

Food Safety Modernization Act (FSMA)

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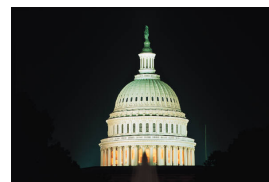
Chestnut Growers of America Conference June 13, 2015

Thanks to Michelle D. Danyluk, University of Florida for sharing her slides

FSMA update

June 13, 2015

- Overview
- Produce Safety Rule
 - Produce Safety Alliance
- Preventive Controls Rule
 - Food Safety Preventive Controls Alliance



**FDA FOOD SAFETY
MODERNIZATION ACT**

What is the New Law?



- Food Safety Modernization Act (FSMA)
- Effective Jan 4, 2011
- Biggest change in food safety regulation since 1938
 - Federal Food Drug & Cosmetic Act

**FDA FOOD SAFETY
MODERNIZATION ACT**

What's so Historic About the Law?

- Involves development of a new food safety system
- Broad prevention mandate and accountability
- New system of import oversight
- Emphasizes partnerships
- Emphasizes farm-to-table responsibility
- Developed through broad coalition

Laws vs. Regulations

- Laws
 - Enacted by Congress and signed by Chief Executive

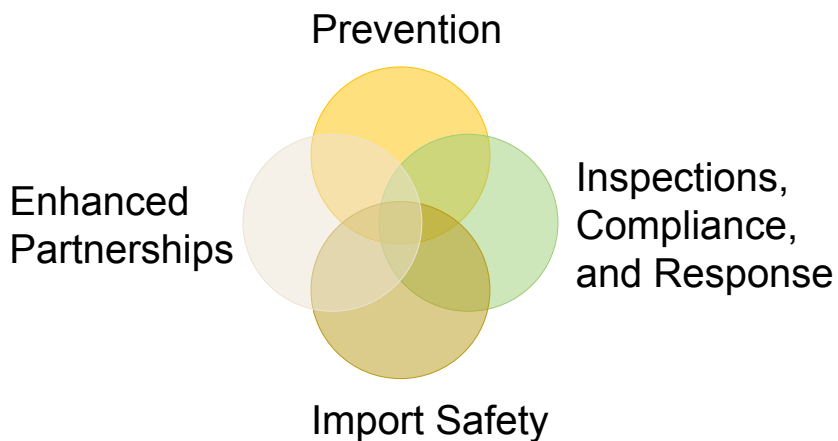


Laws vs. Regulations

- Regulations
 - Developed by Agencies to fulfill those laws
 - Substantive
 - Final Rules – Have Power of Law
 - Use Term “Shall”
 - E.g., Juice HACCP: 21 CFR §120
 - Advisory
 - Recommendations representing current thinking on Agency’s part
 - Guidance
 - Use Term “Should”
 - E.g., Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables
 - Reports
 - Provide information to constituents, in many cases to assist in understanding and fulfilling the letter and spirit of the law



Four Main Themes of FSMA



Inspection, Compliance and Response

- Mandated inspection frequency
 - Prescribed depending on risk

- New tools for FDA
 - Mandatory recall
 - Expanded records access
 - Expanded administrative detention
 - Suspension of registration
 - Enhanced product tracing
 - 3rd party testing



New Food Safety Regulations

- Produce Safety Rule
- Preventive Controls for Human Food Rule
- Foreign Supplier Verification Rule
- Preventive Controls for Animal Food Rule
- Sanitary Transport Rule
- Intentional Adulteration
- Accreditation for 3rd Party Auditors

New Food Safety Regulations

- Produce Safety Rule ← Growers
- Preventive Controls for Human Food Rule
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Packers who pack on the farm
Packers who pack off the farm



THE PRODUCE SAFETY RULE



Produce Safety Rule

- Proposed rule released January 2013
- >15,000 initial comments received
- Supplemental rule released September 2014

- 35,503 covered farms (est.)



