

# FOOD SAFETY MODERNIZATION ACT: A BRIEF REVIEW

GCAD Town Meeting  
January 29, 2014

Diane Wright Hirsch, MPH, RD  
Extension Educator/Food Safety

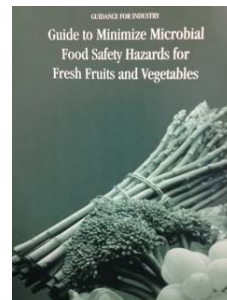


## First came Federal Guidance: GAP

2

Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (Good Agricultural Practices or GAP), 1998

- ▣ Soil and previous land use
- ▣ Water sources and use
- ▣ Manure and municipal biosolids
- ▣ Worker health and hygiene
- ▣ Sanitary facilities (toilets, handwashing, sewage)
- ▣ Field sanitation and harvest practices
- ▣ Packing house sanitation and practices
- ▣ Transportation
- ▣ Traceback and recall programs



## FSMA Rule

3

- GAP was voluntary
- Outbreaks kept happening...and both consumers and industry are looking for more food safety controls
- So FSMA was introduced, passed and signed into law January 2011



## FSMA Rule

4

**The FSMA Rule was signed into law on January 4, 2011.**

### **Title I – Improving Capacity to Prevent Food Safety Problems**

- Registration of food facilities
- Hazard analysis and risk-based preventive controls
- Standards for produce safety
- Protection against intentional adulteration (applies to farms that produce dairy products)
- National agriculture and food defense strategy
- Transportation of food
- Requirement for guidance relating to post-harvest processing of raw oysters

## FSMA Rule

5

### **Title II – Improving Capacity to Detect and Respond to Food Safety Problems**

- Addresses inspection, tracking, tracing food, record keeping, mandatory recall authority
- Surveillance, Improving the reportable food registry
- Improving the training of state, local, territorial, and tribal food safety officials

### **Title III – Improving the Safety of Imported Food**

### **Title IV – Miscellaneous Provisions**

## Produce Safety Rule

6

## FSMA Produce Rule

7

- Establishes science-based standards for the **safe growing, harvesting, packing, and holding of produce in its raw or natural (unprocessed) state on farms.**
- It would **not apply** to raw agricultural commodities that are **rarely consumed raw**, and what is **destined for commercial processing**, such as canning.

## FSMA Produce Rule

8

### Exemptions (related to Tester amendment)

- The **smallest farms** with an average annual value of food sold during the previous three-year period of **\$25,000** or less—would not be covered.
- **Farms that meet two requirements (“qualified exemption”)**
  - First, they must have **food sales averaging less than \$500,000** per year during the last three years (adjusted for inflation).
  - Second, their **sales to qualified end-users must exceed their sales to others** during the same period.
    - A qualified end-user is either a **consumer (in any location) or a restaurant or retail food establishment** located in the same State as the farm or not more than 275 miles away from the farm.

## FSMA Produce Rule

9

### Like GAP, the Produce Rule addresses:

- Worker health and hygiene
- Equipment, tools, buildings and sanitation
- Domestic and wild animals
- **Agricultural water**
- **Biological soil amendments of animal/human origin**
- Traceback and recall programs

## FSMA Produce Rule

10

- **Agricultural water** must be **safe** and of adequate sanitary quality for its ***intended use***
- **Agricultural water must be tested.**
  - Identifies **testing frequency** for non-municipal agricultural water
    - **Well water** must be tested at the beginning of the season and every 3 months thereafter.
    - **Surface water** must be tested every **7 days**
- **Standards are defined** in the rule

## FSMA Produce Rule

11

### Biological Soil Amendments of Animal/Human Origin

- If untreated amendments (amendments that are not **composted** to standards) are applied in a way that they are likely to touch covered produce
  - **They must be applied 9 mos before harvest.**
- If applied in a way that they do not touch covered produce – untreated amendments may be applied 0 days before harvest.
- Treated soil amendments of animal origins may be applied **45 days before harvest**

