

## Bulletin #4296, Explanation of Required Records for the Food Safety Modernization Act Produce Safety Rule

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This fact sheet is designed to help you understand what records describing your farm activities you need to keep under the Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR). The PSR is written in sections, and the end of each section details what records the PSR requires farms to keep for that section. Below we discuss in detail the required records for each section.

All records that you keep for your farm to comply with the FSMA PSR must include the information detailed in each section of the PSR, as well as these four requirements for a complete record:

1. the name and location of the farm
2. accurate values, dates, and observations recorded
3. location of the growing area or other areas (such as a packing shed) applicable to the record
4. the signature or initials of the person who performed the activity.

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## Required Records of the FSMA Produce Safety Rule for Farm Coverage or Exemption Status (Subpart A)

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While most fresh produce is subject to the PSR (it is “covered”), some produce is “not covered” or is eligible for an exemption. Produce that is “not covered” is *not* subject to the PSR at all, and does not have to meet any of the requirements of the rule.

In addition, some “covered produce” in the PSR may be eligible for an “exemption” from some of the rule’s requirements. Any “exempt” produce must still meet modified requirements of the PSR.

Also, some farms may be “partially exempt” and must comply with just some of the rule’s requirements, even if they grow covered produce. FDA calls such farms “qualified exempt.”

Crops “not covered” by the rule include produce that is:

Designated as rarely consumed raw (RCR) within the PSR. Produce **not** on this list cannot be treated as RCR, even if in your experience it is never consumed raw.

FDA’s complete list of RCR produce includes: asparagus; black, great northern, kidney, lima, navy, and pinto beans; garden beet (root and top); sugar beet; cashew; sour cherry; chickpea; cocoa bean; coffee bean; collard; sweet corn; cranberry; date; dill (seed and weed); eggplant; fig; ginger; hazelnut; horseradish; lentil; okra; peanut; pecan; peppermint; potato; pumpkin; winter squash; sweet potato; and water chestnut.

- Grown for Personal or On-Farm Consumption
- Produce designated for On-Farm Processing
- Produce designated for Commercial Processing
- Food Grains

A produce farm is eligible for a qualified exemption if it meets the following three criteria:

1. The farm's 3-year average of annual *produce* sales is above the \$25,000 (adjusted for inflation) threshold.
2. The farm's 3-year average of total *food* sales is below the \$500,000 cap (adjusted for inflation).
3. The farm's 3-year average of total *food* sales to qualified end-users within the 275-mile radius is more than its sales to all other customers.

**If you have questions about FSMA PSR exemptions for your farm, please see UMaine Extension Bulletin #4281.**

If your farm is eligible for a qualified exemption, you will not have to meet the full requirements of the PSR, but you will still have three requirements. If your farm is qualified exempt, you will need to:

- Identify your farm at the point of sale with your farm name and complete business address. That can be done by having labels on every product or by having a big enough sign to be clearly visible to your customers. (NOTE: Your invoice can be the label if it has your complete farm name and address on it. Also, the rule does not specify the dimensions for the sign, just that it must be clearly visible. Use your best judgment.)
- Maintain annual sales records that show you are eligible for the qualified exempt status. If you keep receipts, they should have the date and the location of the sale on the receipt to prove that more than 50% of your sales were within the 275-mile radius to qualified end-users. If you keep a total amount of sales from each day at the farmers market/farm store/stand, you just need to keep a tally of total sales that day from that market or farm store/stand. All records should include the name and address of the farm.
- Perform a documented annual review that your farm continues to meet the criteria for a qualified exemption.

Please see the [Produce Safety Alliance's Record Templates \(PDF\)](#) for an example of what this record can look like to fulfill the PSR.

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## **Required Records of the FSMA Produce Safety Rule for Personnel Qualifications and Training (Subpart C)**

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The FSMA PSR requires farms covered under the PSR to train all workers in some produce safety protocols. The person training the workers can be the farmer, a supervisor, the farm's produce safety specialist, or a third party (e.g., if you subcontract the harvesting crew and they get trained by the contractor). The training must include basic food safety and personal hygiene, as well as how to safely perform the specific duties workers are tasked with as they apply to produce safety (e.g., if a worker will exclusively work in the packing

house, they may not require training on produce safety related to harvesting. But if workers perform multiple tasks, they must be trained on how to perform all those tasks safely). Trainers must introduce workers to the procedures and requirements of the PSR. Trainers must make sure workers are aware of the sources of foodborne pathogens, how the produce may be contaminated (e.g., from people or animals to produce), and explain ways to prevent produce from being contaminated. (For more specifics of training topics required, see **UMaine Extension Bulletin #4283.**)

The PSR requires covered farms to keep records of:

1. the date(s) of training
2. the topics covered (Many farms have this in a written form that they use during the training and also have added to their food safety plan, if they have one.)
3. the name(s) of the worker(s) trained.

