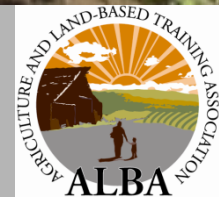


Food Safety and Organic: Side by Side and Simplified



NATIONAL CENTER
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Ecological Farming Conference 2016

Federal Regulations

Organic

“ Organic Regulations”

- Law: *Organic Foods Production Act (OFPA)*
- Regulation: National Organic Program, USDA Organic Regulations 7 CFR Part 205
http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title07/7cfr205_main_02.tpl
- Guidance: NOP Handbook
<http://www.ams.usda.gov/rules-regulations/organic/handbook>

Food Safety

“ Produce Safety Rule”

- Law: *Food Safety Modernization Act (FSMA)*
- Regulation: Final Rule on Produce Safety 21 CFR Part 112 Standards for Growing, Harvesting, Packing and Holding Produce for Human Consumption
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>

Federal Regulations relevant to producers of safe organic food crops.

FDA Definition of Business Size & FSMA Requirements

Produce Safety Rule Effective Date: January 26, 2016

Size of covered farm	Covered activities involving sprouts covered under subpart M (i.e., subject to all requirements of part 112)	Covered activities involving all other covered produce (i.e., subject to part 112, except subpart M)		Farms eligible for a qualified exemption (if applicable)		
		Compliance date for certain specified agricultural water requirements	Compliance date for all other requirements	Compliance date for retention of records supporting eligibility in § 112.7(b)	Compliance date for modified requirement in § 112.6(b)(1)	Compliance date for all other requirements in §§ 112.6 and 112.7
Time periods starting from the effective date of rule (60 days after final rule is published)						
Very small business ≤\$250,000*	3 years	6 years	4 years	Effective date of rule	January 1, 2020	4 years
Small business ≤\$500,000	2 years	5 years	3 years			3 years
All other businesses	1 year	4 years	2 years			N/A

Exemptions

Organic

NOP §205.100: Any production or handling facility ***selling less than \$5,000 dollars annually*** is exempt from the requirement for certification

- Exempt operations selling as organic must follow all other regulatory requirements, including recordkeeping

Food Safety

FDA FSMA Exempt Farms Subpart A §112.4:

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.

The FSMA Qualified Exemption

Subpart A §112.5

Producers 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; AND
- 2)** The average sales were less than \$500,000; AND
- 3)** The farm sales to restaurants and retail were within 274 miles from the farm or within the same state

FSMA exempt farms still must follow :

Subpart A. General Provisions, including §112.6- labeling requirements for direct markets and §112.7 annual review to verify continued eligibility for qualified exemption;

Subpart O. Requirements Applying to Records that you Must Establish and Keep;

Subpart Q. Compliance and Enforcement; &

Subpart R. Withdrawal of Qualified Exemption.

Written Plans



Written Plans

Organic

- Application for Certification
- Organic System Plan (OSP) required by USDA organic regulations. Must include a description of:
 - practices and procedures
 - list of materials to be used
 - monitoring
 - recordkeeping system
 - contamination prevention

Food Safety

- FDA does not specifically require a food safety plan
- Regulations do require an operational assessment of food safety risks and documentation of practices and procedures to minimize pathogen risks.
- Non-FDA third party food safety certification requires a Food Safety Plan; format and content vary according to standards to be met.

Written plans are required for organic;
recommended for food safety.

Land



Land

Organic

Land Use History:

- No use of materials (synthetic fertilizers, pesticides, sewage sludge, etc.) for 36 months before harvest of a crop to be sold or represented as organic.
- Boundaries and buffers prevent contamination (describe in OSP; attach map)

Food Safety

Operational risk assessment:

- Evaluate past or present land use; including adjacent & nearby lands:
 - industrial uses
 - landfill or waste disposal
 - animal husbandry
 - flooding

Risks may affect requirements for water testing profiles

Land use history and production site assessment must address substances prohibited in organic, and risks to food safety.

