

# Farm Food Safety and Organic Certification Co-Compliance Guide for Specialty Crop Farmers

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**Disclaimer:** At the time of publication, FDA's Federal Food Safety Modernization Act Final Rule has been recently released. While this Guide is intended to provide an introductory overview of the FSMA Produce Safety Rule as it applies to farmers, review of this Guide is not a substitute for reading the regulations themselves. Each farm business is responsible for understanding and complying with federal food safety regulations, which can be found in their entirety on the FDA website.

## **ABSTRACT**

ALBA and NCAT have developed this Co-Compliance Guide to Food Safety and Organic Certification to help specialty crop farmers and farm organizations understand the practices and documentation required to comply with both food safety and organic regulations from planting through post-harvest activity. In an effort to thwart the burden of management and recordkeeping for two different standards, we intend to show where commonalities and differences exist. This Guide is cross-referenced to the bilingual Food Safety and Organic Certification Co-Compliance Chart, a tool that provides a quick reference of compliance records required for a food safety audit or an organic inspection.

## INTRODUCTION

In fulfilling organic certification growers provide assurance of integrity to organic food systems. Similarly, fulfilling food safety standards and regulation, growers provide assurance safety to their customers and consumers.

- **FDA Final Rule on Produce Safety Regulations** are based on the Food Safety Modernization Act of 2011. The effective date of the FSMA rule is January 26, 2016. The timeframe for full implementation depends on size of farm. Large farms must comply sooner than small farms (\*\* see text box in “Federal Laws and Regulations section).

In general, the standard for produce safety is to employ science-based standards for the safe growing, harvesting, packing, and holding of produce to minimize hazards that could cause serious adverse health consequences or death.

FDA’s FSMA Final Rule of Produce Safety (21 CFR part 112, Section 105. Standards for Produce Safety) relating to produce typically eaten raw were referenced in the making of this deliverable:

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>

- **USDA Organic Regulations** are based on The Organic Foods Production Act of 1990, full implementation of which began in October 2002. Organic Production is a production system that is managed according to regulations, to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity. Production practices maintain or improve the natural resources of the operation, including soil and water quality. All operations that produce or handle crops, livestock, livestock products, or any agricultural products that are intended to be sold, labeled, or represented as organic in the U.S. (regardless of where they were produced) must be certified. Products may either be certified by a USDA-accredited certifier, or an authorized international standard.

Complete regulations: 7 CFR Part 205—National Organic Program

[www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title07/7cfr205\\_main\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title07/7cfr205_main_02.tpl)

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# FEDERAL LAWS & REGULATIONS

## Food Safety Modernization Act (FSMA) 21 CFR part 112, Section 105. Standards for Produce Safety

FSMA regulations “set forth procedures, processes, and practices to minimize the risk of serious adverse health consequences or death, to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards, including hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism, into fruits and vegetables, including raw agricultural commodities and to provide reasonable assurances that the produce is not adulterated...”

## USDA National Organic Program regulations 7 CFR Part §205.2 and 205.200

Organic Production integrates cultural, biological, and mechanical practices to foster cycling of resources, promote ecological balance, and conserve biodiversity; maintain or improve natural resources including soil and water quality.

### *To Whom Do the Federal Regulations Apply?*

#### FSMA Part 112 (A)(112.1 and 112.2)

The rule applies to all growers of fresh fruits and vegetables typically eaten raw, whether they are produced domestically or imported into the United States.

#### NOP §205.100

Each operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as organic in the United States must be certified by an USDA-accredited certification agency if products sold or represented as organic is more than \$5000/year. See USDA NOP Exemption\*

#### *\*Exemptions:*

#### FDA FSMA Exempt Farms

##### Subpart A §112.4(a)

Any farm or farm- mixed type facility that has a \$25,000 average annual sales or less of produce during the previous 3-year period is exempt from FSMA requirements. However, FDA encourages these farms to follow good agriculture practices to minimize risks of contamination.

##### USDA NOP Exemption §205.100

Any production or handling facility selling less than \$5,000 dollars annually is exempted for undergoing an organic inspection by a USDA accredited organic certification agency.

##### \*\* FDA Definition of Business Size

**Very small Business-** average \$25,000 –no more than \$250,000 produce sales per year on a 3 year average (Subpart B. § 112.3 (b)(1)) have 4 years to comply \*

**Small Business-** average \$250,000-no more than \$500,000 produce sales per year on a 3 year average (Subpart B. § 112.3 (b)(2)) have 3 years to comply\*

**All other farms-sell more than \$500,000 produce sales per year on a 3-year average** are subject to full requirements of FSMA Produce Rule and have 2 years to comply.