**Please see the [Produce Safety Alliance's Record Templates \(PDF\)](#) for an example of what this record can look like to fulfill the PSR.**

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## Required Records of the FSMA Produce Safety Rule for Agricultural Water (Subpart E)

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*NOTE: Subpart E is under review and is not subject to the requirements of the PSR at this time. We recommend you not implement any costly changes regarding the water portion of the rule before FDA has a final word on the matter.*

### Water System Inspection

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The PSR requires covered farms to inspect the farm's agricultural water system. This should be done at the beginning of a growing season, as appropriate, but at least once annually. Your agricultural water system includes water sources, water distribution systems, facilities, and equipment. Sometimes you don't have complete ownership of the water source (e.g., rivers), so farms are only responsible for the part of the water source that is under their control. The rule requires you to identify hazardous conditions or situations in the water system that may introduce hazardous conditions onto covered produce or food contact surfaces. Keep in mind your farm's specific practices and conditions.

Specifically, the PSR requires you to look for hazards or potential problems with the following:

1. each of your agricultural water sources (ground- or surface water)
2. how much control you have over each of your ag water sources
3. the degree of protection from hazards for each ag water source

4. use of adjacent and nearby land
5. other uses of each ag water source outside of your farm (e.g., could other people contaminate that water source off your farm? Could this contaminate your covered produce?)

To the extent that is under your control, you must maintain all agricultural water distribution systems and agricultural water sources so they don't contaminate your covered produce or covered food contact surfaces. You must inspect and adequately store all equipment used in the water system. You also need to maintain wells and everything connected to the wells (e.g., well cap, cross-connections, treatment equipment, and piping tanks are working correctly and not leaking or cracked, etc.).

The PSR says you must establish and keep records of what you find during the annual inspection of your agricultural water system.

## **Water Treatment Monitoring**

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Agricultural water must be safe and of good sanitary quality for its use. When you're treating agricultural water (e.g., with an EPA-approved sanitizer), the treatment must be used according to the label. When using treated water for post-harvest activities (e.g., using a sanitizer in the wash water), the safety of the water must be monitored. Specifically, you should keep track of:

1. water pH
2. temperature
3. turbidity and
4. type and rate of the sanitizer used.

NOTE: When this water treatment is on produce, it must also be logged in the farm's Spray Log for the Maine Board of Pesticide Control.

You must monitor the water throughout the time you are using it, so it stays safe and sanitary. Monitor the quality of the water as much as you think is necessary to keep the water safe and sanitary. NOTE: This may mean you may need to record the pH, temperature, and turbidity multiple times an hour or a day, depending on the water use. The attached template includes space for recording all of those criteria, as well as space for detailing what went wrong and the corrective action taken.

The PSR says you must establish and keep records of monitoring your water treatments.

## **Agricultural Water Die-Off Corrective Measures**

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You must make sure there is no detectable generic *Escherichia coli* (*E. coli*) in 100 mL of agricultural water used for:

1. sprout irrigation
2. application to any covered produce during or after harvest activities (including ice-making)
3. application to food contact surfaces
4. washing hands during and after harvest activities.

When you use agricultural water during growing activities for covered produce (other than sprouts) and the water touches the harvestable part of the crop, the following criteria apply:

1. A geometric mean (GM) of your agricultural water samples of 126 or fewer colony-forming units (CFU) of generic *E. coli* per 100 mL of water (GM is a measure of the central tendency of your water quality distribution)
2. A statistical threshold value (STV) of your agricultural water samples of 410 or fewer CFU of generic *E. coli* per 100 mL of water (STV is a measure of the variability of your water quality distribution). **(This UC Davis [worksheet \(Excel\)](#) calculates these values for you for your surface water source and this UC Davis [worksheet \(Excel\)](#) calculates the values for your ground water source. Both worksheets will also calculate the die-off rate, if needed.)**

