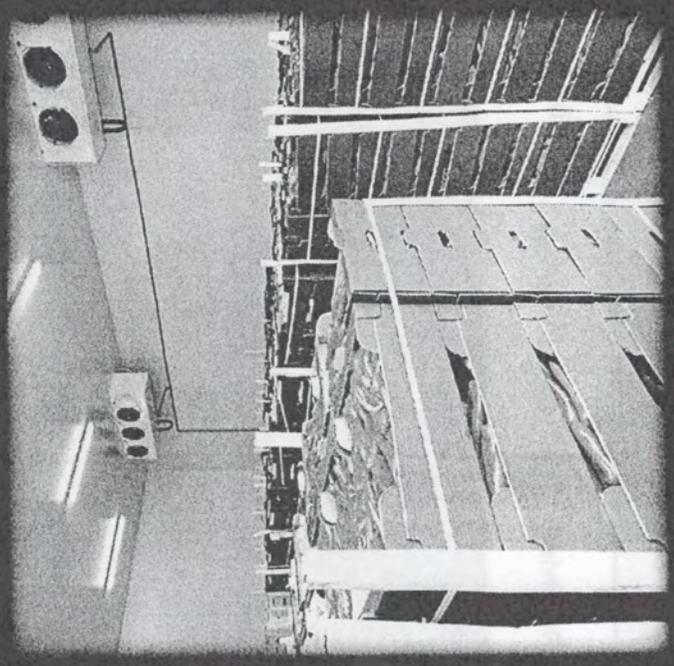


Cooling KDEs (RACs not obtained from a fishing vessel)

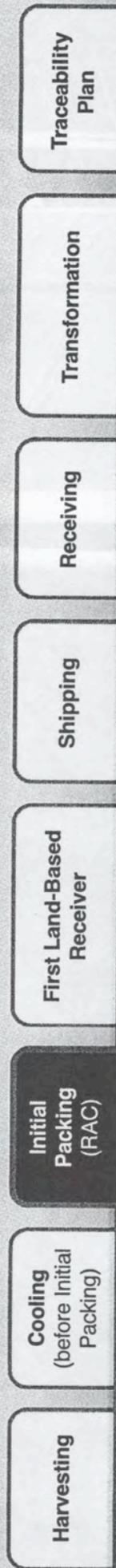
- Location description for the immediate subsequent recipient (other than a transporter) of the food
- Commodity and, if applicable, variety of the food
- Quantity and unit of measure of the food
- Location description for where you cooled the food
- Date of cooling
- Location description for the farm where the food was harvested
- Reference document type and reference document number

Provide to the Initial Packer

- Cooling KDEs (except the reference document type and reference document number)



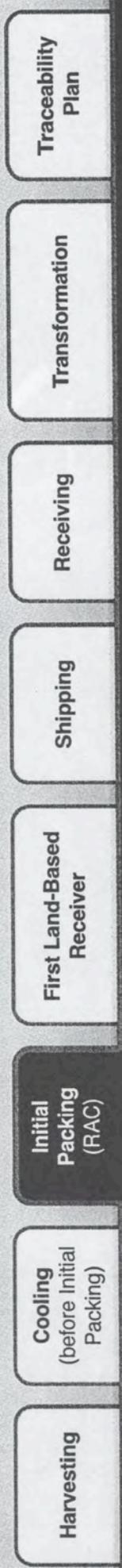
Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)



Initial Packing KDEs of RACs (other than a food obtained from a fishing vessel) KDEs must be linked to the traceability lot you assign for the food that you pack

- Commodity and, if applicable, variety of the food received
- Date you received the food
- Quantity and unit of measure of the food received
- Location description for the farm where the food was harvested
- For produce:
 - Name of the field or other growing area from which the food was harvested (must correspond to the name used by the grower), or
 - Other information identifying the harvest location at least as precisely as field or growing area name
- For aquacultured food:
 - Name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (must correspond to the container name used by the aquaculture farmer), or
 - Other information identifying the harvest location at least as precisely as the container name
- Business name and phone number for the harvester of the food
- Date of harvesting
- Location description for where the food was cooled (if applicable)
- Date of cooling (if applicable)
- Traceability lot code you assigned
- Product description of the packed food
- Quantity and unit of measure of the packed food
- Location description for where you initially packed the food (i.e., traceability lot code source), and (if applicable), the traceability lot code source reference
- Date of initial packing
- Reference document type and reference document number

Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)



Initial Packing KDEs (Sprouts)

KDEs must be linked to the traceability lot for the food

All KDEs on previous slide **AND**:

- Location description for the grower of seeds for sprouting and date of seed harvesting, if either is available
- Location description for the seed conditioner or processor, associated seed lot code, and date of conditioning or processing
- Location description for the seed packinghouse (including any repackers), date of packing (and repacking, if applicable), and any associated seed lot code assigned by the seed packinghouse
- Location description for the seed supplier, any seed lot code assigned by the seed supplier (including master lot and sub-lot codes), and any new seed lot code assigned by the sprouter
- Description of the seeds, including seed type or taxonomic name, growing specifications, type of packaging, and (if applicable) antimicrobial treatment
- Date of receipt of the seeds by the sprouter
- Reference document type and reference document number



Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)

Harvesting

Cooling
(before Initial
Packing)

Initial
Packing
(RAC)

First Land-Based
Receiver

Shipping

Receiving

Transformation

Traceability
Plan

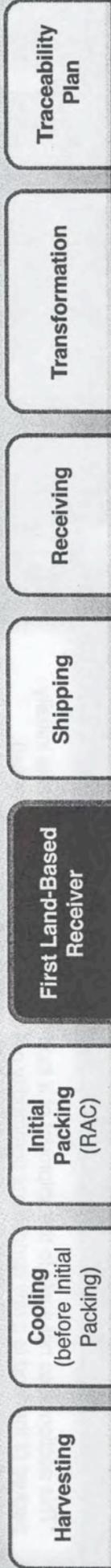
Initial Packing KDEs of RACs (other than a food obtained from a fishing vessel)

For food you receive from a person who is exempt from the rule KDEs must be linked to the traceability lot for the food

- Commodity and, if applicable, variety of the food received
- Date you received the food
- Quantity and unit of measure of the food received
- Location description for the person from whom you received the food
- Traceability lot code you assigned
- Product description of the packed food
- Quantity and unit of measure of the packed food
- Location description for where you initially packed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference
- Date of initial packing
- Reference document type and reference document number



Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)



First Land-Based Receiver KDEs (food obtained from a fishing vessel)
KDEs must be linked to the traceability lot for the food

- Traceability lot code you assigned
- Species and/or acceptable market name for unpackaged food, or the product description for packaged food
- Quantity and unit of measure of the food
- Harvest date range and locations for the trip during which the food was caught
- Location description for the first land-based receiver (i.e., traceability lot code source), and (if applicable) traceability lot code source reference
- Date the food was landed
- Reference document type and reference document number



Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)

Harvesting

Cooling
(before Initial
Packing)

Initial
Packing
(RAC)

First Land-Based
Receiver

Shipping

Receiving

Transformation

Traceability
Plan

Shipping KDEs (maintain and provide)

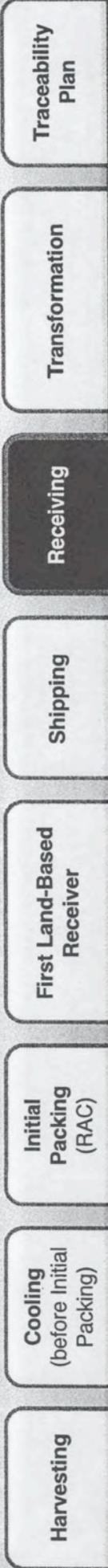
KDEs must be linked to the traceability lot for the food

- Traceability lot code for the food
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate subsequent recipient (other than a transporter) of the food
- Location description for the location from which you shipped the food
- Date you shipped the food
- Location description for the traceability lot code source or the traceability lot code source reference
- Reference document type and reference document number (maintain only)

*This section does not apply to the shipment of a food that occurs before the food is initially packed (if the food is a raw agricultural commodity not obtained from a fishing vessel).



Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)



Receiving KDEs

KDEs must be linked to the traceability lot for the food

- Traceability lot code for the food
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate previous source (other than a transporter) for the food
- Location description for where the food was received
- Date you received the food
- Location description for the traceability lot code source or the traceability lot code source reference
- Reference document type and reference document number

Receiving KDEs

For food you receive from a person who is exempt from the rule KDEs must be linked to the traceability lot for the food

- Traceability lot code for the food, which you must assign if one has not already been assigned (does not apply to RFEs or restaurants)
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate previous source (other than a transporter) for the food
- Location description for where the food was received (i.e, traceability lot code source) and (if applicable) traceability lot code source reference
- Date you received the food
- Reference document type and reference document number

*This section does not apply to receipt of a food that occurs before the food is initially packed (if the food is a raw agricultural commodity not obtained from a fishing vessel) or to the receipt of a food by the first land-based receiver (if the food is obtained from a fishing vessel).

Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)



Harvesting

Cooling
(before Initial
Packing)

Initial
Packing
(RAC)

First Land-Based
Receiver

Shipping

Receiving

Transformation

Traceability
Plan

Transformation KDEs

*FTL food(s) used as ingredient(s)
KDEs must be linked to the new
traceability lot for the food*

- Traceability lot code for the food
- Product description for the food to which the traceability lot code applies
- For each traceability lot used, the quantity and unit of measure of the food used from that lot

Transformation KDEs

*New food produced
KDEs must be linked to the new traceability lot for the food*

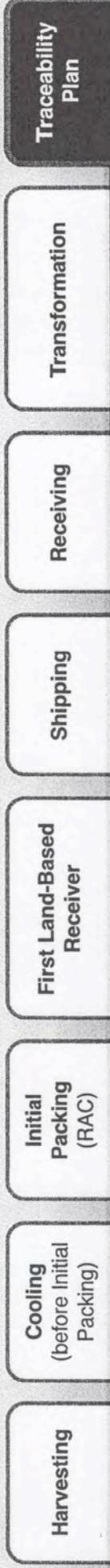
- New traceability lot code for the food
- Location description for where you transformed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference
- Date transformation was completed
- Product description for the food
- Quantity and unit of measure of the food
- Reference document type and reference document number

For RACs (other than a food obtained from a fishing vessel) that were not initially packed prior to your transformation of the food, you must maintain records containing the information specified in § 1.1330(a) or (c).

For sprouts that were not initially packed prior to your transformation of the food, you must maintain records containing the information specified in § 1.1330(a) or (c), and also § 1.1330(b).

*This section does not apply to retail food establishments and restaurants with respect to foods they do not ship (e.g., foods they sell or send directly to consumers).

Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)



Traceability Plan

Required for all persons covered by the rule

- Description of the procedures you use to maintain the required records, including the format and location of the records
- Description of the procedures you use to identify foods on the FTL that you manufacture, process, pack or hold
- Description of how you assign traceability lot codes to foods on the FTL, if applicable
- Statement identifying a point of contact for questions regarding your traceability plan and records
- If you grow or raise a food on the FTL (other than eggs), a farm map showing the areas in which you grow or raise such foods
 - The farm map must show the location and name of each field (or other growing area) in which you grow a food on the FTL, including geographic coordinates and any other information needed to identify the location of each field or growing area
 - For aquaculture farms, the farm map must show the location and name of each container (e.g., pond, pool, tank, cage) in which you raise seafood on the FTL, including the geographic coordinates and any other information needed to identify the location of each container
- You must update your traceability plan as needed to ensure that the information reflects your current practices and to ensure you are in compliance with the rule
- You must retain your previous traceability plan for 2 years after you update the plan





FSMA's Produce Safety Rule

Do you have to comply with the Produce Safety Rule?

WV Food Safety Training Team

In order to understand the Produce Safety (PS) Rule and what parts of the Rule apply to your farm it is important to first define if you grow covered produce (produce that will be inspected) or not and the second step, is to determine if your farm may be eligible for a qualified exemption or may not be covered at all by this Rule. If your farm does not meet the requirements set for qualified exempt farms, it is covered by the PS rule.

Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

1. What produce is covered by the Produce Safety Rule?

a. **“Covered Produce”** by this rule includes all fruits and vegetables that are usually eaten raw and refers to the harvestable or harvested part of the crop.

Fruits and vegetables such as:

Almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy,

mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, sweet cherries, chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and unqi fruit), cowpea beans, cress-

garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydews, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit,

peaches, pears, peas, pigeon peas, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams.

Botanical food crops are required to be cultivated or collected in accordance with the PS Rule if they meet the definition of “covered produce.”

These crops will be inspected under the PS Rule unless the farm meets the conditions for a qualified exemption or is not covered by the Rule. For more information see fact sheet on PSR Rule Exemptions.

b. “Not covered” produce: Fruits and vegetables that are usually not eaten raw.