##### \*\*\*The FSMA Qualified Exemption §112.5

Producers are eligible for a qualified exemption from FSMA for a calendar year 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; AND
- 2) the average sales were less than \$500,000; AND
- 3) the farm sales to restaurants and retail stores were within 275 miles of the farm or within the same state

*FSMA exempt farms still must follow Subparts A, O, Q, & R. In addition, qualified 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.*

## PLANS

### Farm Plans and Worker Training

The FDA may provide subsequent information related to 3rd party certification strategies and FSMA compliance.

Depending on the farming operation's marketing strategies; a customer may require a 3rd party food safety audit, which requires a food safety plan and compliance records.

*Food Safety Plan: Preamble:* "Although FSMA does not require that covered farms conduct operational assessments or develop food safety plans, the FDA continues to believe that such assessments can help farms identify risks and take measures that may be prudent for their individual operations to prevent the introduction of known or reasonably foreseeable hazards, including any non-biological hazards. Implementation of food safety plans that are developed based on operational assessments can help farms to be more proactive and effective in protecting the safety of their produce. The FDA also acknowledges that existing guidance on produce safety, including the GAPs Guide, the Codex Guide, and Industry Harmonized GAPs, all recommend that a farm tailor its food safety practices to the practices and conditions at its individual operation."

#### **FSMA Subpart C. Personnel Qualifications and Training (§§ 112.21, 112.22, and 112.23):**

- a. At least one supervisor or responsible party from the farm must receive and successfully complete food safety training approved by the FDA
- b. All personnel and volunteers must receive basic training in principles of food safety, and the importance of health and personal hygiene to prevent persons, including visitors, from contaminating produce with microorganisms of public health significance.
- c. Anyone harvesting crop must also receive training related to pre-harvest inspections of produce to identify contaminated produce and not harvest it, and also inspecting harvest containers and equipment and to correct any problems that may present a risk of contamination.

#### **NOP §205.201**

As part of initial application for organic certification, every certified operation must develop an Organic System Plan (OSP) that includes a description of practices and procedures, substances, or materials to be used; monitoring practices and their frequency; recordkeeping system, and management practices and barriers to prevent contact of organic production and handling with prohibited substances (such as fertilizers and pesticides used on adjacent land). To maintain certification, farmers must notify the certifier of any changes that may affect its compliance with the regulations, and provide annual OSP updates.

**NOP Handbook:** <http://www.ams.usda.gov/rules-regulations/organic/handbook>

#### **Co-Compliance**

Although a food safety plan is not required under FSMA Produce Safety Rule, FDA encourages producers to develop management plans, and review and update them annually. The FDA does require records of food safety compliance for producers subjected to the FSMA regulations.

Food safety plans are required of producers in order to obtain 3rd party food safety certification due to market and customer demand. Several areas of management are required in both food safety and organic systems. One plan can reference the other when overlap occurs.

# RECORD-KEEPING, AUDIT TRAIL & TRACEABILITY

**Records of sales transactions will be required.**

## FSMA Subpart O. Records

The Produce Safety Rule provides different requirements for recordkeeping per Subpart. Some compliance records kept must be completed, reviewed, signed, and dated by a supervisor or responsible party. The farm should maintain recordkeeping procedures related to the following:

**Record Storage:** Producers may store records off the farm if those records can be retrieved within 24 hours from an onsite location. Any electronic records have to be accessible at farm.

**Record Maintenance:** All records have to be maintained for a minimum of 2 years or as prevailing regulations dictate. Records of sales transactions and water test must be maintained for at least 4 years.

**Type of Records:** Original records, true copies of the original (scanned or photocopied), and electronic records are allowed.

**FDA Access to Records:** On-farm records must be readily available to FDA. Off-site records must be ready and available within 24 hours of agency's request.

## NOP §205.103 Recordkeeping of Certified Operations

Certified operations must maintain compliance records for five years concerning the production, harvesting, and handling of agricultural products to be sold, labeled, or represented as organic. Records must:

- Be adapted to the particular business;
- Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited;
- Be sufficient to demonstrate compliance; and
- Be available for inspection and copying during normal business hours.

