FDA

Food Safety Modernization Act (FSMA)

Barb Hanson
Inspector, AK Division of Agriculture
(907) 761-3854
FSMA

- First Major Overhaul of Federal Food Safety Regulations since 1938

- Shifts Emphasis from RESPONDING to Food Safety Outbreaks to PREVENTING them

- Collaborative Effort: CDC, USDA, States, Academia, Industry, Foreign Govts & The Public
Food Safety Modernization Act

Proposed Law 2009

Public / Industry Input to Congress

Tester-Hagen Amendment
(Small Farms Exemption)

Food Safety Modernization Act
Final Law
Signed Jan. 2011
An Act
To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.

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Food Safety Modernization Act
Final Law

Made Effective Immediately:
- Mandatory Recall Authority in Suspected Outbreaks
- Records Access in Event of Outbreak
- Access to Foreign Facilities
- Whistleblower Protection

Mandated / Allowed Provisions For:
- Rules / Regulations
- Public Comments & Meetings / Reports
- Standards / Assessments
- Guidance Documents

5
Seven Regulations under FSMA have been written/proposed to date

- Standards for Produce Safety *
  - Addresses Farm practices for produce that is generally eaten raw

- Preventive Controls for Human Food
  - Safe handling, processing, storage and distribution of human food

- Preventive Controls for Animal Food
  - Safe production, storage and distribution of feed and pet foods

- Foreign Supplier Verification Programs for Imports
  - Regulates safety of imported foods for both humans and animals

- Accreditation of Third-Party Auditors/Certification Bodies
  - Ensures that food safety audits and certifications are conducted by qualified personnel

- Sanitary Transportation of Human and Animal Food
  - Requires foods to be transported safely

- Mitigation Strategies to Protect Against Intentional Adulteration
  - Addresses bioterrorism concerns for food supplies
Preventive Controls Rule

Facilities that Manufacture, Process, Pack, or Hold Human Food (most are already required to register w/ FDA under FD&C Act)

Produce Safety Rule

Farms that Grow, Harvest, Pack or Hold Produce in its Raw, Natural State
Both Domestic & Imported Foods are regulated

Focus on Identifying/Preventing Hazards

Risk-Based

Exempt:
- Facilities storing only packaged foods
- Facilities storing only raw products destined for processing

Modified Requirements:
- Small/very small facilities (<500 employees/<$250K/$500K/$1M income)
Requirements:

- Facility Registration
- Hazard Analysis/Food Safety Plan
- Process Controls at Hazard Points
- Food Allergen Controls
- Sanitation Controls
- Recall Capability
- Recordkeeping

Already required at most facilities under existing FDA FD&C Code and/or GAP/GHP Audits
Major Changes:

* Definition of Farm
* Required Product & Facility Testing
* Definition of Very Small Business

1st Public Comment Period - Changes Made

2nd Public Comment Period – Additional Changes
Produce Safety Rule

- Science-Based Standards / Risk-Based Inspection Targeting
- Focus on Identifying/Preventing Hazards
- Domestic & Imported Raw, Unprocessed Produce that is Generally Eaten Raw (Exempt Products: Potatoes, Kale, Brussels Sprouts, etc.)
- Exemptions:
  - Produce destined for processing
  - Produce that is generally cooked before eating

- ”Qualified Facilities” are exempt from most requirements, must meet only “Modified Requirements”
Tester – Hagen Amendment

Allows **Exempt** Growers to meet minimum **Modified Requirements**

**Exempt if:**

A) Sell < $25,000 produce annually

or

B) Sell < $500,000 produce annually

and

> 50% of product sold direct sales to consumers, retailers, or restaurants within a 275 mile range **OR** within the same state
Three “Modified Requirements” for Exempt Farms:

1. **Prohibited from selling adulterated food**
   
   (“filthy, putrid, decomposed, unfit for human consumption, or prepared, packed, or held under unsanitary conditions so that is contaminated or may be rendered injurious to health”)

2. **Exempt status may be withdrawn by FDA under certain conditions:**
   * active investigation of a foodborne illness outbreak directly linked to a qualified exempt farm or if necessary to protect the public health

3. **Name and address of farm must be displayed on produce**
   
   either:

   ❖ on the product
   ❖ on a sign at the point-of-sale or
   ❖ on an invoice to the purchaser
Non-Exempt Farms

Requirements For:

