

FDA

Food Safety Modernization Act (FSMA)

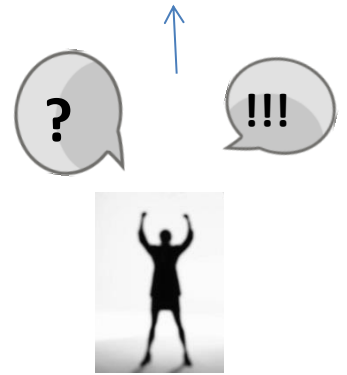
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FSMA

- ❖ 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
DRAFT
Proposed Law
2009

Public / Industry Input
to Congress



**Tester-Hagen
Amendment**

(Small Farms Exemption)



Food Safety
Modernization Act

Final Law

Signed Jan. 2011



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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

Guidance
Documents

Public
Comments
& Meetings
/ Reports

Standards /
Assessments

Seven Regulations under FSMA have been written/proposed to date

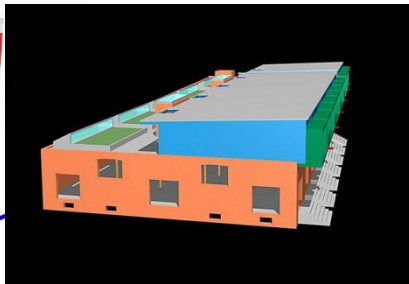


- ❖ **Standards for Produce Safety ***
 - ❖ Addresses Farm practices for produce that is generally eaten raw
- ❖ **Preventive Controls for Human Food**
 - ❖ Safe handling, processing, storage and distribution of human food
- ❖ **Preventive Controls for Animal Food**
 - ❖ Safe production, storage and 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

TITLE I—IMPROVING CAPACITY TO PREVENT FOOD SAFETY PROBLEMS

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**Preventive
Controls
Rule**



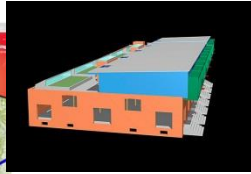
Facilities that Manufacture, Process, Pack, or Hold Human Food (most are already required to register w/ FDA under FD&C Act)

**Produce
Safety Rule**



Farms that Grow, Harvest, Pack or Hold Produce in its Raw, Natural State

Preventive Controls Rule

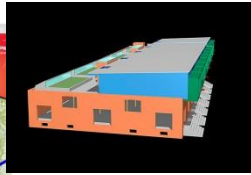


Preventive Controls Rule

Manufacture, Process, Pack, or Hold Human Food

- ❖ 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)

Preventive Controls Rule



Requirements:

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

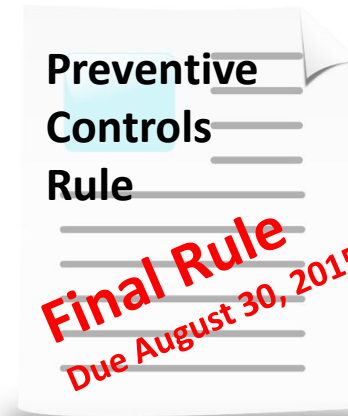
Already required at most facilities under existing FDA FD&C Code and/or GAP/GHP Audits



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



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

Produce
Safety Rule



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

	GAP	FSMA
Guidance vs. Regulatory	Guidance	Regulatory
Requirements/ Exemption	Audits done at request of produce purchasers as condition of sale	FSMA identifies who is exempt; exempt status may be withdrawn in event of outbreak
Inspections / Audits	Audits required – 2 per year, including one unannounced	Inspection frequency based on risk – every 3 to 5 years
Cost to Grower for Inspection / Audit	Hourly fee for prep & audit time, travel, + admin fee	No fees for Initial Inspection; possible fees for re-inspection if failed
Food Safety Plan	Required	Not Required
Practice Standards	Defined by type of audit; customer-driven	Defined by Rule

Produce
Safety Rule



Health / Hygiene Requirements

(Covered Farms Only)

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

Produce
Safety Rule



Water Quality

(Covered Farms Only)

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

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

Number of Samples during growing season

Groundwater

Surface Water

Originally: 4 times / year

Proposed: Reduced to once/year

Originally: Once Per week

Proposed: Reduced after initial baseline tests⁷

Produce
Safety Rule



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)

Produce
Safety Rule



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

Produce
Safety Rule



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:

