Topics

**FEDERAL REGULATIONS GUIDANCE DOCUMENTS AND APPLICABILITY**

**Plan** = Written description of policies and Standard Operating Procedures (SOP) including materials.
**Types of Plans: FSP = Food Safety Plan, required for 3rd party food safety audit, not by FSMA-GSP = Organic System Plan with content based on USDA organic regulations. Each USDA-accredited organic certifier may require use of its own OSP template.

**ORGANIC**

*USDA Organic Regulations*

**Law:** Organic Foods Production Act

**Regulation:** National Organic Program, USDA Organic Regulations

Guidance: NOP Handbook


Exemption: Producers with annual organic production of less than $5,000 are exempt from certification, but must follow all other organic regulations, including recordkeeping.

**FOOD SAFETY**

*FDA Produce Safety Rule*

**Law:** Food Safety Modernization Act (FSMA)

**Regulation:** Final Rule on Produce Safety, Standards for Growing, Harvesting, Packing and Holding Produce for Human Consumption

Exemption: • Produce not eaten raw, food grains, and produce for personal consumption • Any farm or mixed farm facility that has a $25,000 average annual sales or less of covered produce during the previous 3-year period • Qualified Exemption (see criteria in text box)**

**RECORD-KEEPING**

**Written Plans**

FDA's Produce Safety Rule recommends, but does NOT require, a Food Safety Plan

Required for 3rd party food safety audit:

D: Food Safety Plan (FSP)

An Organic System Plan (OSP) is required and based on content as described in USDA organic regulations:

• Description of practices and procedures, list of materials to be used,
• monitoring, recordkeeping system, and contamination prevention.

Plants are farm management tools helpful for establishing operations. A producer must review and update the OSP & FSP at least annually. Information required for both plans may be attached or copied.

**Record-Keeping**

Each subpart of the regulation has its own recordkeeping requirements.

• Sales records to prove and maintain a qualified exemption, kept 4 years.
• Water test records, kept 4 years or longer. • Other records must be kept for 2 years
• Some records must be signed by the person responsible for food safety.

A complete audit trail includes OSP practice descriptions & material lists and:

• Sales records, • Harvest records • Input purchase receipts • Crop production and rotation

All documents and records must be kept for at least 5 years

Worker Health and Hygiene

Training is required.

• Supervisor or responsible party must successfully complete an FDA-approved training in food safety and personal hygiene

Personnel and volunteers must receive basic training in principles of food safety & importance of personal health and hygiene

Harvesting employees crop must be trained on pre-harvest inspections of produce and harvest equipment and packaging materials

Required: W: Worker Training Log / Certificates required

This topic is not addressed directly by USDA organic regulations.

Worker Training Log / Certificates required

**Organic**

• Maintain or improve the natural resources of the operation, including soil, water, wetlands, woodlands, and wildlife.
• Prevent contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances

Required: R: OSP with description of natural resource management and monitoring plans

• Record of worker training.

Monitor crop production and handling areas for evidence of domestic or wild animal intrusion.

FSMA'S Produce Safety Rule does not conflict with, or duplicate regulations of other federal agencies (including USDA NOP) that support natural resource management and conservation practices.

CROP NUTRIENT AND PLANT PROTECTION MANAGEMENT

1. Fertilizer and Soil Amendments of Animal Origin

(Compost, manure, blood meal, feather meal, fish emulsion, hydrolyzed fish)

Produce Safety Rule requires documentation that a scientifically validated treatment process was used & the handling, conveyance and storage of a biological soil amendment of animal origin (BSAO) is adequate to minimize the risk of contamination by an untreated or in-process BSAO.

Bio solids and Sewage Sludge are permitted.

Raw manure: Further research will inform future regulations. Currently, no application interval is given.

Required: D: If purchased from a 3rd party, Certificate of Conformance & Certificate of Analysis required at least annually

R: If self-prepared, record of treatment process controls: time/temperature schedule with signature of responsible party.

Bio solids and Sewage Sludge are NOT permitted

Compost system in- vessel or static aerated pile system: Temperature maintained 131°F to 170°F for 3 days;

Compost system is a windrow: Temperatures above must be maintained for 15 days and turned > 5 times.

Raw manure must be incorporated 90 days prior to harvest of a crop that does not have direct contact with the soil surface around 120 days prior to harvest of a crop that must have direct contact with the soil surface.

Required: B: Verification of treatment process, procedures, temperature, and turning schedule

Biosolids & Sewage Sludge: Certified organic producers are prohibited from using these materials.

Raw Manure application:

Certified organic producers must follow USDA NOP regulations related to raw manure application intervals. All other producers are advised to follow organic regulations’ application interval until the FDA provides an application interval for raw manure.

Both organic and food safety regulations require verification documentation of treatment process, procedures, temperature, and turning schedule and handling.