## Co-Compliance

Maintain all compliance recordkeeping of all activities, policies, and procedures described in any farm management plans you keep, including Food Safety and Organic System Plans, for at least 5 years after their creation, with the exception of water test records, which should be kept forever as a best practice.

Organic records must document all transactions, and provide an audit trail by which any product can be quantitatively accounted for, traced back to its field of origin and all methods and materials used to produce it, and traced forward to its point of final sale (release of custody).

Attach to your plans a sample copy of your audit trail, describing, as needed, the correspondence between documents that allows a product to be traced forward to its final sale, and backward to the field location in which it was grown, the seeds, fertilizers and pesticides used, and understanding and adherence by workers to policies and procedures.



# LAND USE HISTORY AND MANAGEMENT

Land Use History, Site Assessment, Borders with Adjacent Land, Buffer Zones

## FSMA STANDARDS FOR PRODUCE SAFETY SEC. 105 (a)(3)(A-F)

describes how rulemaking must be applicable to operations that are diverse in scale, products and marketing. Producers must consider both naturally occurring and intentionally introduced hazards in the growing, harvesting, sorting, packing of their produce, and include science-based standards for all their activities including soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water. They must consider practice standards and policies established by Federal agencies with respect to the protection of public health, conservation of natural resources, wildlife and the environment. FSMA will not include any regulations that conflict with organic production by producers who are certified organic.

FSMA recommends an operational assessment, but does not require one. Should a farming operation, choose to perform an operational assessment, it should include past, current, and adjacent land uses. If a hazard is found or suspected, producers must take reasonable measures to minimize the risk to food safety.

## NOP §205.202 & 205.2 Terms defined: Buffer zone

Organic regulations require documentation of the absence of application of prohibited materials (synthetic fertilizers, pesticides) to the land for 36 months before harvest of a crop that is to be sold, labeled or represented as organic. The OSP must include a description of boundaries and buffer zones, and management practices or barriers to prevent contact with prohibited materials.

Additional records used to verify land use history may include: complete input application records, Pesticide Use Reports to the County Agricultural Commissioner (required in California), a current organic certification with location map from prior producer, or an affidavit from the land owner or prior manager. These must be presented upon application for certification.

## Co-Compliance

Organic regulations require documentation of land-use history of the past 3 years for initial certification. FSMA Produce Safety Rule doesn't require an assessment of the operation, including land, but recommends it. On the other hand, a third party food safety audit does require documentation that land-use history is absent of risk to food safety.

FDA has finalized the produce safety regulation to the scope of biological hazards and science-based standards necessary to minimize the risk of serious adverse health consequences or death associated with biological hazards. Although the potential for physical or chemical (including radiological) contamination of produce exists, FDA does not believe new regulations are necessary to address those hazards.

For 3rd party food safety and organic certification, a producer may provide a signed letter (affidavit) from a past land manager or landowner with accurate knowledge of the past three years' land use AND the capacity to verify that the land use practices and the last date of application of prohibited substances to the land comply with organic regulations. The food safety certificate of a prior land manager cannot be used to demonstrate past land use history for a food safety audit.

# WORKER HEALTH AND HYGIENE

## FSMA Subpart D. Worker Health and Hygiene (§ 112.31- § 112.33)

Producers must prevent pathogens of public health significance, including communicable diseases, from contaminating produce and food contact surfaces.

### *FSMA requirements to prevent pathogens and communicable disease contamination to produce include:*

1. Employee training on all policies related to Health, Hygiene and Personal injury
2. Maintenance of bathroom and handwashing facilities and procedures
3. Restriction of sick or injured employees or visitors from working in crop production and handling areas
4. Avoiding contact with animals, other than working animals, and minimizing the likelihood of contamination of covered produce when in direct contact with working animals
5. Glove use is not required. However, if gloves are used, they must be maintained intact and sanitary or replaced when unsanitary.
6. Jewelry, watches, or other items must not be worn or brought into production areas if they pose a threat to food safety
7. Restriction of eating, chewing gum and use of tobacco products to designated areas.

## NOP §205.203( c) and (d); §205.239(e)

Organic regulations emphasize overall ecological balance, including soil health and water quality and biodiversity. *Worker Health and Hygiene is not addressed directly by USDA organic regulations.*

## Co-compliance

Producers must develop, follow, and document implementation of policies and procedures related to training of all workers and ensuring personal hygiene practices and procedures are followed, even by visitors.

