FSMA Regulations That May Affect Fresh Fruit and Vegetable Growers

Steve Ingham
Administrator
Division of Food Safety
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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

Who must register?

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

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

Examples

- Farmer grows seed for other farmers: NO if planted, YES if fed to animals
- Farmer washes lettuce with chlorinated water: NO if \( \leq 200 \) 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

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)
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
- Process of seafood, juice, low-acid canned foods, dietary supplements, alcoholic beverages

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)

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)

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

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

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

Proposed Regulations

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

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

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!

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

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
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

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)

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

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

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?

Steve Ingham
608-224-4701
steve.ingham@wi.gov