

# Produce Safety


## ALLIANCE

### Records Required by the FSMA Produce Safety Rule

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*\*This publication has not been approved by the FDA and should not be considered legal guidance. It is provided in response to PSA training participants who asked for examples of records required by the FSMA Produce Safety Rule.*

The FSMA Produce Safety Rule (PSR) requires a few specific records. This publication summarizes the provisions requiring records and includes template records to help establish records to meet FSMA PSR requirements. Growers may want or need to keep additional records to ensure that required practices are being carried out correctly, to meet buyer requirements, and/or participate in a third party audit. Other documentation, such as Standard Operating Procedures (SOPs), may be helpful to support the implementation of practices on the farm.

Throughout this factsheet, the  icon indicates a template record is provided. Clicking on the icon will take you to an example record. The template records provided are examples of required records. They have not been approved by FDA and other formats may be used. This publication should be used in conjunction with the Produce Safety Alliance (PSA) Grower Training Curriculum and the PSR preamble and codified regulation. It should not be used as a standalone reference.

All records required by the PSR must contain certain information as outlined in § 112.161. Except as otherwise specified, all required records must include:

- The name and location of the farm
- Actual values and observations obtained during monitoring
- An adequate description of covered produce, if applicable to the record (e.g. the commodity name, or the specific variety or brand name of a commodity, and any lot number or other identifier)
- The location of a growing area or other area, if applicable to the record (e.g. a specific field or packing shed)
- The date and time of the activity documented

Records must also be created at the time an activity is performed or observed, be accurate, legible, indelible, dated, and signed or initialed by the person who performed the activity.

### Records to Support a Farm's Coverage or Exemption Status


*Subpart A, General Provisions, outlines what farms and commodities are covered by the Produce Safety Rule*

§ 112.2 requires documentation to support an exemption from FSMA Produce Safety Rule requirements for produce undergoing a further processing step. Broadly, this includes:


- Farm documentation accompanying the produce stating that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”
- A written assurance from the customer that the produce will be processed to adequately reduce microorganisms of public health significance. This assurance must be obtained annually.

Qualified Exemption Review Template	
Name and address of farm: _____ Date: _____	
<b>Total food sales</b> (in addition to produce, these sales include all other food for humans, feed for animals, and sales of live food animals)	
Year 1 (Sales year: _____)	\$ _____
Year 2 (Sales year: _____)	\$ _____
Year 3 (Sales year: _____)	\$ _____
<b>Average total food sales</b>	\$ _____ <b>A</b>
<b>Inflation adjusted* threshold for (range)</b>	\$ _____ <b>B</b>
(for example, B is \$584,908 for 2019-2021)	
<b>Sales to qualified end users</b> (QEURs) (e.g. consumers anywhere, or grocery stores and restaurants within 275 miles or within the same state or Indian reservation)	
Year 1 (Sales year: _____)	\$ _____
Year 2 (Sales year: _____)	\$ _____
Year 3 (Sales year: _____)	\$ _____

A must be smaller than B for eligibility

§ 112.7 requires records to establish eligibility for a qualified exemption. Records, such as receipts, must demonstrate that the farm satisfies the criteria for a qualified exemption. This includes a written record reflecting that the grower has performed an annual review and verification of the farm's continued eligibility for the qualified exemption. Receipts must be dated, but no signature is required. The annual review verifying the farm's qualified exemption must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after the records are made. 

### Personnel Qualifications and Training (Subpart C)

§ 112.30 requires documentation of required training. Documentation must include the date of training, topics covered, and the names of persons trained. Required training topics are outlined in § 112.22. Training records must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after the records are made. 

**Worker Training Record Template**

Name and address of farm: \_\_\_\_\_ Date: \_\_\_\_\_

Trainer: \_\_\_\_\_ Training time: \_\_\_\_\_

Topics Covered: \_\_\_\_\_

Training materials: Please attach any printed materials related to the training. Also reference any relevant SOPs or sections of the farm food safety plan that apply.

