



Idaho Produce Safety Video Series
 Brought to you by:
 Idaho State Department of Agriculture
 University of Idaho Extension



Records

Contents

<i>Introduction:</i>	1
<i>Websites:</i>	2
<i>Record Keeping:</i>	2
<i>Records Must Contain:</i>	4
<i>Personnel Qualifications and Training:</i>	5
<i>Biological Soil Amendments of Animal Origin (BSAAO):</i>	5
<i>Equipment, Tools, Buildings and Sanitation:</i>	7
<i>Records:</i>	9
<i>References:</i>	10
<i>Contact Information:</i>	10

****websites and links, CTRL+click to follow link****

Introduction:

Hello! This video will cover required record keeping for the Produce Safety Rule. Before we get started, let's review how the FDA Produce Safety Rule is laid out.

The Food and Drug Administration Produce Safety Rule is one part of the FDA code of Federal Regulations. This database includes a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government.

Within 21 Code of Federal Regulations Part 112 are subparts that include: general requirements, personnel qualifications and training, Health and Hygiene, Agricultural water, and more.

Notes Section

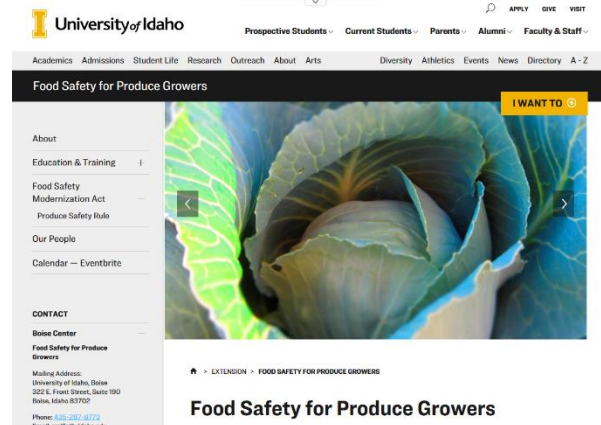


Pay attention to the word **MUST** and **SHOULD**. **MUST** indicates that it is required by the Produce Safety Rule. **SHOULD** indicates suggested good agricultural practices.

For example, under 21 CFR 112 Subpart D -- Health and Hygiene -- section 112.33 outlines measures you **MUST** take to prevent visitors from contaminating covered produce and food contact surfaces. We will reference subparts and sections throughout this presentation.

You may print out this presentation and keep it for your records to use anytime you would like. This will be available for viewing on the Idaho State Department of Agriculture and the University of Idaho Extension websites. It is a good idea to have a copy of the [Produce Safety Rule](#) with you, so you can reference the rule throughout this presentation and you may pause this video at any time.

Websites:



The Food Safety Modernization Act Produce Safety Rule is focused on preventing foodborne outbreaks before they occur by taking a proactive approach instead of a reactionary approach to food safety.

The Produce Safety Rule requires a few very specific records to be kept and maintained on your farm to satisfy the requirements of this rule.

Record Keeping:

Record keeping requirements are listed in each subpart of the Produce Safety Rule and under Subpart O--Records. This presentation will cover the records you are required by the Produce Safety Rule to keep and maintain on your farm.

Notes Section

If you're already keeping records for buyers or third-party auditors and those records contain the same information that's required by the Produce Safety Rule, there's no need to duplicate the records. Simply provide the records you have when requested.



If the records you're currently keeping DO NOT include the required information, your current record can be supplemented to include the required information or new information required by the rule may be kept separately or combined with existing records.

I'll be sharing some templates in this presentation that were created by the Produce Safety Alliance that you might consider adopting. The Produce Safety Alliance templates are available on the Produce Safety Alliance website and on the Idaho State Department of Agriculture website. You are not required to use these templates, there are many templates online available for your use.

You can also create your own farm specific template as long as they meet the



requirements listed under Subpart O--Records Section 112.161.

Produce Safety Alliance

Training PSA Curriculum Resources News Food Safety Modernization Act The Alliance Contact Us



WELCOME TO THE PRODUCE SAFETY ALLIANCE WEBSITE!

