Welcome

OnTrak with FSMA: A Webinar Series
Hosted by: ReposiTrak® and The Acheson Group
Unraveling FSMA for Distributors, Wholesalers & Retailers

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Overview

About FSMA

Rule by rule requirements
1. Produce safety
2. Preventive controls
3. FSVP
4. Food defense
5. Sanitary Transport

Questions
Today’s Challenges

- Complex & global supply chains
- Consumer demands require sourcing from around the world
- Emerging threats
  - Hazards don’t have passports
- Improving epidemiology
- Influence of media
- Litigation
- New regulations
Food Safety Modernization Act (FSMA)

- Prevention
- Enhanced Partnerships
- Import Safety
- Inspections, Compliance, and Response
About FSMA

- Written by Congress (not by FDA)
  - It is the law and will not change
- Requires FDA to do many things, include write many regulations
  - FDA must *implement* FSMA and keep to what Congress specified
## FSMA Status: “The 7 Pillars”

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But there’s more!!

- Traceability recordkeeping rules
- Voluntary qualified importer program
- Accreditation of laboratories
- Certificates required for import of “high risk” foods
- Food allergen guidance for schools
- Standardized recall notices at retail stores
- ...and more!

Plus, there are rules in effect...
So who does FSMA impact?

Everyone...

...but differently
For Distributors, Wholesalers & Retailers (D-W-R)

- Most rules apply to the FACILITY not the COMPANY

- Retailer
  - Retail stores
  - Warehouse/distribution center
  - Private label manufacturing facility
1. Produce Safety Rule
Produce Safety Rule:

Impact on D-W-R

- No impact
- Rule affects farms growing produce that will be consumed raw
  - Impacts domestic and foreign farms
- What you should know
  - FDA will be requiring farms to follow specific practices to protect produce from microbial hazards
    - Hygiene requirements
    - Water testing
    - Animal intrusion
    - Training
    - Exemptions/mods for “local” (<$500K sales, 275 miles, straight to store); < $25K produce sales
2. Preventive Controls
(human and animal)
Preventive Controls (human and animal): Impact on D-W-R

- Generally, applies to FDA registered facilities
- No impact on retail stores
- Some impact on warehouses and DCs
Is ALL food fully packaged and NOT exposed to the environment?

Yes, fully packaged, not exposed

Is temperature control required FOR SAFETY?

Yes: monitor temperature

No: nothing related to PC needed

No, some is exposed

Need to fully follow the Preventive Control rule
Food Safety Plan

Part of FSMA and FDA preventive control requirements

- Hazard Analysis
- Preventive Controls
- Documentation
- Verification
- Monitoring
- Corrective Actions

Process controls, allergen controls, supplier control, sanitation control
3. Foreign Supplier Verification Program (FSVP)
FSVP:
Impact on D-W-R

Do you import food?

No (are you sure?)

Yes

Do you rely on the supplier to control a significant hazard?
FSVP in a Nutshell

- Hazard analysis
- Determine supplier risk
- Approve suppliers
- Determine verification activities
- Identify yourself as an importer
- Need a Qualified Individual
Supplier Controls

- Used if you RELY on the supplier to control a specific hazard (identified during hazard analysis)

- Evaluate supplier risk
  - Regulatory compliance
  - History with them

- Have a supplier approval process

- Determine appropriate supplier verification activities based on risk
  - Audit
  - Testing
  - Review of food safety programs/documentation
Who is your foreign supplier?

- An establishment that grows, harvests, or manufactures/processes food (including animals) for export to the U.S.
  - Does not cover establishments that merely hold or pack food for export to the U.S. (Different from the coverage of the Preventive Controls Proposed Rule).
  
  - If you source from an overseas distributor, FDA wants you to keep going back in the supply chain to verify the actual grower/processor that is controlling the hazard
FSVP – Exemptions

- Covers all FDA regulated food with some exemptions
  - Juice and seafood from facilities that are in compliance with the Hazard Analysis & Critical Control Points (HACCP) regulations, which contain their own supplier verification provisions;
  - Food imported for research or evaluation purposes
  - Food imported for personal consumption
  - Alcoholic beverages, meat and poultry
  - Food that is transshipped or imported for further processing and export
Compliance Dates

In general, the compliance date would be 18 months after publication of the final FSVP regulations. There would be some exceptions.

- For the importation of food that is also subject to the preventive controls and produce safety rules, the importer would be required to comply with FSVP regulations six months after the foreign supplier is required to comply with preventive controls or produce safety regulations. The compliance dates for those regulations vary, depending on the rule and size of the operation.
4. Food Defense
Food Defense: Impact on D-W-R

- Applies to companies with more than $10M food sales
- Target is manufacturers
  - If you just hold food, you are exempt
  - Focus is on large scale attack, not tampering
5. Sanitary Transport
THE SLEEPER!!!
Sanitary Transport: Impact on D, W, R

A LOT

Covers ALL products including meat and poultry- not just FDA regulated products

Doesn’t matter if food is produced under HACCP

Does NOT apply if all foods are fully packaged, shelf stable

DOES apply if foods are fully packaged and require temperature control for safety or major quality (spoilage)
What is covered?

- Shippers
- Carriers
- Receivers
- One company can be the shipper, the carrier, and the receiver
- Applies to vehicles and rail cars
Key Points

- Condition and cleanliness/sanitation of the vehicle/rail car
- Specifying sanitation and temperature requirements
- Inspection prior to loading
- Temperature control - equipment and monitoring
- Sanitation - procedures, documentation, sharing information
- Hand washing facilities if food is not fully packaged
Conclusions

- Distributors, Wholesalers and Retailers have fewer obligations than Manufacturers and Growers
  - “modified” preventive controls MAY apply
  - FSVP likely applies
  - Sanitary transport may apply
- Most rules apply at the facility, not corporate level
- We know enough to begin preparing now
- Compliance dates vary by rule
- Consider how you will handle documentation
Conclusions

- Spared in FSMA- but other regulations apply!!
  - Facility registration- manufacture, process, pack or hold
  - Traceability recordkeeping requirements
    - In effect today
    - Will become more demanding for “high risk foods” in the future
  - Still subject to FDA inspections at registered facilities
Rule Making Process

1. Congress gives FDA the authority
2. FDA drafts new regulation
3. Health and Human Services approves the draft
4. Draft reviewed by the Office of Management and Budget
5. Draft released for public comment

Cycle Repeats
Supply Chain Risk
Internal Operations
Crisis and Recall Preparedness
Environmental & Testing Strategies

Social Media
Development of Communication Strategies & Programs
Strengthen stakeholder relationships

Food Regulations and Compliance
Expertise on FSMA
Crisis Response to regulatory issues, crisis and recalls

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  - Wednesday, February 18th | 11am est

Food Defense and Intentional Adulteration
  - Tuesday, March 17th | 11am est
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