
FSMA 101

Jennifer McEntire, Ph.D.
VP Food Safety & Technology
jmcentire@unitedfresh.org

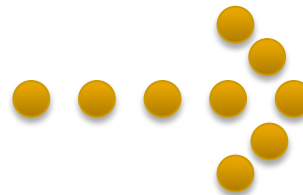


How a Bill Becomes a Law

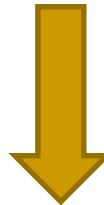
Senate Bill 510



House Bill 2749



President signs

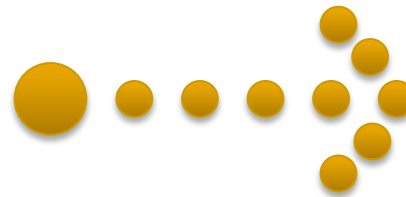


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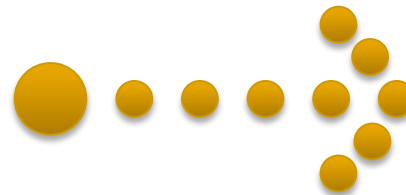
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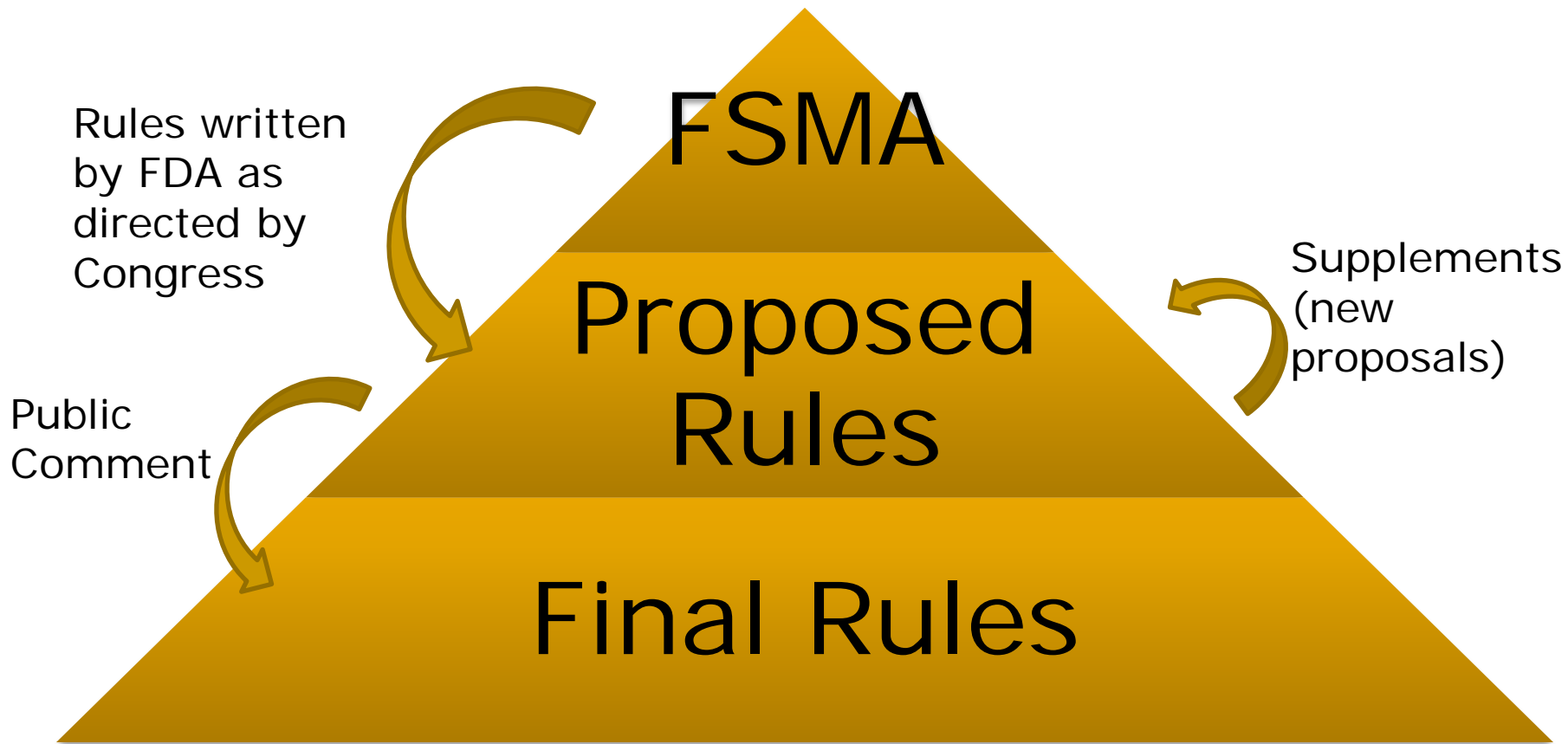
Source of confusion over what is/ isn't required