Asparagus, beans (black, great Northern, kidney, lima, navy, pinto), garden beets (roots and tops), sugar beets, cashews, sour cherries, chickpeas, cocoa beans, coffee beans, collards, sweet corn, cranberries, dates, dill (seeds and weeds), eggplants, figs, ginger, hazelnuts, horseradish, lentils, okra, peanuts, pecans, peppermint, potatoes, pumpkins, winter squash, sweet potatoes, and water chestnuts. **If the commodity you grow is listed here, the PS Rule does not cover it, these crops will not be inspected.**

c. Do you grow produce that is intended for commercial processing that adequately reduces pathogens (for example, commercial processing with a “kill step”)?

If the answer is “Yes”, then the farm must annually obtain a written assurance from either the customer performing the commercial processing or from your customer that an entity in the distribution chain subsequent to customer will perform commercial processing. **Produce for which the grower has a written assurance that it will be commercially processed with a kill step is exempt from the PS Rule.**

Processing includes: refining, distilling, manufacturing/processing produce into sugar, oil, spirits, wine, beer or similar products. Examples of possible products: Produce that is used in the production of spices, ingredients of dietary supplements, or food additives.

If taking advantage of this exemption, the grower is required to get the letter of assurance by January 2020, but the farm can obtain the letter before that to have proof of the “exempt” status.

2. Farms under the Produce Safety Rule can be classified as:

a) Not covered by the PS Rule:

- ✓ If the average annual farm sales are \$26,632* or less in **produce** from 2014 to 2016. To determine annual farm sales add ALL produce sales = Covered produce + not covered + exempt produce.
- ✓ If all the produce grown is for personal consumption.

b) Eligible for a qualified exemption and modified requirements.

For a farm to be eligible for a qualified exemption, it must meet the conditions in both numerals (1) and (2).

- (1) The farm must sell the majority of the **food**** to qualified end users. Qualified end users are consumers, restaurants or retail establishments*** within WV or not more than 275 miles of the farm or via internet sales. Total annual food sales to businesses (i.e. brokers) must be 49% or less.

AND

- (2) The total **food*** sales for the farm are less than \$532,645* annually (average value of sales from 2014-2016).

Qualified Exemptions require farms to keep financial records to prove food sales (Effective- 1/26/2016) and comply with labeling requirements. The labeling requirement consists of including the name and complete business address of the farm where the produce was grown either on the label of the produce or to display the same information at the point-of-purchase. The labeling requirement will be effective on 1/20/2020. As long as a farm satisfies these requirements and FDA has not withdrawn a qualified exemption then the farm is compliant with the Produce Safety Rule. Nonetheless it is important for produce growers to understand the importance of following food safety practices and the conditions under which a qualified exemption can be withdrawn.

* These are average values, adjusted for inflation for years 2014-2016. Source:

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

*****“Food”** means articles used for food or drink for human or animal consumption, or articles used to make components of it. Includes seeds and beans used to grow sprouts. As farms calculate food sales take into account that cotton, tobacco and timber are not considered food.

Examples of food include: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages

(including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods. Livestock and meat are both food within this definition. FDA may interpret the term “food” to “include live animals raised for food”. There are instances when live animals are sold for purposes other than for food, such as being sold as pets (e.g., dogs), pets are not considered food.

FDA notes that only the value of food “sold” during the year should be counted to determine the eligibility for the qualified exemption.

***A “**retail food establishment**” is an establishment that sells food products directly to consumers as its primary function and includes grocery stores, convenience stores, and vending machine locations.

A “retail food establishment” also includes certain farm-operated businesses selling food directly to consumers as their primary function.

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

- (i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);
- (ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and
- (iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

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

- (i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);
- (ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

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

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

c) “Covered farms”.

These farms did not meet the conditions set for a qualified exemption and have to comply with the Produce Safety Rule and must follow the standards set for worker health and hygiene, agricultural water, biological soil amendments, domesticated and wild animals, equipment, tools, sanitation and growing, harvesting, packing and holding activities. Covered farms need to have at least one representative attend a **Produce Safety Alliance (PSA) Grower training** by the respective compliance date. The PSA Training is an all-day training that goes over the 7 modules and outlines the practices that farms must comply with.

Compliance dates for “Covered Farms”.

Covering	All other businesses (Sales over \$500K)	Small businesses (\$250K-\$500K Produce sales)	Very small Businesses (\$25K- \$250K Produce sales)
Most provisions in the Rule	1/26/2018	1/28/2019	1/27/2020
For water related regulations outlined in the Rule (UNDER REVISION)	1/27/2020	1/26/2021	1/26/2022
Sprouts	1/26/2017	1/26/2018	1/28/2019

This document is not to be considered legal advice. This is a summary of the published guidelines by FDA for FSMA’s Produce Safety Rule (7/18/2017).

FSMA's Produce Safety Rule

Produce Safety Rule: Records and recordkeeping

WV Food Safety Training Team

This is a summary of the records and recordkeeping requirements that farms must follow to comply with the Produce Safety Rule.

General requirements for records

1. Records must include the name and location of the farm.
 2. Actual values and observations obtained during monitoring must be recorded.
 3. An adequate description (such as commodity name, or the specific variety or brand name of a commodity, or when available any lot number or other identifier) of covered produce applicable to the record.
 4. Location of a growing area (for example, a specific field) or other areas (specific packing shed) applicable to the record.
 5. The date and time of the activity documented.
 6. Records must be created at the time an activity is performed or observed.
 7. Records must be accurate, legible and indelible.
 8. **All records** must be dated, signed or initialed by the person who performed the activity documented.
 9. The **following records** must be reviewed, dated, and signed within a reasonable time after the records are made **by a supervisor or responsible party**.
 - Records that demonstrate that a farm satisfies the criteria for a qualified exemption annually.
 - Records of training that document required training of personnel, including the date of training, topics covered and the person(s) trained.
 - Documentation of the results of all analytical tests conducted on agricultural water for purposes of compliance. 112.5(b)(2).
 - Documents of the results of water treatment monitoring if a water treatment system is used. 112.5(b)(4).
 - Records that document any time interval or log reduction applied when agricultural water does not meet the requirements set for microbial quality. 112.5(b)(6).
 - For treated biological soil amendment of animal origin that a farm produces for its own covered farm(s), documentation that process controls (for example time, temperature and turnings) were achieved. 112.6 (b)(2).
 - Records that detail date and methods for cleaning and sanitizing of equipment used in covered harvesting, packing and holding activities. 112.140 (b)
- The following records apply to sprout operations in addition to the ones listed above.
- Records that detail date and methods for cleaning and sanitizing of equipment used in growing operations. 112.4(b)(1)

- Documents of the treatment of seeds or beans to reduce microorganisms of public health significance in the seeds or beans at the farm if a certificate of conformance from a seed supplier is not available.
- Documents of the results of all analytical tests needed to comply with the Produce Safety Rule. 112.15(b)(4)
- Documents and actions a farm takes when:
 - ✓ There is reason to believe a lot of seeds or beans may be contaminated with a pathogen. 112.42(b).
 - ✓ There is reason to believe a lot of seeds or beans may be contaminated based only on microbial test results. 112.142(c).
 - ✓ The growing, harvesting, packing or holding area tests positive for listeria species or *L. monocytogenes*. (112.146).
 - ✓ Samples of spent sprout irrigation water or sprouts test positive for a pathogen. (112.148).

Storing records

- Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review.
- Electronic records are considered to be onsite at the farm if they are accessible from an onsite location at the farm.

Use of existing records

- Existing records (such as those kept to comply with other Federal, State and local regulations or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this part.
- Existing records may be supplemented as necessary to include all the required information.
- The information required does not need to be kept in one set of records, any new information required by the PS Rule can be kept either separately or combined with existing records.

How long must records be kept for?

- Records must be kept for at least **two years** past the date the record was created.
- Records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for the **qualified exemption**, must be retained as long as necessary to support the farm's status during the applicable calendar year.
- Records that relate to the **general adequacy of the equipment or processes or records that relate to analyses sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations**, must be retained at the farm for **two years** after the use of such equipment or processes, or records related to analyses, sampling or action plans, is discontinued.

What formats are acceptable for records?

- Original records
- True copies (such as photocopies, pictures, scanned copies, microfilm, microfiche or other accurate reproductions of original records).
- Electronic records. Electronic record means any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

What requirements apply to making records available to FDA?

- All records required for the PS Rule must be made available and accessible during the retention period for inspection and copying by FDA upon oral or written request.
- A farm has 24 hours to obtain records kept offsite and make them available to FDA.
- If records are kept electronically, or keep true copies of records, or if reduction techniques such as microfilm are, records must be provided in a format they are accessible and legible.
- If a farm is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to the farm within 24 hours for official review upon request.

Can records provided to FDA be disclosed to persons outside of FDA?

Records obtained by FDA in accordance with the PS Rule are subject to the disclosure requirements under part 20 of the CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES. Chapter 20 states the following about the policy on disclosure of Food and Drug Administration records: The Food and Drug Administration will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.

For more details on FDA's policy on disclosure of records visit: <http://www.ecfr.gov/cgi-bin/text-idx?SID=4032a725693074be7371d49f19a47ab3&mc=true&node=pt21.1.20&rgn=div5>

This document is not to be considered legal advice, it is a summary of the requirements published in Subpart O of the Produce Safety Rule. Date: 3/15/2017

What requirements apply to making records available to FDA?

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This document is not to be considered legal advice, it is a summary of the requirements published in Subpart O of the Produce Safety Rule. Date: 3/15/2017

FSMA's Produce Safety Rule (PSR)

Understanding Qualified Exemptions and Modified Requirements

WV Food Safety Training Team

Under the Produce Safety Rule, farms can be classified as: a) Not covered by the Rule, b) Farms eligible for a qualified exemption and modified requirements or c) Covered farms.

This document focuses on explaining the requirements for produce farms that fall under the **qualified exemption and modified requirements**. For more information about farms not covered and covered farms by the PS Rule visit: <https://ncfreshproducesafety.ces.ncsu.edu/produce-safety-rule/>

I. In order to be eligible for a qualified exemption produce farms must meet these two requirements:

- 1). The farm must sell the majority of the **food*** directly to consumers, restaurants or retail food establishments within WV or not more than 275 miles from the farm or via internet sales (If the farm sells produce to a broker or any other type of business, those sales should be 49% or less of total food sales).
- 2). The total **food*** sales for the farm must be less than \$532,645 annually (to calculate use average sales from 2014-2016).

*Food is defined as articles used for food or drink for man or animals, or articles used to make components of it. It includes seeds and beans used to grow sprouts. As farms calculate food sales take into account that cotton, tobacco and timber are not considered food.

Any farm, CSA or U-pick operation can be eligible for a qualified exemption and modified requirements as long as they meet the two conditions set above by the PS Rule.

II. What do "Qualified exempt" farms have to do to be in compliance with the Produce Safety Rule?

These farms have to comply with two requirements: keep financial records and follow modified labeling requirements.

1. Records: A farm must establish and keep adequate records necessary to demonstrate that the farm satisfies the criteria for a qualified exemption, including a written record reflecting that an annual review has been performed and verification of the farm's continued eligibility for the qualified exemption. Farms must keep financial records to prove food sales are under \$532,645 from 2014-2016. For future calculations, use the values of the sales for the past three years.

Any records established and kept for compliance with the Produce Safety Rule must include the following information and adhere to these guidelines:

- ✓ Include the name and location of the farm
- ✓ Provide an adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record.
- ✓ Provide the location of growing areas and packing sheds
- ✓ Records need to be created at the time an activity is performed or observed.
- ✓ Records must be accurate, legible and indelible.
- ✓ Existing records to comply with other federal, state or local regulations can be used.
- ✓ Records to substantiate the qualified exemption must be kept for **3 years**.
- ✓ Records can be kept electronically; true copies are accepted or can be handwritten.

- ✓ A farm has **24 hours** to obtain records kept offsite and make them accessible to FDA for inspection and copying upon oral or written request.
- ✓ The records must be signed by the person who created them and by the farm supervisor or owner.

These records do not need to be submitted to FDA, WVDA or any other agency. These records must be kept by the farm on file in case they are formally requested by an inspector.

2. Labeling: The labeling requirement consists of including the name and complete business address of the farm where the produce was grown either on the label of the produce or to display the same information at the point-of-purchase. The labeling requirement will be effective on 1/20/2020.

Specific guidelines about labeling produce:

- Include the name and the business address of the farm where the produce was grown on any food packaging label.
- When food packaging label is not required, display at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard or documents delivered with the produce in the normal course of business, or in the case of Internet sales, in an electronic notice.
- The complete business address must include: street address or post office box, city, state and zip code for domestic farms, and comparable full address information for foreign farms.

As long as a farm satisfies the requirements for records and labeling listed above or the FDA has not withdrawn a qualified exemption then the farm is compliant with the Produce Safety Rule. Qualified exempt farms are not considered "covered farms" by the Rule and consequently they will not be inspected or checked for the practices/standards set in the Rule as covered farms will. Nonetheless, FDA is expecting these farms to grow, harvest, pack, hold and distribute produce under sanitary conditions. Failure to comply with requirements listed is prohibited by the FDA.