Produce Safety



Please note: farms that are considered “qualified exempt” under the Produce Safety Rule have specific record keeping requirements. Those as well as the Agricultural water record requirements will be addressed in separate video presentations. Let's get started!

Notes Section

Objectives:

Identify key records required by the Produce Safety Rule, 21 CFR 112

Learn what information your records **MUST** contain

Learn how to manage the records required by the Produce Safety Rule

Learn where records can be stored and for how long

These are the specific records you **MUST** keep and maintain on your farm. Next to each record, you will see the Produce Safety Rule section number so you can reference the rule anytime. Remember to refer back to your own copy of the Produce Safety Rule. Feel free to pause the presentation at any time.

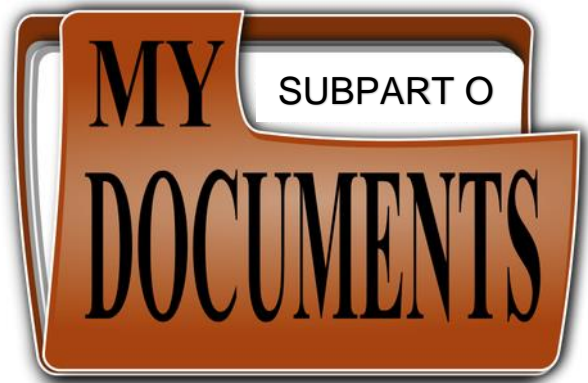
First, we will discuss general record keeping requirements and what information all records **MUST** contain. Next, we will discuss records required for training, biological soil amendments of animal origin, cleaning and sanitation of equipment used in covered harvesting, packing, or holding activities, storage and allowable type of records required of farms. We will review each in depth throughout this presentation.

All records required by the Produce Safety Rule **MUST** contain information outlined in Subpart O—Records section 112.161.

Records Must Contain:

Except as otherwise stated in each subpart of the regulation, all records **MUST** contain:

- **THE NAME AND LOCATION OF THE FARM;**



- **ACTUAL VALUES AND OBSERVATIONS OBTAINED DURING MONITORING;**
- **AN ADEQUATE DESCRIPTION OF COVERED PRODUCE APPLICABLE TO THE RECORD;**
- **THE LOCATION OF A GROWING AREA OR OTHER AREA;**
- **AND THE DATE AND TIME OF THE ACTIVITY DOCUMENTED.**

Training records ***MUST*** also:

- **BE CREATED AT THE TIME AN ACTIVITY IS PERFORMED OR OBSERVED;**
- **BE ACCURATE, LEGIBLE, AND INDELIBLE; MEANING THE INFORMATION CANNOT BE REMOVED OR ERASED;**
- **BE DATED AND SIGNED OR INITIALED BY THE PERSON WHO PERFORMED THE ACTIVITY DOCUMENTED; AND**
- **CERTAIN RECORDS *MUST* BE REVIEWED, DATED, AND SIGNED WITHIN A REASONABLE TIME AFTER THE RECORDS ARE MADE BY A SUPERVISOR OR RESPONSIBLE PARTY.**

We'll now go through examples of records required in each Subpart of the Produce Safety Rule.

Personnel Qualifications and Training:

Subpart C--Personnel Qualifications and Training section 112.30 requires you to establish and keep documentation of worker training. Worker training requirements will be covered in a separate video. ([Template](#))

Specifically, documentation MUST include:

NAME OF PERSONS TRAINED

DATE TRAINED AND

TOPICS COVERED.

As noted in Subpart O Records, the following information MUST also be included on training records:

NAME AND LOCATION OF FARM.

AND AN AREA TO DESIGNATE THAT THE RECORD WAS REVIEWED, DATED, AND SIGNED WITHIN A REASONABLE TIME AFTER RECORDS ARE MADE BY A SUPERVISOR OR RESPONSIBLE PARTY.

Biological Soil Amendments of Animal Origin (BSAAO):

The next section of the rule relates to biological soil amendments of animal origin.

Which means: a biological soil amendment that 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 amendments of animal origin does not include human waste.



We often refer to these soil amendments simply as compost, but compost can actually include a myriad of different products. The Produce Safety Rule is particularly concerned with soil amendments of animal origin because animal waste can carry and spread human pathogens of public health significance.