# NATURAL RESOURCES & DOMESTICATED AND WILD ANIMALS

## FSMA

FDA's FSMA encourages the implementation of practices that enhance food safety, but FDA has stated that these must not conflict with or duplicate regulations of other federal agencies, including those that support natural resource management and conservation practices, including USDA's National Organic Program.

### FSMA Subpart I. §112.83 Domesticated and Wild Animals

A producer must assess crop production, storage and handling areas and take certain steps to prevent contamination of covered produce that is at probable high risk of contamination by grazing animals, working animals, or animal intrusion.

Routine and pre-harvest monitoring are required steps to take to assess, address, and prevent actual risks to food safety.

### NOP §205.2 Terms defined Organic Production, Natural Resources of the Operation. §205.200 General

Organic production must respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity. Organic production practices must maintain or improve the natural resources of the operation: its physical, hydrological, and biological features including soil, water, wetlands, woodlands, and wildlife.

### Co-Compliance

Organic producers must maintain or improve natural resources and soil organic matter; conserve soil, nutrients and biodiversity, and promote ecological balance. Organic regulations specifically include wetlands, woodlands, and wildlife in the definition of natural resources that must be maintained or improved. All farms include some type of natural resources, at a minimum soil and water, that occupy a place in the watershed and bioregional habitat.

Producers whose farms or ranches include on-site wildlife habitat, natural resource areas, or implementation of NRCS conservation agriculture practice standards must manage natural areas or conservation agriculture practices to ensure the safety of food produced.

FSMA requires immediately prior to and during harvest activities, producers to take all measures necessary to identify, and not harvest, produce that is reasonably likely to be contaminated. This requires monitoring and documenting control measures when contaminated produce or harvest equipment is observed.

# CROP NUTRIENT AND PLANT PROTECTION MANAGEMENT

## Crop Management Methods and Materials

This section is divided into 3 subparts, including Crop Nutrient Management, Plant Protection Materials and Seeds and Planting Stock

### 1. Crop Nutrient Management: Soil and Fertilizers Amendments NOT of Animal Origin

**FSMA definition of soil amendment:** “Any chemical, biological, or physical material (such as elemental fertilizers, humus stabilized compost, manure, non-fecal animal byproducts, peat moss, perlite, pre- consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea and yard trimmings) intentionally added to the soil to improve the chemical or physical condition of soil in relation to plant growth or to improve the capacity of the soil to hold water. The term soil amendment also includes growth media that serve as the entire substrate during the growth of covered produce (such as mushrooms and some sprouts).”

FDA’s Produce Safety Rule does not provide requirements for soil and fertilizer amendments that are NOT of animal origin.

For producers having 3rd party food safety audits, application records of all crop nutrient inputs must be documented: date, location, quantity, acres, crop, product, manufacturer, and application method. The auditing body is concerned with the source of the materials and the methods of manufacturing, processing, and treatment/handling of materials so they do not present a risk to the safety of fruits and vegetables. For 3rd party audits, producers must maintain letters of guarantee from distributors or manufacturers of crop nutrient and plant protection materials.

## NOP

Organic regulations require that a producer’s OSP include a list all materials used or planned for use, including seed or planting stock, soil amendments or crop nutrients, pest management materials used on crops or in packing facilities, and post-harvest handling materials.

**Crop Nutrient Management §205.203** Organic producers’ soil and crop nutrient management must improve soil quality and build soil organic matter. Sewage sludge (biosolid material) is prohibited for use in organic production.

## Crop Rotation §205.205

Crop rotation must be used. Rotation is defined as a planned pattern or sequence of crop and non-crop plantings that avoids sequential repetition of annual crops. Rotation introduces biological diversity, cycles nutrients, maintains or improves soil organic matter, manages plant nutrients, provides for pest and disease management, and minimizes erosion. Perennial cropping systems employ crop rotation through alley cropping, intercropping, and hedgerows to introduce biological diversity in lieu of crop rotation.

Producers must recycle crop residues, and they must use allowed nutrient sources in ways that prevent contamination of crops, soil, or water by plant nutrients,

pathogenic organisms, heavy metals, or residues of prohibited substances. Burning may be used to suppress the spread of disease or to stimulate seed germination.

## Co-Compliance

Organic regulations require a complete audit trail related to input application and purchasing, where as FSMA regulations do not. If a producers must undergo a 3rd party food safety audit, the application to purchase audit trail is required.

