

March 25, 2013



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FSMA Regulations That May Affect Fresh Fruit and Vegetable Growers



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Registration of Food Facilities w/ FDA

- **NO FEE**
- **Only** facilities processing food for wholesale or warehousing processed food
- **Biennial registration**
- Registration = consent to inspection
- Electronic or paper

<http://www.fda.gov/food/guidancecomplianceregulatoryinformation/registrationoffoodfacilities/default.htm>

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Who must register?

- Processing plants
 - Includes farms where produce is "processed"
- Warehouses
- Several exemptions

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Exemption From Registration

- **Farms**
 - Includes on-farm packing if all produce is grown, raised or consumed on that farm or another farm under same ownership
- **Retail Food Establishments**
 - Regulated by state and local jurisdictions
 - Restaurants
 - Grocery / Convenience stores
 - Direct sales to consumers
 - Roadside stands and farmers' markets
 - Community-supported agriculture

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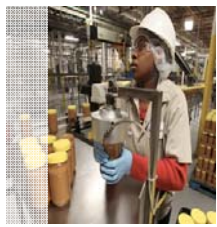
Examples

- Farmer grows seed for other farmers: NO if planted, YES if fed to animals
- Farmer washes lettuce with chlorinated water: NO if ≤ 200 ppm Cl, YES if >200 ppm Cl
- Farmer puts stickers on fruits: NO if all fruit is from his/her farm, YES if fruit from other farms
- Farmer grows, harvests, packs own crop and ships it elsewhere: NO
- Produce grown and harvested, trimmed at one location, but then packed at a different location: NO for farm, YES for packing shed

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Risk-Based Preventive Controls

- Similar to HACCP
 - Registered facilities only
 - Hazard analysis, including intentional adulterants
 - Preventive controls
 - Monitoring
 - Corrective actions
 - Verification that preventive controls work
 - Record-keeping and retention (2 years)



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Risk-Based Preventive Controls - Exemptions

- Very small businesses (yet to be defined) OR
- Direct sales to "qualified end users" are more than 50% of total sales, total sales < \$500,000 AND
 - Documented hazard analysis, preventive controls, and monitoring OR
 - Documented compliance with State or local food safety law AND display of address on label or placard
 - "Qualified end user" = consumer; restaurant or retail establishment in same state or ≤ 275 miles away
- Processors of seafood, juice, low-acid canned foods, dietary supplements, alcoholic beverages

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Risk-Based Preventive Controls - Exemptions

- Certain manufacturing, processing, packing and holding activities conducted on specific foods by small and very small on-farm businesses
- Facilities such as warehouses that only store packaged food not exposed to the environment (modified requirements apply if the food must be refrigerated for safety)

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Written Food Safety Plan

- Prepared by a trained or suitably experienced person
- Hazard Analysis by trained/experienced person
 - Known or reasonably foreseeable hazards for each type of food at the facility
 - Includes radiological hazards, intentionally introduced hazards, environmental pathogens (when RTE foods exposed)

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Written Food Safety Plan

- Preventive Controls
 - May or may not be Critical Control Points
 - Address hazards that were identified in Hazard Analysis as reasonably likely to occur
 - Include parameters for control
 - Process controls
 - Food allergen controls
 - Sanitation controls
 - Recall plan

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Written Food Safety Plan

- Monitoring procedures
 - Ensure preventive controls are consistently performed
 - Procedures and frequencies are written
 - Records kept
- Corrective actions if preventive controls aren't properly implemented
 - Planned vs. "default"
 - Correct problem and minimize recurrence
 - Gain control of product and decide its fate
 - Re-assess food safety plan

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Written Food Safety Plan

- Verification
 - Validation of preventive controls by qualified person
 - Verify that monitoring and corrective actions are done as written
 - Calibration
 - Re-assess food safety plan at least every 3 years
- Seeking comments on product / environmental testing programs, mandatory review of customer and other complaints

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Written Food Safety Plan

- Record-keeping (retain for 2 years)
 - Hazard Analysis
 - Monitoring
 - Corrective actions
 - Verification Activities
 - Validation
 - Calibration
 - Records review
 - Re-analysis
 - Training

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Proposed Regulations

- Published 1/4/2013
- Comment period is open
- 1, 2, or 3 year period to achieve compliance (depends on establishment size)

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Proposed Produce Safety Standards

- Published 1/4/2013
- Mandatory for safe production and harvesting of "covered" produce
- Virtually all fresh produce is "covered"
- Several exemptions
- Focus on key GAPs
- Only deal with biological hazards



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What is covered? What is not covered?

