Are you in or out? Overview of new regulations and who they apply to

Faith Critzer
Food Safety Assistant Professor
Food Safety Modernization Act (FSMA)

- Most sweeping reform of our food safety laws in more than 70 years
- Signed into law by President Obama on January 4, 2011
- Aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it
FSMA Regulations

- Produce Safety
- Preventative Controls for Human Food
- Foreign Supplier Verification
- Accredited Third-Party Certification
- Preventative Controls for Animal Food
The Process

Proposed Regulations Released

Comment Period

Final Regulation Released

Proposed Regulations V2

Comment Period
Part 112: Standards For The Growing, Harvesting, Packing, And Holding Of Produce For Human Consumption AKA Produce Safety Rule

http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm
Breakdown of the Proposed Produce Safety Rule

- Subpart A- General provisions
- Subpart B- General requirements
- Subpart C- Personnel qualifications and training
- Subpart D- Worker health and hygiene
- Subpart E- Agricultural water
- Subpart F- Biological soil amendments of animal origin and human waste
- Subpart I- Domesticated and wild animals
Who’s In?

- Farms that grow, harvest, pack or hold most produce in raw or natural state (raw agricultural commodities)
- Farms and mixed-type facilities
- Domestic and imported produce
- Farms with annual sales of produce $>25,000 per year
  - Previous 3 yr period
What is produce?

- “Produce” defined as fruits and vegetables
- Produce includes mushrooms, sprouts, herbs and tree nuts
  - Section 112.1- list that is not exhaustive
- Produce does not include grains
- Some limitations on covered produce
What/Who’s Not Covered

- Produce for personal or on-farm consumption
- Produce that is not a Raw Agricultural Commodity
  - Bagged salads
- Certain produce rarely consumed raw
  - Section 112.2- list is exhaustive
- Produce that will receive commercial processing
- Farms with less than or equal to $25,000 in produce sales (3 yr)
Produce Rarely Consumed

Raw

- Asparagus
- Beans/Peas/Pulses
  - Black, Chickpeas, Great Northern, Kidney, Lentil, Lima, Navy, and Pinto
- Garden beets (roots and tops) and sugar beets
- Nuts
  - Cashews, Peanuts, Pecans, Hazelnuts
- Sour cherries
- Cocoa beans
- Coffee beans
- Collards
- Sweet corn
- Cranberries
- Dates
Produce Rarely Consumed Raw

- Dill (seeds and weed)
- Eggplants
- Figs
- Horseradish
- Okra
- Peppermint
- Potatoes
- Pumpkins
- Winter squash
- Sweet potatoes
- Water chestnuts
Who’s Not Covered

- Qualified exemptions and modified requirements (Tester-Hagan Amendment)
- Must meet all three requirements
  - <$500,000 in sales of all foods (not just produce)
  - >50% in sales to qualified end-users
  - In same state or 275 miles
    - Qualified end user - direct to business (restaurant, farmers market, retail store)
    - Distribution center NOT a qualified end-user
Standards for Produce Safety

Focus on routes of microbial contamination
- Worker health and hygiene
- Agricultural water
- Biological soil amendments of animal origin
- Domesticated and wild animals
# Compliance Dates

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## Compliance Dates - Qualified Exemption

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Resources to Learn More

- FDA Produce Safety
  - [http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm304045.htm](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm304045.htm)

- Produce Safety Alliance
  - [http://producesafetyalliance.cornell.edu](http://producesafetyalliance.cornell.edu)

- University of Tennessee Fruit and Vegetable Food Safety
  - [http://vegetables.tennessee.edu/food_safety.html](http://vegetables.tennessee.edu/food_safety.html)
Part 117: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventative Controls for Human Food AKA Preventative Controls

- http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm
Breakdown of the Preventative Controls Rule

- Subpart A - General provisions
- Subpart B - Current Good Manufacturing Practice
- Subpart C - Hazard Analysis and Risk-based Preventative Controls
- Subpart D - Modified Requirements
- Subpart E - Withdrawal of an Exemption Applicable to a Qualified Facility
- Subpart F - Requirements Applying to Records that Must be Established and Maintained
Who’s In?

- Facilities that manufacture, process, pack or hold human food
  - Food facility registration (sec. 415 of the Food Drug & Cosmetic Act) - you’re in unless exempt
- Domestic and Imports
Who’s Out?

- Tester amendment
- Very small business exemption ($1 mil in sales)
- Low-acid canned foods - for microbiological risks only
- Dietary supplements
- Alcoholic beverages
- Foods already subject to HACCP - seafood and juice
- Facilities that store raw agricultural commodities
What’s the big change?

- Good Manufacturing Practices (cGMPs)
- Updates cGMPs
- Protection against allergen cross-contact
- Updated language
What’s the big change?

- Requirements for Hazard Analysis and Risk-based preventative controls
  - Written Food Safety Plan
    1) Hazard Analysis
    2) Preventative Controls
    3) Monitoring Procedures
    4) Corrective Actions
    5) Verification Procedures
    6) Recall Plan
  - Updated at least every 3 yrs
# Compliance Dates

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<th>Category</th>
<th>2015</th>
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<td>All others</td>
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Resources to Learn More

- FDA Preventative Controls
  - [http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm#Compliance_Dates](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm#Compliance_Dates)

- Food Safety Preventative Controls Alliance
  - [http://www.iit.edu/ifsh/alliance/](http://www.iit.edu/ifsh/alliance/)

- University of Tennessee Food Science
  - [tiny.utk.edu/FST-EXT](http://tiny.utk.edu/FST-EXT)
Questions?