## 2) Crop Nutrient Management : Biological Soil Amendments of Animal Origin (BSAAO) and Human Waste

**FSMA Subpart F § 112.51** This includes, but not limited to, the following soil amendments: bone meal, feather meal, blood meal, hydrolyzed fish or fish emulsions, compost, sewage sludge, biosolids, and composted and raw manure.

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 (BSAAO) is adequate to minimize the risk of contamination by an untreated or in-process BSAAO.

Sewage Sludge and Biosolids: Class A biosolids per EPA 503 and sewage sludge are permitted under FSMA produce safety rule.

**Raw manure:** Under FSMA, there is no defined application interval between date of application of raw manure and harvest of the product. The FDA does not object to the NOP regulations for raw manure while they research further to fully understand the issue.

### **Treated Biological Soil Amendments of Animal Origin from a 3rd party §112.60(a)**

Annual documentation from the manufacturer should include evidence that:

- A scientifically valid process was used to treat the biological soil amendment of animal origin and that it 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.

### **Treated Biological Soil Amendment of Animal Origin Made by Producer §112.60(b)**

- Documentation that process controls (time, temperature, and turnings) were achieved.

### **NOP Compost and Manure §205.203(c)**

Sewage Sludge and Biosolids: are prohibited from use in certified organic production.

**Raw Manure:** Crop nutrients and soil amendments may include raw manure or other animal products IF used for a crop NOT intended for human consumption. If the crop is for human consumption raw manure must:

1. Be incorporated into the soil at least 90 days prior to harvest of a product whose edible portion does not have direct contact with the soil surface or
2. Be incorporated in to the soil at least 120 days prior to the harvest of a product whose edible portion does have direct contact with the soil surface or soil particles.
3. Grazing of domestic animals in crop production areas must be managed in the same manner as if the producer were directly applying raw manure by any other method, and follow the application intervals outlined above.

Composting procedures for plant and animal materials: initial carbon to nitrogen (C:N) ratio of between 25:1 and 40:1; temperature maintained at 131°F to 170°F for three days using an in-vessel or static aerated pile system; or for 15 days using a windrow system, during which period the materials are turned at least five times.

## Co-Compliance

FSMA Produce Safety regulations describe a broader range of soil amendments than does the NOP. While FSMA lists sewage sludge and Class A biosolids, per EPA 503, as allowed soil amendments, organic regulations specifically prohibit the use of any sewage sludge. In terms of compost and composted animal manures, FSMA and NOP regulations are similar. FSMA requires a manufacturing process that has been scientifically validated to meet bacterial standards, while NOP requirements include C:N ratios, temperature ranges and number of turnings over specific timeframes for different compost production methods. Because FSMA reserved an application interval between application of raw manure and harvest of a product for human consumption until the FDA's risk assessment on the subject is complete, co-compliance will currently be achieved by following NOP application intervals of 90/120 days, depending on the crop. FSMA regulations may change in the next 5-10 years as more research is done to determine an adequate application interval.

Certified organic farmers may continue to use inputs according to organic requirements for compost production and use, raw manure application, including documentation of application intervals before harvest of a crop for human consumption. In the interim period in which FSMA does not specify an application interval for raw manure, it is recommended that producers who are not certified organic follow the NOP regulations of a 90/120-day application interval between use of raw manure and harvest of a crop intended for human consumption.

## 3) Plant Protection and Pest Management

### FSMA: topic not addressed by regulations

FSMA does not regulate plant protection or pest management practices. Other government agencies, such as the Environmental Protection Agency (EPA) and county Agriculture Commissioners Offices do regulate plant protection and pest management practices. Such farm input application records must include date of application, product formulation and manufacturer, quantity applied, location, and method of application.

In addition to farm input application records, a producer obtaining 3rd party food safety certification must also show Pesticide Use Reports and Operator Identification Number or Private Applicator Certificate, in addition to letters of guarantee from product suppliers demonstrating GMP practices.

### NOP §205.103

Recordkeeping by organic producers must “fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited” ...and be “sufficient to demonstrate compliance.” What this means in practice is that producers should keep records of all input purchases, application records, and Pesticide Use Reports, as applicable, and have these available during organic inspections.

## Co-Compliance

All producers must follow plant-protection product label instructions, and comply with local and state regulations regarding pesticide application, use and reporting, as applicable. Producers must have records of all input application and quantities used, as well as a copy of any required Pesticide Use Report (required in California for all materials bearing an EPA registration number). Additionally, original or copies of receipts for products should be available for inspection, and should correspond to input application records.