- Fruits and vegetables, peanuts, tree nuts, herbs, mushrooms, sprouts, mixes of intact fruits and vegetables → COVERED
- Produce that is rarely consumed raw → NOT COVERED
- Produce that is grown for personal or on-farm consumption → NOT COVERED
- Produce that is grown for further processing that adequately reduces pathogens → NOT COVERED
 - Keep records of who does the processing!

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Exemption from Produce Safety Standards

- Very small businesses: <\$25,000 per year over past 3 years
- "Qualified Exemption"
 - > 50% of sales to "qualified end users":
 - consumers
 - restaurants, retail in same state OR within 275 miles of farm
 - Total sales < \$500,000
 - Packaging / placards indicate source

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Training Requirement

- All personnel who harvest or handle covered produce
 - Upon hire
 - At start of each growing season
 - Periodically thereafter
- Supervisors – training at least equivalent to a standard curriculum recognized by FDA
- Training must be understandable for audience and documented
- Training topics are listed by topic in the regulation

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Worker Health Requirements

- Exclude ill workers who may contaminate produce or food-contact surfaces
- Personnel must be trained to notify their supervisor when they are ill
- Hand-washing at specified times



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Water Quality Requirements

- Inspect water system at start of growing season
- Maintain water sources and distribution systems
- When problems are detected:
 - halt use,
 - re-inspect,
 - make necessary changes,
 - test water to show changes were effective or treat the water with antimicrobial compound (EPA-registered)

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Water--No detectable *E. coli* (100 ml sample)

- Direct contact with produce during or after harvest
- Treated agricultural tea
- Direct contact with food-contact surfaces
- Made into ice
- Hand-washing during or after harvest

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Water --*E. coli* tolerance level

- Water used for growing activities with direct application
- No more than 235 CFU/MPN *E. coli* per 100 ml for any sample AND
- Rolling geometric mean (n = 5) of no more than 126 CFU/MPN *E. coli* per 100 ml



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How often must agricultural water be tested?

- Beginning of growing season, every 3 months thereafter, unless:
 - Treated or from an approved municipal source
- Untreated surface water that may receive runoff
 - Every 7 days during growing season
- Underground aquifer water held above-ground and maintained to minimize runoff
 - Monthly during growing season

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Biological Soil Amendment of Animal Origin

- Physical and/or chemical treatments must result in
 - No *L. monocytogenes* in 5 g
 - < 3 MPN *Salmonella* in 4 g total solids
 - < 0.3 MPN *E. coli* O157:H7 in 1 g
- OR
 - < 3 MPN *Salmonella* in 4 g total solids
 - < 1,000 MPN fecal coliforms per g
- Composting must result in
 - < 3 MPN *Salmonella* in 4 g total solids
 - < 1,000 MPN fecal coliforms per g

Critical Factors in Composting

- Static and aerobic
 - At least 131°F for 3 days, followed by adequate curing
- Turned and aerobic
 - At least 131°F for 15 days, with at least 5 turnings, followed by adequate curing
- Other scientifically valid, controlled processes

Minimum Application Intervals for Manure

- Untreated, no contact during application, minimal contact after application → 9 mo.
- Untreated, no contact during or after application → 0 d
- Treated, meets microbial standards → 0 d
- Composted, meets microbial standards; minimal contact during / after application → 45 d (0 d if no contact)

Alternatives to Regulations

Alternatives to regulations can be used when:

- Water testing, and responding to test results
- Composting of biological soil amendments of animal origin
- Application intervals for untreated biological soil amendments of animal origin or compost agricultural tea
- You must have adequate data to validate the alternative

Animal Control Requirements

- If animals graze or work in produce fields, you must:
 - Ensure an "adequate waiting period between grazing and harvesting"
 - Take measures to prevent introduction by working animals of hazards into or onto produce
- If animal intrusion is reasonably likely:
 - Monitor
 - Evaluate whether uncontaminated produce can be harvested

"No Drops" Requirement

- "You must not distribute covered produce that drops to the ground before harvest..."
- Exemption for crops that will be processed to kill pathogenic bacteria
- Exemption for root crops and crops that grow on ground, e.g. cantaloupe



Equipment, Tools, Building

- Equipment and tools for harvesting, packing, holding
 - Emphasis on cleanability and maintenance
 - Inspect → maintain → clean (and sanitize for food-contact surfaces) when appropriate
- Building
 - Sufficient space and separation
 - Ease of cleaning and repair
 - Prevents contamination of produce, food-contact surfaces, packaging materials
 - Adequate drainage, pest control, facilities, waste disposal

Required Records

- Training: dates, topics, names
- Water system inspection results
- Water testing results
- Treatment of biological soil amendments
- Application of biological soil amendments
- Cleaning and sanitizing of equipment, tools, food-contact surfaces
- Validation results for water, manure treatments
- Retain the records for 2 years

Questions?

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