If the farm is not currently implementing good agricultural practices, it is important for the farmer to attend a training session or an educational program to learn about the topic and voluntarily implement practices that reduce the risk of foodborne illness.

Important aspects of Compliance and Enforcement

- FDA can withdraw a qualified exemption if produce has been grown, harvested, packed or held in a farm under such conditions that it is unfit for food or if it has been prepared, packed or held under unsanitary conditions where it can be contaminated with filth or have been rendered injurious to health.
- An exemption can be withdrawn in the event of an active investigation of a foodborne illness outbreak that is directly linked to a farm; or if FDA determines that is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the farm that are material to the safety of the food.

FDA will have procedures in place to:

- ✓ Withdraw exemptions.
- ✓ For farms to submit a hearing and appeals.
- ✓ Submit appeals by farms that have lost their qualified exempt status.
- ✓ Reinstate qualified exemptions.

This information is not legal advice. It is based on the information published in Subparts A, O, Q and R of the PS Rule.

How do GAP and GMP Certifications compare to FSMA’s Produce Safety (PS) Rule?

Elena Toro Rogers, Area Specialized Agent, Food Safety- Fresh Produce
 Department of Horticultural Sciences/ NC State Extension

This document provides a general comparison between GAP and GMP certifications that produce operations have been undergoing for the past decade and the new requirements set by FSMA’s Produce Safety Rule. Despite the fact that the Produce Safety Rule was published on November 27, 2015 there are guidance documents and inspection guidelines that are being developed at the time of this publication and therefore do not allow for a full comparison of the Rules.

GAP and GMP Certifications	FSMA- Produce Safety Rule
<p>All the Good agricultural practices (GAPs) and Good Manufacturing Practice (GMPs) audits that produce farms have undergone up to this point have been buyer-driven. After passing an audit, the farm receives a GAP and/or GMP Certification.</p> <p>For the past decade, farms selling primarily wholesale have been required to pass a third party audit annually in order to sell to a specific outlet.</p> <p>GAP Audits often include a field and harvest crew audit. GMP audits cover packinghouses and if any produce is processed the facility is often required to have a HACCP plan.</p>	<p>The Produce Safety Rule is a federal law that requires all segments of the industry to grow, harvest, pack and hold produce in such a way that minimizes the risk of causing food borne illness.</p> <p>The PS Rule has set the requirements for a regulatory program that is based on inspections, not audits. Further guidance is expected on this note.</p> <p>The PS Rule is based on Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs).</p> <p>The PS Rule will come into effect starting in 2017 for sprout growers and 2018 for all other operations. (See compliance dates for the PS Rule).</p>
<p>There are numerous companies that offer auditing services; each one has a slightly different scheme (guidance documents, auditing guidelines and fees). Examples of companies include: Primus labs, SQF and USDA.</p>	<p>The Food and Drug Administration (FDA) and the North Carolina Department of Agriculture & Consumer Services/Food and Drug Protection Division regulate the PS Rule. FDA has published the requirements, but the inspection guidelines are forthcoming.</p>
<p>If a grower currently sells to different buyers the farm may be doing audits with different companies.</p>	<p>FDA and NCDA&CS/Food and Drug Protection Division inspectors will conduct inspections. The frequency of the inspections is not outlined in the Rule.</p>
<p>The grower pays for the cost of the audits. Cost share is available to offset some of the costs.</p>	
<p>An audit is only conducted after a grower has requested the service, set a date and paid the fees. The fees are non-refundable if the farm fails the audit.</p>	<p>Inspections may be unannounced. A farm legally has 24 hours to provide records if FDA or NCDA&CS/Food and Drug Protection Division inspectors request these.</p>

<p>Audits have changed the way many farms operate. Many farms have adopted a food safety culture, but audits are only a snapshot of what happened that day at the farm and/or packinghouse.</p>	<p>It will be much easier for a farm that is already following a food safety plan and passing audits to comply with the PS Rule. Records to comply with the PS Rule do not need to be duplicated, just supplemented with any additional requirements.</p>
<p>Audits usually cover the whole operation: adjacent areas, wildlife intrusion, employee hygiene, compliance with city, state and federal laws regarding labor laws, compliance with all pesticide laws and applications, fertilizer (synthetic and organic) applications and laws, harvest practices, water testing and inspection of the water sources, tool inventory, all chemicals used in the operation, maintenance of equipment, pest control, harvest practices, inventory of all the materials supplied, post harvest handling, safe transport, trace back and recall protocols, pre inspection audits by the farm, records and training for all employees that handle the crop. Depending on the audit, there may be more or less requirements.</p> <p>Audits require the grower to develop and implement a food safety plan at the farm.</p>	<p>The PS Rule covers the following:</p> <ul style="list-style-type: none"> - Training - Agricultural water - Biological soil amendments of animal origin - Domesticated and wild animals - Equipment, tools, building and sanitation - Sprouts <p>The rule does not cover aspects of the operation that are already being regulated by other agencies (such as pesticide and fertilizer laws).</p> <p>The rule does not require a farm to have a food safety plan.</p>
<p>Audits require growers to prove they have attended training during the year and to train their employees.</p>	<p>The Rule requires all farms that grow covered produce and do not meet the guidelines to be exempt or qualified exempt to have a supervisor or representative for the farm attend a Produce Safety Alliance Grower training. This is a one-time requirement.</p> <p>In addition, training requirements for employees is very similar in the PS Rule and for food safety certifications.</p>
<p>Any crop can be audited and be certified, as long as the grower requests it.</p>	<p>The PS Rule covers crops that are considered raw agricultural commodities (RACs) and that will not receive commercial processing.</p> <p>The PS Rule provides exemptions and qualified exemptions, so not all operations have to comply with the rule in its entirety. Become familiar with the exemptions and the requirements for these farms if your farm is eligible as there are some record keeping and labeling requirements that will still apply.</p>
<p>In the event of a food safety outbreak, all documents used to build a food safety plan are legally binding, regardless of the fact that FDA does not regulate audits.</p>	<p>In the event of a food safety outbreak, all records must be provided to FDA within 24 hours of a formal request made by the agency to any operation that is being investigated for a possible food safety outbreak.</p>

Harvesting and Postharvest Handling of Vegetables for Market

Lewis W. Jett

Most vegetables are at their peak quality and nutritional value for a relatively short period of time. Harvesting vegetables at the right stage of growth maximizes both marketable yield and quality. Generally speaking, many vegetables are best when harvested in a small and tender stage and are often called “baby vegetable”. Below is a list of popular high tunnel and field vegetables and the optimal time for harvest of each crop.

Crop	Harvest Information
Arugula	Begin harvesting when leaves are 2-3 inches in length.
Artichoke (globe)	Heads which are firm, tight with even color.
Basil	Harvest beginning when the plant has produced at least 4 nodes. Harvest the top 2 nodes. Pinch blooms to keep vegetative.
Beans (snap)	Harvest when beans are green, firm and tender and the diameter of a pencil. Filet beans are harvested when they are 1/8 inch in diameter. (every 2-3 days)
Beets	Root beets are harvested when they reach a diameter of 1-2 inches. Bunch 6 beets and sell with tops. Trim tops to 1 inch if putting in storage.
Broccoli	Broccoli should be harvested with a compact head with small, tight beads which is 4-6” in diameter. Sprouting broccoli is harvested as loose florets.
Brussels sprouts	Harvest sprouts/buds when they are 1 inch in diameter. Top the plant to concentrate yield.
Cabbage (green)	Harvest firm, solid heads before any signs of head splitting.
Cantaloupe	Harvest cantaloupes when the cantaloupe fruit slips from the vine. This can be one-half or full-slip. Charentais melons should be harvested when the leaf closes to the fruit stem turns yellow.
Carrot	Baby carrots can be harvested when they are 1/4” to 3/4” in diameter. For storage, trim the tops to 1 inch.
Cauliflower	Cauliflower is harvested when the curds are compact and white (cultivar dependent). Usually 4-6 inches in diameter for heads
Celery	Harvest stalks when they are at least 6 inches long.
Chinese Cabbage (napa)	Heads should be firm and at least 6 inches in diameter.
Chinese Cabbage (bok choy)	Can be harvested at any stage of maturity. Over mature bok choy is “slimy” and discolored.
Cucumbers	Cucumbers should be harvested before fruit begins to develop a yellow, dull color. <i>Slicing cucumbers</i> : 4-8 inches in length <i>Burpless cucumbers</i> : 4-12 inches in length <i>Pickling cucumbers</i> : 2-4 inches in length
Eggplant	Eggplants are excellent when harvested as a baby vegetable. Harvest when the skin of the fruit is glossy and tender and before seeds develop within the fruit. Use pruners.
Garlic	When bottom leaves turn yellow and tops begin to fall over.
Kale	Full-size leaves are harvested when they are greater than 4” in length. Bunch approximately 15-20 leaves with a rubber band. Baby kale is harvested similar to leaf lettuce.

Crop	Harvest Information
Kohlrabi	Harvest stems which are 1-3 inches in diameter.
Leeks	Leeks can be harvested as a baby vegetable or when stem shanks are white. Full-sized leeks are about an inch in diameter.
Lettuce (leaf)	Leaf lettuce is harvested by once-over cutting leaving about 2 inches of growth.
Lettuce (head)	Head lettuce is harvested >6" head diameter before bolting.
Microgreens	Microgreens are harvested when the seedling have 1-2 true leaves.
Okra	Harvest okra when pods are 3-5 inches long.
Onions	Green onions can be harvested at any size. Dry bulb onions are harvested when tops begin to fall over on one-half of the plants.
Parsley	Parsley leaves or "sprigs" harvested when leaves are at least 2 inches in length.
Parsnip	Dig roots after a couple hard frost in fall or mulch for overwinter. Do not pull roots.
Peas (shell)	Pods are dark green and glossy. Frequent harvesting stimulates production of more peas.
Peppers (bell)	When harvesting colored peppers, wait until full color has been attained. Use pruners to cut fruit from the plant.
Potatoes (Irish)	New potatoes can be harvested beginning at flowering of the potato plant before the skin as set on the potato. Storage potatoes can be harvested after the potato vines have died.
Radishes	Radishes are harvested when the root diameter is ½-2 inches.
Shallots	Shallots are harvested green or when the tops have fallen over.
Spinach	Leaves should be at least 2 inches in length, with good color.
Sweetpotatoes	Harvest before frost. Roots should be 1-2" in diameter. Avoid oversized storage roots.
Summer Squash (yellow summer; zucchini)	Summer squash are excellent when harvested as a baby vegetable (2-4-inch length) when the skin is glossy and tender. Should be harvested before fruit reaches 6-inch length.
Tomatoes	Harvest at full color development (vine-ripened) and before the fruit becomes soft.
Turnips	Turnips are harvested when the root diameter is 1-2 inches.
Watermelon	Watermelons are harvested when the ground spot is yellow and the tendril closest to the fruit stem is dried.

Vegetable Crop	Optimal Temp (F) for storage	Curing	Washing prior to packaging?
Arugula	32-36	no	yes
Asparagus	32-36	no	no
Basil	50-55	no	no
Beans (snap)	40-45	no	no
Beets	32-36	no	yes
Broccoli	32-36	no	no
Brussels sprouts	32-36	no	no
Cantaloupe	36-41	no	no
Carrot	32-36	no	yes
Cauliflower	32-36	no	no
Celery	32-36	no	no
Chinese Cabbage	32-36	no	yes
Corn (Sweet)	32-36	no	no
Cucumbers	50-55	no	no
Eggplant	50-55	no	no
Garlic	32-50	yes	no
Kale	32-36	no	yes
Leeks	32-36	no	yes
Lettuce (leaf)	32-36	no	yes
Lettuce (head)	32-36	no	yes
Microgreens	32-36	no	no
Okra	45-50	no	no
Onions (bulb)	32-50	yes	no
Onions (bunching)	32-50	no	yes
Parsley	32-36	no	no
Parsnip	32-36	no	yes
Peas (shell/sugar snap)	32-36	no	no
Peppers	45-55	no	no
Potatoes (Irish)	40-50	yes	yes
Radishes	32-36	no	yes
Shallots	32-50	no	no
Spinach	32-36	no	yes
Summer Squash (yellow summer; zucchini)	40-50	no	no
Winter Squash	50-55	yes	no
Sweetpotatoes	55-60	yes	no
Tomatoes	60-65	no	no
Turnips	32-36	no	yes
Watermelon	50-60	no	no