## 4) Seed and Planting Stock

FSMA establishes measures that must be taken related to seeds or beans for sprouting (§ 112.142).

- Treatment of seeds or beans for sprouting is required
- Bacterial test of growing environment for Listeria required
- Bacteria test of spent irrigation water or sprouts for E.coli O157:H7 and Salmonella required

**FSMA** does not discuss the topic of seed and planting stock for other fruits and vegetables. For producers obtaining 3<sup>rd</sup> party audits, seed and planting stock must come from reliable sources demonstrating compliance with good agriculture practices via a letter of guarantee stating adherence to GAPs or a GAP audit from the planting material source or distributor.

### NOP §205.204

Organic producers must use organically grown annual seedlings, seeds, and planting stock. They may use nonorganic, non-GMO, untreated seeds or planting stock when an equivalent organic variety is documented to be unavailable for purchase in the form, quantity, or quality needed. Producers must verify that all seed treatments and coatings are allowed, and inoculants are non-GMO. They must include these treatments, coatings, and inoculants in their OSP materials list.

Annual seedlings and seed for edible sprouts must be organic. Planting stock to be sold as organic must be managed organically for at least one year.

### Co-compliance

To comply with both organic and food safety requirements, growers must have the verification documents from suppliers of seed, planting stock, and annual seedling-including on-farm propagated seedlings, and sales records for any seed or planting stock sold, available for inspection.

# AGRICULTURAL WATER

## 1) Crop Production Water:

*This section addresses water used for crop irrigation, excluding sprouts, and water used for input applications.*

### FSMA Subpart E. Agricultural Water §112.41-112.44

All agricultural water must be safe and of adequate sanitary quality for its intended use. <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM415227.pdf>

Water systems must be inspected at least once annually to identify foreseeable hazards of contamination to the water source, crop fields and food contact surfaces. All producers must maintain the water source and system free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practical.

During the growing season, the water used for irrigation, fertilizer and pesticide application the water must test:

- 1) Geometric mean less than 126 CFU (coliform forming units) of generic E.coli per 100 mL of water AND
- 2) A statistical threshold value (STV) of 410CFU or less of generic E.coli / 100mL of water

If the water does not meet the microbial quality criteria, FSMA requires that a producer take certain corrective measures as soon as practicable, and no later than the following year. Those corrective measures provide additional means by which to achieve the microbial quality criteria, allowing you to continue to use agricultural water that does not initially satisfy those criteria but satisfies the criteria after accounting for microbial die-off.

FSMA Subpart E § 112.45(b) discusses various corrective measures to take specifically in relation to irrigation water and other water directly applied

to covered produce other than sprouts during the growing season to achieve the microbial quality criteria. Covered farms may:

- Apply a time interval (in days) between last irrigation and harvest using a microbial die-off rate of 0.5 log per day, but not more than four consecutive days; and/or
- Apply a time interval (in days) using an appropriate microbial die-off rate between harvest and end of storage; and/or
- Achieve appropriate microbial removal rates during activities such as commercial washing, provided the farm has adequate supporting scientific data and information for the microbial die-off and/or removal rates.; and/or
- Use of an alternative microbial die- off rate between last irrigation and harvest and an accompanying maximum time interval; and/or
- Treat agricultural water in accordance with § 112.43

### NOP §205.200 General, and §205.2 Terms defined: Organic Production, Natural resources of the operation, §205.203(c ) and (d), §205.239(e)

Organic growers must manage plant and animal materials, crop nutrients, and manure in a manner that protects crops, soil, and water from contamination by crop nutrients, heavy metals, or pathogens. Synthetic substances may be used, with the provision that their use in organic crop production does not contribute to contamination of crops, soil, or water. Substances allowed include some disinfectants and sanitizers.

### §205.601 Synthetic substances allowed for use in organic crop production

(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.

(1) Alcohols. (i) Ethanol. (ii) Isopropanol.

(2) Chlorine materials—For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.



(i) Calcium hypochlorite. (ii) Chlorine dioxide. (iii) Sodium hypochlorite.”Further clarification of allowable uses of chlorine is provided in The Use of Chlorine Materials (NOP 5026), which can be found in the NOP Program Handbook <http://www.ams.usda.gov/AMSV1.0/NOPProgramHandbook>.

(3) **Copper sulfate**—for use as an algicide in aquatic rice systems, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

(4) **Hydrogen peroxide.**

(5) **Ozone gas**—for use as an irrigation system cleaner only.