Employee Name (please print)	Employee Signature
1. _____	_____
2. _____	_____

### Agricultural Water (Subpart E)

*Note: Only some Subpart E requirements, for agricultural water used during harvest and postharvest activities on covered produce, are inspected starting 2023. Requirements in Subpart E for pre-harvest activities are under enforcement discretion while revisions are made. For more information, refer to the FDA fact sheet [“Requirements for Harvest and Post-Harvest Agricultural Water in Subpart E for Covered Produce Other than Sprouts”](#).*

**Agricultural Water System Inspection Record Template (1 of 2)**  
§§ 112.42(a)(1-5) Requirements Relating to Agricultural Water Source or System



Name and address of farm: \_\_\_\_\_ Date and time of inspection: \_\_\_\_\_ Name and Initials: \_\_\_\_\_


Water source ID: \_\_\_\_\_ Pond #1: \_\_\_\_\_

**Agricultural Water System Inspection Record Template (2 of 2)**  
§ 112.50(b)(1) Findings of Annual Agricultural Water System Inspection  
Also addresses §§ 112.42(b-d) for routine monitoring (documentation not required)

Date, time, and type of monitoring	Water Source and/or Distribution System	Observations	Actions Taken	Initials
Annual 5/20/24 7:05 AM	Pond #1	Berm along northwest edge of pond shows signs of disrepair	Berm reinforced with riprap and additional fill	EAB
Routine 6/22/24 9:00 AM	Pond #1	Significant geese presence	Scared geese until they left, introduced swan decoys. Will monitor	EAB

§ 112.50(b) requires the following records that are relevant to agricultural water:

1. The findings of the inspection of the agricultural water system in accordance with the requirements of § 112.42(a). This record does not require supervisor review but it is a best practice to have records reviewed to assure they are correct.  
2. Results of any analytical tests conducted on agricultural water to comply with FSMA Produce Safety Rule provisions. Test results are obtained from the lab and must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after the records are made. [“FSMA Produce Safety Rule: Documentation Requirements for Water Laboratory Analysis Results”](#) describes the required elements for the record of analytical test results so it is clear what should be on the record provided by the laboratory.
3. Scientific data or information growers rely on to support the adequacy of the methods used to satisfy the requirements of § 112.50(b)(3) (i.e., water treatment). Additional regulations besides the FSMA Produce Safety Rule may apply to water treatment methods (e.g., Federal Insecticide, Fungicide, and Rodenticide Act and associated EPA labeling).  
When produce wash water is treated using an EPA-labeled sanitizer, the EPA label is one way to address the requirement in § 112.50(b)(3). One example efficacy statement reads “Use SaniDate 15.0 to reduce (in 90 seconds) 99.9% of pathogenic bacteria: *Escherichia coli* O157:H7, *Salmonella enterica*, and *Listeria monocytogenes* in processing waters used for washing fruits, and vegetables.”  
Other sources of science-based information may be suitable to address the requirement in § 112.50(b)(3) related to chemical sanitizers that are not EPA labeled, or pesticide devices like filtration systems that do not carry an EPA label.

4. Documentation of the results of water treatment monitoring carried out under § 112.43(b). Water treatment monitoring records must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after the records are made. 

Water Treatment Monitoring Record Template

Name and address of farm: \_\_\_\_\_

Please see the food safety plan for overall water treatment procedures.

Date	Time	Water pH	Water Temperature	Turbidity	Sanitizer (name & rate)	Corrective Action Needed (yes or no)	Initials
10/14/16	8:35 am	8.5	68° F	25 NTU	NaOCl 75 ppm	Yes - pH was too high, added citric acid, retested - pH 7.0	EAB
10/14/16	12:00 pm	7.0	72° F	47 NTU	NaOCl 55 ppm	no	EAB

5. Scientific data or information relied upon to support the microbial die-off rate between harvest and end of storage or removal rate during activities such as washing, if used in accordance with § 112.45(b)(1)(ii). No template is available while this recordkeeping requirement, along with die-off rates described in § 112.45(b)(1)(ii), is under revision.

6. Documentation of corrective measures taken in accordance with § 112.45 if agricultural water does not meet the numerical water quality criteria in § 112.44.

- For the re-inspection corrective measure, the template for re-inspection in § 112.50(b)(1) can be found above in (1).
- For treatment of agricultural water, templates for water treatment methods in § 112.50(b)(3) and monitoring in § 112.50(b)(4) can be found above in (3) and (4).
- There is no template for die-off as a corrective measure in § 112.50(b)(5) while § 112.45(b)(1) is under revision.

This record must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after the record is made.

7. Annual documentation of the analytical results or certificates of compliance from a public water system as outlined in §§ 112.46(a)(1) or (2), as applicable. Annual records from the public water system can be obtained from the water authority. The provision requires that the documentation should be annual. In some cases the water system may delay releasing their annual report so it is recommended, at least once a year, to document that the report in the file is the most current report.

