FDA Produce Safety Rule recommends, but does not require, a Food Safety Plan.

Required for 3rd party food safety audit:
D: Food Safety Plan (FSP)

A complete audit trail includes OSP practice descriptions & material lists and:
• Sales records
• Harvest records
• Input application records
• Input purchase receipts
• Crop production and rotation
All documents and records must be kept for at least 5 years

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.

Worker Health and Hygiene
Training is required:
• Supervisor or responsible party must successfully complete an FDA-approved training in food safety and personal health and 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

Natural Resources, Domesticated & Wild Animals
• Monitor crop production and handling areas for evidence of domestic or wild animal intrusion.
• Prevent contamination of produce by pathogens from animals, both domesticated and wild, and the environment.

Crop Nutrient and Plant Protection Management
This topic is not addressed directly by USDA organic regulations.

Required for 3rd party audits:
D: Supplier letters of guarantee that materials do not contain prohibited substances

Crop solids and Sludge Sludge are NOT permitted
Compost system in-vehicle 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 or 120 days prior to harvest of a crop that does have direct contact with the soil surface.

Bio solids and Sewage Sludge are NOT permitted
Compost system in-vehicle 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 or 120 days prior to harvest of a crop that does have direct contact with the soil surface.

2. Biological Soil Amendments of Animal Origin (Compost, manure, blood meal, feather meal, fish emulsion, hydrolyzed fish)

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

Qualify for use in organic production:
• Use organic soil and nutrient management, seed & planting stock, pest management, and crop rotation.

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

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.
FOOD SAFETY

CROP NUTRIMENT AND PLANT PROTECTION MANAGEMENT (1st Part)


4. Seed and Planting Stock

WATER

1. Crop Production Water: Irrigation, Fertilizer and Pest Protection Product Application

Requirements for crop production water, EXCLUDING sprouts:
- inspection of water system
- Water source sampling methods, frequency, analysis
- Bacterial analysis: generic E. coli ≤ 126 CFU/100 mL, and S. V. 410 CFU/100 mL
- Data collection: verify treatment efficiency, delivery, and any mitigation strategies

Required: R: Record of Corrective Action when bacterial levels exceed threshold

2. POST HARVEST: Water in direct contact with crop for itching, cooling, equipment cleaning, hand washing, and sprout irrigation

Post-harvest water and sprout irrigation water standards:
- Bacterial Analysis demonstrating 0 CFU/100 mL of generic E. coli at water source
- Standard Operating Procedures on how to sample water

Required: R: Record of Corrective Action when bacterial levels exceed threshold

HARVEST AND POST-HARVEST: Produce, Tools, equipment, and containers

- Maintain and store harvest, tools, equipment and containers to prevent contamination of crops
- Perform a pre-inspection of produce to be harvested and any harvest equipment and packaging
- Properly handle and pack harvested produce to prevent contamination

Required: R: Documentation of field and harvest tools pre-inspection required

This chart intends to provide farmers with the understanding they need to design, implement, and document compliant practices with federal regulations for both food safety and organic certification. ALBA/NCAT’s On-Farm Food Safety and Organic Certification Guide for Crop Producers, parallels this chart to provide more detailed explanation.

**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 crop 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."

CO-COMPLIANCE

A complete audit trail includes tracking of all substances used. Although FDA Produce Safety Rule does not specifically require input applications in the audit trail, many third party auditors require both input material and application method as more.

Required: D: Product Labels and Receipts

R: Farm Input Application Records

Seed & planting stock must meet detailed quality requirements to protect against pathogens and comply with federal regulations.

Required: D: Input purchases receipts specifying type (certified organic, or if commercially unavailable, untreated and documented to be non-GMO).

R: Documentation of seed/bean treatment for sprouts

Seed, transplanting or sprouting records

REGULATORY RESOURCES:

Full FDA FSMA Regulation

http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm472549.htm

USDA National Organic Program (NOP)


Disclaimer regarding Food Safety and Organic Compliance: Before using any of these guidelines, 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.