Produce Safety Rule

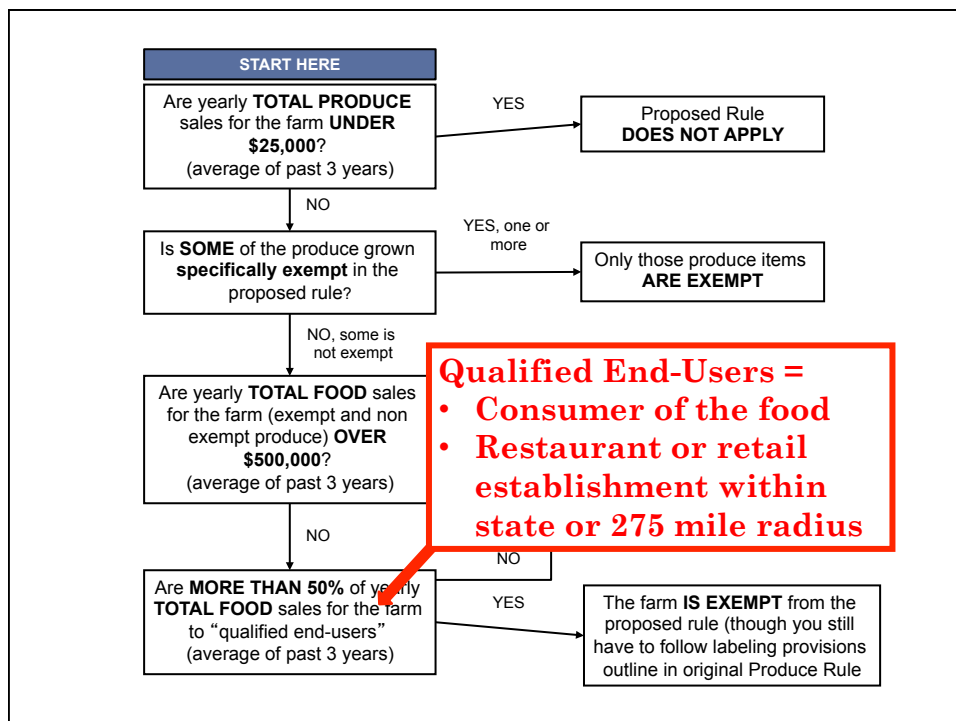
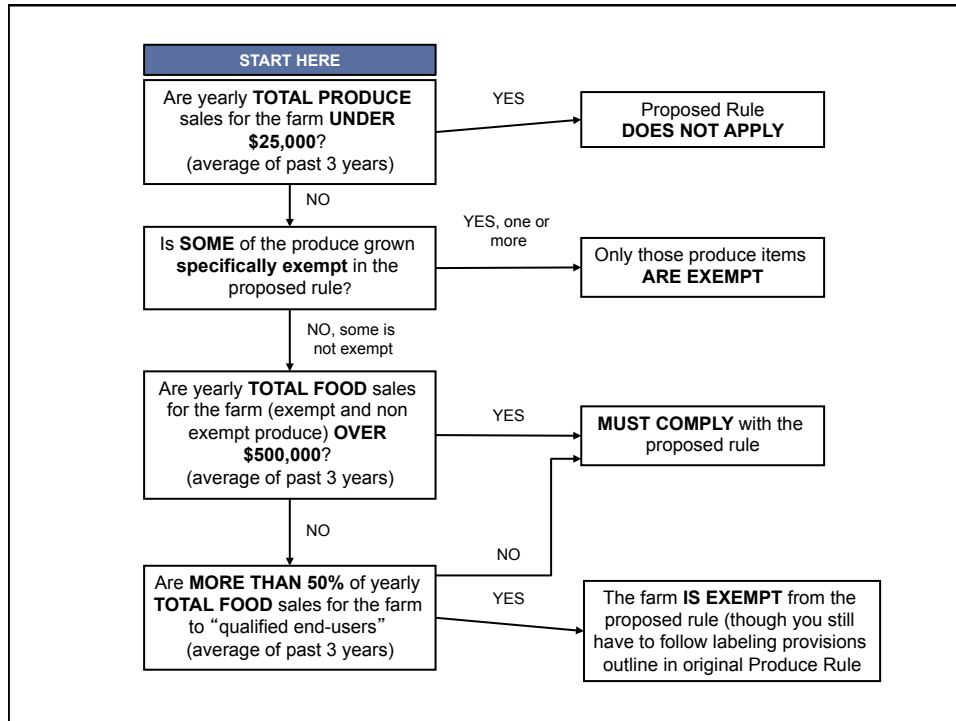
- Science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms.
- New standards in the following major areas:
 - Worker Training and Health and Hygiene
 - Agricultural Water
 - Biological Soil Amendments of Animal Origin
 - Domesticated and Wild Animals
 - Equipment, Tools, and Buildings



Who is covered?