- Health & Hygiene Training
- Water Quality
- Biological Soil Amendments
- Wildlife / Livestock in Growing Areas
- Sanitation - Tools, Buildings, Equipment

* Specific requirements for Sprout Growers (nonexempt)
## GAP Audit vs. FSMA

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<td>Regulatory</td>
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<td><strong>Requirements/ Exemption</strong></td>
<td>Audits done at request of produce purchasers as condition of sale</td>
<td>FSMA identifies who is exempt; exempt status may be withdrawn in event of outbreak</td>
</tr>
<tr>
<td><strong>Inspections / Audits</strong></td>
<td>Audits required – 2 per year, including one unannounced</td>
<td>Inspection frequency based on risk – every 3 to 5 years</td>
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<td><strong>Cost to Grower for Inspection / Audit</strong></td>
<td>Hourly fee for prep &amp; audit time, travel, + admin fee</td>
<td>No fees for Initial Inspection; possible fees for re-inspection if failed</td>
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<td><strong>Food Safety Plan</strong></td>
<td>Required</td>
<td>Not Required</td>
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<td><strong>Practice Standards</strong></td>
<td>Defined by type of audit; customer-driven</td>
<td>Defined by Rule</td>
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Proper hygiene practices must be followed – personal hygiene, animal contact, appropriate glove use

Food Safety Training for Growers/Handlers/Supervisors

Ill Workers banned from food contact

Toilet & Hand Washing Facilities must be available
Water Quality
(Covered Farms Only)

For Irrigation Water In Direct Contact with harvestable portion of Crop:

EPA Recreational Water Standard for Swimming Beaches
(Avg ≤ 126 cfu generic E.coli per 100 ml ≤ 235 / any single sample)

Number of Samples during growing season

Groundwater
- Originally: 4 times / year
- Proposed: Reduced to once/year

Surface Water
- Originally: Once Per week
- Proposed: Reduced after initial baseline tests
Water Quality
(Covered Farms Only)

- Produce Wash Water
- Processing Water
- Food Contact Surfaces
- Hand Wash Water
- Ice
- Sprout Irrigation Water
- Water for Agricultural Teas

EPA Drinking Water Standard
(No Detectable E.coli per 100 ml)
Water Quality
(Covered Farms Only)

Options for water that does not meet EPA Standard:

Treatment  (Chlorination/Filtration/Ozone/Effective Alternatives)

Pre-Harvest Interval  (0.5 log / day reduction rate)

Harvest – End of Storage Interval  (based on log reduction)
Biological Soil Amendments of Animal Origin
(Covered Farms Only)

Compost / Compost Tea / Raw & Aged Manure

Establishes requirements for proper Treatment, Storage & Use, and Recordkeeping

Human Waste: Prohibited except as allowed by EPA

Raw Manure:

*Originally proposed: 9 month pre-harvest interval after use*

*Grower Concerns: NOP Standard is only 90 / 120 days*

*Revised Rule: 9-month interval was removed, awaiting data before reestablishing standard*
Wildlife/Livestock in Growing Areas
(Covered Farms Only)

If Working or Grazing Animals are allowed in field:
Pre-harvest interval after grazing
Prevent contamination from working animals in crop areas (paths, etc.)

If Animals have Intruded in Growing Areas:
Monitoring and evaluation of product/crop areas

Rule Does NOT Require:
- Exclusion of farm animals or wildlife from fields
- Clearing of Farm Borders
- Fencing
Equipment, Tools, Buildings, Sanitation
(Covered Farms Only)

Adequate Design, Construction

Equipment Properly Stored

Maintained, Cleaned & Sanitized Adequately

Instruments must be Properly Calibrated

Covered Produce must be Protected from Contamination
Recordkeeping
(Covered Farms Only)

- Water Test Results
- Manure / Compost Treatment Records

* Records kept for other audits/programs need not be duplicated
Two Public Comment Periods
Changes Made in Response to Comments:

• Water Quality Testing
• Manure/Biological Amendments Use
• Definition Small/Very Small Farm
Phase-in Period

Have 2 – 5 years to comply with requirements
Assistance & Noncompliance

- Resources – web-based/regional call centers
- Training
- Compliance Assistance - state cooperators

- Administrative Remedies
  - Notices
  - Warnings
  - Consent Decrees
  - Detention Of Product
  - Fines
  - Legal Remedies – cases of willful negligence/intentional adulteration
FSMA in The News
Food Safety Modernization Act

Proposed Law 2009

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Questions?

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