

OVERVIEW

FOOD SAFETY MODERNIZATION ACT

FSMA



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for Training, Education, Extension, Outreach, and
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What is FSMA?

- Food Safety Modernization Act:
FSMA
- The most sweeping reform of Food Safety Laws in over 70 years
- Signed into LAW by President Obama
 - Effective Jan 4, 2011



Why FSMA? Food Safety & Public Health

- Foodborne illness major contributing factor to morbidity and mortality in the United States and Worldwide.
- Substantial economic and public health burden
- Many zoonotic and non-zoonotic sources



Why FSMA? Other Considerations

- Globalization
 - 15% US food supply imported (75% seafood, 50% fruits, 20% vegetables)
- New hazards in foods not previously seen
- Several methods of food production, processing, storage, distribution, and service
 - Variety of foods available and demanded
 - Number of people involved in food preparation
- Changing demographics
 - Increasing number of elderly and immuno-compromised - more susceptible to foodborne pathogens
 - Growing population (~30%) is "at risk"



Why is it HISTORIC?



- Biggest change since 1938
 - Federal Food, Drug & Cosmetic Act
- Aim: Safe Food Supply
- Shifting Focus from Response (to contamination) to Prevention



Why is it HISTORIC?

- Creation 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

- Products of written statutes
- Passed by the US Congress or State Legislatures (*after creating bills that are passed by a vote*)
- Signed by Chief Executive
- Specify a responsible federal agency or agencies
- Published in US Code (USC)

REGULATIONS

- Standards and rules adopted by administrative agencies that govern how laws will be enforced
- Have the power of law and must be observed
- Published in Code of Federal Regulations (CFR)



Rule-making Process

- **Pre-rule Phase**
 - Fact finding and solicitation from experts
 - Optional Advance Notice of Proposed Rulemaking (ANPRM) in the Federal Register (FR)
- **Proposed Rule Phase**
 - Regulations in proposal form published in FR
 - Comments Period
- **Final Rule Phase**
 - Published in the FR and codified in CFR
 - Published at least 30 days before effective date
 - Have the effect of law upon the date stated

<http://www.fda.gov/food/quidanceregulation/fsma/ucm249243.htm#rulemaking>



Four Main Themes of FSMA



PREVENTION

- Mandatory Preventive Controls for Food Facilities
- Written PC plans:
 - Hazard evaluation
 - Preventive steps or controls
 - Monitoring controls
 - Record-keeping
 - Corrective actions
- Mandatory Produce Safety Standards
- Authority to Prevent Intentional Contamination

INSPECTION AND COMPLIANCE RESPONSE

INSPECTION COMPLIANCE



- Mandated Inspection Frequency
 - Based on risk
- Records Access
- Testing by Accredited Laboratories

RESPONSE



- New tools for FDA
 - Mandatory recall
 - Expanded administrative detention
 - Suspension of registration
 - Enhance product tracing
 - Additional record-keeping for high-risk foods



Four Main Themes of FSMA

IMPORT SAFETY



- Importer Accountability
 - Foreign suppliers have adequate PC
- Third-Party Certification
 - Foreign food facilities comply with US food-safety standards
- Certification for High-Risk Foods
- Voluntary Qualified Importer Program
 - Provides for expedited review and entry of imported foods
- Authority to Deny Entry
 - If FDA denied access by the facility or country



Four Main Themes of FSMA

ENHANCED PARTNERSHIPS

- Formal system of collaboration with other government agencies, domestic and foreign
- Examples of Enhanced Collaboration:
 - State and Local Capacity Building
 - Foreign Capacity Building
 - Reliance on Inspection by Other Agencies



Four Main Themes of FSMA



New Rules Under FSMA

REGULATION	PUBLISHED
Produce Safety	Nov 27, 2015
Preventive Controls for Human Food	Sep 17, 2015
Foreign Supplier Verification	Nov 27, 2015
Mitigation Strategies Against Intentional Adulteration	May 27, 2016
Preventive Controls for Animal Food	Sep 17, 2015
Sanitary Transportation of Human and Animal Food	April 6, 2016
Accredited Third-Party Certification	Nov 27, 2015





New Rules Under FSMA

- Effective 60 days after publication of final rules
- Compliance dates different based on the size of businesses/facilities
 - Refer to a specific rule



Who Needs to Pay Attention?

