

Farm Food Safety and Organic Federal Co-Compliance Chart for Crop Producers

Plan = Written description of policies and Standard Operating Procedures (SOPs) including materials.

Types of Plans: FSP = Food Safety Plan, required for 3rd party food safety audit, not by FSMA

OSP = Organic System Plan with content based on USDA organic regulations. Each USDA-accredited organic certifier may require use of its own OSP template.

Types of recordkeeping reviewed and verified during a food safety audit or organic inspection:

Document (D): the evidence of something (ex. seed or input material purchase invoice and label, or letter of guarantee, organic system plan)


Record (R): certain documents that are completed and managed in a way that's compliant with industry, federal and state guidelines. (ex. Water test, equipment cleaning log, input application record)

| Topics | FOOD SAFETY | ORGANIC | CO-COMPLIANCE |
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| FEDERAL REGULATIONS GUIDANCE DOCUMENTS AND APPLICABILITY | <p>“FDA Produce Safety Rule” <i>Law:</i> Food Safety Modernization Act (FSMA) <i>Regulation:</i> Final Rule on Produce Safety, Standards for Growing, Harvesting, Packing and Holding Produce for Human Consumption <i>Exemption:</i> <ul style="list-style-type: none"> 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)** </p> | <p>“USDA Organic Regulations” <i>Law:</i> Organic Foods Production Act <i>Regulation:</i> National Organic Program, USDA Organic Regulations <i>Guidance:</i> NOP Handbook http://www.ams.usda.gov/rules-regulations/organic/handbook <i>Exemption:</i> Producers with annual organic production of less than \$5,000 are exempt from certification, but must follow all other organic regulations, including recordkeeping.</p> | <p>Producers should be familiar with and follow USDA Organic and FDA Produce Safety Rule, as applicable to their food production, handling and sales activities.</p> <p>Keep records to show how your operation meets exemption criteria AND complies with applicable regulations.</p> |
| WRITTEN PLANS | <p>FDA's Produce Safety Rule recommends, but does NOT require, a Food Safety Plan.</p> <p>Required for 3rd party food safety audit: <i>D: Food Safety Plan (FSP)</i></p> | <p>An Organic System Plan (OSP) is required and based on content as described in USDA organic regulations:</p> <ul style="list-style-type: none"> Description of practices and procedures, list of materials to be used, monitoring, recordkeeping system, and contamination prevention. | <p>Plans 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.</p> |
| RECORD-KEEPING | <p>Each subpart of the regulation has its own recordkeeping requirements.</p> <ul style="list-style-type: none"> 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. | <p>A complete audit trail includes OSP practice descriptions & material lists and :</p> <ul style="list-style-type: none"> Sales records, Harvest records Input purchase receipts Post-Harvest Handling records Input application records Crop production and rotation <p>All documents and records must be kept for at least 5 years</p> | <p>Plans, Records and Documents are all critical recordkeeping components that show implementation of good organic and food safety practices.</p> <p>Keep records and documents for at least 5 years to meet both sets of regulations.</p> |
| LAND Land Use History and Production Site Assessment | <p>FDA's Produce Safety rule recommends, but does NOT require, a farm to carry out an operational assessment</p> <p>Required for a 3rd party food safety audit: <i>D: Risk assessment and Affidavit of land use history</i></p> | <ul style="list-style-type: none"> 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. <p>Required: D: Lan use letter from landowner or prior land manager, county agricultural commissioner or R: Pesticide Use Reports, or previous organic certificate</p> | <p>Production land use history assessment must address both substances prohibited for use in organic systems, and risks to food safety.</p> <p>Land use documentation should meet both food safety and organic requirement; Include site map showing boundaries and buffers.</p> |
| WORKER HEALTH AND HYGIENE | <p>Training is required.</p> <ul style="list-style-type: none"> 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 <p>Required: <i>R: Worker Training Log / Certificates required</i></p> | <p><i>This topic is not addressed directly by USDA organic regulations.</i></p> | <p>Train all workers in good personal hygiene practices and procedures.</p> <p>R: Record of worker training.</p> |
| NATURAL RESOURCES, DOMESTICATED & WILD ANIMALS | <ul style="list-style-type: none"> 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. <p>Required: <i>R: Field monitoring Log/ Pest Control Log</i> <i>R: Pre-harvest risk assessment</i></p> | <ul style="list-style-type: none"> 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 <p>Required: D: OSP with description of natural resource management and monitoring plans R: Monitoring records appropriate to the operation</p> | <p>Monitor crop production and handling areas for evidence of domestic or wild animal intrusion.</p> <p>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.</p> |
| CROP NUTRIENT AND PLANT PROTECTION MANAGEMENT 1. Fertilizer and Soil Amendments Not of Animal Origin | <p>This topic is not addressed directly by FDA Produce Safety Rule</p> <p>Required for 3rd party audits : <i>D: Supplier letters of guarantee that materials do not present a contamination risk to crops or soil</i></p> | <ul style="list-style-type: none"> Producers must verify that all material is allowed for use in organic production, AND Materials must be in the producer's OSP and approved for their intended use by the certifier <p>Required: D: Approved material's list</p> | <p>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.</p> <p>Required: D: Product Labels and Receipts R: Farm Input Application Records</p> |
| 2. Biological Soil Amendments of Animal Origin (Compost, manure, blood meal, feather meal, fish emulsion, hydrolyzed fish) | <p>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 (BSOAO) is adequate to minimize the risk of contamination by an untreated or in-process BSOAO.</p> <p>Bio solids and Sewage Sludge are permitted. Raw manure: Further research will inform future regulations. Currently, no application interval is given.</p> <p>Required: <i>D: If purchased from a 3rd party, Certificate of Conformance & Certificate of Analysis required at least annually</i> <i>R: If self-prepared, record of treatment process controls: time/temp/turning schedule with signature of responsible party.</i></p> | <p>Bio solids and Sewage Sludge are NOT permitted</p> <p>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 or 120 days prior to harvest of a crop that does have direct contact with the soil surface.</p> <p>Required: R: Verification of treatment process, procedures, temperature, and turning schedule</p> | <p>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.</p> |