(6) **Peracetic acid**—for use in disinfecting equipment, seed, and asexually propagated planting material. Also permitted in hydrogen peroxide formulations as allowed in §205.601(a) at concentration of no more than 6% as indicated on the pesticide product label,

(7) **Soap-based algicide/demossers and**

(8) **Sodium carbonate peroxyhydrate (CAS #-15630-89-4)**—Federal law restricts the use of this substance in food crop production to approved food uses identified on the product label.

## 2) Post-Harvest Handling Water

*This section addresses water used to wash produce, make ice, and wash food contact surfaces and hands, and used to irrigate sprouts.*

### FSMA Subpart E. Standards Directed Towards Agricultural Water §112.44 (a) 1-4

All agricultural water must be safe and of adequate sanitary quality for its intended use.

Water presents a higher level of risk when it comes into contact with crop products after harvest and soon before they are packaged, shipped, sold and eaten. There shall be NO detectable generic E. coli in 100mL of water that is used for irrigation of sprouts, or is applied in a manner that directly contacts covered produce in harvest activities (wash water, ice, cooling water), food contact surfaces, or is used as handwashing during harvest and post-harvest handling.

To ensure there is NO detectable generic E. coli in 100 milliliters (mL) of agricultural water, producers must test the quality of water for these uses according to the requirements in §112.46, using a quantitative, EPA approved 1603 method of analysis provided in subpart N of this part of the regulations.

When agricultural water does not meet the microbial threshold of no detectable E.coli /100mL, under FSMA §112.45(a), a covered farm can:

- Re-inspect the entire affected agricultural water system to the extent it is under the farm’s control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and take adequate steps to determine if the changes were effective, and, as applicable, adequately ensure that the agricultural water meets the CFU E.coli /100mL microbial standard; and/or
- The covered farm may also treat the water in accordance with the requirements in § 112.43; and/or
- If the water meets the microbial quality standard of 126 CFU E.coli/ 100mL and STV of 410 CFU E.coli/100mL, the water can be used on covered produce, except for sprouts, for irrigation or direct contact during the growing season rather than post-harvest water.

## NOP §205.601

While organic regulations require that producers manage their operations to protect crops from contamination with pathogens, they do not include specific methods of bacterial testing or results. The producer's OSP should include monitoring methods and procedures to be used. Organic producers should refer to seek to employ good agricultural practices for food safety for specific guidelines, and also to §205.601 to ensure that their methods and materials also fulfill requirements for use of materials (proper purpose, concentration, and rinse, as applicable), and prevention of contamination by prohibited materials.

### Co-Compliance

Water is one of the biggest risks for carrying pathogens and contaminating foods because it comes into contact with crops through many means, including irrigation, application of fertilizers or pesticides, surface runoff during the growing season, and post-harvest handling. Post-harvest water quality poses a higher risk to food safety, and therefore, a zero bacterial threshold exists, according to FSMA.

All producers should identify and assess potential sources of contamination of water used for any purpose, and take appropriate measures to minimize risks. Producers must monitor water quality and sources for presence of contaminants, including, bacteria levels in water and plant nutrients, heavy metals, and prohibited materials or their residues, for organic certification. Water sources, storage tanks, and irrigation systems should all be monitored regularly and maintained in proper working condition.

A producer should test water quality at the source according to FSMA standards, as a minimum, for bacterial contamination of water. Only approved laboratories and water test methods compliant with FSMA standards can be used. If treatment is called for due to abnormal bacterial test results, then organic producers should sanitize water according to NOP rules. Producers who are not certified are encouraged to follow NOP water sanitation rules to minimize their environmental impact.

Organic producers must include, in their OSP any sanitation products used to wash the irrigation system or input application equipment and monitoring methods to be used. Before using any material, producers must be sure that each one is approved by their organic certifier for its intended use and followed by adequate rinse or testing, as applicable.

If a producer has a food safety plan, it should include a policy and procedures to follow when bacterial levels of water are above the threshold allowed under FSMA.

#### Untreated Water Sources

**NOTE:** FSMA Agricultural Water Testing Requirements §112.46

For water from any public water supply system that can provide a certificate of bacterial analysis for water, no further testing is required, as long as the producer has a copy of that analysis.

For any water system treated according to §112.46, no testing is required.