**LAND**

Land Use History and Production Site Assessment

FDA's Produce Safety rule recommends, but does NOT require, a farm to carry out an operational assessment

Required for a 3rd party food safety audit:

D: Risk assessment & Affidavit of land use history

Must not use prohibited materials (synthetic fertilizers, pesticides, sewage sludge, etc.) for 36 months before harvest of a certified organic crop

Must use organic soil and nutrient management, seed & planting stock, pest management, and crop rotation.

• Boundaries and buffers must prevent contamination & be described in OSP.

Required: D: Land use letter from landowner or prior land manager, county agricultural commissioner or R: Pesticide Use Reports, or previous organic certificate

Production land use history assessment must address both substances prohibited for use in organic systems, and risks to food safety.

Land use documentation should meet both food safety and organic requirement; include site map showing boundaries and buffers.

**2. Biological Soil Amendments of Animal Origin**

2.1. Compost, manure, blood meal, feather meal, fish emulsion, hydrolyzed fish

Produce Safety Rule requires documentation that a scientifically validated treatment process was used & the handling, conveyance and storage of a biological soil amendment of animal origin (BSAO) is adequate to minimize the risk of contamination by an untreated or in-process BSAO.

Bio solids and Sewage Sludge are permitted.

Raw manure: Further research will inform future regulations. Currently, no application interval is given.

Required: D: If purchased from a 3rd party, Certificate of Conformance & Certificate of Analysis required at least annually

R: If self-prepared, record of treatment process controls: time/temperature schedule with signature of responsible party.

Biosolids & Sewage Sludge: Certified organic producers are prohibited from using these materials.

Raw Manure application:

Certified organic producers must follow USDA NOP regulations related to raw manure application intervals. All other producers are advised to follow organic regulations’ application interval until the FDA provides an application interval for raw manure.

Both organic and food safety regulations require verification documentation of treatment process, procedures, temperature, and turning schedule and handling.
This topic is not addressed directly by FDA Produce Safety Rule. Required for 3rd party food safety audits:
D: Approved Supplier List
D: Product Label and Safety Data Sheets
D: Farm Input Report
R: Pesticide Use Report

FDA Produce Safety Rule establishes requirements ONLY for seeds or beans used for sprouting. Verify that the seed or bean is not a contaminant to crops or soil by:
• preventing hazards,
• visually examine seeds, beans & packaging, &
• discontinue use of all seeds & beans with issues and report issues to supplier,
• or rely on prior treatment of seeds and beans with documentation of such treatment.
Required:
D: Documentation of seed/bean treatment required

Any material used to clean or sanitize the irrigation system must be listed in the producer’s OSP and approved by the certifier for its intended use. Allowed:
• Alcohol
• Chlorine (see NOP Guidance)
• Copper sulfate, as algacide in aquatic rice systems;
• Ozone gas, as an irrigation system cleaner only

Producers must implement measures necessary to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances, such as:
• Packaging, storage containers or bins containing a synthetic fungicide, preservative, fungiment
• Use or reuse of any container that would compromise organic integrity (thorough cleaning is an option, with organic integrity (thorough cleaning is an option, with documented to be non-GMO).

Producers must manage harvest and post-harvest handling facilities, food contact surfaces, containers, tools and packaging to prevent contamination of produce with pathogens or with materials prohibited for use in organic produce handling and production.
R: Harvest Equipment Cleaning Logs

**The FSMA Qualified Exemption**

Growers are eligible for a qualified exemption for a calendar year from FSMA rules if the following are true in the past 3 years:
1) The average food sales sold to qualified end users (direct to consumer, restaurant, or retail) is more than the average sales of covered produce to non-qualified end users;
2) the average sales were less than $500,000; and
3) the average sales were adjusted to inflation using 2011 as the baseline year.

*FSMA exempt farms still must follow Subparts A, O, Q, & R. In addition, exempt producers must adhere to Subpart A §112.6 labeling requirements for direct markets and §112.7 annual review to verify continued eligibility for qualified exemption.*

Disclaimer regarding Food Safety and Organic Compliance:
Before using any of these sample templates or forms, please check with your intended certifier. Although content is based on regulations, the format or terminology of specific forms required may vary between certification agencies.

Regulatory References:
Full FDA FSMA Regulation http://www.fda.gov/Food/GuidanceRegulation/FSMA/UCM472499.pdf

Other Resources:
Food Safety On-Farm Food Safety Project http://ontarfarmsafety.org/

Produce Safety Alliance (PSA) from Cornell University Department of Food Science http://produce safet yalliance.cornell.edu/


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2) the average sales were less than $500,000; and
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*FSMA exempt farms still must follow Subparts A, O, Q, & R. In addition, exempt producers must adhere to Subpart A §112.6 labeling requirements for direct markets and §112.7 annual review to verify continued eligibility for qualified exemption.*