Topics

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| <p>CROP NUTRIENT AND PLANT PROTECTION MANAGEMENT <i>(continued)</i></p> <p>3. Pest Management Practices and Plant Protection Products</p> | <p>This topic is not addressed directly by FDA Produce Safety Rule.</p> <p>Required for 3rd party food safety audits: <i>D: Approved Supplier List</i> <i>D: Product Label and Safety Data Sheets</i> <i>D: Farm Input Record</i> <i>R: Pesticide Use Report</i></p> | <p>First use preventative practices including crop rotation, cultural, biological, physical and mechanical control practices as outlined in OSP.</p> <p>Only when preventative controls are insufficient, allowed materials may be applied. All materials must be listed and approved by organic certifier</p> <p>Required: <i>D: Approved Materials List</i></p> | <p>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 an more.</p> <p>Required: <i>D: Product Labels and Receipts</i> <i>R: Farm Input Application Records</i></p> |
| <p>4. Seed and Planting Stock</p> | <p>FDA Produce Safety Rule establishes requirements ONLY for seeds or beans used for sprouting.</p> <p>Verify that the seed or bean is not a contaminant to crops or soil by:</p> <ul style="list-style-type: none"> preventing hazards, visually examine seeds, beans & packaging, & discontinue use of all seeds & beans with issues and report issues to supplier, treat or rely on prior treatment of seeds and beans with documentation of such treatment. <p>Required: <i>D: Documentation of seed/bean treatment required</i></p> | <ul style="list-style-type: none"> Annual seedlings and seed for edible sprouts must be organic. Must use organically grown seed and planting stock; Except: May use nonorganic, untreated, non-GMO seed or stock when an equivalent organic variety is commercially unavailable (form, quality, or quantity) <p>Documentation:</p> <ul style="list-style-type: none"> Inoculants must be non-GMO. Seed treatments must be allowed. Perennial stock sold as organic must be managed organically ≤ 1 year. | <p>Seed & planting stock must meet detailed quality requirements to protect against pathogens and comply with federal regulations.</p> <p>Required: <i>D: Input purchases receipts specifying type (certified organic, or if commercially unavailable, untreated and documented to be non-GMO).</i> <i>D: Documentation of seed/bean treatment for sprouts</i> <i>R: Seeding, transplanting or sprouting records</i></p> |
| <p>WATER</p> <p>1. Crop Production Water: Irrigation, Fertilizer and Plant Protection Product Application</p> | <p>Requirements for crop production water, EXCLUDING sprouts:</p> <ul style="list-style-type: none"> Inspection of water system Water source sampling methods, frequency, analysis Bacterial analysis: generic E. coli ≤ 126 CFU/100 mL and STV 410 CFU/100 mL Data collection: verify treatment efficiency, delivery, and any mitigation strategies <p>Required: <i>R: Record of Corrective Action when bacterial levels exceed threshold</i></p> | <p>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.</p> <p>Allowed:</p> <ul style="list-style-type: none"> Alcohols (ethanol and isopropanol) as algaecides, disinfectants, sanitizers, irrigation system cleaning Chlorine (see NOP Guidance) Copper sulfate, as algaecide in aquatic rice systems; Ozone gas, as an irrigation system cleaner only | <p>Minimize risks of contamination of produce and protect water quality.</p> <ul style="list-style-type: none"> Inspect and maintenance water sources, storage, transport and application systems Monitor and test water as regulations require Treat water as appropriate to control microbial levels for food safety using materials that comply with organic regulations. |