APPENDIX I

Storage Conditions for Vegetables and Fruits					
	Temperature F	% Relative humidity	Precooling method	Storage life Days	Ethylene sensitive
Apples	30-40	90-95	R, F, H	90-240	Y
Apricots	32	90-95	R, H	7-14	Y
Asparagus	32-35	95-100	H, I	14-21	Y
Avocados	40-55	85-90		14-28	Y
Bananas	56-58	90-95		7-28	Y
Beans, snap	40-45	95	R, F, H	10-14	Y
Beans, lima	37-41	95		7-10	
Beets, roots	32	98-100	R	90-150	
Blackberries	31-32	90-95	R, F	2-3	
Blueberries	31-32	90-95	R, F	10-18	
Broccoli	32	95-100	I, F, H	10-14	Y
Brussel sprouts	32	95-100	H, V, I	21-35	Y
Cabbage	32	98-100	R, F	90-180	Y
Cantaloupe	36-41	95	H, F	10-14	Y
Carrots, topped	32	98-100	I, R	28-180	Y
Cauliflower	32	90-98	H, V	20-30	
Celery	32	98-100	I	14-28	Y
Cherries, sweet	30-31	90-95	H, F	14-21	
Corn, sweet	32	95-98	H, I, V	4-6	
Cranberries	36-40	90-95		60-120	
Cucumbers	50-55	95	F, H	10-14	Y
Eggplant	46-54	90-95	R, F	10-14	Y
Endive	32	90-95	H, I	14-21	Y
Garlic	32-34	65-75	N	90-210	
Grapefruit	50-60	85-90		28-42	
Grapes	32	85	F	56-180	
Kiwifruit	32	95-100		28-84	Y
Leeks	32	95-100	H, I	60-90	Y
Lemons	50-55	85-90		30-180	
Lettuce	32	85-90	H, I	14-21	Y
Limes	48-50	85-90		21-35	
Mushrooms	32	95		12-17	
Nectarines	31-32	95	F, H	14-18	Y
Okra	45-50	90-95		7-14	Y
Onions, bulb	32	65-70	N	30-180	
Onions, green	32	95-100	H, I	7-10	
Oranges	32-48	85-90		21-56	
Peaches	31-32	90-95	F, H	14-28	Y

	Temperature F	% Relative humidity	Precooling method	Storage life Days	Ethylene sensitive
Pears	32	90-95	F, R, H	60-90	Y
Peas, in pods	32	95-98	F, H, I	7-10	Y
Peppers, bell	45-55	90-95	R, F	12-18	Y
Peppers, hot	45-50	60-70	R, F	14-21	Y
Pineapple	45-55	85-90		14-36	
Plums	32	90-95	F, H	14-28	Y
Potatoes, early	50-60	90	R, F	56-140	
Potatoes, late	40-50	90	R, F	56-140	Y
Pumpkins	50-60	50-75	N	84-160	
Radishes	32	95-100	I	21-28	
Raspberries	32	90-95	R, F	2-3	Y
Rutabagas	32	98-100	R	120-180	
Spinach	32	95-100	H, I	10-14	Y
Squash, summer	41-50	95	R, F	7-14	Y
Squash, winter	50-55	50-70	N	84-150	
Strawberries	32	90-95	R, F	5-10	
Sweet potatoes	55-60	85-90	N	120-210	Y
Tangerines	40	90-95		14-28	
Tomatoes	62-68	90-95	R, F	7-28	Y
Turnips	32	95	R, H, V, I	120-150	
Watermelon	50-60	90	N	14-21	

F = forced-air cooling, H = hydrocooling, I = package icing, R = room cooling, V = vacuum cooling, N = no precooling needed. Sources: USDA Agricultural Marketing Service, Kansas State University Cooperative Extension Service

Covered Produce (Check all boxes for Covered Produce that you grow)

<input type="checkbox"/> Apples	<input type="checkbox"/> Garlic	<input type="checkbox"/> Plums
<input type="checkbox"/> Apricots	<input type="checkbox"/> Genip	<input type="checkbox"/> Plumcots
<input type="checkbox"/> Apriums	<input type="checkbox"/> Gooseberries	<input type="checkbox"/> Quince
<input type="checkbox"/> Artichokes - globe type	<input type="checkbox"/> Grapes	<input type="checkbox"/> Radishes
<input type="checkbox"/> Asian Pears	<input type="checkbox"/> Green Beans	<input type="checkbox"/> Raspberries
<input type="checkbox"/> Babacos	<input type="checkbox"/> Herbs (basil, chives, cilantro, oregano, & parsley)	<input type="checkbox"/> Rhubarb
<input type="checkbox"/> Belgian Endive	<input type="checkbox"/> Honeydews	<input type="checkbox"/> Rutabagas
<input type="checkbox"/> Blackberries	<input type="checkbox"/> Huckleberries	<input type="checkbox"/> Scallions
<input type="checkbox"/> Blueberries	<input type="checkbox"/> Jerusalem Artichoke	<input type="checkbox"/> Shallots
<input type="checkbox"/> Boysenberries D Broad Beans	<input type="checkbox"/> Kale	<input type="checkbox"/> Snow Peas
<input type="checkbox"/> Broccoli	<input type="checkbox"/> Kohlrabi	<input type="checkbox"/> Soursop
<input type="checkbox"/> Brussels Sprouts	<input type="checkbox"/> Leek	<input type="checkbox"/> Spinach
<input type="checkbox"/> Burdock	<input type="checkbox"/> Lettuce	<input type="checkbox"/> Sprouts (alfalfa & mung bean)
<input type="checkbox"/> Cabbages	<input type="checkbox"/> Melons	<input type="checkbox"/> Strawberries
<input type="checkbox"/> Chinese Cabbages (boy choy, mustard, & napa)	<input type="checkbox"/> (canary, crenshaw, & persian)	<input type="checkbox"/> Summer Squash (patty pan, yellow, & zucchini)
<input type="checkbox"/> Cantaloupes	<input type="checkbox"/> Mulberries	<input type="checkbox"/> Sweetsop
<input type="checkbox"/> Caram bolas D Carrots	<input type="checkbox"/> Muscadines	<input type="checkbox"/> Swiss Chard
<input type="checkbox"/> Cauliflower	<input type="checkbox"/> Mushrooms	<input type="checkbox"/> Taro
<input type="checkbox"/> Celeriac	<input type="checkbox"/> Mustard Greens	<input type="checkbox"/> Tomatoes
<input type="checkbox"/> Celery	<input type="checkbox"/> Nectarines	<input type="checkbox"/> Turmeric
<input type="checkbox"/> Cherries	<input type="checkbox"/> Onions	<input type="checkbox"/> Turnips (roots & tops)
<input type="checkbox"/> Chestnuts	<input type="checkbox"/> Papayas	<input type="checkbox"/> Walnuts
<input type="checkbox"/> Chicory (roots & tops)	<input type="checkbox"/> Parsnips	<input type="checkbox"/> Watercress
<input type="checkbox"/> Cowpea Beans	<input type="checkbox"/> Passion Fruit	<input type="checkbox"/> Watermelons
<input type="checkbox"/> Cress-Garden	<input type="checkbox"/> Peaches	<input type="checkbox"/> Yams
<input type="checkbox"/> Cucumbers	<input type="checkbox"/> Pears	<input type="checkbox"/> Other
<input type="checkbox"/> Curly Endive	<input type="checkbox"/> Peas	
<input type="checkbox"/> Currants	<input type="checkbox"/> Peas-Pigeon	
<input type="checkbox"/> Dandelion Leaves	<input type="checkbox"/> Peppers (bell & hot)	
<input type="checkbox"/> Fennel-Florence		

Growing Season Months:

Non-Covered Produce (Check all boxes for Non-Covered Produce that you grow)

<input type="checkbox"/> Asparagus	<input type="checkbox"/> Cocoa Beans	<input type="checkbox"/> Lentils	<input type="checkbox"/> Food Grains:
<input type="checkbox"/> Black beans	<input type="checkbox"/> Coffee Beans	<input type="checkbox"/> Okra	<i>(barely, dent- or</i>
<input type="checkbox"/> Great Northern Beans	<input type="checkbox"/> Collards	<input type="checkbox"/> Peanuts	<i>flint-corn, sorghum,</i>
<input type="checkbox"/> Kidney Beans	<input type="checkbox"/> Sweet Com	<input type="checkbox"/> Pecans	<i>oats, rice, rye, wheat,</i>
<input type="checkbox"/> Lima Beans	<input type="checkbox"/> Cranberries	<input type="checkbox"/> Peppermint	<i>amaranth, quinoa,</i>
<input type="checkbox"/> Navy Beans D Pinto Beans	<input type="checkbox"/> Dates	<input type="checkbox"/> Potatoes	<i>buckwheat, & oilseeds</i>
<input type="checkbox"/> Garden Beets (roots & tops)	<input type="checkbox"/> Dill (seeds & weeds)	<input type="checkbox"/> Pumpkins	<i>(e.g. cotton seed,</i>
<input type="checkbox"/> Sugar Beets	<input type="checkbox"/> Eggplants	<input type="checkbox"/> Winter Squash	<i>flax seed, soybean, &</i>
<input type="checkbox"/> Cashews	<input type="checkbox"/> Figs	<input type="checkbox"/> Sweet Potatoes	<i>sunflower seed)</i>
<input type="checkbox"/> Sour Cherries	<input type="checkbox"/> Horseradish	<input type="checkbox"/> Water Chestnuts	
<input type="checkbox"/> Chickpeas	<input type="checkbox"/> Hazelnuts		

Signature: _____

Date: _____

Return to produce@wvda.us or WVDA-Produce 1900 Kanawha Blvd, E., Charleston, WV 25305.
Call 304-558-2227 with questions.

West Virginia Department of Agriculture

Kent A. Leonhardt, Commissioner
Joseph L. Hatton, Deputy Commissioner



Dear Landowner:

You are receiving this letter because you were identified as a produce grower by the West Virginia State Farm Census - Farm Use Valuation Application information or our current produce farm inventory.

In January 2011, the Food Safety Modernization Act (FSMA) was signed into law, and the nation's first Produce Safety Rule (PSR) was authorized. The focus of FSMA is a more effective prevention of food safety issues in the United States food supply for both the grower and consumer. As a result, the West Virginia Department of Agriculture, operating under the U.S. Food & Drug Administration (FDA) authority, is working to build an inventory of produce growers within the state to identify those requiring inspection.

We are operating under an "educate while regulate" mentality. Resources are available for those who qualify for and wish to prepare for an actual FSMA inspection and those who don't qualify but want more information. An "On-Farm Readiness Review" can be requested free of charge to have your operation evaluated for produce safety concerns before the actual inspection occurs, giving you the opportunity to make adjustments/improvements where needed.

Per the FDA, an exemption must be filed for your operation to determine your status, or you remain eligible for an inspection. Filing your exemption is simple, please complete and return the enclosed "2024 Produce Safety Program Exemption Application" in the enclosed postage paid envelope, mail to WVDA- Produce 1900 Kanawha Blvd East, Charleston, WV 25305, or send via email to: produce@wvda.us

The West Virginia Department of Agriculture realizes that many of our producers will be exempt from inspection; however, it is still essential you **SUBMIT YOUR APPLICATION** to determine your exemption status. Please follow the directions on the form, complete in its entirety, and return.

Please select only one check box in the Basic or Processing Exemption section and only complete the Qualified Exemption section if you sell produce and have made more than \$31,925 in average sales from 2021-2023. Please remember to complete the back of the application to identify the types of produce grown (if applicable) and sign and date the form.

If you have any additional questions regarding Produce Safety or need assistance with completing your application, please contact Andrea O'Dell, WVDA Produce Safety Program Manager, at aodell@wvda.us or 304-521-5968.

Note: WVDA does not share names and addresses obtained from the Farm Census or this application for non-program purposes.

Sincerely,

Andrea L O'Dell

Andrea O'Dell, Produce Safety Program Manager
Regulatory & Environmental Affairs Division

2024 Produce Safety Program Exemption Application

Name: _____

Title: _____

Mailing address: _____

Phone number: _____

Email: _____

Farm name: _____

Farm address: _____

County: _____

Basic or Processing Exemptions: Please select the box below that best describes your operation. CHECK ONLY ONE BOX in this section:

- I do not grow produce of any kind (fruits, vegetables).
- I only grow produce that is rarely eaten raw/usually cooked before eating. (See "Non-covered produce" list on back, check all that apply).
- I grow produce but consume it myself and do not sell any.
- I grow produce and sell it (or buy from others and resell) but have made less than \$31,925 in produce sales on average the last three years (2021-2023) (if sales greater than \$31,925, please complete Qualified Exemption section below.)

Name of Farmers Market(s) where sold: _____

- ALL the produce I grow receives commercial processing.

What is the name of your processor? _____

Qualified Exemption: Please complete this section if you grow produce and sell it (or buy from others and resell) but make MORE than \$31,925 in produce sales on average the last three years (based on 2021-2023 sales).

My three year average (2021-2023) of annual combined FOOD sales is less than \$638,491. (FOOD is defined as (1) items that could be used for food or drink for man or other animals (i.e., meat, eggs, grains), (2) chewing gum, and (3) articles used for components of any such article. Include total produce sales in this number.

- YES NO - stop

If yes above, is the majority (over 50%) of the FOOD sold to a qualified end user (the consumer of the food, farmers market patrons, restaurant, or retail food establishment)?

