


Records Required by the FSMA Produce Safety Rule

K. Woods, D. Pahl, D. Stoeckel, B. Fick, G. Wall, and E.A. Bihn

**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”

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: _____)	\$ _____	

Average total food sales \$ _____ **A**

Inflation adjusted¹ threshold for (range) \$ _____ **B**


(for example, B is \$550,551 for 2016-2018)

A must be smaller than B for eligibility


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: _____)	\$ _____	

- 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.

§ 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. _____	_____
3. _____	_____

Agricultural Water (Subpart E)

§ 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 a 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.
3. Scientific data or information growers rely on to support the adequacy of the methods related to water treatment.
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. 
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).

Water System Inspection Record Template

Name and address of farm: _____

See farm policy for specific water distribution system inspection procedures.


Date	Time	Water Source and/or Distribution System	Observations	Corrective Actions Taken	Initials
4/22/16	7:00 AM	Well 1, north field	Well casing in good shape, backflow prevention device in place, no broken pipes	None	EAB
4/22/16	9:00 AM	Pond, south field	Significant geese presence	Introduced swan decoys. Will monitor	EAB

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 85 ppm	no	EAB

6. Documentation of corrective measures taken in accordance with § 112.45(b) if agricultural water does not meet the numerical water quality criteria in § 112.44. A template corrective measures record specifically for the die-off provision § 112.45(b)(1) is provided as a resource. This record must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after the records are made. 

Agricultural Water Die-Off Corrective Measures Record Template

Name and address of farm: _____

Water source: _____

Current calculated GM: _____ CFU/100 mL water
 Current Calculated STV: _____ CFU/100 mL water
 Calculated Interval*: _____ Days
 Adjusted GM: _____ CFU/100 mL water
 Adjusted STV: _____ CFU/100 mL water

EXAMPLE

Water source: *Southwest pond*
 Current Calculated GM: *100* CFU/100 mL water
 Current Calculated STV: *600* CFU/100 mL water
 Calculated Interval: *1* days (0.5-log)
 Adjusted GM: *60* CFU/100 mL water
 Adjusted STV: *220* CFU/100 mL water

Field	Crop	Date and time of beginning of crop harvest	Date and time of end of last water application	Time interval since last water application	Harvest Supervisor Initials
2A	Cortland Apple	9/23/2016, 1:00 PM	9/21/2016, 4:00 PM	2 days	DMP
2A	Cortland Apple	9/25/2016, 10:00 AM	9/21/2016, 4:00 PM	4 days	DMP


7. Annual documentation of the 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.

8. Scientific data or information to support any alternative microbial water quality criteria, die-off rates, or sampling frequencies established and used on the farm in accordance with § 112.49.

9. Support for any equivalent analytical methods used in lieu U.S. EPA method 1603 (modified mTEC).

Biological Soil Amendments of Animal Origin (Subpart F)

§ 112.60(b) requires records for 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: *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

For 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.

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 tool/equipment	Cleaned and/or Sanitized?	Method used	Cleaned By (Initials)
10/1/16	10:07 AM	Harvest tools	cleaned	See Cleaning SOP (Removed dirt with brush, washed with detergent, rinsed, air dried)	EAB
10/1/16	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 adjusted¹ threshold for (range) \$ _____ **B**

(for example, B is \$550,551 for 2016-2018)

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.

¹FDA updates the inflation adjusted value (B) yearly:

<https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm>

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

Water System Inspection Record Template

Name and address of farm: _____

See farm policy for specific water distribution system inspection procedures.

Date	Time	Water Source and/or Distribution System	Observations	Corrective Actions Taken	Initials
4/22/16	7:00 AM	Well 1, north field	Well casing in good shape, backflow prevention device in place, no broken pipes	None	EAB
4/22/16	9:00 AM	Pond, south field	Significant geese presence	Introduced swan decoys. Will monitor	EAB

Reviewed by: _____

Title: _____

Date: _____

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

Modified from On-Farm Decision Tree Project: Agricultural Water for Production—v4. 07/17/2014
E.A. Bihn, M.A. Schermann, A.L. Wszelaki, G.L. Wall, and S.K. Amundson, 2014 www.gaps.cornell.edu

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

Agricultural Water Die-Off Corrective Measures Record Template

Name and address of farm: _____

EXAMPLE	
Water source: <u>Southwest pond</u>	
Current Calculated GM: <u>190</u> CFU/100 mL water	
Current Calculated STV: <u>690</u> CFU/100 mL water	
Calculated Interval*: <u>1</u> days (0.5-log)	
Adjusted GM: <u>60</u> CFU/100 mL water	
Adjusted STV: <u>220</u> CFU/100 mL water	

Water source: _____
 Current calculated GM: _____ CFU/100 mL water
 Current calculated STV: _____ CFU/100 mL water
 Calculated Interval*: _____ Days
 Adjusted GM: _____ CFU/100 mL water
 Adjusted STV: _____ CFU/100 mL water

Field	Crop	Date and time of beginning of crop harvest	Date and time of end of last water application	Time interval since last water application	Harvest Supervisor Initials
2A	Cortland Apple	9/23/2016, 1:00 PM	9/21/2016, 4:00 PM	2 days	DMP
2A	Cortland Apple	9/25/2016, 10:00 AM	9/21/2016, 4:00 PM	4 days	DMP

* Attach documentation to support calculations (e.g. the Ag Water Excel Tool at wafs.ucdavis.edu). If a die-off rate other than the specified 0.5 log/day in § 112.45(b)(1) is used, include documentation supporting the alternative die-off rate as required by § 112.50(b)(8).

Reviewed by: _____

Title: _____

Date: _____

FSMA PSR reference § 112.50(b)(6) Confidential Record

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 NaOC)	EAB

Reviewed by: _____ Title: _____ Date: _____

FSMA PSR reference § 112.140(b)(2) Confidential Record