There are two records required if your farm is using biological soil amendments of animal origin as stated in Subpart F section 112.60 (b)(1). These records **MUST** be kept in accordance with the requirements of Subpart O-Records.

First, if you receive treated biological soil amendments of animal origin from a third party, you **MUST** keep records such as a Certificate of Conformance at least annually. Third party documentation **MUST** include the name and address of the supplier, what soil amendments are purchased, the date and amount purchased, and lot information (if available). This documentation is required to ensure that the supplier is using a scientifically validated method or process and to ensure the soil amendments have been handled, conveyed, and stored in a manner to minimize the risk of contamination by untreated soil amendments of animal origin.

Second, if you're treating biological soil amendments of animal origin on your farm, you **MUST** document that treatment processes such as time, temperature and turnings were achieved.

This is an example of a record keeping template you can use for treated biological soil amendments of animal origin produced on your farm. As you can see, the following items are included on the template:

- NAME AND ADDRESS OF FARM. COMPOST METHOD.***
- DATE THE RECORD WAS TAKEN INCLUDING THE DATE THE TREATMENT STARTED AND THE DATE IT WAS FINISHED.***
- AN ADEQUATE DESCRIPTION OF COMMODITY, IN THIS CASE WOULD BE THE LIST OF INGREDIENTS IN THE COMPOST.***
- ACTUAL VALUES AND OBSERVATIONS, IN THIS CASE THAT WOULD BE TIME, TEMPERATURE, AND NUMBER OF TURNINGS AND WHEN THESE OBSERVATIONS OCCURRED.***

Notes Section

AND LASTLY THE INITIALS OF THE PERSON PERFORMING THE ACTIVITY.

This record **MUST** be reviewed signed and dated by a supervisor.

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. Bilhn, M.A. Schermann, A.L. Wszelaki, G.L. Wall, and S.K. Amundson, 2014 www.gaps.cornell.edu

Equipment, Tools, Buildings and Sanitation:

The next area of the rule requiring records is in Subpart L -- Equipment, tools, buildings, and sanitation. Section 112.140(b)(2) requires that farms keep track of the date and method they are using to clean and sanitize any equipment used in growing sprouts or any other covered harvesting, packing or holding activities.

Equipment cleaning and sanitation records **MUST** be reviewed, dated and signed by a supervisor or responsible party within a reasonable time after the records are made.

Subpart L-- Equipment, Tools, Buildings, and Sanitation, Section 112.123(d)(1) are the requirements that apply to the cleaning and sanitizing of food contact surfaces and equipment.



Notes Section

This is an example of a cleaning and sanitizing record template. All the necessary parts in Subpart O –Records are listed as applicable as well as the method used for cleaning and sanitizing.

Cleaning and Sanitizing Record *Template*

Name and address of farm: _____

List the date, time, tool or equipment name, and method for each 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: _____

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

You can see the name and address of the farm, the date, and time the task was completed, what was being cleaned and/or sanitized, the methods, and the initials of who was performing the task. Lastly, at the bottom is a place for the record to be reviewed, dated, and signed by a supervisor or responsible party.

This example demonstrates that you can use the same template for a variety of cleaning and sanitizing activities. Best practice, however, would be to keep each record separate and in a place that's easily accessible to the tools and equipment being cleaned or sanitized so the record is available when you need it. For example, keeping this form inside a sheet protector on a clipboard next to the dump tank would make it very convenient to record when necessary cleaning and sanitizing occurs.

Notes Section

In addition to the items that ***MUST*** be listed on all records that we've discussed throughout this video, Subpart O—Records includes general information about the storage of your records, allowable types of records you keep, and acceptable formats for the records.

As a reminder, if you're using records for compliance with other regulations, the records do not need to be duplicated so long as they contain the information needed for compliance with the Produce Safety Rule. You may need to adjust or supplement your current records to include required items listed in the Produce Safety Rule.

Records:

Records required by the Produce Safety rule ***MUST*** be kept as original records true copies such as photocopies, pictures, scanned copies, microfilm, microfiche, any other accurate reproductions of the original records or electronic records. The original records ***MUST*** be completed at the time when the activity is performed and they ***MUST*** be dated and have the operator's original signature or initials on them.