- YES NO - stop

If yes above, is the qualified end user located in WV or within 275 miles of your farm?

- YES NO

More on back

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: What You Need to Know About the FDA Regulation: Guidance for Industry Small Entity Compliance Guide

*Additional copies are available from:
Office of Food Safety
Division of Produce Safety (HFS-317)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740.*

<https://www.fda.gov/FoodGuidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <http://www.regulations.gov>

You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket No: FDA-2011-N-0921 listed in the notice of availability that publishes in the *Federal Register*.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition**

September 2024

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Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: What You Need to Know About the FDA Regulation: Guidance for Industry¹

Small Entity Compliance Guide

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

The FDA Food Safety Modernization Act of 2011 (FSMA) directs the Food and Drug Administration (FDA) as the food regulatory agency of the U.S. Department of Health and Human Services to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety. As a key element of the preventive approach to better protect public health, FDA published in the *Federal Register* the final rule entitled “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (the produce safety rule, or the rule) (80 FR 74354, November 27, 2015). The produce safety rule establishes, for the first time, science-based minimum standards for the safe growing, harvesting, packing and holding of fruits and vegetables grown for human consumption. The regulations are found at Title 21 of the Code of Federal Regulations part 112 (21 CFR part 112). The rule became effective on January 26, 2016, but compliance dates are staggered – see section II. F “When Do I Have to Comply with the Rule?”

We have prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. Law 104-121). This guidance

¹ This guidance has been prepared by the Office of Food Safety, Division of Produce Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

document is intended to assist small entities in complying with the rule set forth in 21 CFR Part 112 concerning Produce Safety. The rule is binding and has the full force and effect of law.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. OVERVIEW OF THE RULE

A. Key Requirements

The key requirements include:

- Personnel Qualifications and Training (21 CFR Part 112, subpart C)
- Health and Hygiene (21 CFR Part 112, subpart D)
- Agricultural Water (21 CFR Part 112, subpart E)
- Biological Soil Amendments (21 CFR Part 112, subpart F)
- Domesticated and wild animals (21 CFR, Part 112, subpart I)
- Equipment, tools, and building (21 CFR, Part 112, subpart L)
- Sprouts (21 CFR, Part 112, subpart M)

B. Who Must Comply With The Rule?

Covered farms must comply with this rule. (21 CFR 112.4(a))

Farms or farm mixed-type facilities with an average annual monetary value of produce (as defined in 21 CFR 112.3) sold during the previous 3-year period of more than \$25,000 (on a rolling basis), adjusted for inflation using 2011 as the baseline year, are considered "covered farms" and are subject to the applicable requirements of part 112 when conducting a covered activity on covered produce. (21 CFR 112.4(a))

A farm is not a covered farm if it meets the requirements for a qualified exemption (see section III of this guidance for additional detail). (21 CFR 112.4(b))

C. What Produce Is Covered Under The Rule?

Unless it is excluded under 21 CFR 112.2, food that is produce within the meaning of part 112 and that is a raw agricultural commodity (RAC) is covered by part 112. This includes a produce RAC that is grown domestically and a produce RAC that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. (21 CFR 112.1(a))

Covered produce includes, but is not limited to, all of the following:

- **Fruits and vegetables such as:** almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams. (21 CFR 112.1(b)(1))
- **Mixes of intact fruits and vegetables,** such as fruit baskets. (21 CFR 112.1(b)(2))

This list of covered produce is not intended to be an exhaustive, exclusive nor a complete list and serves only as examples of produce covered by the rule.

D. Key Terms

The produce safety rule uses a substantial number of terms in very specific ways. A full list of these terms appears in this guidance in section XV “Definitions.” Table 1 lists some of the key terms used in this document.

Table 1 – Key Terms Used in Part 112

Term	Definition
Agricultural Water	Water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).
Biological Soil Amendment	Any soil amendment containing biological materials such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids,

Term	Definition
	table waste, agricultural tea, or yard trimmings, alone or in combination.
Farm	<p>(1) Primary Production Farm. A Primary Production Farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term “farm” includes operations that, in addition to these activities:</p> <ul style="list-style-type: none"> (i) Pack or hold raw agricultural commodities; (ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(I) of this definition; and (iii) Manufacture/process food provided that: <ul style="list-style-type: none"> (A) All food used in such activities is consumed on that farm or another farm under the same management; or (B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of: <ul style="list-style-type: none"> (I) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing); (2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and (3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or <p>(2) Secondary Activities Farm. A Secondary Activities Farm is an operation, not located on a Primary Production Farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the Primary Production Farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the Secondary Activities Farm owns, or jointly owns, a majority interest in the Secondary Activities Farm. A Secondary Activities Farm may also conduct those additional activities allowed on a Primary</p>

Term	Definition
	Production Farm as described in paragraphs (1)(ii) and (iii) of this definition.
Produce	<p>Any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (<i>e.g.</i>, cotton seed, flax seed, rapeseed, soybean, and sunflower seed).</p>
Qualified Exemption	<p>A farm is eligible for a qualified exemption and associated modified requirements in a calendar year if:</p> <p>(1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in 112.3) the farm sold directly to qualified end-users (as defined in 112.3) during such period exceeded the average annual monetary value of the food the farm sold to all other buyers during that period; and</p> <p>(2) The average annual monetary value of all food (as defined in 112.3) the farm sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.</p>

E. Which Commodities And Farms Are Exempt From The Requirements Of Part 112 Or Eligible For An Exemption?

Table 2 identifies products and farms that are exempt or eligible for an exemption from part 112.

Table 2 – Commodities and Farms Exempt From the Requirements of Part 112 or Eligible for an Exemption

Exemption	Conditions
<p>Farms with limited sales are not covered by part 112</p> <p>21 CFR 112.4(a)</p>	<p>Farms with produce sales of ≤ \$25,000 per year (during the previous 3 year period) are not covered by part 112.</p>
<p>Food grains are not produce and therefore are not covered by part 112</p> <p>21 CFR 112.3</p>	<p>Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).</p>
<p>Produce that is rarely consumed raw is not covered by part 112</p> <p>Produce identified as rarely consumed raw: 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; ginger; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts.</p> <p>21 CFR 112.2(a)(1)</p>	<p>Not subject to the requirements of part 112.</p> <p>(If you grow, harvest, pack, or hold more than one produce commodity, you should consider this question separately for each one to determine whether that particular produce commodity is covered by the produce safety rule).</p>
<p>Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management is not covered by part 112.</p> <p>21 CFR 112.2(a)(2)</p>	<p>Not subject to the requirements of part 112.</p> <p>Farms where the produce is not for sale.</p>
<p>Produce that is not a “raw agricultural commodity” is not covered by part 112.</p> <p>21 CFR 112.2(a)(3)</p>	<p>Not subject to the requirements of part 112.</p>
<p>Produce that receives commercial processing (“kill step” or other process) that adequately reduces the presence of microorganisms of public health significance is eligible for an exemption from part 112.</p>	<p>You must disclose in documents accompanying the produce in accordance with the practice of trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance;”</p>

Exemption	Conditions
21 CFR 112.2(b)(1)	<p>annually obtain written assurances from the customer; and document compliance with required disclosures and written assurances.</p> <p>21 CFR 112.2(b)(2) through (b)(6)</p>
<p>A farm is eligible for a qualified exemption and associated modified requirements in a calendar year if:</p> <p>(1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in 21 CFR 112.3) the farm sold directly to qualified end-users (as defined in 21 CFR 112.3) during such period exceeded the average annual monetary value of the food the farm sold to all other buyers during that period; and</p> <p>(2) The average annual monetary value of all food (as defined in 21 CFR 112.3) the farm sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.</p> <p>21 CFR 112.5</p>	<p>Farms eligible for qualified exemptions are subject to the requirements of:</p> <ol style="list-style-type: none"> 1. Subpart B (General Provisions) 2. Subpart O (Records) 3. Subpart Q (Compliance and Enforcement); and 4. Subpart R (Withdrawal of Qualified Exemption) <p>21 CFR 112.6(a)</p> <p>Farms eligible for qualified exemption are required to include the name and complete business address of the farm where the produce was grown on the food packaging label or display at the point of purchase, the name and complete business address of the farm where the produce was grown. 21 CFR 112.6(b)</p> <p>A farm’s qualified exemption may be withdrawn if there is an active investigation of an foodborne illness outbreak that is directly linked to the farm, or if FDA determines it is necessary to protect the public health and prevent or mitigate an outbreak based on conduct or conditions associated with the farm that are material to the safety of the food that would be covered by the produce safety rule.</p> <p>21 CFR 112.201(a)</p>

F. When Do I Have To Comply With The Rule?

Table 3 describes the general compliance dates for requirements under part 112.

Table 3 – Compliance Dates for Part 112

Business Size	Compliance date for covered activities involving sprouts covered under subpart M (i.e., subject to all requirements of part 112)	Compliance date for covered activities involving all other covered produce (i.e. subject to part 112, except subpart M), for provisions related to harvest and post-harvest agricultural water	Compliance date for covered activities involving all other covered produce (i.e. subject to part 112, except subpart M), for provisions related to pre-harvest agricultural water	Compliance date for covered activities involving all other covered produce (i.e. subject to part 112, except subpart M), for all other requirements
Very Small Business	January 28, 2019	January 26, 2024	April 5, 2027	January 27, 2020
Small Business	January 26, 2018	January 26, 2023	April 6, 2026	January 28, 2019
All Other Businesses	January 26, 2017	January 26, 2022	April 7, 2025	January 26, 2018

III. INFORMATION FOR FARMS ELIGIBLE FOR QUALIFIED EXEMPTIONS

A. How Can I Tell If My Business Is Eligible For A Qualified Exemption?

A farm is eligible for a qualified exemption and associated modified requirements in a calendar year if (21 CFR 112.5(a)):

(1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food the farm sold directly to qualified end-users during such period exceeded the average annual monetary value of the food the farm sold to all other buyers during that period; and

(2) The average annual monetary value of all food (as defined in 21 CFR 112.3) the farm sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.

For the purpose of determining whether the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011. (21 CFR 112.5(b))

Qualified end-user means the consumer of the food (where “consumer” does not include a business); or a restaurant or retail food establishment located in the same state or Indian reservation as the farm, or located within 275 miles from the farm. (21 CFR 112.3)

B. What Records Must I Establish And Keep If My Farm Is Eligible For A Qualified Exemption?

If your farm is eligible for a qualified exemption, you must establish and keep records:

- Required in accordance with the requirements of subpart O of part 112, except that the requirement in 21 CFR 112.161(a)(4) for a signature or initial of the person performing the activity is not required for sales receipts kept in the normal course of business. However, such receipts must be dated (21 CFR 112.7(a)); and
- Records necessary to demonstrate that your farm satisfied the criteria for a qualified exemption, including a written record reflecting that you have performed an annual review and verification of your farm's continued eligibility for the qualified exemption. (21 CFR 112.7(b))

C. What Modified Requirements Are Farms Eligible For Qualified Exemption Subject To?

If your farm is eligible for a qualified exemption, you are subject to the requirements of:

- Subpart A of part 112 (General Provisions),
- Subpart O of part 112 (Records),
- Subpart Q of part 112 (Compliance and Enforcement); and
- Subpart R of part 112 (Withdrawal of Qualified Exemption).

(21 CFR 112.6(a))

Subpart A establishes the eligibility criteria for a qualified exemption and the record keeping requirements for farms eligible for a qualified exemption.

Subpart O establishes the requirements for records required under part 112, including what documents satisfy the requirements, how documents must be stored, how records must be made available to FDA, and how long records must be kept.

Subpart Q establishes that failure to comply with the requirements of part 112 is a prohibited act and the criteria and definitions in part 112 apply in determining whether a food is adulterated (grown, harvested, packed or held in such conditions that it is unfit for food or food that has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health) or in violation of section 361 of the Public Health Service Act (42 U.S.C. 264). (21 CFR 112.192)

Subpart R outlines the circumstances and requirements for withdrawal of a qualified exemption.

