FreshTech Learning Center

20 THINGS YOU NEED TO KNOW ABOUT FSMA

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Top 20 Things You Need To Know About the Five FSMA Rules

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Seven FSMA Proposed Rules *Finalized*

- Produce Safety Standards
- Preventive Controls for Human Food
- Foreign Supplier Verification Program
- Accredited Third Party Certification
- Preventive Controls for Animal Feed
- Sanitary Transportation
- Intentional Adulteration (Vulnerability Assessment & Mitigation) and
- Designation of High Risk Foods (pending)
- Reportable Food Registry ANPR (pending)
Produce Safety Rule

1. Exempt or Covered?
Covered, except

- Produce rarely consumed raw
- If processed (fresh-cut) or not a farm (PC rule)
- If <$25K annual produce sales (exempt)
- If “qualified” (modified requirements)
  - <$500K annual food sales AND
  - More than half goes direct to “qualified end-users” within state or 275 miles
Produce Safety Rule

2. Farm or Not a Farm?

**Primary Production Farm**: An operation under one management in one general, but not necessarily contiguous, physical location devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities. In addition to these activities, a primary production farm can:

- Pack or hold RACs (regardless of who grew or raised them)
- Manufacture/process, pack, or hold processed foods so long as:
  - All such food is consumed on that farm or another farm under the same management; or
  - The manufacturing/processing falls into limited categories.
Produce Safety Rule

2. Farm or Not a Farm?

Secondary Activities Farm: An operation not located on a primary production farm devoted to harvesting, packing, and/or holding RACs

- The primary production farm(s) that grow, harvest, and/or raise the majority of those RACs must own or jointly own a majority interest in the secondary activities farm

- The definition also allows certain, limited additional manufacturing/processing, packing, and holding
  - Same as those for a primary production farm
Produce Safety Rule

3. General Requirements
Covers same risk factors as most GAP audits:
• Workers: health/hygiene/training
• Animals: monitor/don’t harvest contaminated produce
• Water: testing, standards for preharvest/post-harvest
• Soil amendments: compost standards, untreated
• Food contact surfaces: appropriate, clean and sanitized
Separate covered and excluded produce not grown in accordance to the rule
Produce Safety Rule

4. Water Testing

Only applies to direct contact water:

- Preharvest: GM <126 gen. E. coli/100 mL; STV <410
  - Ground water: 4 tests initial survey, annual after
  - Surface water: 20 tests initial survey, 5/yr after
- Allows for microbial die-off in-field, between last irrigation and harvest, of up to 4 consecutive days
- Allows for microbial reduction or removal post-harvest, including through commercial practices or storage
Produce Safety Rule

4. Water Testing

Harvest/post-harvest/food contact surface/handwashing:
- no detectable E. coli/100 mL

No microbial testing required if from municipal source or treated to meet standard (records required)
Produce Safety Rule

5. Training

• All personnel who contact covered produce or food-contact surfaces
  – Health/hygiene/produce rule requirements
  – Harvesters: special training
  – Training records
• “At least one supervisor or responsible party for your farm...” Produce Safety Alliance training
• Farms must make visitors aware of policies
Preventive Controls for Human Food Rule

6. Good Manufacturing Practices (subpart B)

- Replaces current 21 CFR part 110
- Includes all the same requirements, plus training and prevention of allergen cross-contact
- Special GMP provisions for human food by-products destined for animal food
7. Preventive Controls (subpart C)

Written Food Safety Plan, with
- Written Hazard Analysis for biological (environmental), chemical, physical and economically motivated adulteration hazards
- Written Preventive Controls (sanitation, allergen, process, supply-chain)
- Written Monitoring procedures
- Written Corrective Action procedures
- Written Verification procedures
Records of performance of above procedures

Written Recall Plan

Written Validation of Process Controls

Reanalysis of Food Safety Plan
Preventive Controls for Human Food Rule

8. Preventive Controls Qualified Individual

“...a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.”

Food Safety Preventive Controls Alliance
9. Processor vs. Packhouse/Warehouse

- Fresh-cut clearly under PCHF
- Requirements for operations that only handle RACs less clear
  - “Specific steps necessary to ensure the safety of produce would generally be the same”
- Hazard analysis vs. supplier-applied controls
- PCQI training materials, FDA guidance not yet available
10. Exempt or Covered?

