Overview of FSMA: What applies to your packinghouse?

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FSMA

- Food Safety Modernization Act
  - A law in the United States (not a rule)
  - Written by Congress (not US FDA- Food and Drug Administration)
  - Requires FDA to write rules based on the law, do studies, etc.

- Biggest change to US food safety system in decades
Regulations Governing Produce Safety

• Historically
  – Federal Food, Drug & Cosmetic Act
  – GMPs for fresh-cut & distributors
  – Food Code for retail/foodservice

• Today
  – All of those, plus
  – Produce Safety Rule
  – Preventive Controls
  – Sanitary Transport
  – Foreign Supplier Verification Program
  – Intentional Adulteration (limited)
There is no “FSMA Rule”
There is no “FSMA Compliant”

Each rule is different:
• Impacts a different part of the supply chain
• Has different requirements
• Has different exemptions
• Has different compliance dates
How a Law Becomes Regulations

FSMA

Proposed Rules

Final Rules

Rules written by FDA as directed by Congress

Public Comment

Supplements (new proposals)
How a Law Becomes Regulations

FSMA
Proposed Rules
Final Rules
(draft) Guidance (not required)

Rules written by FDA as directed by Congress

Public Comment
White House oversight of FDA

- Reviews proposed/ final rules for
  - Alignment with other rules
  - Alignment with international standards
  - Economic impact
The Big 7 Rules

- Produce Safety Rule
- Preventive Controls- Human Food
- Preventive Controls- Animal Food
- Foreign Supplier Verification Programs
  - *Importers* must comply, not foreign suppliers
- Accredited 3\textsuperscript{rd} Party Certification
- Sanitary Transportation
- Intentional Adulteration
FDA FSMA Authorities

• FDA authority to require a food recall
  – You will have the chance to voluntarily recall first

• FDA authority to access records
  – Each rule requires records to be kept
  – FDA has access to all of them, even if there is no problem
    o If there is a problem, they have access to even more records
• Domestic and foreign food facilities required to renew FDA registration every two years
  – Farms shouldn’t register
  – Registration not required for import/export
  – Registration required if you manufacture, process, pack or hold food

• FDA can suspend a facility’s registration if reasonable probability that food presents serious health hazard (Salmonella, Listeria etc.)
  – Basically shuts a company down
Produce Safety Rule

• “Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption”

• Applies to “covered produce” that is generally consumed raw
  – “exhaustive list” of rarely consumed raw

• Addresses microbiological hazards only (not pesticides)

• Requires someone trained to Produce Safety Alliance curriculum (or equivalent)
Produce Safety Rule

- **Agricultural water** that contacts produce (irrigation, crop chemicals, washing) or food contact surfaces (including hands)
- **Domesticated and wild animals** and their excreta that may come into contact with produce
- **Biological soil amendment of animal origin (manure)** that may reasonably come into contact with produce
- **Health and hygiene of workers** that contact produce (harvesters, sorters, packers)
- **Equipment, tools, buildings and sanitation** (tools, utensils, containers, equipment)
- **Growing, harvesting, packing, and holding activities** that may reasonably be a source of contamination
What’s a “Farm”

- Secondary Activities Farm

- Stay Tuned!
Preventive Controls

- Updates cGMPs for human food (110 -> 117)
- Requires cGMPs for animal food
- Requires a food safety plan
  - Hazard analysis
    - *evaluate* *Listeria* in RTE foods
  - Preventive controls
    - Process PC (HACCP CCPs)
    - Allergen PC (not for animals)
    - Sanitation PC (verify through env. monitoring)
    - Supply chain program
      - “receiving facilities”
Preventive Controls (cont)

• Oversight and management of preventive controls
  • Monitoring
  • Corrective actions and corrections
  • Verification
• Recall plan

• Many tasks done by a Preventive Controls Qualified Individual
  • Education, training, experience
  • FSPCA Course available globally www.fspca.net
Farm vs Registered Facility

- Produce Safety Rule
  - PSA
- Sanitation GMPs
- No traceability requirement
- Mostly state inspectors
- No mandatory recall authority
- Exempt from Sanitary Transport rule

- Preventive Controls
  - PCQI
- Must consider *Listeria*
- Bioterrorism Act recordkeeping reqs
- Mostly FDA inspectors
- Mandatory recall authority
- Sanitary Transport rule applies

Everyone must produce safe food

*United Fresh Produce Association*
Foreign Supplier Verification Programs

- Rule applies to importers, not foreign suppliers
- FSVP importer ≠ importer of record
  - If you own or have agreed in writing to purchase
- Supplier ≠ 1 back in the supply chain (i.e., it’s the farm or fresh-cut processor)

- Result: US importers will be asking growers for information so the importer is in compliance
Basic FSVP requirements

- Need a FSVP for each food/supplier pair
- Steps
  - Written hazard analysis
  - Evaluate suppliers
  - Approve suppliers
  - Ongoing verification
  - Corrective actions
  - Reanalysis
  - Identify yourself as an importer

All done by qualified individuals

PCQI ≠ FSVP QI
Voluntary Qualified Importer Program (VQIP)

- VOLUNTARY for importers
  - Annual fee
- Allows expedited entry into the US
- Importer needs to have a Quality plan
- Foreign suppliers must have a special certification (see next slide)
- (listen to Nov 27 UFPA archived webinar)
Accredited 3rd Party Certification

• Very limited application!
  – Evaluate foreign suppliers for VQIP inclusion
  – Provide foreign facility certification if FDA requires it

• Has nothing to do with GFSI, 3rd party audits, etc.

• FDA has recognized several accreditation bodies
  – One Certification body can perform these special audits so far
Sanitary Transportation

- Short: Read the rule!
- Training required; Free FDA training available online
- Farms are exempt; applies to railcars, vehicles (including containers on ships)

- Shippers (who arrange transportation)
- Loaders
- Transporters
- Receivers
Intentional Adulteration

• AKA food defense
• Only applies to registered facilities (not farms)
  – With <$10M annual revenue
• Similar approach to Preventive Controls
  – Identify vulnerabilities
  – Put in mitigation steps
  – Monitoring, corrective actions, etc.
But Wait... There’s more!

• Traceability
  – “high risk foods” list
• Laboratory Accreditation
• And more!
Continuum of regulation

Supplier

Preventive Controls

San. Transp

Receiving Facility

Preventive Controls

San. Transp

Customer

Preventive Controls

Produce Safety

FSVP?
Resources

• www.fda.gov/fsma
  – Summaries and full versions of each rule (multiple languages)
  – Guidance and other notices
  – Technical Assistance Network


• www.unitedfresh.org/fsma-faqs

• www.Fspca.net

• https://producesafetyalliance.cornell.edu/
Questions?

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