In addition, if your farm is eligible for a qualified exemption you are subject to the following modified requirements:

- When a food packaging label is required on food that would otherwise be covered produce under the FD&C Act or its implementing regulations, you must include

prominently and conspicuously on the food packaging label the name and the complete business address (street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms) of the farm where the produce was grown. (21 CFR 112.6(b)(1) and (3))

- When a food packaging label is not required on food that would otherwise be covered produce under the FD&C Act, you must prominently and conspicuously display, at the point of purchase, the name and complete business address (street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms) of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice. (21 CFR 112.6(b)(2) and (3))

D. When Must Farms Eligible For A Qualified Exemption Comply With Part 112?

Table 4 – Compliance Dates for Part 112 for Farms Eligible for a Qualified Exemption (if applicable)

Business Size	Compliance date for retention of records supporting eligibility in 21 CFR 112.7(b)	Compliance date for modified requirements in 21 CFR 112.6(b)(1)	Compliance date for all other requirements in 21 CFR 112.6 and 112.7 for farms producing sprouts	Compliance date for all other requirements in 21 CFR 112.6 and 112.7 for farms not producing sprouts
Very Small Business	January 26, 2016	January 1, 2020	January 28, 2019	January 27, 2020
Small Business			January 26, 2018	January 28, 2019
All other Businesses			N/A	N/A

E. Can A Farm’s Qualified Exemption Be Withdrawn?

Yes, a farm’s qualified exemption can be withdrawn in the event of an active investigation of an outbreak that is directly linked to the farm, or if FDA determines it is necessary to protect public health based on conduct or conditions on the farm that may pose a risk to public health. (21 CFR 112.201(a))

Before FDA issues an order to withdraw a qualified exemption, FDA:

- May consider other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal or food offered for import, seizure, and injunction;

- Must notify the owner, operator, or agent in charge of the farm, in writing, of circumstances that may lead FDA to withdraw the exemption and provide an opportunity for the owner, operator, or agent in charge of the farm to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification; and
- Must consider the actions taken by the farm to address the circumstance that may lead FDA to withdraw the exemption.

(21 CFR 112.201(b))

F. What Procedure Will FDA Use To Withdraw An Exemption?

FDA will issue an order to withdraw the exemption in writing to the owner, operator, or agent in charge of the farm. The order must be in writing, and signed and dated by the officer or qualified employee of FDA who is issuing the order. (21 CFR 112.202)

G. If My Qualified Exemption is Withdrawn, Under What Circumstances Would FDA Reinstate My Qualified Exemption?

If FDA determines that your farm has adequately resolved any problems with the conduct and conditions that are material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, FDA will, on its own initiative or at your request, reinstate the qualified exemption. (21 CFR 112.213(a))

You may ask FDA to reinstate a qualified exemption that has been withdrawn by submitting a request in writing and presenting data and information to demonstrate that you have adequately responded to any problems with the conduct and conditions that are material to the safety of the food produced and harvested at your farm. (21 CFR 112.213(b))

If your qualified exemption was withdrawn because of an active foodborne illness outbreak directly linked to your farm and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will reinstate your qualified exemption and will notify you in writing that your exempt status has been reinstated. (21 CFR 112.213(c))

IV. PERSONNEL QUALIFICATIONS AND TRAINING – SUBPART C

All personnel (including temporary, part time, seasonal, and contracted personnel) who handle (contact) covered produce or food contact surfaces, or who are engaged in the supervision thereof are required to:

- Receive adequate training, as appropriate to the person's duties, upon hiring, and periodically thereafter, at least once annually. (21 CFR 112.21(a))

- Have a combination of education training, and experience necessary to perform the person's assigned duties in a manner that ensures compliance with this part. (21 CFR 112.21(b))

A. What Are The Specific Requirements For Training Personnel?

The training must be appropriate to the person's duties and conducted in a manner that is easily understood by personnel being trained to ensure compliance with the rule (21 CFR 112.21(c) and 112.22(a)(3)). Personnel must be trained on certain topics, including:

- The principles of food hygiene and food safety (21 CFR 112.22(a)(1)); and
- The importance of health and employee hygiene (21 CFR 112.22(a)(2)).

B. What Additional Training Is Required For Persons Who Conduct Harvest Activities?

Persons who conduct harvest activities for covered produce must also receive training on the following:

- Recognizing produce that must not be harvested, including covered produce that may be contaminated with known or reasonably foreseeable hazards (21 CFR 112.22(b)(1));
- Inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so that they do not become a source of contamination (21 CFR 112.22(b)(2)); and
- Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor, as appropriate to the person's job responsibilities (21 CFR 112.22(b)(3)).

C. After the Initial Training, Is There A Requirement For Continuing Education?

Yes, all personnel must receive training upon hiring and then periodically thereafter, at least once annually. The training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA in subparts C through O of the rule. (21 CFR 112.21(a) and (d))

D. What Requirements Apply Regarding Supervisors?

You must assign or identify personnel to supervise (or otherwise be responsible for) your operations to ensure compliance with the requirements of part 112 (21 CFR 112.23). Supervisors must also be trained according to the requirements under 21 CFR 112.21 and 112.22.

E. Is There A Requirement To Maintain Records For Training?

Yes. You must establish and keep records that document required training of personnel, including the date of training, topics covered, and the person(s) trained in accordance with subpart O (records). (21 CFR 112.30(b))

V. HEALTH AND HYGIENE – SUBPART D

A. What Hygienic Practices Must Personnel Use?

Personnel who work in an operation in which covered produce or food contact surfaces are at risk of contamination with known or reasonably foreseeable hazards must use hygienic practices while on duty to the extent necessary to protect against such contamination. (21 CFR 112.31(a))

When handling or contacting covered produce or food contact surfaces, personnel must (21 CFR 112.31(b)):

- Maintain adequate personal cleanliness to protect against contamination of covered produce and food contact surfaces;
- Avoid contact with animals, other than working animals, and take appropriate steps to minimize the likelihood of contamination of covered produce when in direct contact with working animals;
- Wash hands thoroughly, including scrubbing with soap (or other effective cleanser) and running water that meets the requirements of rule for water used to wash hands, as well as drying hands thoroughly using single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices. Hands must be washed:
 - Before starting work;
 - Before putting on gloves;
 - After using the toilet;
 - Upon return to the work station after any break or other absence from the work station;
 - As soon as practical after touching animals (including livestock and working animals), or any waste of animal origin; and
 - At any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of produce with known or reasonably foreseeable hazards.
- Remove or cover hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce is manipulated by hand; and
- Not eat, chew gum, or use tobacco products in an area used for an activity covered by the rule. However, drinking beverages is permitted in designated areas).
- If personnel use gloves when handling covered produce or food contact surfaces, the gloves must be changed often to ensure they are maintained in an intact and sanitary condition.

B. Are There Any Requirements To Restrict Ill Personnel?

Yes. You must exclude any person from working in any operations that may result in contamination of covered produce or food contact surfaces with microorganisms of public health significance. Ill or infected personnel must not be allowed to return to work until his/her health condition no longer presents a risk to public health. (21 CFR 112.31)

VI. AGRICULTURAL WATER – SUBPART E

Subpart E² establishes requirements related to agricultural water. “Agricultural water” refers, in part, to water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food-contact surfaces. (See 21 CFR 112.3). If water is intended to, or is likely to, contact covered produce or food contact surfaces, then it meets the definition of “agricultural water,” and the provisions of subpart E apply.

The requirements in subpart E that apply based on use of agricultural water are outlined below:

- If a covered farm uses agricultural water for growing covered produce (other than sprouts)...
 - The farm must meet these requirements:
 - 21 CFR 112.41 (quality standard)
 - 21 CFR 112.42 (inspections and maintenance)
 - 21 CFR 112.43 (agricultural water assessment)
 - 21 CFR 112.50 (records)
 - If applicable, the farm must also meet these requirements:
 - 21 CFR 112.45 (measures)
 - 21 CFR 112.46 (treatment)
 - 21 CFR 112.47 (who may test)
 - 21 CFR 112.151 (test methods)

- If a covered farm uses agricultural water for sprout irrigation water...
 - The farm must meet these requirements:
 - 21 CFR 112.41 (quality standard)
 - 21 CFR 112.42 (inspections and maintenance)
 - 21 CFR 112.44(a) (microbial quality criterion)
 - 21 CFR 112.50 (records)
 - If applicable, the farm must also meet these requirements:
 - 21 CFR 112.44(b) (testing untreated ground water)

² On May 6, 2024, FDA published a final rule that revised certain agricultural water requirements in the produce safety rule applicable to agricultural water for covered produce other than sprouts using a direct application method during growing activities (commonly referred to as “pre-harvest agricultural water”) (89 FR 37448). The rule also made additional amendments to subpart E, such as adding examples and making other edits that are designed to provide clarity (for example, by reorganizing subpart E to group provisions of a similar nature). This document reflects the changes made to the regulation with that rule.

- 21 CFR 112.45 (measures)
 - 21 CFR 112.46 (treatment)
 - 21 CFR 112.47 (who may test)
 - 21 CFR 112.151 (test methods)
- If a covered farm uses agricultural water for harvesting, packing or holding covered produce...
 - The farm must meet these requirements:
 - 21 CFR 112.41 (quality standard)
 - 21 CFR 112.42 (inspections and maintenance)
 - 21 CFR 112.44(a) (microbial quality criterion)
 - 21 CFR 112.44(d) (additional management and monitoring)
 - 21 CFR 112.50 (records)
 - If applicable, the farm must also meet these requirements:
 - 21 CFR 112.44(b) (testing untreated ground water)
 - 21 CFR 112.45 (measures)
 - 21 CFR 112.46 (treatment)
 - 21 CFR 112.47 (who may test)
 - 21 CFR 112.151 (test methods)

(21 CFR 112.40)

Subpart E includes requirements to ensure that all agricultural water is safe and of adequate sanitary quality for its intended use. (21 CFR 112.41)

A. What Requirements Apply To Inspecting and Maintaining Agricultural Water Systems?

At the beginning of a growing season, as appropriate, but at least once annually, you must inspect all of your agricultural water systems to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces. Inspections include consideration of the following (21 CFR 112.42(a)):

- Nature of each agricultural water source;
- Extent of your control over each agricultural water source;
- Degree of protection of each agricultural water source;
- Use of adjacent and nearby land; and
- Likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before it reaches the covered farm.

You also must meet requirements related to maintaining all agricultural water systems, to the extent they are under your control, as necessary and appropriate to prevent the systems from being a source of contamination to covered produce, food contact surfaces, or areas used for a

covered activity. Requirements for maintenance of agricultural water systems can be found at 21 CFR 112.42(b).

B. What Are The Requirements For Pre-Harvest Agricultural Water Assessments For Covered Produce (Other Than Sprouts)?

Based in part on the results of inspection and maintenance conducted under 21 CFR 112.42, at the beginning of the growing season, but at least once annually, you must prepare a written agricultural water assessment for water that you apply to covered produce (other than sprouts) using a direct application method during growing activities. The agricultural water assessment must identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce (other than sprouts) or food contact surfaces, based on an evaluation of the following:

- Each agricultural water system, including:
 - The location and nature of the water source;
 - The type of water distribution system; and
 - The degree of protection from possible sources of contamination, including by other water users; animal impacts; and adjacent and nearby land uses related to animal activity, application of biological soil amendments of animal origin (BSAAO), or presence of untreated or improperly treated human waste;
- Agricultural water practices, including the type of direct application method and the time interval between the last direct application of agricultural water and harvest of the covered produce;
- Crop characteristics, including the susceptibility of the covered produce to surface adhesion or internalization of hazards;
- Environmental conditions, including the frequency of heavy rain or extreme weather events that may impact the agricultural water system or covered produce during growing activities, air temperatures, and sun exposure; and
- Other relevant factors, including, if applicable, the results of any testing conducted under 21 CFR 112.43(d).

(21 CFR 112.43(a))

1. Are there any exemptions from the requirement to prepare an agricultural water assessment for covered produce (other than sprouts)?

You may be eligible for an exemption from the pre-harvest agricultural water assessment requirements if you can demonstrate that your water:

- Meets certain requirements in 21 CFR 112.44(a), including the microbial water quality criterion and the prohibition on the use of untreated surface water, and, if untreated ground water, also meets relevant testing requirements (21 CFR 112.43(b)(1)(i));
- Meets certain requirements for water from a public water system or supply and you have public water system results or certificates of compliance that demonstrate that the water meets relevant requirements (21 CFR 112.43(b)(1)(ii)); or
- Is treated in accordance with 21 CFR 112.46 (21 CFR 112.43(b)(1)(iii)).

Additionally, it must be reasonably likely that the quality of water in 21 CFR 112.43(b)(1) will not change prior to being used as agricultural water (for example, due to the manner in which the water is held, stored, or conveyed). (21 CFR 112.43(b)(2))

2. What are the requirements for outcomes of an agricultural water assessment for covered produce (other than sprouts)?

Based on your evaluation in 21 CFR 112.43(a), you must make a written determination as to whether measures are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with your agricultural water used in growing covered produce (other than sprouts). Table 5 provides a summary of the outcomes of a pre-harvest agricultural water assessment.