Worker Health and Hygiene

Germ Farm



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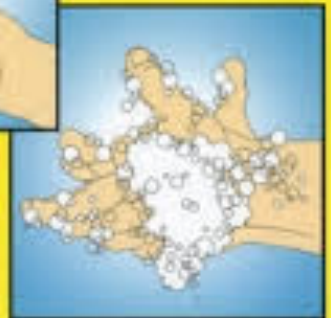
**POR FAVOR, LÁVESE LAS
MANOS FRECUENTEMENTE**



**ANTES Y DESPUÉS
DE USAR EL BAÑO,
MANIPULAR FRUTAS Y
VERDURAS, COMER,
BEBER, O FUMAR**

BEFORE AND AFTER

**USING THE TOILET,
HANDLING FRUITS
AND VEGETABLES,
EATING, DRINKING,
OR SMOKING**



**PLEASE WASH
YOUR HANDS OFTEN!**

Worker Health and Hygiene

Organic

- This topic is not addressed directly by USDA organic regulations.

Food Safety

- Supervisor or responsible party must successfully complete an FDA-approved training in food safety and the importance of personal health and hygiene
- Personnel and volunteers must receive basic training in principles of food safety, and the importance of health and personal hygiene
- Those harvesting crop receive training on pre-harvest inspection of produce and harvest equipment/ packaging materials
- Record: Worker Training Log/ Certificates required

Train all employees in good personal hygiene practices and procedures; Keep a record of training.

Natural Resources & Domesticated and Wild Animals



Natural Resources & Domesticated and Wild Animals

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

Food Safety

- 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.

FDA's food safety regulations will not conflict with or duplicate regulations of other federal agencies (e.g. USDA, NRCS) that support natural resource management & conservation practices.

Crop Nutrient & Pest Management



Crop Nutrient & Pest Management

1. Biological Soil Amendments Not of Animal Origin

Organic

Producers track all inputs used in crop production:

- OSP Materials List
- Purchase Receipts
- Application Records (date, rate, crop, location)

Food Safety

- Produce Safety Rule does not directly address this topic.
- For third party food safety certification, producers must verify & document that inputs do not present a food safety hazard, and record all inputs including application method

A complete organic audit trail includes tracking of all substances used. FDA does not require input applications in the audit trail. Many third party auditors do, including input application

Crop Nutrient & Pest Management

2. Biological Soil Amendments of Animal Origin

Organic

- Composting process for plant and animal materials with an initial C:N ratio of 25:1 to 40:1.
 - **In vessel or static aerated pile** the temperatures maintained between 131°F and 170°F at least 3 days, or
 - **In a windrow** temps maintained between 131°F and 170°F for 15 days during which it is turned a minimum of 5 times.
- **Raw manure** must be incorporated
 - Not less than 90 days prior to harvest of a crop that does not have direct contact with the soil
 - Not less than 120 days prior to harvest of a crop that does have direct contact with the soil surface.

Food Safety

- Scientifically validated treatment process was used &
- Handling, conveyance and storage of product is adequate to minimize the risk of contamination by an untreated or in-process BSAAO
 - **If purchased from a 3rd party**, Certificate of Conformance & Certificate of Analysis required at least annually
 - **If self-prepared**, record of treatment process controls: time/temp/turning schedule with signature of responsible party
- **Raw manure**- further research will provide future regulation. Currently, no application interval is given

Both organic and food safety regulations require documentation of processing/treatment of materials to minimize contamination risks.

Crop Nutrient & Pest Management

3. Pest Management Practices & Plant Protection Products

Organic

- Use preventative practices: crop rotation, cultural, biological, physical and mechanical controls
- Allowed materials may be applied to prevent, suppress, or control pests, weeds, or diseases only when preventative controls are insufficient; and
- D: OSP includes: preventative pest management practices, allowed materials list, and conditions for intended use

Food Safety

- Produce Safety Rule does not directly address this topic.
- Local County Agriculture Commissioners require Pesticide Use Reports

Crop Nutrient and Pest Management

4. Seed and Planting Stock

Organic

- Annual seedlings and seed for edible sprouts must be organic.
- Must use organically grown seed and planting stock;
 - May use nonorganic, untreated, non-GMO seed or stock when an equivalent organic variety is commercially unavailable (form, quality, or quantity)
D: Document.
- Inoculants must be non-GMO.
- Seed treatments must be allowed.
- Perennial stock sold as organic must be managed organically ≤ 1 year.