Applies to FDA-registered facilities except:

- “Very small business (including any subsidiaries or affiliates) averaging less than $2,500,000, adjusted for inflation, per year, in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale)”

- “…on-farm packing or holding of processed animal food by a very small business, if the only packing or holding activities… [subject to Produce Safety Standards ]”
Preventive Controls for Animal Food Rule

11. Human Food By-Products for Animal Food

• Must be held in a manner that protects against contamination
  – Containers cleaned as necessary
  – Must be accurately identified during holding
  – Labeling that identifies common or usual name must be affixed to or accompany when distributed

• Shipping containers examined before use
Preventive Controls for Animal Food Rule

12. Animal Food from PCHF Facility

“...the facility may choose to comply with the requirements in [subparts B and C of] part 117 as to the manufacturing, processing, packing, and holding of animal food at the facility, instead of [subparts B and C of] part 507, provided the food safety plan also addresses hazards for the animal food, if applicable, that require a preventive control.”
Foreign Supplier Verification Program Rule

13. Who’s covered?

• “Importer” is U.S. owner or consignee of a food at time of U.S. entry

• If no U.S. owner or consignee at entry, importer is U.S. agent or representative of the foreign owner or consignee, as confirmed in signed statement of consent

• Except: Food that is transshipped; Food that is imported for processing and export; U.S. food returned; Facilities subject to parts 117 (PCHF) or 507 (PCAF)
Foreign Supplier Verification Program Rule

14. Approve suppliers and determine appropriate supplier verification activities

• Risk posed by the food (written hazard analysis)
• Entities controlling hazards or verifying control
• Supplier characteristics (procedures, processes, and practices; FDA compliance; food safety history)

Procedures to ensure food is obtained from approved suppliers

Written procedures for verification activities, including when using unapproved suppliers on temporary basis
Foreign Supplier Verification Program Rule

15. Supplier verification activities

- onsite auditing
- sampling and testing
- review of supplier records
- other appropriate measures
- Annual onsite auditing is default approach when a food has a SAHCODHA hazard (fresh produce)
- Consider applicable FDA food safety regulations
Foreign Supplier Verification Program Rule

16. Who is the “supplier”?  
• “...the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a *de minimis* nature.”
• If purchasing from a broker or aggregator, must reach back to the grower of the imported lot
Foreign Supplier Verification Program Rule

17. Who does the audit?
• 2\textsuperscript{nd} or 3\textsuperscript{rd} party audit; no first party audit
• Qualified auditor (does not need to be FDA-accredited)
• May be government employee
• Special provisions when importing from country whose food safety system FDA has officially recognized as comparable or determined to be equivalent (NZ, CA)
• May rely on another entity’s audits, but must review and assess results
Accredited Third Party Certification Rule

18. Who’s covered?

- “…a voluntary program for the accreditation of third-party auditors, also known as certification bodies, to conduct food safety audits and issue certifications of foreign facilities and the foods for humans and animals they produce.”
Accredited Third Party Certification Rule

19. When are certifications needed?
• Importers will not generally be required to obtain certifications
• Certifications will be used for two purposes:
  1. by importers to establish eligibility for participation in the Voluntary Qualified Importer Program (VQIP)
  2. for admissibility of a food subject to a risk-based determination by FDA (to be determined)
20. Compliance Dates
Produce Safety Regulation Compliance Dates

Publication of Final Rule
Nov 27, 2015

Effective
Jan 26, 2016

Sprouts - All Others
All Provisions
Jan 26, 2017

Sprouts - Very Small
All Provisions
Jan 26, 2019

Farms - Small
Except Water *
Jan 26, 2019

Farms - Small
All Provisions
Jan 26, 2021

Farms - Very Small
All Provisions
Jan 26, 2022

Full Implementation & Transition to Operational Mode
2022

* Only applies to certain water requirements
Small Businesses – average produce sales over 3 years > $250,000 and ≤ $500,000
Very Small Businesses – average produce sales over 3 years > $25,000 and ≤ $250,000
≤ $25,000 in average produce sales over 3 years is not a covered farm
Preventive Controls Human Food Regulation Compliance Dates*

Publication Date of Final Rule
Sept 17, 2015

Effective Nov 16, 2015

Businesses Other than Small or Very Small
Sept 19, 2016

Small Businesses
Sept 18, 2017

Qualified Facilities (including Very Small Businesses)
Sept 17, 2018

Full Implementation & Transition to Operational Mode
2019

Very Small Businesses retain records to support Qualified Facility Status
Jan 1, 2016

Businesses subject to the Pasteurized Milk Ordinance
Sept 17, 2018

Small Businesses – business with fewer than 500 full-time equivalent employees

Very Small Businesses – average less than $1M per year in sales of human food plus the value of such food manufactured, processed, packed or held without sale

*Compliance dates for supply-chain program may differ.
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Questions?

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