Table 5 – Summary of Outcomes of a Pre-Harvest Agricultural Water Assessment for Covered Produce (Other than Sprouts) (21 CFR 112.43(c))

If you determine...	Then you must...
that your agricultural water is not safe or is not of adequate sanitary quality for intended use(s)	immediately discontinue use(s) <u>AND</u> take corrective measures before resuming use of the water for pre-harvest activities (21 CFR 112.43(c)(1))
there is one or more known or reasonably foreseeable hazards related to animal activity, BSAAOs, or untreated or improperly treated human waste on adjacent or nearby land for which mitigation is reasonably necessary	implement mitigation measures promptly, and no later than the same growing season (21 CFR 112.43(c)(2))
there is one or more known or reasonably foreseeable hazards not related to animal activity, BSAAOs, or untreated or improperly treated human waste on adjacent or nearby land, for which mitigation is reasonably necessary	implement mitigation measures as soon as practicable and no later than the following year <u>OR</u> test water as part of the assessment and implement measures, as needed, based on the outcome of the assessment (21 CFR 112.43(c)(4))
there are not any known or reasonably foreseeable hazards for which mitigation is reasonably necessary	regularly (at least once each year) inspect and adequately maintain the water system(s) (21 CFR 112.43(c)(3))

3. What requirements apply if testing pre-harvest agricultural water as part of an assessment?

If testing pre-harvest agricultural water as part of an assessment under 21 CFR 112.43(c)(4)(ii), samples must be tested for generic *Escherichia coli* (*E. coli*) or for another scientifically valid indicator organism, index organism, or other analyte (21 CFR 112.43(d)(2)). The frequency of testing samples and any microbial criterion (or criteria) applied must be scientifically valid and appropriate to assist in determining, in conjunction with other data and information evaluated under 21 CFR 112.43(a), whether measures under 21 CFR 112.45 are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with your agricultural water used in growing covered produce (other than sprouts) (21 CFR 112.43(d)(3)).

4. What requirements apply for conducting a reassessment?

You must conduct an agricultural water assessment at least once annually, and whenever a significant change occurs that makes it reasonably likely that a known or reasonably foreseeable hazard will be introduced into or onto covered produce (other than sprouts) or food contact surfaces through direct application of agricultural water during growing activities. Your reassessment must evaluate any factors and conditions that are affected by such change. (21 CFR 112.43(e))

C. What Requirements Apply To Agricultural Water Used As Sprout Irrigation Water And In Harvesting, Packing, And Holding Covered Produce?

For certain uses of agricultural water, you must not use untreated surface water and you must ensure that there is no detectable generic *E. coli* in 100 mL of agricultural water. These requirements apply for uses of agricultural water in which it is reasonably likely that potentially dangerous microbes, if present, would be transferred to produce through direct or indirect contact. Examples include water used for washing hands during and after harvest, water used on food contact surfaces, water used to directly contact produce (including to make ice) during or after harvest, and water used for sprout irrigation. (21 CFR 112.44(a))

1. What are the requirements for testing untreated ground water used for the purposes listed in 21 CFR 112.44(a)?

For untreated ground water that is used for the purposes listed in 21 CFR 112.44(a), you must initially test the untreated ground water at least four times during the growing season or over a period of one year. You must determine whether the water can be used for the intended purpose based on these results.

- If the four initial sample results meet the no detectable generic *E. coli* per 100 mL of agricultural water criterion, testing can be done once annually thereafter, using a minimum of one sample.
- If any annual test fails to meet the microbial quality criterion, farms must resume testing at least four times per growing season or year.

(21 CFR 112.44(b))

2. Are there any exemptions from the requirement to test agricultural water used for the purposes listed in 21 CFR 112.44(a)?

There is no requirement to test agricultural water that is used as sprout irrigation water or for harvesting, packing, or holding covered produce if the water is received from public water systems or supplies that meet requirements established in the rule (provided you have public water system results or certificates of compliance demonstrating that the water meets relevant requirements), or if the water is treated in accordance with the requirements in 21 CFR 112.46. (21 CFR 112.44(c))

D. What Are The Requirements For Additional Management And Monitoring Practices For Agricultural Water Used In Harvesting, Packing, and Holding Covered Produce?

You must manage the water used during harvest, packing, and holding activities for covered produce as necessary, including by establishing and following water-change schedules for non-single-pass water (including recirculated water or reused water) to maintain its safety and adequate sanitary quality and minimize the potential for contamination of covered produce and food-contact surfaces with known or reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce) (21 CFR 112.44(d)(1)). Further, you must visually monitor the quality of water for build-up of organic material (such as soil and plant debris) (21 CFR 112.44(d)(2)). Additionally, you must maintain and monitor the temperature of water at a temperature that is appropriate for the commodity and operation and that is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce (21 CFR 112.44(d)(3)).

E. What Measures Must I Take For Agricultural Water To Reduce The Potential For Contamination Of Covered Produce Or Food Contact Surfaces With Known Or Reasonably Foreseeable Hazards?

If your agricultural water is not safe or is not of adequate sanitary quality for its intended use(s) and/or if your agricultural water used as sprout irrigation water or for harvesting, packing, or holding activities does not meet the requirements in 21 CFR 112.44(a) (including the microbial quality criterion), you must immediately discontinue such use(s). Corrective measures you can take in order to resume use of the agricultural water include (21 CFR 112.45(a)):

- Re-inspecting the entire affected agricultural water system to the extent that it is under your control and, among other steps, making necessary changes and taking adequate measures to determine if your changes were effective;
- Treating the water in accordance with the requirements in 21 CFR 112.46.

If you determine that mitigation measures are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with your pre-harvest agricultural water for covered produce (other than sprouts), the required timing of such measures will depend on the outcomes

of your agricultural water assessment (see Table 5 above). Mitigation measures include (21 CFR 112.45(b)):

- Making necessary changes (for example, repairs);
- Increasing the time interval between the last direct application of agricultural water and harvest of the covered produce to allow for microbial die-off, provided you have adequate support;
- Increasing the time interval between harvest and the end of storage to allow for microbial die-off, and/or conducting other activities during or after harvest to allow for microbial die-off or removal, provided you have adequate support;
- Changing the method of water application to reduce the likelihood of contamination of the covered produce;
- Treating the water in accordance with the requirements in 21 CFR 112.46; and
- Taking an alternative mitigation measure, provided that you satisfy the requirements in 21 CFR 112.12.

F. What Requirements Apply To Treating Agricultural Water?

Any method you use to treat agricultural water must be effective to make the water safe and of adequate sanitary quality for its intended use(s) and/or meet the microbial quality criterion in 21 CFR 112.44(a), as applicable. Examples of treatment methods include (21 CFR 112.46(a)):

- Physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA);
- EPA-registered antimicrobial pesticide product; or
- Other suitable method.

You must deliver and monitor any treatment of agricultural water to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use(s) and, if applicable, also meets the microbial quality criterion in § 112.44(a) (21 CFR 112.46(b) and (c)).

VII. BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN AND HUMAN WASTE – SUBPART F

Subpart F of part 112 establishes requirements for the use of biological soil amendments of animal origin (BSAAO) and human waste. A soil amendment is a material, including manure that is intentionally added to the soil to improve its chemical or physical condition for growing plants or to improve its capacity to hold water.

A. How Do You Determine The Status Of A BSAAO?

A BSAAO is considered treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the standards set by 21 CFR 112.54. (21 CFR 112.51(a))

A BSAAO is considered untreated in several circumstances including if it:

- Has not been processed to completion in accordance with 21 CFR 112.54;
- Has become contaminated after treatment;
- Has been recombined with an untreated BSAAO;
- Is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard that has been associated with foodborne illness; or
- It is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive.

(21 CFR 112.51(b))

B. What Are The Requirements For Untreated BSAAO?

FDA is conducting a risk assessment and extensive research on the number of days needed between the applications of untreated BSAAO (e.g., raw manure) and harvesting to minimize the risk of contamination.

At this time, FDA does not object to farmers complying with the United States Department of Agriculture (USDA) National Organic Program Standards related to raw manure use, which call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for the crops not in contact with the soil.

Untreated BSAAO, such as raw manure, must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with produce after application. (21 CFR 112.56(a)(1))

C. What Are The Requirements For Treated BSAAO?

Part 112 establishes microbial standards that set limits on detectable amounts of bacteria (including *Listeria monocytogenes*, *Salmonella* species, fecal coliforms, and *E. coli* O157:H7) for processes used to treat BSAAO, including manure.

1. Are there microbial testing requirements for BSAAO?

No. The produce safety rule has established microbial standards only to validate treatment processes. If the scientifically valid treatment processes listed in 21 CFR 112.54 (e.g., physical, chemical, biological, or in combination) have been documented to meet the respective microbial

standards in 21 CFR 112.55, then the application requirements and minimum application intervals in 21 CFR 112.56(a) apply to the BSAAO in question.

2. What regulations apply to stabilized compost?

The produce safety rule includes two examples of scientifically valid composting methods, 21 CFR 112.54(b)(1) and (b)(2), that meet the microbial standard in 21 CFR 112.55(b). Growers that prepare their own stabilized compost only need to document the process controls (e.g. time/temperature and turnings). If the stabilized compost was purchased from a third party supplier, annual documentation would also be required that a valid process was used to treat the compost as well as documentation that the product was handled, conveyed and stored in a manner and location to minimize the risk of re-contamination (21 CFR 112.60(b)(1)(i) and (b)(1)(ii)). Stabilized compost that meets treatment requirements of 21 CFR 112.54(b) to meet the microbial standard in 21 CFR 112.55(b) may be applied with a zero day application interval, but must be applied in a manner that minimizes the potential for contact with produce during and after application. (21 CFR 112.56(a)(2))

Examples of scientifically valid composting methods include:

- Static composting that maintains aerobic (i.e. oxygenated) conditions at a minimum of 131°F (55°C) for 3 consecutive days and is followed by adequate curing; and
- Turned composting that maintains aerobic conditions at a minimum of 131°F (55°C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.

(21 CFR 112.54)

D. Can I Use Human Waste?

No. You may not use human waste for growing covered produce, except sewage sludge biosolids used in compliance with U.S. Environmental Protection Agency (EPA) regulations (40 CFR part 503) or equivalent regulatory requirements. (21 CFR 112.53)

VIII. DOMESTICATED AND WILD ANIMALS – SUBPART I

Subpart I of Part 112 addresses concerns about the feasibility of compliance for farms that rely on grazing animals (such as livestock) or working animals for various purposes. It establishes the same standards for these animals as it does for intrusion by wild animals (such as deer or feral swine). Farmers are required to take all measures reasonably necessary to identify and not harvest produce that is likely to be contaminated. (21 CFR 112.83)

A. What Must I Do When Contaminated Produce Is Identified?

If significant evidence of potential contamination by animals is found (e.g. significant amounts of excreta or crop destruction), you must identify and not harvest such contaminated crops. You must also take measures which might include, for example, placing flags outlining the affected

area to identify, and not harvest, produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard. (21 CFR 112.112 and 112.83(b)(2)).

B. What If My Farm Allows Grazing Between Harvests?

Although the produce rule does not require establishing waiting periods between grazing and harvest, the FDA encourages farmers to voluntarily consider applying such intervals as appropriate for the farm's commodities and practices.

C. Are Animals Required To Be Excluded From The Growing Areas?

No. Farms are not required to exclude animals from outdoor growing areas, destroy animal habitat, or clear borders around growing or drainage areas. Nothing in the rule should be interpreted as requiring or encouraging such actions. (21 CFR 112.84)

IX. GROWING, HARVESTING, PACKING, AND HOLDING ACTIVITIES – SUBPART K

A. What Measures Must I Take If I Grow, Harvest, Pack, or Hold Both Covered And Excluded Produce?

If you grow, harvest, pack or hold produce that is not covered in this part (i.e., excluded produce in accordance with 21 CFR 112.2) and also conduct activities on covered produce, and the excluded produce is not grown, harvested, packed or held in accordance with the regulations, you must take measures to:

- Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and
- Adequately clean and sanitize, as needed, any food contact surfaces that contact excluded produce before using the surface for covered activities on covered produce.

(21 CFR 112.111)

B. What Measures Must I Take Immediately Prior To And During Harvest Activities?

You must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. (21 CFR 112.112)

C. How Must I Handle Harvested Covered Produce During Covered Activities?

You must handle harvested covered produce during covered activities in a manner that protects against contamination with known or reasonably foreseeable hazards, for example, by avoiding, to the degree practicable, contact of cut surfaces of harvested produce with soil. (21 CFR 112.113)

D. What Requirements Apply To Dropped Covered Produce?

You must not distribute dropped covered produce that has fallen 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). (21 CFR 112.114)

E. Are There Any Packaging Requirements?

Yes. You must package covered produce in a manner that prevents the formation of *Clostridium botulinum* toxin if such toxin is a known or reasonably foreseeable hazard (such as mushrooms). (21 CFR 112.115)

F. Are There Any Requirements For Food-Packing Material?

Yes. You must use food-packing material that is adequate for its intended use, is cleanable or designed for single use and is unlikely to support the growth or transfer of bacteria. (21 CFR 112.116 (a))

G. Can I Reuse Food-Packing Material?

Yes. If you reuse food-packing material, you must take adequate steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner. (21 CFR 112.116 (b))

X. EQUIPMENT, TOOLS, AND BUILDING – SUBPART L

Subpart L of part 112 establishes standards related to equipment, tools, and buildings to prevent these sources, and inadequate sanitation, from contaminating produce.

