



## Produce Safety and FSMA (Food Safety Modernization Act)

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## FDA Food Safety Modernization Act & Proposed Produce Safety Rule

- Signed into law January 4, 2011
- Draft released January 4, 2013
- Produce Safety regulation one of six major preventive control areas
- Focus on the growing, harvesting, post-harvest handling (e.g., washing, grading) of fresh produce
- Prevention, not detection of issues




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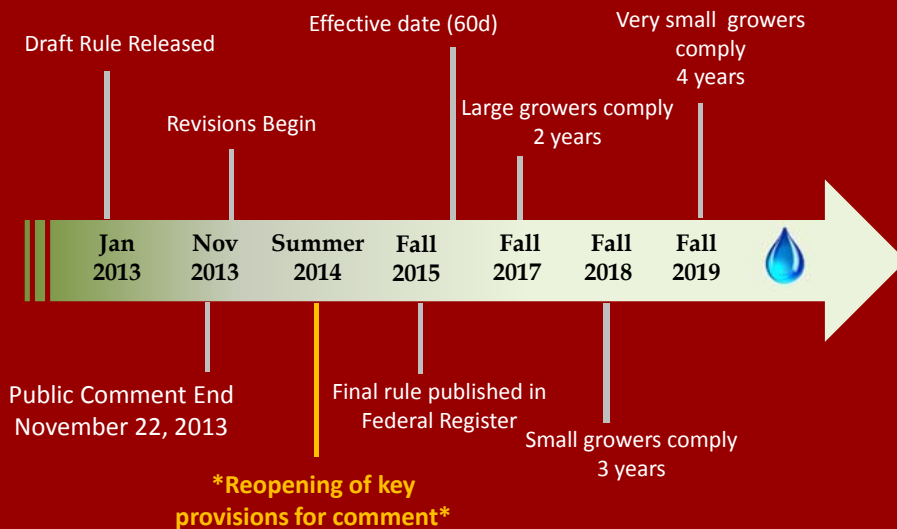
## FSMA Produce Rule: Areas of Focus

- Agricultural water
- Biological soil amendments
- Domesticated and wild animals
- Personnel qualifications, training, and health and hygiene
- Equipment, tools, buildings, and sanitation



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## FSMA Time Frame...in Theory!





## Proposed Exemptions

- Produce rarely consumed raw
- Produce destined for “kill-step” processing
- Produce for personal/on-farm consumption
- Make <\$25,000 in all food sales (3 year average)
- **FDA Resource**
  - **Produce Safety: Does this Rule Apply to You?**



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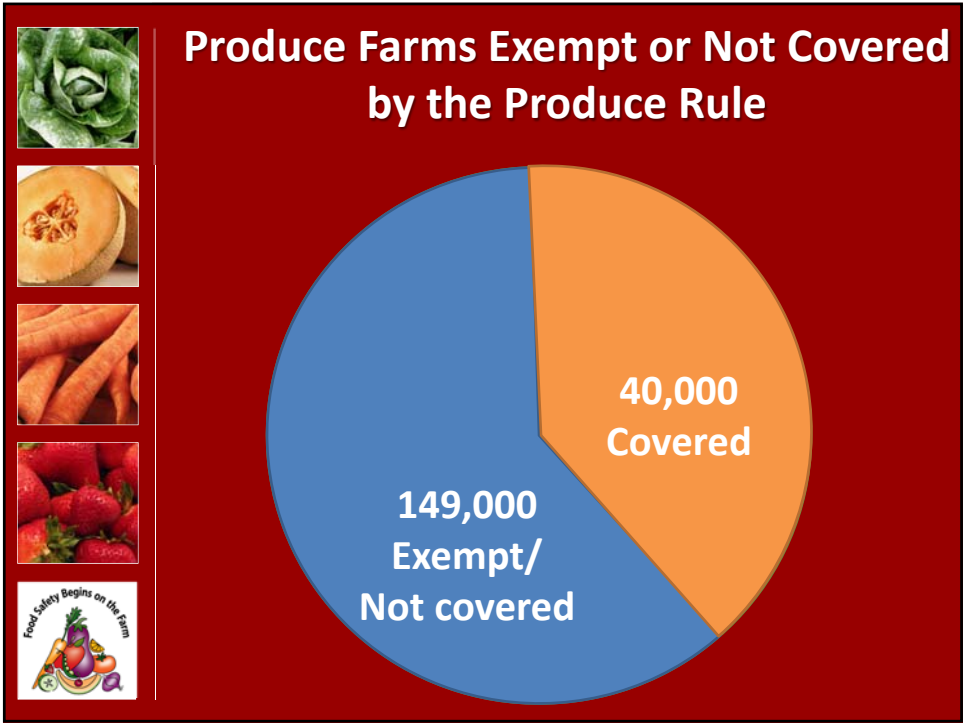


## Proposed Exemptions

- **Farms may be exempt if they:**
  - Average gross sales of food sold in previous 3 years is <\$500,000  
AND
  - Sell to qualified end users either\*:
    - A. Direct to consumer
    - B. Restaurant, retail food establishment in same state or within 275 miles of where produce was grown



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## Growers may be exempt from the regulation, but not from the market place.