## FSMA Produce Rule

12

### Records

Records must be kept to show that you are in compliance with all rules

## FSMA Produce Rule

13

### Compliance dates for produce rule

- **Less than \$250,000** of total food sales/yr averaged over 3 years → You will have **4 yrs** to come into compliance, **6 for some water requirements**
- **Less than \$500,000** of total food sales/yr averaged over 3 years – > You will have **3 yrs** to come into compliance, **5 for some water requirements**
- **Everyone else** – You will have **2 yrs** to come into compliance, 4 for some water requirements

## FSMA Produce Rule

### FSMA vs GAP

	GAP	FSMA
Guidance vs Regulatory	Guidance	Regulatory
Requirements/Exemptions	Customers decide if you must comply	FSMA identifies who is exempt from rules; if an outbreak occurs, you may lose exemption status
Inspections/audits	Audits required; at least 2 per year, one unannounced	Inspections will be based on risk—most risky, every 3 years, less risky, every 5
Costs to farmer: Inspections/audits	Audit fees based on minimum plus hourly for time spent by auditor—may include travel time	No fees for initial inspection, possibly for reinspection if inspection is failed.
Food safety plan	Required	Not required
Practice standards	Defined in audit standard; customer demand	Defined by rule

14

## FSMA Produce Rule



### FSMA vs GAP

- Having a GAP program does not exempt you from FSMA, though FDA may consider a (passed) audit in lieu of inspection
- Being regulated by FSMA does not mean that you will not have to participate in GAP (if your customer wants it)

## GAP/FSMA and USDA/AMS?

16

- **The USDA Agricultural Marketing Service provides an auditing program/service to farmers**
- **It is NOT the food safety regulatory authority for produce**
  - USDA auditors provide audits
  - A list of farms that have passed the audit appears on the USDA/AMS web site

*This is in essence a marketing program—marketing food safety*

(Other third party auditors provide GAP audits as well)



# Preventive Controls Rule

17

## FSMA Preventive Controls Rule

18

**Who is covered?**

- Facilities that manufacture, process, pack or hold human food
- Generally applies to facilities that must register with FDA under current food facility registration regulations
  - Manufacturers
  - Processors
  - Warehouses
  - Storage tanks
  - Grain elevators
- **NOT FARMS...unless**

## FSMA Preventive Controls Rule

19

### ...You are a Farm “Mixed-Type Facility”

- Do you **manufacture, process, pack or hold food** that is not grown, raised or consumed on any farm you own?
  
- Do you **manufacturer or process** any food produced on your farm (or another farm that you own) that is **not consumed on any farm you own?**

## FSMA Preventive Controls Rule

20

### Exemptions

- If you are a **small/very small business**
  - ▣ Small business: employ fewer than 500 persons
  - ▣ Three options are being proposed for the definition of very small business: less than \$250,000, less than \$500,000 or less than \$1 million
  
- **And** you engage in certain **on-farm low-risk manufacturing/processing** activities

## FSMA Preventive Controls Rule

21

- **Examples of on-farm low-risk manufacturing/processing**
  - Making jams, jellies, preserves from acidic fruits
  - Making maple syrup
  - Shelling nuts
  - Artificial ripening of intact fruits and vegetables
  - Cooling intact fruits and vegetables with air
  - Drying/dehydrating intact fruits and vegetables
  - Labeling/stickering intact fruits and vegetables
  - Shelling/hulling intact fruits and vegetables (e.g., dried beans and peas)

## FSMA Preventive Controls Rule

22

### Exemptions

- If you fit the definition of “**Qualified Facility**”, you are subject to **modified requirements**
  - A very small business
  - A facility that on average over the previous three years has less than \$500,000 in annual value of food sold AND the majority of the food is sold directly to “qualified end users” (consumers in any location or a restaurant or retail food establishment in the same state or within 275 miles of your farm)
- **Modified requirements** – submit certain documentation and provide complete business address