A. What Are the Requirements for Equipment and Tools?

You must ensure that appropriate measures are taken to use equipment and tools that are of adequate design and construction to enable adequate cleaning and maintenance and prevent contamination of covered produce and food contact surfaces including, for example, appropriate storage, maintenance and cleaning of equipment, tools, instruments (including transport equipment) and building structures. (21 CFR 112.123)

Equipment and tools include those that are intended to, or likely to, contact covered produce. Examples include knives, mechanical harvesters, cooling equipment, grading belts, dump tanks, and vehicles or other equipment for transport. (21 CFR 112.121)

B. What Are the Requirements for Buildings Used for Covered Activities?

The produce safety rule covers any fully or partially-enclosed buildings that are used for covered activities, as well as storage sheds, buildings or other structures used to store food contact surfaces (such as harvest containers and food packing materials). (21 CFR 112.122)

Buildings must be suitable in size, construction, and design to facilitate maintenance and proper sanitation to reduce the potential for contamination from, for example, condensate, domesticated animals, and pests. (21 CFR 112.126 – 112.128)

Adequate and readily accessible toilet and hand washing facilities are required. (21 CFR 112.129 and 112.130)

And proper disposal of sewage and other trash, litter, and waste in areas used for covered activities is also required. (21 CFR 112.131 – 112.132)

XI. SPROUTS – SUBPART M

Subpart M of Part 112 includes requirements to help prevent the contamination of sprouts. The requirements of subpart M apply to the growing, harvesting, packing, and holding of all sprouts, except soil- or substrate-grown sprouts harvested without their roots. (21 CFR 112.141)

A. Why Are There Different Requirements For Sprouts?

Sprouts have been frequently associated with foodborne illness outbreaks and are especially vulnerable to dangerous microbes because of the warm, moist and nutrient-rich conditions needed to grow them.

B. What Requirements Apply to Seeds or Beans Used To Grow Sprouts?

Requirements that apply to seeds or beans used to grow sprouts include:

- Taking measures to prevent the introduction of dangerous microbes into or onto seeds or beans used for sprouting, and
- Treating seeds or beans that will be used for sprouting (or relying on prior treatment by the seed/bean grower, distributor, or supplier with appropriate documentation) to reduce microorganisms of public health significance.

(21 CFR 112.142)

C. What Requirements Apply To The Growing, Harvesting, Packing and Holding Of Sprouts?

Requirements that apply to the growing, harvesting, packing, and holding of sprouts include:

- Sprouts must be grown, harvested, and packed in fully enclosed buildings and have established written and implemented sampling plans to test water or sprouts for pathogens, as well as corrective actions if pathogens are detected. (21 CFR 112.143)
- Using a valid testing method to test of spent sprout irrigation water from each production batch of sprouts, or in-process sprouts from each production batch (if testing water is not practical), for *E. coli* O157:H7, *Salmonella* species and any other pathogen meeting the criteria in 21 CFR 112.144(c). (21 CFR 112.144)

- Validated testing methods for the growing, harvesting, packing, and holding environments and spent sprout irrigation water (or sprouts) can be found in 21 CFR 112.152 and 112.153.
- Testing the growing, harvesting, packing, and holding environment for the presence of *Listeria* species or *L. monocytogenes*. (21 CFR 112.145)
- Taking corrective actions if spent sprout irrigation water, sprouts, and/or an environmental sample tests positive. (21 CFR 112.146 and 112.148)

D. When Must I Comply With The Requirements for Sprouts?

Sprout operations will have less time to come into compliance with the rule than farms growing other produce. They will have one to three years to comply based on the size of their operation, with no additional time to meet the water requirements. See section II.F “When Do I Have To Comply With The Rule?”

XII. ANALYTICAL METHODS – SUPPART N

A. What Methods Must I Use To Test The Quality of Water To Satisfy The Requirements In Subpart E?

If testing agricultural water for generic *E. coli*, you must test the quality of water using:

- EPA’s “Method 1603: *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC)” (December 2009) (21 CFR 112.151(a)), or
- A scientifically valid method that is at least equivalent to the method of analysis in 21 CFR 112.151(a) in accuracy, precision, and sensitivity (21 CFR 112.151(b)(1)).

If testing pre-harvest agricultural water for non-sprout covered produce for any other indicator of fecal contamination, index organism, or other analyte pursuant to 21 CFR 112.43(d), you must use a scientifically valid method (21 CFR 112.151(b)(2)).

(21 CFR 112.151)

B. What Methods Must I Use To Test The Growing, Harvesting, Packing, and Holding Environment for *Listeria* species or *L. monocytogenes* for 21 CFR 112.144(a)?

You must test the growing, harvesting, packing and holding environment for *Listeria* species or *L. monocytogenes* using:

- The method of analysis described in “Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples,” FDA, or
- A scientifically valid method that is at least equivalent.

(21 CFR 112.152)

C. What Methods Must I Use To Test The Growing, Harvesting, Packing, and Holding Environment for *Listeria* species or *L. monocytogenes* for 21 CFR 112.144(b) and (c)?

You must test spent sprout irrigation water (or sprouts) from each production batch using:

- The method of analysis described in “Testing Methodologies for *E. coli* O157:H7 and *Salmonella* species in Spent Sprout Irrigation Water (or Sprouts), Version 1, October 2015, FDA, or
- A scientifically valid method that is at least equivalent

(21 CFR 112.153)

XIII. RECORDS – SUBPART O

A. What Are The General Records Requirements For The Produce Rule?

All records under part 112 must be created at the time an activity is performed or observed; be accurate, legible, and indelible; be dated, and signed or initialed by the person who performed the activity documented; and include the following, as applicable:

- The name and location of your farm,
- Actual values and observations obtained during monitoring,
- An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record, and
- The date and time of the activity documented.

(21 CFR 112.161(a))

B. Must I Store My Records Onsite?

No. Offsite storage of records is permitted if the records can be retrieved and provided onsite within 24 hours of a request for official review. (21 CFR 112.162(a))

C. Are Electronic Records Acceptable?

Yes. Electronic records are acceptable and are considered to be onsite at your farm if they are accessible from an onsite location at your farm. (21 CFR 112.162(b))

D. How Long Must I Keep Records?

You must keep records required by this part for at least 2 years past the date the record was created. (21 CFR 112.164(a)(1))

Records that relate to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued. (21 CFR 112.164(b))

E. Does The 2 Year Period Also Apply to Records Used To Be Eligible For A Qualified Exemption?

No. Records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption, in accordance with 21 CFR 112.5 and 112.7, must be retained as long as necessary to support the farm's status during the applicable calendar year. (21 CFR 112.164(a)(2))

XIV. VARIANCES – SUBPART P

A. Can A Farm Apply For A Variance?

No. The produce rule permits States, tribes, or foreign countries to submit a petition, along with supporting information, to FDA requesting a variance(s) from the requirements of the produce rule.

B. Who May Request a Variance?

States, tribes, or foreign countries from which food is imported into the United States may submit a petition, along with supporting information, to FDA requesting a variance(s) from one or more of the requirements under the produce rule if the state, tribe, or country concludes that meeting one or more of the requirements would be problematic in light of local growing conditions. The state, tribe, or foreign country must demonstrate that the requested variance is reasonably likely to ensure that the produce is not adulterated and provides the same level of public health protection as the corresponding requirement(s) in the produce rule. (21 CFR 112.171)

C. How May a Variance Be Requested?

To request a variance from one or more requirements of this rule, the competent authority (i.e., the regulatory authority for food safety) for a State, tribe, or a foreign country must submit a petition under 21 CFR 10.30. (21 CFR 112.172)

In addition to the requirements of 21 CFR 10.30, a Statement of Grounds must be included in a petition for a variance. (21 CFR 112.173)

D. When Does a Variance Approved by FDA Become Effective?

A variance approved by FDA becomes effective on the date of FDA's written decision on the petition. (21 CFR 112.179)

E. Under What Circumstances May FDA Modify or Revoke an Approved Variance?

FDA may modify or revoke a variance if it is determined that the variance is not reasonably likely to ensure that the produce is not adulterated under section 401 of the FD&C Act and to provide the same level of public health protection as the requirements of this rule. (21 CFR 112.180)

XV. DEFINITIONS (21 CFR 112.3)

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

Adequately reduce microorganisms of public health significance means reduce the presence of such microorganisms to an extent sufficient to prevent illness.

Agricultural water means water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).

Agricultural water assessment means an evaluation of an agricultural water system, agricultural water practices, crop characteristics, environmental conditions, and other relevant factors (including test results, where appropriate) related to growing activities for covered produce (other than sprouts) to:

- (1) Identify any condition(s) that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces; and
- (2) Determine whether measures are reasonably necessary to reduce the potential for contamination of covered produce or food contact surfaces with such known or reasonably foreseeable hazards.

Agricultural water system means a source of agricultural water, the water distribution system, any building or structure that is part of the water distribution system (such as a well house, pump station, or shed), and any equipment used for application of agricultural water to covered produce during growing, harvesting, packing, or holding activities.

Animal excreta means solid or liquid animal waste.

Application interval means the time interval between application of an agricultural input (such as a biological soil amendment of animal origin) to a growing area and harvest of covered produce from the growing area where the agricultural input was applied.

Biological soil amendment means any soil amendment containing biological materials such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative

waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination.

Biological soil amendment of animal origin means 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.

Composting means a 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, 3 days) at a designated temperature (for example, 131 °F (55 °C)), followed by a curing stage under cooler conditions.

Covered activity means growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of "farm" as defined in this chapter. Providing, acting consistently with, and documenting actions taken in compliance with written assurances as described in 112.2(b) are also covered activities. This part does not apply to activities of a facility that are subject to part 117 of this chapter.

Covered produce means produce that is subject to the requirements of part 112 in accordance with 21 CFR Part 112.1 and 112.2. The term “covered produce” refers to the harvestable or harvested part of the crop.

Direct water application method means using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food contact surfaces during use of the water.

Farm means:

(1) *Primary production farm.* A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term "farm" includes operations that, in addition to these activities:

(i) Pack or hold raw agricultural commodities;

(ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(I) of this definition; and

(iii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same management; or

(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(2) *Secondary activities farm.* A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes seeds and beans used to grow sprouts.

Food contact surfaces means those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. “Food contact surfaces” includes food contact surfaces of equipment and tools used during harvest, packing and holding.

Ground water means the supply of fresh water found beneath the Earth's surface, usually in aquifers, which supply wells and springs. Ground water does not include any water that meets the definition of surface water.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include

cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Hazard means any biological agent that has the potential to cause illness or injury in the absence of its control.

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

Known or reasonably foreseeable hazard means a biological hazard that is known to be, or has the potential to be, associated with the farm or the food.

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

Manure means animal excreta, alone or in combination with litter (such as straw and feathers used for animal bedding) for use as a soil amendment.

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

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

Monitor means to conduct a planned sequence of observations or measurements to assess whether a process, point or procedure is under control and, when required, to produce an accurate record of the observation or measurement.

Non-fecal animal byproduct means solid waste (other than manure) that is animal in origin (such as meat, fat, dairy products, eggs, carcasses, blood meal, bone meal, fish meal, shellfish waste (such as crab, shrimp, and lobster waste), fish emulsions, and offal) and is generated by commercial, institutional, or agricultural operations.

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

Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro).

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

Sewage sludge biosolids means the solid or semi-solid residue generated during the treatment of domestic sewage in a treatment works within the meaning of the definition of “sewage sludge” in 40 CFR 503.9(w).

Small business means a farm that is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in this section) the farm sold during the previous 3-year period is no more than \$500,000; and the farm is not a very small business as defined in this section.

Soil amendment means any chemical, biological, or physical material (such as 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) 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. The term soil amendment also includes growth media that serve as the entire substrate during the growth of covered produce (such as mushrooms and some sprouts).

Spent sprout irrigation water means water that has been used in the growing of sprouts.

Stabilized compost means a stabilized (*i.e.*, finished) biological soil amendment produced through a controlled composting process.

Surface water means all water open to the atmosphere (rivers, lakes, reservoirs, streams, impoundments, seas, estuaries, etc.) and all springs, wells, or other collectors that are directly influenced by surface water.

Turned composting means a process to produce stabilized compost in which air is introduced into biological material (in a pile, row, or enclosed vessel) by turning on a regular basis. Turning is the process of mechanically mixing biological material that is undergoing a composting process with the specific intention of moving the outer, cooler sections of the material being composted to the inner, hotter sections.

Very small business means a farm that is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in this section) the farm sold during the previous 3-year period is no more than \$250,000.

Visitor means any person (other than personnel) who enters your covered farm with your permission.

Water distribution system means a system to carry water from its primary source to its point of use, including pipes, sprinklers, irrigation canals, pumps, valves, storage tanks, reservoirs, meters, and fittings.

We means the U.S. Food and Drug Administration (FDA).

You, for purposes of part 112, means the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements of part 112.

XVI. DOCUMENT HISTORY

Status of Guidance	Timing of Current Version	Description of Changes
Final guidance	September 2017	First version
Final guidance	September 2024	Revisions to reflect the final rule, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water” (May 6, 2024 (89 FR 37448))