

FSMA Produce Rule Record Keeping Requirements

SUBPART O - GENERAL RECORD KEEPING REQUIREMENTS

Subpart O applies to all record keeping requirements, with exceptions for Qualified Exemptions

The general record keeping standards requires all records to include:

- Name and location of the farm
- Actual values and observations collected during monitoring activities
- An adequate description of the produce applicable to the record (e.g., commodity name, specific variety, or other identifier, such as a lot number)
- Location of the growing area or other area applicable to the record
- Date and time that an activity was performed or observed.

The records must be:

- Taken at the time an activity is performed or observed
- Must be accurate and legible
- Must be dated and signed by the person doing the activity

Record requirements below marked with an asterisk (*) must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or food safety responsible party.

Records can be based on existing records, be written or electronic, be either the original or photo/scanned copies, and be stored offsite as long as they can be retrieved and provide within 24 hours of request for official review.

Records must be kept for 2 years (3 if to demonstrate satisfying criteria for a qualified exemption)

§ 112.7 RECORDS FOR A QUALIFIED EXEMPTION

What Records Must You Keep

You must establish and keep adequate records necessary to:

- Demonstrate that your farm satisfies the criteria for a qualified exemption (begin as of 1/26/16)
- Reflect that you have performed an annual review and verification of your farm's continued eligibility for the qualified exemption. * (Compliance date a year after general compliance date)

Records for a Qualified Exemption do not have to be submitted to FDA, but they must be retained and made available upon request.

These records are subject to the same general requirements for all records kept under the Produce Rule: they must be detailed, accurate, legible, dated and signed or initialed by the person performing the documented activity; they can be stored offsite as long as they can be retrieved within 24 hours of request for official review; they can be written or electronic; they must be original or true copies; and they can be based on existing records. Sales receipts retained to document the \$500,000 threshold for qualified exempt farms do not need to be initialed, but they should be retained long enough to document the qualified exempt status for the applicable year, based on the rolling three-year average.

SUBPART C: PERSONNEL QUALIFICATIONS AND TRAINING

* Document training of personnel, including:

- The date of training
- The topics covered
- The persons(s) trained

SUBPART E: AGRICULTURAL WATER

For all agricultural water keeps records of:

- Inspection of agricultural water sources and systems, and pooling of water
- Generic *E. coli* test results
- Water treatment monitoring
- Public water (annual) documentation
- Scientific data or information you rely on to support the adequacy of a method used to treat water

Irrigation water that directly contacts harvestable portion:

- Microbial die-off or removal rates, and scientific documentation of method
 - Scientific data or information you rely on to support a microbial die-off or removal rate
 - Documentation of actions that support a microbial die-off or removal rate
-

SUBPART F: BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN AND HUMAN WASTE

For a treated biological soil amendment of animal origin you receive from a third party (e.g. compost from a compost maker):

- Annual documentation (such as a Certificate of Conformance):
 - The process used is scientifically valid and has been carried out with appropriate monitoring; and
 - It is handled, conveyed and stored in a manner and location to minimize the risk of contamination

For a treated biological soil amendment of animal origin (e.g. compost) you make yourself for your farm:

- You must be able to document that you are using a valid controlled biological process known to meet the relevant microbial standard. *
 - If you are using the static or turned composting method, then you do not have to test that the process has resulted in an amendment that meets the standard, but you do need to document that you're following process controls (e.g. with records of time, temperature, turning (as appropriate), and curing.*
-

SUBPART L: EQUIPMENT, TOOLS, BUILDINGS, AND SANITATION

Record the date and method of cleaning and sanitizing equipment used for harvesting, packing, and holding activities. *

This includes:

- Toilet and hand washing facilities
- Produce contact surfaces
- Harvest tools and equipment
- Harvest and transport vehicles
- Harvest containers
- Coolers, ice machines
- Packing shed
- Storage areas, food and equipment
- Measuring instruments