A water utility annual report may certify that the water system is not in violation of Safe Drinking Water Act requirements, as shown in Figure 1. Analytical results for *E. coli* are relevant to the FSMA Produce Safety Rule. If you are unsure whether the report you obtained is sufficient to meet this requirement, reach out to the FDA or the agency that inspects your farm for confirmation.

Contaminant	Violation Y/N	Total Sample Collected	Total Coliform* Positive	E-Coli** Positive	E-Coli MCLG	Likely Source of Contamination
Microbiological Contaminants						
Routine Samples	N	1806	6	0	0	Naturally present in the environment
Repeat Samples	N	18	0	0	0	Human and animal fecal waste


Figure 1: Example from a drinking water utility annual report. Information in the red box represents compliance with Safe Drinking Water Act requirements.

8. Scientific data or information to support alternatives to subpart E requirements, as described in § 112.49. No templates are available while § 112.49 is under revision.

9. Support for any equivalent analytical methods used in lieu U.S. EPA Method 1603 (modified mTEC). The FDA released a guidance document called [“Equivalent Testing Methodology for Agricultural Water”](#). This document is one way to support the equivalency status of many testing methodologies used by commercial laboratories.

## Biological Soil Amendments of Animal Origin (Subpart F)

§ 112.60(b) requires records for treated biological soil amendments of animal origin.

For soil amendments that growers treat and apply on their own farms, records must be kept to document that process controls (e.g., time, temperature, and turnings) were achieved. Records related to on-farm soil amendment treatment must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after the records are made. 

Compost Treatment Record Template					
Name and address of farm: _____					
Type of compost method: <u>Windrow</u> Date piled: <u>9-15-2016</u> Date finished: _____ Row number: <u>2</u>					
List all ingredients added to compost: <u>Poultry litter, kitchen scraps, dried leaves, straw</u>					
Use this record for on farm composting. Record the date piled, turning dates, and the temperatures maintained. Use one sheet for each pile or row.					
Date Turned	Temp/Time Test Area 1	Temp/Time Test Area 2	Temp/Time Test Area 3	Temp/Time Test Area 4	Initials
9-25-2016	135 F/ 2:00 PM	136 F/ 2:01 PM	140 F/ 2:03 PM	135 F/ 2:04 PM	EAB
9-26-2016	137 F/ 2:15 PM	137 F/ 2:18 PM	138 F/ 2:19 PM	137 F/ 2:28 PM	EAB


For treated soil amendments received from a third party, growers must document annually that:

- The process used to treat the biological soil amendment of animal origin is a scientifically valid process that was carried out with appropriate process monitoring; and
- The biological soil amendment of animal origin has been handled, conveyed, and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin.

[“FSMA Produce Safety Rule: Documentation Requirements for Commercial Soil Amendment Suppliers”](#)

describes the recordkeeping requirements and includes a model certificate of conformance for third-party soil amendments.

## Equipment, Tools, Buildings, and Sanitation (Subpart L)

§ 112.140(b)(2) requires that growers subject to the rule establish and keep a record of the date and method of cleaning and sanitizing equipment used in covered harvesting, packing, or holding activities. This record must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after the records are made. 

Cleaning and Sanitizing Record Template					
Name and address of farm: _____					
List the date, time, tool or equipment name, and method for each cleaning or sanitizing activity.					
Date	Time	List tools/equipment	Cleaned and/or Sanitized?	Method used	Cleaned By (Initials)
10/11/16	10:07 AM	Harvest tools	cleaned	See Cleaning SOP (Removed dirt with brush, washed with detergent, rinsed, air dried)	EAB
10/11/16	10:30 AM	Dump Tank	cleaned and sanitized	See Dump Tank Cleaning and Sanitizing SOP (drained tank, washed with detergent, rinsed, sanitized with 150 ppm NaOCl)	EAB

## Storage of Records, Allowable Record Types, and Off-Site Storage (Subpart O)

§ 112.162 allows for the storage of records offsite if such records can be retrieved and provided onsite within 24 hours of official request. Electronic records are acceptable if they can be accessed on the farm.

§ 112.163 specifies that existing records do not need to be duplicated if they contain all of the required information. For instance, if records are kept for organic certification and they include the required information, there is no need to duplicate these records.

§ 112.164 requires that records be kept for at least 2 years past the date the record was created. Records that a farm relies on to support a qualified exemption must be retained as long as necessary to support the farm’s status.

§ 112.165 requires the records be kept as original records, true copies or electronic records.

§ 112.166 outlines requirements for making records available and accessible to FDA.

- Records must be readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request. Growers have 24 hours to obtain records kept offsite, even if the farm is closed for a prolonged period.
- Records must be provided to FDA in a format that is accessible and legible.