RULE	APPLIES TO
Produce Safety	Farms growing, harvesting, packing, and holding Produce for Human Consumption
PC for Human Food	Registered Human Food Facilities
FSVP	Importer of Food into United States
Intentional Adulteration	Registered Food Facilities
PC for Animal Food	Registered Animal Food Facilities
Accredited 3 rd Party Certification	Accreditation bodies seeking recognition by FDA, and 3 rd party certification bodies seeking accreditation
Sanitary Transportation	Shippers, loaders, carriers, and receivers involved in transport of human and animal food consumed or distributed in the US



Who Would be Affected?

- All food facilities and farms that grow, manufacture, process, pack, transport or hold food for human and animal consumption
- Different requirements depending on the size of facilities



Small Businesses

- Fewer than 500 full-time equivalent employees for all rules except PSR
- PSR - >\$250K-\$500K< annual produce sales during the previous 3 years



Very-Small Businesses

Rule	Very Small
Produce Safety	>\$25K-\$250K< average annual produce sales during the previous 3 years
PC for Human Food	<\$1 million/year (adjusted for inflation) in sales of human food + market value of human food manufactured/processed/ packed/held without sale
PC for Animal Food	<\$2.5 million in sales of animal food + market value of animal food manufactured/processed/packed/ held without sale
FSVP	<\$1 million - human food <\$2.5 million - animal food
Intentional Adulteration	Averaging <\$10,000,000, (including subsidiaries and affiliates)
Sanitary Transportation	<\$500,000 in total annual sales



Preventive Controls for Animal Food

- Apply to Domestic and Imported Animal Food
- Current Good Manufacturing Practices (CGMPs) for Animal Food Production
 - Exception: Processors already implementing human food safety requirements when supplying by-product, except to prevent physical & chemical contamination during holding and distribution
 - Further processed by-products (dry, pellets), requires compliance (company can choose).