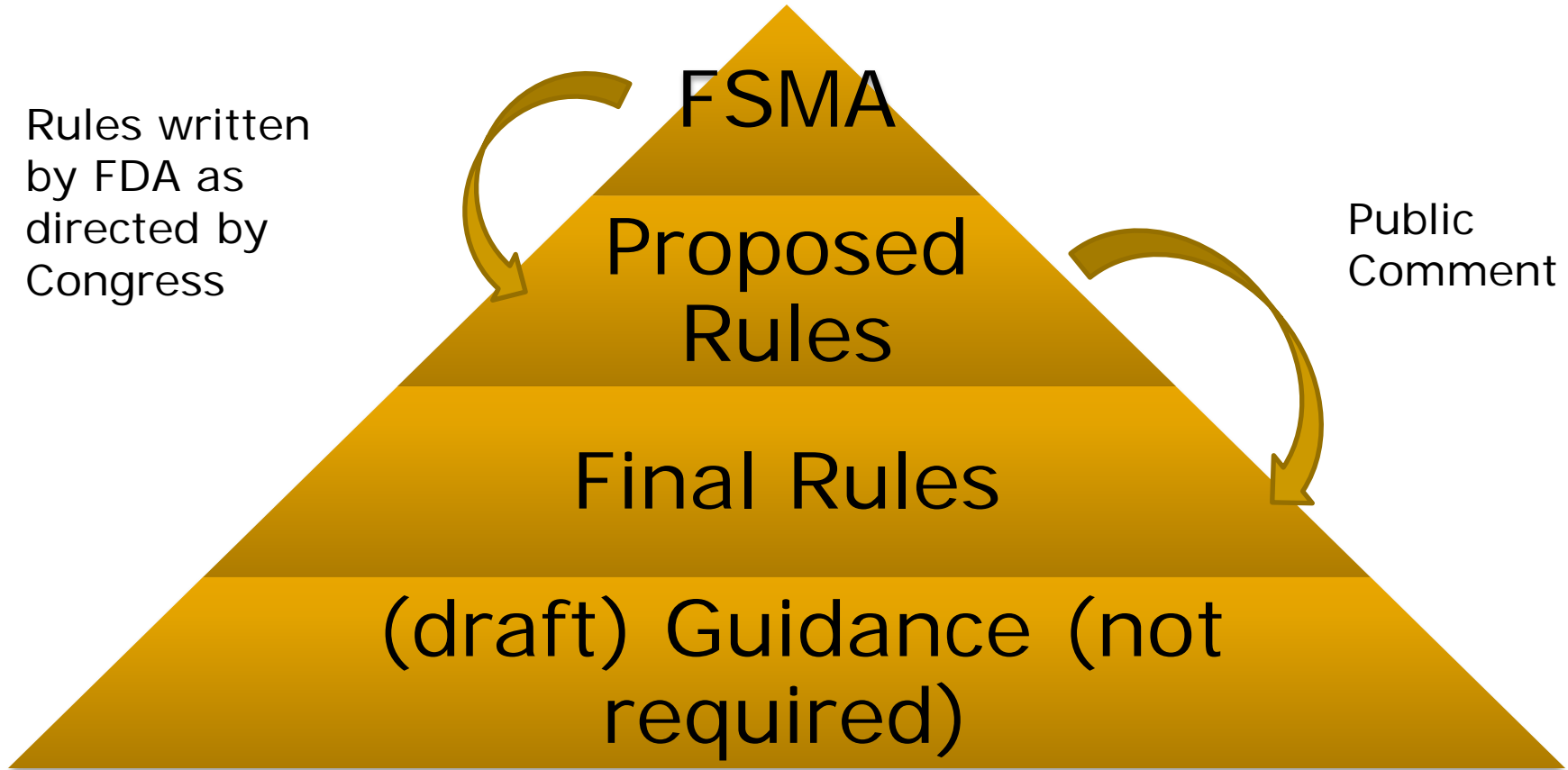
President signs



How a Law Becomes Regulations



How a Law Becomes Regulations



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



- 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 \neq importer of record
 - If you own or have agreed in writing to purchase
- Supplier \neq 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

- <http://www.gcca.org/resources/sanitary-transportation-food-compliance-resources/>

| Sanitary Transportation of Food ~ Compliance Checklist | | | | | | | | | | |
|--|-----------------------|--|-----------------|---|---|---|---------|---|----------|---|
| Matrix Key: | | | 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 | | | | | |
| | | | Responsibility: | | I | This sector has PRIMARY responsibility for understanding and IMPLEMENTING the industry Best Practice and/or regulatory requirement to achieve regulatory compliance. | | | | |
| | | | | | V | This sector should understand the industry Best Practice and/or regulatory requirement and has SECONDARY responsibility for VERIFYING that compliance was met by others in the integrated cold chain. | | | | |