Records ***MUST*** be accurate, legible, clearly readable, and indelible, which means permanent or written in ink.

If you make a mistake on a record, simply strike through the mistake with one single indelible line, date and initial it; then legibly write the correct information next to it.



Records ***MUST*** be kept for at least 2 years past the date the record was created. All required records ***MUST*** be readily available and accessible for inspection upon request. Offsite storage is permitted if records can be retrieved and provided onsite within 24 hours of a request for review by an inspector.

All records obtained in accordance with the Produce Safety Rule are subject to the disclosure requirements under 21 CFR 20-Public Information Act.

In summary, record keeping is a critical step in documenting the steps you've taken to reduce food safety risk on the farm and meet the requirements of the Produce Safety Rule.

Don't hesitate to contact the Idaho State Department of Agriculture or University of Idaho Extension for more information on record keeping requirements related to the Produce Safety Rule.

Thank you!

References:

1. "Produce Safety Alliance." *Welcome to the Produce Safety Alliance Website!* Produce Safety Alliance, www.producesafetyalliance.cornell.edu/
2. NASDA, www.nasda.org/
3. *US Food and Drug Administration Home Page*, Center for Biologics Evaluation and Research, www.fda.gov/
4. "UC Davis." *UC Davis*, www.ucdavis.edu/
5. ECFR.io. "e-CFR: Code of Federal Regulations." *ECFR.io*, www.ecfr.gov/
6. "Produce Safety Rule." *University of Idaho*, www.uidaho.edu/extension/food-safety-for-produce-growers/food-safety-modernization-act/produce-safety-rule
7. "Idaho State Department of Agriculture." *Idaho State Department of Agriculture*, www.agri.idaho.gov/main/

Idaho Produce Safety Video Series

Presented by Idaho State Department of Agriculture and University of Idaho Extension

Funding for this video was made possible, in part, by grant number 5U18FD005916-02 from the FDA. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.

Contact Information:

Email Address: FSMA@isda.idaho.gov

Physical Address: [2270 Old Penitentiary Road, Boise, ID 83712](#)

Mailing Address: PO Box 7249, Boise, ID 83707

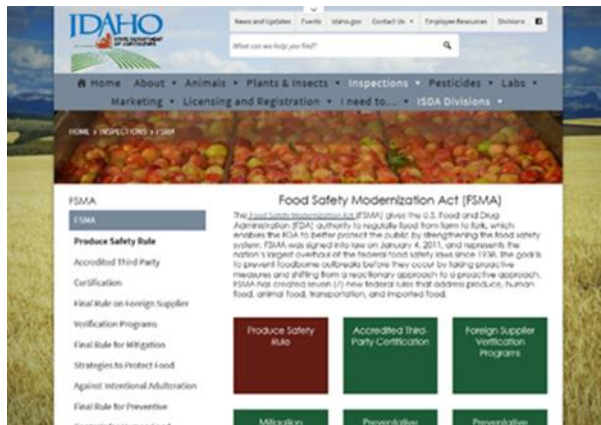
Phone Number: [\(208\) 332-8698](tel:(208)332-8698)

Fax Number: (208) 334-2170

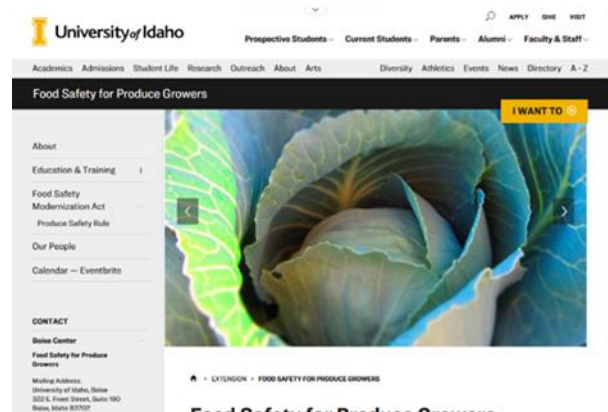
Notes Section



Notes



ISDA Website:
www.agri.idaho.gov/psr



Food Safety for Produce Growers
 UI Website:
www.uidaho.edu/extension/food-safety-for-produce-growers