| <p>2. POST HARVEST: Water in direct contact with crops for icing cooling, equipment cleaning, hand washing, and sprout irrigation</p> | <p>Post-harvest water and sprout irrigation water standards:</p> <ul style="list-style-type: none"> Bacterial Analysis demonstrating 0 CFU/100 mL of generic E. coli at water source Standard Operating Procedures on how to sample water & corrective procedures if water exceeds bacterial threshold <p>Required: <i>R: Record of Corrective Action when bacterial levels exceed threshold</i></p> | <p>Any material used in wash water or surfaces that come into contact with crops must be in your OSP and approved for its intended use.</p> <p>Allowed sanitizer materials:</p> <ul style="list-style-type: none"> Alcohols Chlorine materials <4PPM in final crop rinse Hydrogen peroxide Peracetic acid in wash/rinse water per FDA limitations, as a sanitizer on food contact surfaces, facility and equipment; for disinfecting seed & asexually propagated planting material; permitted in hydrogen peroxide formulations at <6% per product label. | |
| <p>HARVEST AND POST-HARVEST: Produce, Tools, equipment, and containers</p> | <ul style="list-style-type: none"> 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 <p>Required: <i>R: Documentation of field and harvest tools pre-inspection required</i> <i>R: Documentation of cleaning and sanitation noting date and method of cleaning/sanitation required</i></p> | <p>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:</p> <p>Packaging, storage containers or bins containing a synthetic fungicide, preservative, fumigant</p> <ul style="list-style-type: none"> Use or reuse of any container that would compromise organic integrity (thorough cleaning is an option, with records kept). | <p>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 production and handling.</p> <p><i>R: Harvest Equipment Cleaning Logs</i></p> |

ORGANIZATIONS THAT ASSIST WITH FOOD SAFETY AND ORGANIC COMPLIANCE



USDA
 National Organic Program (NOP)
http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title07/7cfr205_main_02.tpl



FDA
 FDA Final Rule on Produce Safety (FSMA)
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>



Agriculture and Land-Based Training Association (ALBA)
<http://www.albafarmers.org>
Se habla español



NCAT
 NATIONAL CENTER FOR APPROPRIATE TECHNOLOGY

National Center for Appropriate Technology (NCAT)
ATTRA Sustainable Agriculture Program
<https://attra.ncat.org/>
Se habla español

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**

<http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472499.pdf>

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.*

Regulatory References:

Full FDA FSMA Regulation
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247548.htm#SEC105>

USDA National Organic Program (NOP)
http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title07/7cfr205_main_02.tpl

Other Resources:

- Food Safety**
- On-Farm Food Safety Project**
<http://onfarmfoodsafety.org/>
- Produce Safety Alliance (PSA) from Cornell University Department of Food Science**
<http://producesafetyalliance.cornell.edu/>
- Organic**
- NOP Handbook**
<http://www.ams.usda.gov/rules-regulations/organic/handbook>

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