- Farms that grow, harvest, pack or hold certain types of produce unless...
 - Less than \$25,000 in sales of total produce OR
 - Small or very small farms (food sales <\$500,000) who sell directly to qualified end users
 - Consumers (any location)
 - Restaurants/retail
 - In-state or within 275 miles
- Even if exempt
- Packaging or point-of-sale labeling required
 - Name and address of business








What is/is not covered?

- Covered
 - Domestic and imported produce
 - Raw agricultural commodities, including fruits, vegetables, mushrooms, tree nuts, sprouts and mixes of intact fruits and vegetables:
 - the harvestable portion (including peels/shells)
- Not covered
 - List “rarely consumed raw”
 - Produce that is commercially processed
 - Must have records of who processed it




What is/is not covered?


- Covered
 - Domestic and imported produce
 - Raw agricultural commodities, including fruits, vegetables, mushrooms, tree nuts, sprouts and mixes of intact fruits and vegetables:
 - the harvestable portion (including peels/shells) but not
- If you sell 100% of your product for further processing (i.e. juice, jam/jelly, canning, etc.) you fall under “commercially processed” exemption**
- Produce that is commercially processed
 - Must have records of who processed it



Exempt Produce

Rarely Consumed Raw

Arrowhead	Crab apples	Parsnips	Sweet potatoes
Arrowfruit	Cranberries	Peanuts	Taro
Artichokes	Eggplant	Pinto beans	Turnips
Asparagus	Figs	Plantains	Water chestnuts
Beets	Ginger root	Potatoes	Winter squash (acorn & butternut)
Black-eyed peas	Kale	Pumpkin	Yams
Bok choy	Kidney beans	Rhubarb	
Brussels sprouts	Lentils	Rutabaga	
Chick-peas	Lima beans	Sugar beet	
Collard greens	Okra	Sweet corn	



Approach

- “Risk based” approach that looks at “high risk” practices not “high risk” commodities
 - Allows for different practices
 - Recognizes further processes and rarely consumed raw
 - Recognizes not all water or soil amendments are the same
 - No prescriptive requirements for uncontrollable factors (i.e., wildlife)



Worker training

- All personnel handling produce or food-contact surfaces or supervising those who do
 - food hygiene and food safety
 - health and personal hygiene
 - FSMA standards relevant to job
- Harvesters need additional training
 - Recognizing contamination
 - Inspecting containers and equipment
 - Corrective actions
- Supervisors (at least one farm rep)
 - Standardized PSA curriculum



Worker health & hygiene

- Reassignment of ill workers
- Personal cleanliness
- Avoid animal contact
- Hand washing
- Visitor policy



Agricultural water

- Agricultural water is defined in part as water that is intended to, or likely to, contact the harvestable portion of covered produce or food-contact surfaces
- Preharvest
 - irrigation water directly applied
 - preparing crop sprays
- Harvest/Postharvest (harvesting/packing/holding)
 - Washing or cooling produce
 - Preventing dehydration



Testing agricultural water

- Inspect entire water system “under your control” (source, distribution system, facilities and equipment).
- Water Quality Profile
 - Untreated surface water
 - Minimum 20 samples over minimum 2 years
 - *E. coli* levels in 100 ml
 - Calculate Geometric Mean and
 - Statistical Threshold Value
 - Calculation tools will be available

Biological soil amendments of animal origin

- Concerns material that
 - Contacts covered produce
 - Contacts produce contact surfaces
 - Potentially contaminates agricultural water

Biological soil amendments of animal origin

Further guidance expected

- Raw manure*
 - To be further studied...
 - 90/120 NOP standard
- Treated
 - Physical/chemical process (validated)
 - Composting (prescribed conditions)
 - No time interval, BUT:
 - Must meet microbial standard



Domesticated and wild animals

- Domestic/Working Animals
 - “Adequate waiting period” after allowing animals to graze
 - “Measures to prevent” if animals allowed where crop is planted
- Wild Animal Intrusion
 - “Must monitor” during season, and immediately prior to harvest
 - If intrusion occurs, evaluate whether to harvest or not



Equipment, tools, and buildings

- Likely to contact covered produce:
 - Knives, implements, containers, bins, packing material, dump tanks, flumes and other equipment used for transport, harvesting, waxing, cooling, packing, etc.
- Any full or partial enclosure used for covered activities or storage of food-contact surfaces



Equipment, tools, and buildings

- Design must allow adequate cleaning and maintenance
- Storage should prevent contamination and harborage of pests
- Clean and sanitize as necessary
- Adequate drainage of discharge in and near buildings
- Restrooms & hand washing facilities



What is expected?