| Sub Section | Best Practice Section | Synopsis of Regulatory Requirement | Sector | | | | | | | |
| | | | Shipper/Broker | | Loader | | Carrier | | Receiver | |
| | | | I | V | I | V | I | V | I | V |
| 1.906a | 3.1 | Appropriate vehicle and transportation equipment design for sanitary food transport | ✓ | | | ✓ | ✓ | | | ✓ |
| 1.906b | 3.1 | Appropriate equipment maintenance for sanitary food transport | ✓ | | | ✓ | ✓ | | | ✓ |
| 1.906c | 3.1 | Vehicles and transportation equipment properly designed, maintained and equipped for sanitary food transport | ✓ | | | ✓ | ✓ | | | ✓ |
| 1.906d | 3.2 | Proper storage of vehicles and transportation equipment when not in use | ✓ | | | ✓ | ✓ | | ✓ | |
| 1.908a | 2.2 | Competent supervisory personnel | ✓ | | ✓ | | ✓ | | ✓ | |
| | 3.3 | Transportation operations conducted in a safe manner | ✓ | | ✓ | | ✓ | | ✓ | |
| | 3.4 | Transportation parameters specified | ✓ | | | ✓ | | ✓ | | ✓ |
| | 3.3 | Written food safety procedures in place | ✓ | | ✓ | | ✓ | | ✓ | |
| | 3.4 | Food safety checks if a temperature deviation occurs | | | | | | | ✓ | |
| | 3.5 | | | | | | | | ✓ | |