For all other untreated water delivery systems the following applies:

1) Perform and Initial Survey to Develop a Microbiological Profile Baseline		
	# Samples	Time Period
Surface Water	20	2-4 years
Ground Water	4	1 year during the growing season
2) Conduct Annual Water Testing		
Surface Water	Minimum 5	1 year
Ground Water	Minimum 1	1 year
3) Update the Microbiological Profile Using Most Recent Past 4 Years Water Test Results		
Surface Water	20	Use current survey and new data
Ground Water	4	Use current survey and new data
4) Modify Water Use Based on new Microbiological Profile Results		

*Samples: Must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest. Samples must be tested with the EPA approved 1603 method.*

# HARVEST AND POST-HARVEST HANDLING OF PRODUCE

## FSMA Subpart K Growing, Harvesting, Packing, and Holding Activities §112.111-112.116

### Key practices for producers to follow:

- Keep covered produce separate from excluded produce during growing, harvesting, packing, and holding as applicable, except when covered produce and excluded produce are placed in same container for distribution, to avoid physical contact between the two categories so as to minimize risk of transfer of pathogens from one to the other.
  - Take all necessary measures to identify, and not harvest, produce that is reasonably likely to be contaminated immediately prior to and during harvest.
  - Handle harvested covered produce in a manner that protects against contamination with known or reasonably foreseeable hazards, including pathogens that may be present in soil, to the degree practical.
- Not distribute covered produce that drops to the ground before it is harvested (dropped covered produce) unless it receives commercial processing to adequately reduce the presence of microorganisms of public health significance. Dropped covered produce does not include root crops (such as carrots) that grow underground or crops (such as cantaloupe) that grow on the ground or produce that is intentionally dropped to the ground as part of the harvesting method.
  - Food-packing materials used must be adequate for their intended use, which includes being cleanable or designed for single use and unlikely to support growth or transfer of bacteria.
  - If food-packing materials are reused, then a producer must take adequate steps to ensure that food-contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner. If food-packing materials are reused after non-covered produce, then producers are required to adequately clean and sanitize, as necessary, any food-contact surfaces that contacted excluded produce before using such food-contact surfaces for covered activities on covered produce.

**For 3rd party food safety audits, producers must maintain written policies and procedures related to the above topics.**

## FSMA Subpart L. Equipment, Tools, Buildings and Sanitation

Regulates harvest equipment tools, packing materials, box storage areas, and packing areas.

### Key practices for producers to follow:

- Use tools and equipment that are of adequate design; constructed to be properly cleaned, and maintained so as to prevent risks of contamination.
- Inspect, maintain, clean, and sanitize when appropriate, and as frequently as necessary to prevent risks to food safety, all food contact surfaces of equipment and tools used in harvest of covered produce.
- Maintain all non-food contact surfaces and equipment to protect against contamination during harvest and packing activities.
- Adequately clean any vehicle used to transport equipment before use
- Ensure that buildings provide ample space for their intended use, and have adequate drainage.
- Verify that written policies describing the exclusion of domestic animals and animal pests are implemented and documented.
- Maintain records of maintenance, cleaning, and sanitation of all equipment, tools, buildings, and sanitation as required in Subpart O. Records

## **NOP §205.272 Commingling and contact with prohibited substance prevention practice standard**

Organic operations' OSP must describe management practices and physical barriers to prevent commingling of organic and nonorganic products, and to protect organic products from contact with prohibited substances. Regulations specifically prohibit the use of packaging materials, storage containers, or bins that contain a synthetic fungicide, preservative, or fumigant; and use or reuse of any container or substance that would compromise the organic integrity of any organically produced product or ingredient.

### **Co-compliance**

Organic OSP and food safety policies and procedures should describe the cleaning and sanitation of harvest equipment and packaging materials. Harvest Equipment Cleaning and Sanitation Records can be used for dual purposes. Organic growers ensure that use of any sanitation products is approved for use by organic certifier, used in accordance with NOP rules, and listed on their OSP. Keep clear records regarding the origin, clean storage, cleaning (if any), and use of all harvest containers and packaging materials. Ensure the absence of biological, chemical, or physical contamination.

## RESOURCES



### ORGANIZATIONS:

**Agriculture and Land-Based Training Association (ALBA)**

<http://www.albafarmers.org>

Se habla español



**National Center for Appropriate Technology (NCAT) /ATTRA**

<https://attra.ncat.org>

Se habla español

### REGULATORY REFERENCES:

**FDA Food Safety Modernization Act (FSMA) Final Rule on Produce Safety**

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>



**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](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>