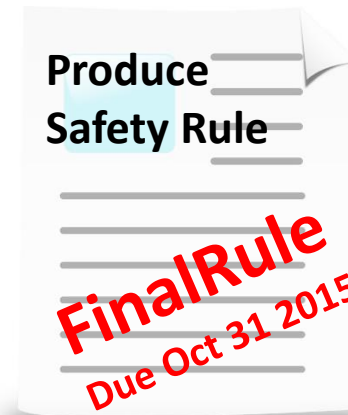
- Water Quality Testing
- Manure/Biological Amendments Use
- Definition Small/Very Small Farm



↓
Public Comment
Period on Proposed
Rule



→
Public Comment
Period on
Supplemental Rule



Phase-in Period

Have 2 – 5 years to comply with requirements

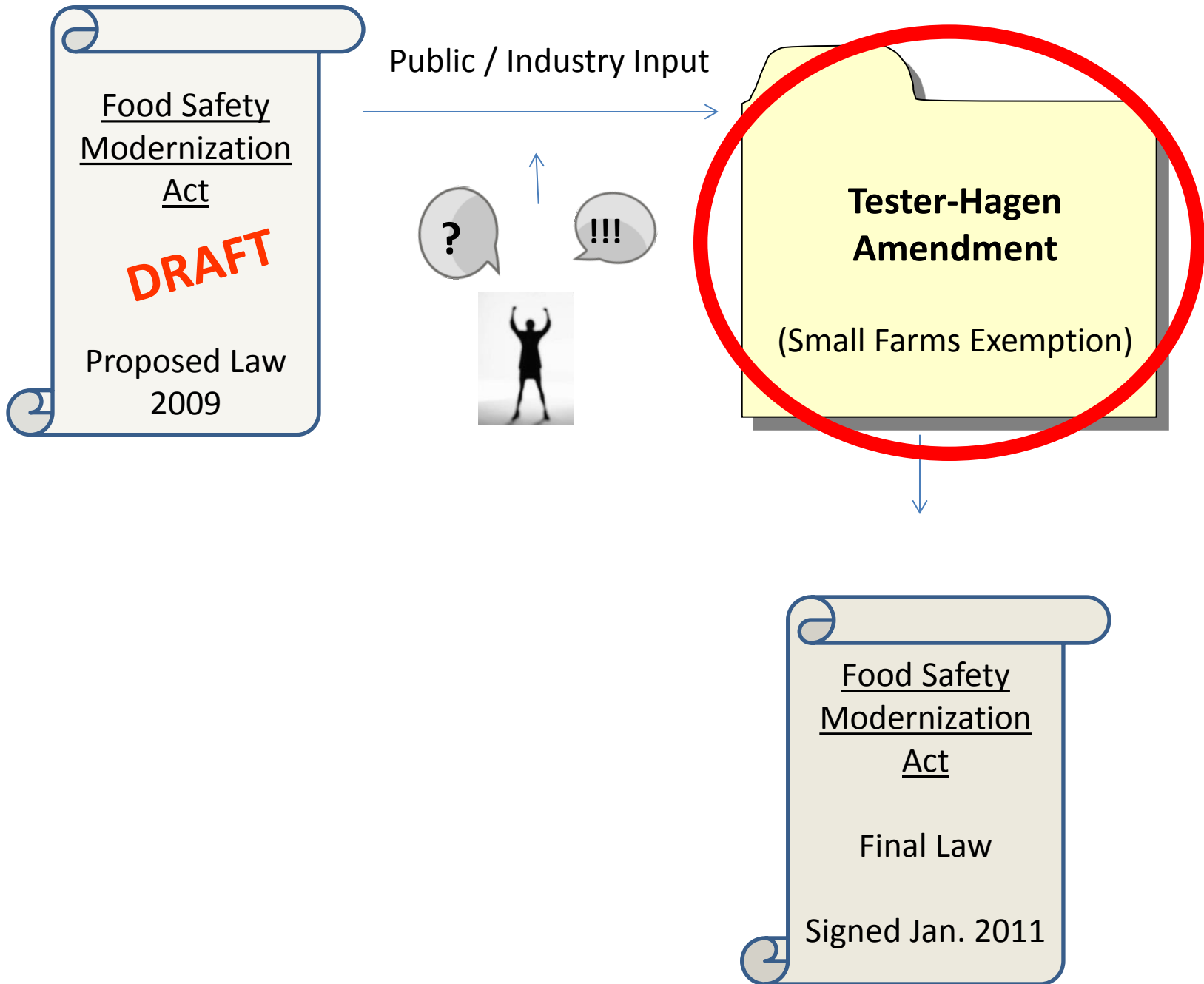
Assistance & Noncompliance

- ❖ 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





Questions?

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