Food Safety

- Produce Safety Rule gives detailed measures to prevent and mitigate food safety hazards for **seeds or beans for sprouting ONLY**
 - 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

Seed & planting stock must meet detailed quality requirements.

WATER

1. Crop Production: Irrigation, Fertilizer and Pesticide Application

Organic

- Any material used to clean or sanitize the irrigation system must be listed in OSP and approved by certifier for its intended use.
- Allowed:
 - Alcohols (ethanol and isopropanol) as algaecides, disinfectants, sanitizers, irrigation system cleaning
 - Chlorine (see Guidance)
 - Copper sulfate, as algaecide in aquatic rice systems;
 - Ozone gas, as an irrigation system cleaner only

Food Safety

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

WATER

2. Post-Harvest: Direct contact with crop for icing cooling, equipment cleaning, and hand washing & sprout irrigation

Organic

- 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.
- Allowed sanitizer materials:
 - 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.

Food Safety

- All agricultural water must be safe and of adequate sanitary quality for its intended use.
- 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
 - R: Record of contamination mitigation of any high bacterial levels

FSMA Agricultural Water Testing Requirements §112.46

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.

Water systems treated according to §112.46, no testing is required.

Untreated Water Sources : *Test 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.*

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		

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

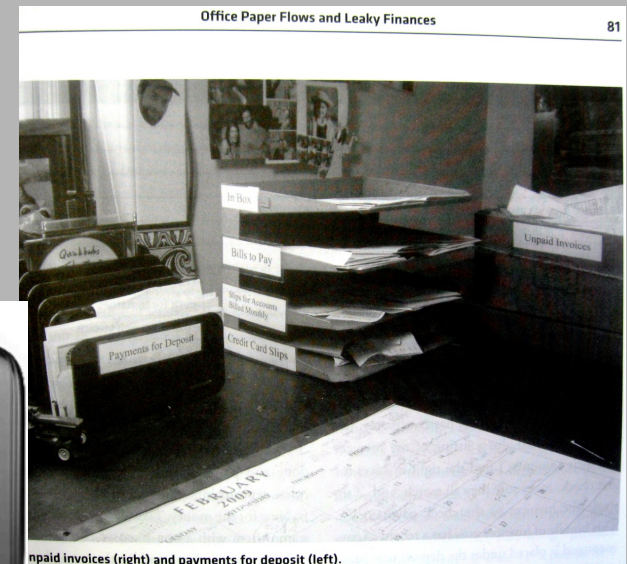
Organic

- Must implement measures necessary to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances.
- Prohibited are:
 - Packaging, storage containers or bins containing a synthetic fungicide, preservative, fumigant
 - Use or reuse of any container that would compromise organic integrity (thorough cleaning is an option, with records kept).

Food Safety

- Harvest, tools, equipment and containers must be maintained and stored in a manner that prevents contamination of crop products.
- Harvested produce must be handled and packed so as to prevent contamination.
- Pre-inspection of produce to be harvested and any harvest equipment and packaging
- Sanitation records with date and method of cleaning/sanitation used required

RECORDKEEPING, TRACE-ABILITY & AUDIT TRAIL



RECORDKEEPING, TRACE-ABILITY & AUDIT TRAIL

Organic

A complete audit trail includes Organic System Plan practice descriptions & material lists.

D: Input purchase receipts

R: Crop production and rotation with field identification and input application records

R: Harvest/post-harvest handling

D: Sales (date, product, quantity)

Food Safety

- Each subpart of the regulation has its own recordkeeping requirements
 - Most records must be kept 2 years
 - Sales records to prove and maintain a qualified exemption = 4 years
 - Water test record = 4 years.
- Some records must be signed by the person responsible for food safety.

Plans, Records and Documents are each a critical component in implementation of good organic and food safety practices.

**Non-Profit Organizations
Providing Information, Resources and Assistance in
Food Safety & Organic Compliance**

Agriculture and Land-Based Training Association (ALBA)

<http://www.albafarmers.org>

Se habla español



National Center for Appropriate Technology (NCAT)

ATTRA Sustainable Agriculture Program

<https://attra.ncat.org/>

See new Food Safety Resources website section:

https://attra.ncat.org/food_safety.html

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