If you have figured out that your agricultural water does not meet the microbial quality criteria (or any alternative microbial quality criteria, if applicable) as stated above, as soon as you can and no later than the following year, you must stop using that water source, unless you:

1. Apply a time interval(s) (in days) and/or a (calculated) log reduction using a microbial die-off rate of 0.5 log\* per day by:
  - a. Applying a time interval between last irrigation and harvest, or
  - b. Applying a time interval between harvest (or post-harvest activities involving agricultural water contacting the produce) and the end of storage.
2. Re-inspect the entire affected agricultural water system that you control to identify any conditions that are likely to introduce hazards into or onto covered produce or food contact surfaces. Then make necessary changes and evaluate your changes: Were the changes effective to adequately ensure that your agricultural water meets the microbial quality criteria (as listed above)?
3. Treat the water in accordance with the requirements of [CFR 112.43](#).

\*0.5 log per day means that after 2 days (1 log reduction) you will have only 90% of the microbes that you had when the water was sampled.

The PSR says you must establish and keep records of the actions you take when your agricultural water is not meeting the microbial quality criteria. This record must include:

1. the specific time interval or log reduction applied

2. how the time interval or log reduction was determined
3. the dates and use of the water (such as the dates of the last irrigation and/or the dates of activities such as commercial washing).

Please see the [Produce Safety Alliance's Record Templates \(PDF\)](#) for an example of what this record can look like to fulfill the PSR.

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## Required Records of the FSMA Produce Safety Rule for Biological Soil Amendments of Animal Origin (Subpart F)

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### Compost Treatment Record

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Most farms apply soil amendments to their fields to increase fertility. The PSR is specific only to the Biological Soil Amendments of [Animal Origin](#) (BSAAO) (i.e., soil amendments that include animal manures or animal parts in the mixture). Some soil amendments are made on-farm, and some are purchased off the farm.

1. Some BSAAO are untreated (i.e., not composted). Untreated soil amendments must be applied so that they do not contact covered produce during or after application.
2. Some BSAAO are treated (e.g., composted). These soil amendments must be treated according to a scientifically valid, controlled physical (e.g., thermal), biological (e.g., composting) or chemical (e.g., high alkaline pH) process (or a combination thereof) that meets the microbial standards for that process. There are two composting methods listed as acceptable treatment processes to meet the microbial standard to kill *Salmonella* species and fecal coliforms.
  1.
    - a. Static composting: This process maintains aerobic conditions at a minimum of 131°F (55°C) for 3 consecutive days and is followed by adequate curing.
    - b. Turned composting: This process 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.

If you are creating your own treated BSAAO (e.g., compost) on-farm, you must establish and keep records of the process used to treat the soil amendments. You must keep written records of the steps of the treatment process (i.e., time, temperature, and turnings). (Please see this [composting](#) link for more detailed info on how-to make compost.)

Please see the [Produce Safety Alliance's Record Templates \(PDF\)](#) for an example of what this record can look like to fulfill the PSR.

# Required Records of the FSMA Produce Safety Rule for Equipment, Tools, Buildings, and Sanitation (Subpart L)

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## Cleaning and Sanitizing

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The only requirement for recordkeeping in equipment, tools, buildings, and sanitation is that you must document *when* and *what method* you use to clean and sanitize equipment. Specifically, this is the equipment used during the covered activities of harvesting, packing, and holding covered produce, and during the growing operations of sprouts.

Please see the [Produce Safety Alliance's Record Templates \(PDF\)](#) for an example of what this record can look like to fulfill the PSR.

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## Resources

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- [Produce Safety Alliance's Record Templates \(PDF\)](#)
  - [FDA's FSMA Produce Safety Rule](#)
  - [UC Davis' Surface Water Microbial Water Quality Profile Calculator \(Excel\)](#)
  - [UC Davis' Ground Water Microbial Water Quality Profile Calculator \(Excel\)](#)
  - [University of Arizona Microbial Water Quality Profile Calculator](#)
  - [Produce Safety Alliance's Produce Safety Rule general information](#)
  - [Produce Safety Alliance's PSR Compliance Dates](#)
  - [University of Maine Cooperative Extension's Produce Safety Alliance Grower Training website](#)
  - [University of Missouri's fact sheet for Making and Using Compost](#)
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