FSMA 101

Jennifer McEntire, Ph.D.
VP Food Safety & Technology
jmcentire@unitedfresh.org
How a Bill Becomes a Law

Sequence:
1. Senate Bill 510
2. House Bill 2749
3. Conference?
4. S510
5. President signs
6. FSMA

2017 – FreshTEC
How a Bill Becomes a Law

Senate Bill 510

House Bill 2749

Confere...?

S510

President signs

FSMA
How a Bill Becomes a Law

Senate Bill 510

House Bill 2749

Source of confusion over what is/ isn’t required

Conf.?

President signs

S510

FSMA

2017 – FreshTEC
How a Law Becomes Regulations

FSMA

Proposed Rules

Final Rules

Rules written by FDA as directed by Congress

Supplements (new proposals)

Public Comment

2017 – FreshTEC
How a Law Becomes Regulations

- **FSMA**: Rules written by FDA as directed by Congress
- **Proposed Rules**
- **Final Rules**
- **(draft) Guidance (not required)**

Public Comment
Side note: OMB

- **OMB** = Office of Management & Budget
  - Office of the President
- **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
- Accredited 3rd Party Certification
- Sanitary Transportation
- Intentional Adulteration
FDA FSMA Authorities

- FDA authority to mandate a food recall
- FDA authority to access records
- Domestic and foreign food facilities required to renew FDA registration every two years
  - Farms shouldn’t register
  - Registration not required for import/ export
- FDA can suspend a facility’s registration if reasonable probability that food presents serious health hazard
- FDA can require certification of food or food facility when certain statutory criteria are met related to the risk of the food
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)
What’s a “Farm”

• Secondary Activities Farm

Farm

Facility

Packinghouse

• Stay Tuned!
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
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
    - 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
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)
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
Supplier Program Learning Center

- Thursday at 12:30
  - Donna Lynn Browne, Naturipe
  - Bill Gerlach, Melissa’s
  - Andrew Kesler, Taylor Farms
  - David Durkin, OFW Law
Accredited 3rd Party Certification

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

• Not in effect yet!
Sanitary Transportation

• Should have been simple
• Read the rule!
• Training required; FDA training not out yet
# Global Cold Chain Alliance


## Sanitary Transportation of Food ~ Compliance Checklist

<table>
<thead>
<tr>
<th>Sub Section</th>
<th>Best Practice Section</th>
<th>Synopsis of Regulatory Requirement</th>
<th>Sector</th>
</tr>
</thead>
</table>
| 1.906a      | 3.1                   | Appropriate vehicle and transportation equipment design for sanitary food transport | V  
| 1.906b      | 3.1                   | Appropriate equipment maintenance for sanitary food transport | V  
| 1.906c      | 3.1                   | Vehicles and transportation equipment properly designed, maintained and equipped for sanitary food transport | V  
| 1.906d      | 3.2                   | Proper storage of vehicles and transportation equipment when not in use | V  
| 2.2         |                       | Competent supervisory personnel | V  
| 3.3         | 3.3                   | Transportation operations conducted in a safe manner | V  
|             | 3.4                   | Transportation parameters specified | V  
|             | 3.3                   | Written food safety procedures in place | V  
|             | 3.5                   | Food safety checks if a temperature deviation occurs | V  
|             | 3.4                   | V  

**Sector Scope:** Refrigerated transport of perishable food, within the context of this document, applies to the use of Refrigerated Truck Trailers, Refrigerated Truck Bodies and Multi-Temperature Trailers. This document does not apply to rail, air or ocean transport.

**Matrix Key:**
- I = This sector has **PRIMARY** responsibility for understanding and implementing the industry Best Practice and regulatory requirement to achieve regulatory compliance.
- V = This sector should understand the industry Best Practice and regulatory requirement and has **SECONDARY** responsibility for verifying that compliance was met by others in the integrated cold chain.
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
• Laboratory Accreditation
• Voluntary Qualified Importer Program
• And more!
Continuum of regulation

Supplier → Receiving Facility → Customer

Preventive Controls → San. Transp → Preventive Controls

FSVP?
Resources

• [www.fda.gov/fsma](http://www.fda.gov/fsma)
  - Summaries and full versions of each rule (multiple languages)
  - Guidance and other notices
  - Technical Assistance Network
• [www.Fspca.net](http://www.Fspca.net)
• [https://producesafetyalliance.cornell.edu/](https://producesafetyalliance.cornell.edu/)
Questions?

Jennifer McEntire, Ph.D.
VP Food Safety & Technology
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