§ 112.167 specifies that records obtained by FDA in accordance with the Produce Safety Rule are subject to the disclosure requirements under 21 CFR part 20 (Public Information). All of the templates provided in this document are marked Confidential to reduce the likelihood that farm records would be released in response to a Freedom of Information Act (FOIA) request submitted to FDA should they obtain or copy farm records.

# Qualified Exemption Review *Template*

Name and address of farm: \_\_\_\_\_ Date: \_\_\_\_\_

**Total food sales** (in addition to produce, these sales include all other food for humans, feed for animals, and sales of live food animals)

Year 1 (Sales year: \_\_\_\_\_) \$ \_\_\_\_\_  
Year 2 (Sales year: \_\_\_\_\_) \$ \_\_\_\_\_  
Year 3 (Sales year: \_\_\_\_\_) \$ \_\_\_\_\_

**A** must be  
smaller than **B**  
for eligibility

**Average** total food sales \$ \_\_\_\_\_ **A**  
Inflation adjusted<sup>1</sup> threshold for (range) \$ \_\_\_\_\_ **B**  
(for example, B is \$584,908 for 2019-2021)

**Sales to qualified end users** (QEUs) (e.g. consumers anywhere, or grocery stores and restaurants within 275 miles or within the same state or Indian reservation)

Year 1 (Sales year: \_\_\_\_\_) \$ \_\_\_\_\_  
Year 2 (Sales year: \_\_\_\_\_) \$ \_\_\_\_\_  
Year 3 (Sales year: \_\_\_\_\_) \$ \_\_\_\_\_

**Average** food sales to QEUs \$ \_\_\_\_\_ **C**

**Sales to non-QEUs** (e.g. wholesale buyers)

Year 1 (Sales year: \_\_\_\_\_) \$ \_\_\_\_\_  
Year 2 (Sales year: \_\_\_\_\_) \$ \_\_\_\_\_  
Year 3 (Sales year: \_\_\_\_\_) \$ \_\_\_\_\_

**C** must be  
larger than **D**  
for eligibility

**Average** food sales to non-QEUs \$ \_\_\_\_\_ **D**

Based on this information, this farm meets the criteria for a qualified exemption.

Reviewed by: \_\_\_\_\_ Title: \_\_\_\_\_ Date: \_\_\_\_\_

Sales receipts must also be retained to support this record.

<sup>1</sup>FDA updates the inflation adjusted value (B) yearly:

<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs>

**FSMA PSR Reference § 112.7(b) Confidential Record**

# Worker Training Record *Template*

Name and address of farm: \_\_\_\_\_ Date: \_\_\_\_\_

Trainer: \_\_\_\_\_ Training time: \_\_\_\_\_

Topics Covered: \_\_\_\_\_

**Training materials:** Please attach any printed materials related to the training. Also reference any relevant SOPs or sections of the farm food safety plan that apply.

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

Reviewed by: \_\_\_\_\_ Title: \_\_\_\_\_ Date: \_\_\_\_\_

## FSMA PSR reference § 112.30(b) Confidential Record

Modified from On-Farm Decision Tree Project: Worker Health, Hygiene, and Training—v14 07/16/14  
E.A. Bihn, M.A. Schermann, A.L. Wszelaki, G.L. Wall, and S.K. Amundson, 2014 [www.gaps.cornell.edu](http://www.gaps.cornell.edu)

**Agricultural Water System Inspection Record Template (1 of 2)**  
**§§ 112.42(a)(1-5) Requirements Relating to Agricultural Water Source or System**

Name and address of farm: \_\_\_\_\_

Date and time of inspection: \_\_\_\_\_ Name and Initials: \_\_\_\_\_

Water source ID	General description of water source	Nature of the source (e.g., ground, surface)	Extent of control over water source	Describe the extent of your control over the water. If water source is not under your full control, explain why.
Pond #1	½ acre spring-fed pond, northwest of house	Surface	Partial control	Runoff from property to the northwest of farm property flows to pond

Water source ID	Degree of protection from hazards	Describe the degree of protection for this water source	Describe potential concerns from adjacent and nearby land uses	Describe any prior uses of the water that may introduce hazards
Pond #1	Mostly protected	Spring fed, only a little fill from runoff. No exclusion to prevent wildlife access to pond.	Property to the northwest of farm property is used as a horse grazing pasture	No prior users of the water

**FSMA PSR reference § 112.50(b)(1) Confidential Record**

**Agricultural Water System Inspection Record Template (2 of 2)**  
**§ 112.50(b)(1) Findings of Annual Agricultural Water System Inspection**