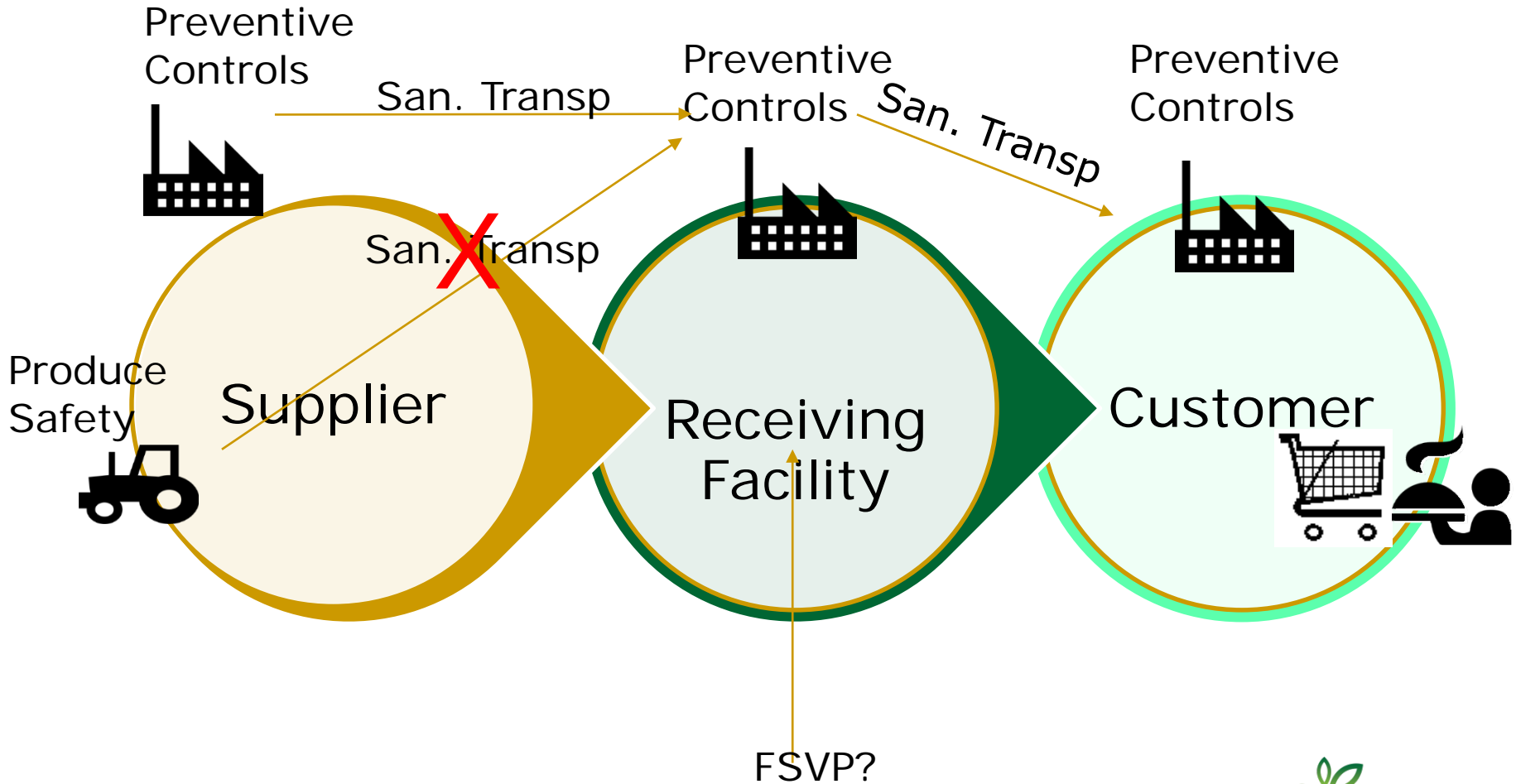
Intentional Adulteration

- 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



Resources

- www.fda.gov/fsma
 - Summaries and full versions of each rule (multiple languages)
 - Guidance and other notices
 - Technical Assistance Network
- <http://www.unitedfresh.org/food-safety/food-safety-modernization-act/>
- www.Fspca.net
- <https://producesafetyalliance.cornell.edu/>

Questions?

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