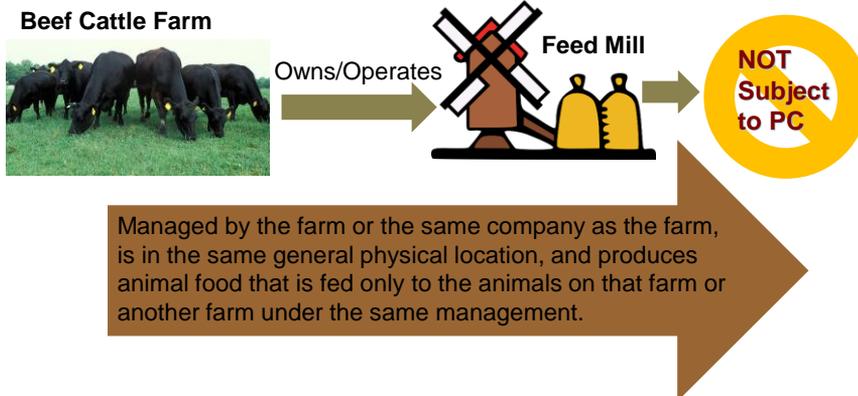


Preventive Controls for Animal Food

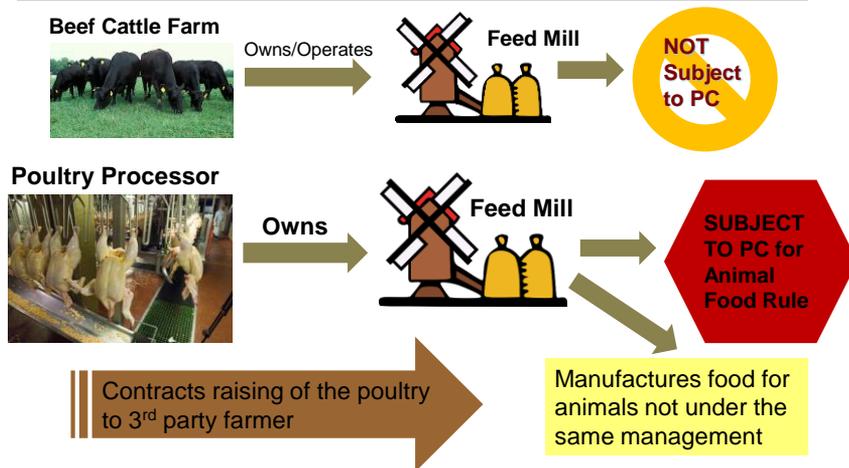
- Written Food Safety Plan to Include:
 - Hazard Analysis
 - Risk-Based Preventive Controls (PC)
 - Oversight and Management of PC
 - ✓ Monitoring and Verification
 - ✓ Corrective Actions and Corrections
 - Recall Plan



PC for Animal Food Other Features



PC for Animal Food Other Features



PC for Animal Food Compliance



BUSINESS SIZE	CGMP COMPLIANCE	PC COMPLIANCE
Other than Small and Very Small	1 Year	2 Years
Small (<500 full-time equivalent employees)	2 Years	3 Years
Very Small (< \$2.5 million/year)	3 Years	4 Years, except for record to support its status as very small (Jan 1, 2017)



Accreditation of Third-Party Auditors

- Establishes a voluntary program - Voluntary Qualified Importer Program (VQIP)
- For the accreditation of 3rd party certification bodies, aka 3rd party auditors, to conduct food safety audits and issue certifications of foreign entities and the foods for humans and animals they produce.
- Establishes requirements for.....
 - Accreditation bodies seeking recognition by the FDA - Could be a foreign government/agency or a private third party.
 - Third-party certification bodies seeking accreditation



Accreditation of Third-Party Auditors Requirements

RECOGNIZED ACCREDITATION BODIES

- Assess 3rd party certification bodies for accreditation
- Monitor performance of 3rd party certification bodies
- Submit monitoring and self-assessment reports and other notifications to the FDA

THIRD-PARTY CERTIFICATION BODIES

- Two kinds of audits: Consultative and Regulatory
- Perform unannounced facility audits and notify FDA of a condition posing serious risk to public health
- Ensure audit agents are competent and objective
- Verify effectiveness of corrective actions

- Assess and correct any problems in their own performance
- Maintain and provide the FDA access to records required to be kept under the program

Sanitary Transportation Rule

- Applicable to....
 - Shippers, receivers, loaders and carriers
 - ✓ Transport (domestic or import) human and animal food in the US
 - ✓ By motor or rail vehicle, whether or not the food is offered for or enters interstate commerce
 - ✓ By ship or air, arranged for transfer of intact container onto motor or rail

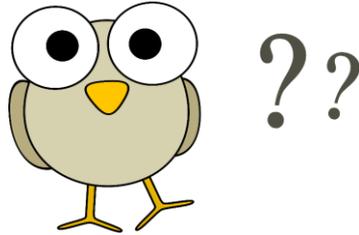


Sanitary Transportation Rule

- Written procedures required for
 - Vehicle and transportation equipment
 - ✓ Design and Maintenance
 - Transportation Operations
 - ✓ Sanitary conditions
 - ✓ Temperature control
 - ✓ Prior cargo
 - ✓ Prevention of cross-contamination
- Training and Recordkeeping



THANK YOU!!!



**QUESTIONS ARE GUARANTEED IN LIFE.....
ANSWERS AREN'T!!!**