- Preventive controls
- Documentation!
 - Worker training, health, and hygiene
 - Agricultural water
 - Biological soil amendments of animal origin
 - Domesticated and wild animals
 - Equipment, tools, and buildings



THE PREVENTIVE CONTROLS RULE

This section is truncated because it was not covered in the presentation.



New Food Safety Regulations

- Produce Safety Rule   Growers
Packers who pack on the farm
- Preventive Controls for Human Food Rule  Packers who pack off the farm
- Foreign Supplier Verification Rule
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- Sanitary Transport Rule

Preventive Controls Rule

- Modernize
 - Current Good Manufacturing Practices Regulation
- Add
 - Requirements to establish and implement hazard analysis and risk-based preventive controls for human food

Modernization of cGMPs

- Modernizes Current Good Manufacturing Practices (cGMP) regulations
- Replaces 21 CFR part 110, current GMPs with 21 CFR part 117
- Includes almost everything currently in part 110
- Adds prevention of “cross-contact” and other allergen controls

Preventive Controls Rule

- Each covered facility to prepare and implement a written food safety plan, which would include the following:
 - Hazard Analysis;
 - Risk based Preventive Controls;
 - Monitoring procedures;
 - Corrective actions;
 - Verification; and
 - Recordkeeping

Key requirements of a food safety plan

- Owner, operator or agent in charge of the facility must prepare, or have prepared and implement a written Food Safety Plan
- Required to sign and date upon completion and any modification
- Must be a qualified individual or overseen by a Qualified Individual

Who is a Qualified Individual?

- Successfully completed training in the development and application of risk based preventive controls
 - Training recognized by FDA
 - E.G. FSPCA is currently in the process of developing the standardized training curriculum
 - Training must be documented


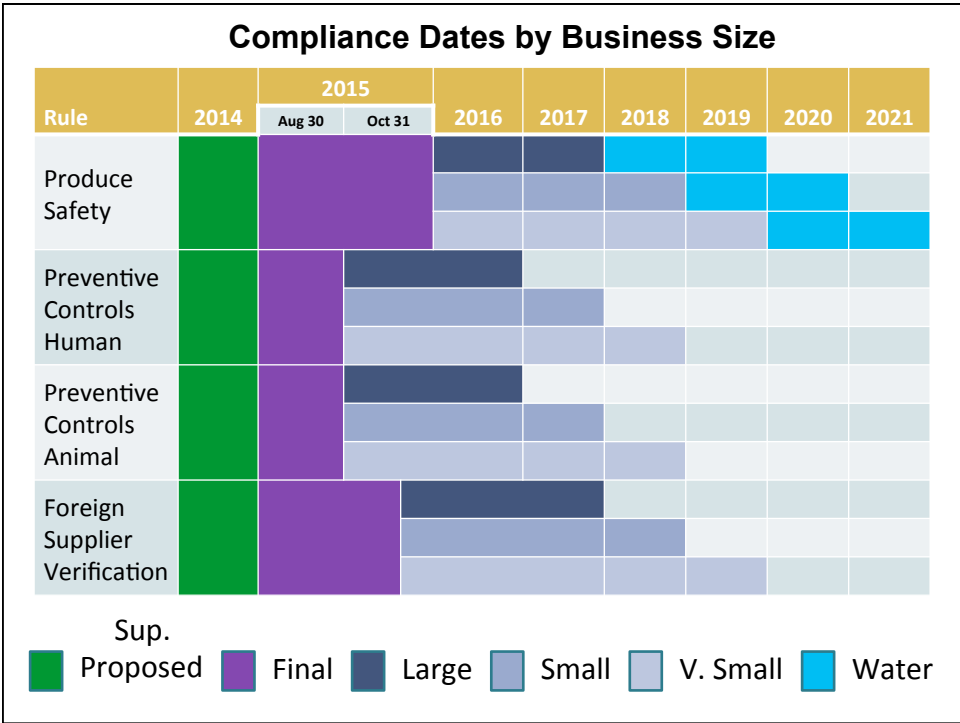
- Or qualified through job experience to develop and apply a food safety system