The slide features three photographs of produce in a market setting. The top-left photo shows a man in a white shirt and dark pants standing in an aisle of a grocery store, looking at produce. The bottom-left photo shows a display of various fresh vegetables in wooden crates. The bottom-right photo shows a refrigerated produce display case filled with various fruits and vegetables. The same vertical column of five images from the first slide is positioned on the left side of this slide. At the bottom center, there is the Cornell University logo and the text 'Cornell University Department of Food Science'.



## Things in the Produce Rule that may be Tough for Growers

- Weekly water testing
  - Access to qualified labs
  - Cost, usefulness, etc.
  - Accepted and effective in-field treatments
- Increase in manure application timetable
  - Manure holding
  - Expense of setting up compost



## More Challenges

- Advancing to Preventive Control Rule
  - Handling/buying others' produce
  - Normal harvest procedures counting as processing
  - Understanding when you are and are not subject to a new rule (can you switch back?)



## Postharvest Challenges

- Lack of sanitary design in equipment
- Lack of infrastructure
  - Water, drains, appropriate flooring
- Lack of understanding of GMP requirements
  - Fresh produce operations have been exempt
  - Difference between cleaning and sanitizing
  - Access to appropriate chemicals
    - Detergents, sanitizers
    - Volumes

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## Produce Safety Market Issues

- Still many different requirements in market
  - Some not even applicable, but demanded
  - Audit fatigue
- Lack of streamlining or consistency
- Lots of requirements and little data to show reduction in risks
  - What reduction in risk are we expecting?
  - Way to analyze to prioritize which practices are key?
    - Really important when time, money, and people are limited!

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## Things I Think are Worth Discussing

- What is the acceptable risk for consuming produce raw?
  - Zero is unachievable
  - This question impacts standards
  - Move to consumer education to cook?
- How do we factor in risk vs. benefit
  - Impact on cost and availability
  - Impact on cancer risk profile
  - Impact on obesity



## Farm Bill Considerations

- Sec. 7209: High priority research/ext. initiatives
- Sec. 10010: Specialty crop block grants
- Sec. 11022: Research and development priorities
- Sec. 12311: Scientific and economic analysis of the FDA FSMA
- Sec. 12201: Outreach for socially disadvantaged farmers, rangers, and veterans



## Produce Safety Alliance

- Cooperative agreement between Cornell University, FDA, and USDA
- Focused on outreach and education to assist growers with meeting regulatory and market food safety requirements



## Primary Goals



- Education and outreach to improve understanding and implementation of Good Agricultural Practices (GAPs) and co-management strategies
  - Growers, Regulatory Personnel, others
- Developing a standardized training and education program to assist with the implementation of FDA's requisite produce safety regulation



## Curriculum Development Process



- 10 WCs, 72 calls
- 178 Unique WC Members
- 549 Total WC Members



- 8 Nationwide grower focus groups

### Identify GAPS Challenges

Complete: May 2012

### Set Goals

Complete: June 2012

### Develop Learning Objectives

Complete: Dec 2012

Create Content

Current Focus



## Produce Safety Alliance Curriculum Goals

Our aim is to build seven hours of dedicated instruction including six modules:

- Worker Health, Hygiene, and Training
- Water
- Soil Amendments
- Wildlife and Domestic Animals
- Facilities, Equipment, and Tools
- How to Develop a Farm Food Safety Plan



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## The PSA Website

<http://producesafetyalliance.cornell.edu/>

- Provides a way to join and be involved with the PSA
- All progress, updates, and outcomes are available.
- Easy way to reach us!
- Easy way for us to share information with you!



## PSA-FDA Produce Rule Question and Answer Calls



- Mar 18: Understanding Exemptions : 136 callers
- Mar 25: Agricultural Water: 157 callers
- Apr 22: Soil Amendments: 115 callers
- May 3: Wildlife and Domestic Animals: 71 callers
- May 6: Growing, Harvesting, Packing, & Holding Activ.: 69 callers
- May 8: Equipment, Tools, Buildings, & Sanitation: 49 callers
- May 10: Health, Hygiene, & Training of Workers: 35 callers
- May 13: Recordkeeping, Compliance, & Enforcement: 86 callers

**Total participants: 718**



**Thank you for your attention!**

**Questions?**

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