*Also addresses §§ 112.42(b-d) for routine monitoring (documentation not required)*

Name and address of farm: \_\_\_\_\_

Date and time of inspection: \_\_\_\_\_ Name and Initials: \_\_\_\_\_

Date, time, and type of monitoring		Water Source and/or Distribution System	Observations	Actions Taken	Initials
Annual 5/20/24	7:05 AM	Pond #1	Berm along northwest edge of pond shows signs of disrepair	Berm reinforced with riprap and additional fill	EAB
Routine 6/22/24	9:00 AM	Pond #1	Significant geese presence	Scared geese until they left, introduced swan decoys. Will monitor	EAB

Modified from On-Farm Decision Tree Project: Soil Amendments—v5 7/16/2014  
E.A. Bihn, M.A. Schermann, A.L. Wszelaki, G.L. Wall, and S.K. Amundson, 2014 www.gaps.cornell.edu

**FSMA PSR reference § 112.50(b)(1) Confidential Record**

# Water Treatment Monitoring Record Template

Name and address of farm: \_\_\_\_\_

Please see the food safety plan for overall water treatment procedures.

Date	Time	Water pH	Water Temperature	Turbidity	Sanitizer (name & rate)	Corrective Action Needed (yes or no)	Initials
10/14/16	8:35 am	8.5	65° F	25 NTU	NaOCl 75 ppm	Yes - pH was too high, added citric acid; retested -pH 7.0	EAB
10/14/16	12:00 pm	7.0	72° F	47 NTU	NaOCl 55 ppm	no	EAB

\*Not all of the above factors may need to be recorded. Refer to the product's EPA label for specific use instructions.

Reviewed by: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

## FSMA PSR reference § 112.50(b)(4) Confidential Record

Modified from On-Farm Decision Tree Project: Postharvest Water—v7 07/16/2014  
E.A. Bihn, M.A. Schermann, A.L. Wszelaki, G.L. Wall, and S.K. Amundson, 2014 [www.gaps.cornell.edu](http://www.gaps.cornell.edu)

# Compost Treatment Record Template

Name and address of farm: \_\_\_\_\_

Type of compost method: Windrow Date piled: 9-15-2016 Date finished: \_\_\_\_\_ Row number: 2

List all ingredients added to compost: Poultry litter, kitchen scraps, dried leaves, straw

Use this record for on farm composting. Record the date piled, turning dates, and the temperatures maintained. Use one sheet for each pile or row.

Date Turned	Temp/Time Test Area 1	Temp/Time Test Area 2	Temp/Time Test Area 3	Temp/Time Test Area 4	Initials
9-25-2016	135 F/ 2:00 PM	138 F/2:01 PM	140 F/ 2:03 PM	135 F/ 2:04 PM	EAB
9-26-2016	137 F/ 2:15 PM	137 F/2:18 PM	138 F/ 2:19 PM	137 F/ 2:25 PM	EAB

Proper compost production requires a minimum temperature of 131°F be maintained for 3 days using an enclosed system OR a temperature of at least 131°F for 15 days using a windrow system, during which the materials must be turned 5 times (FSMA Produce Rule. 2015. Rule 21 CFR part 112.54(b)).

Reviewed by: \_\_\_\_\_ Title: \_\_\_\_\_ Date: \_\_\_\_\_

## FSMA PSR reference § 112.60(b)(2) Confidential Record

Modified from On-Farm Decision Tree Project: Soil Amendments—v5 7/16/2014  
E.A. Bihn, M.A. Schermann, A.L. Wszelaki, G.L. Wall, and S.K. Amundson, 2014 www.gaps.cornell.edu

# Cleaning and Sanitizing Record Template

Name and address of farm: \_\_\_\_\_

List the date, time, tool or equipment name, and method for each cleaning or sanitizing activity.

Date	Time	List tools/equipment	Cleaned and/or Sanitized?	Method used	Cleaned By (initials)
10/11/16	10:07 AM	Harvest tools	cleaned	See Cleaning SOP (Removed dirt with brush, washed with detergent, rinsed, air dried)	EAB
10/11/16	10:30 AM	Dump Tank	cleaned and sanitized	See Dump Tank Cleaning and Sanitizing SOP (drained tank, washed with detergent, rinsed, sanitized with 150 ppm NaOCl)	EAB

Reviewed by: \_\_\_\_\_ Title: \_\_\_\_\_ Date: \_\_\_\_\_