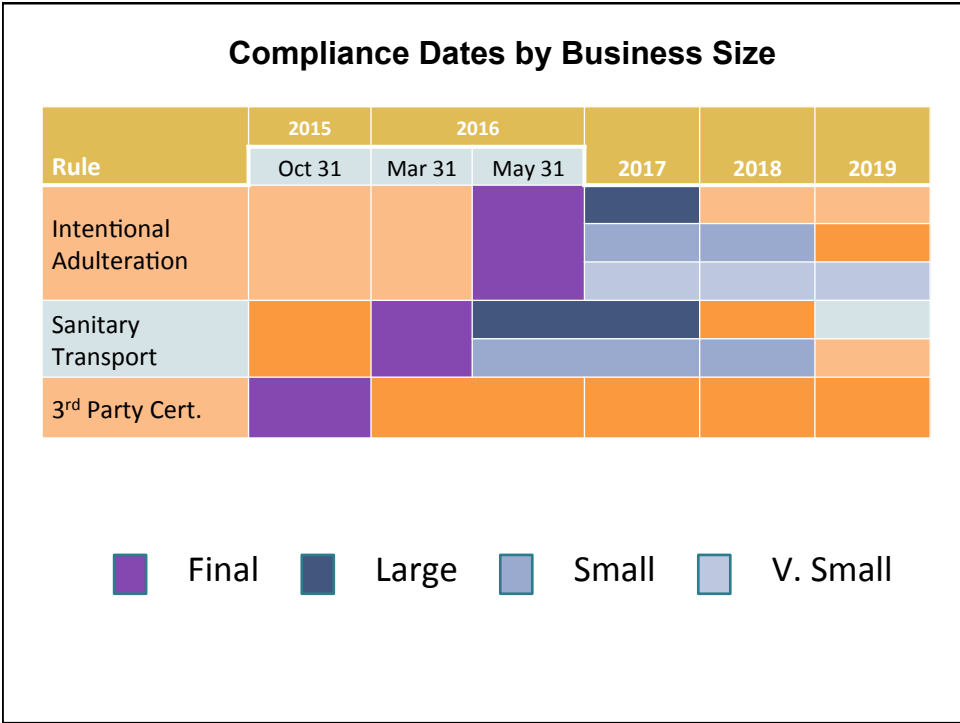
Qualified Individual Responsibilities

- Validation of Preventive Controls
- Review of records for implementation & effectiveness of PCs and appropriateness of corrective actions
- Reanalysis of Food Safety Plan

Summary

- The Produce Safety Rule is basically a formalized GAPS program, similar to the LGMA and T-GAPs
- The Preventive Controls Rule is similar to a HACCP-based system



Training


- Standardized curriculum to become “qualified individual” – available AFTER final rule
- Produce Safety Alliance:
 - 2 day workshop
 - <http://producesafetyalliance.cornell.edu/>
- Food Safety Preventive Controls Alliance:
 - 2.5 day workshop
 - <http://www.iit.edu/ifsh/alliance/>



Curriculum

- Preventive Controls
 - Worker health, hygiene, and training
 - Soil Amendments
 - Wildlife and domestic animals
 - Production water
 - Postharvest water
- Farm food safety plan

<http://producesafetyalliance.cornell.edu>




FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Curriculum

- HARPC-based food safety plan
 - GMPs and other prerequisite programs
 - Hazards
 - Hazard analysis
 - Food allergen PC
 - Sanitation PC
 - Supplier program
 - Recall plan
 - Verification and validation
 - Recordkeeping
 - Regulation overview

<http://www.iit.edu/ifsh/alliance/>



Resources

- FDA's FSMA Website
 - <http://www.fda.gov/fsma>
- Trade Associations for Produce
 - Produce Marketing Association:
<http://www.pma.com/resources/hot-topics/food-safety-modernization-act>
 - United Fresh:
http://www.unitedfresh.org/newsviews/food_safety_resource_center/food_safety_modernization_act_implementation
 - Institute for Food Technologists:
<http://www.ift.org/public-policy-and-regulations/fsma/>
- Ucfoodsafety
 - <http://ucfoodsafety.ucdavis.edu>