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# 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)



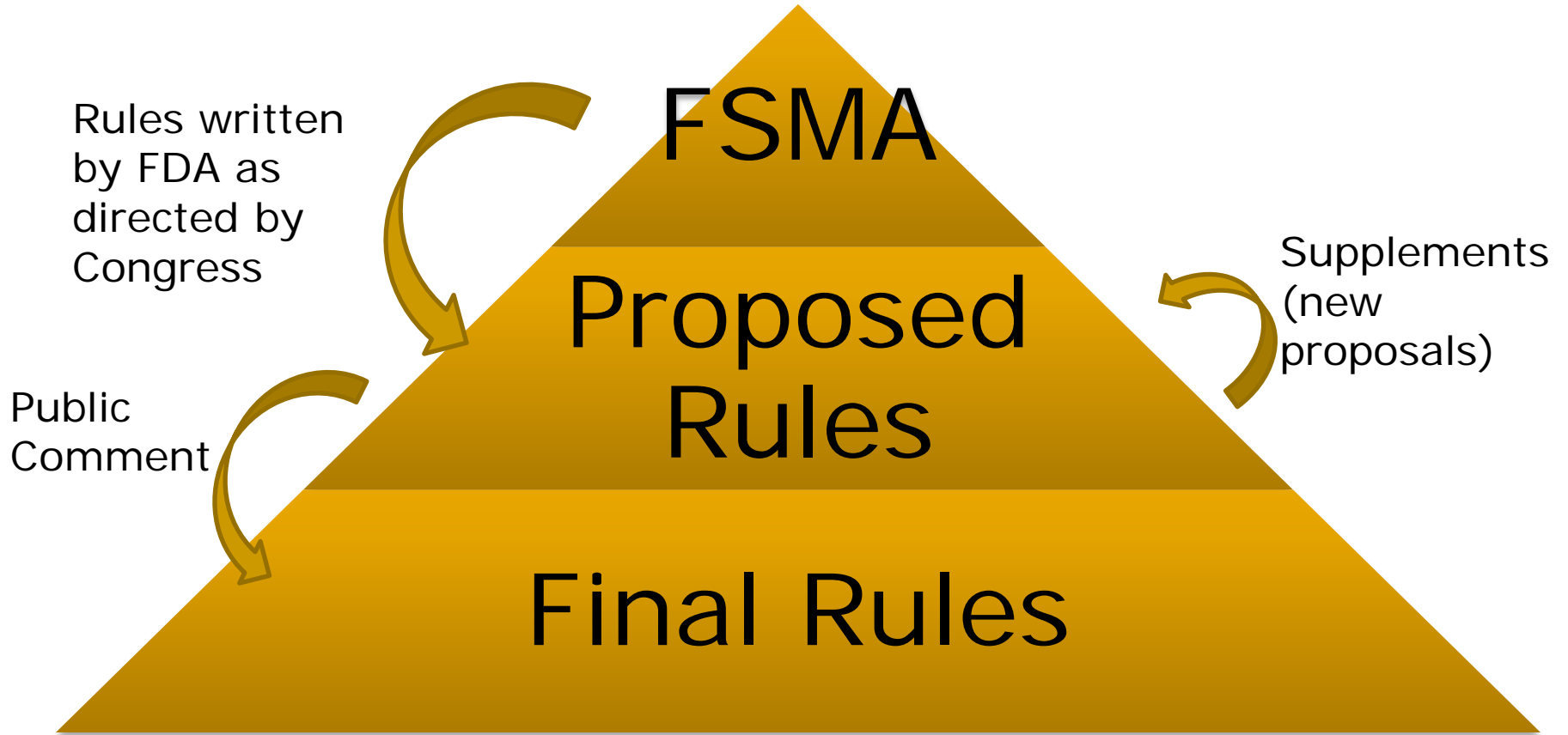
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There is no “FSMA Rule”  
There is no “FSMA Compliant”

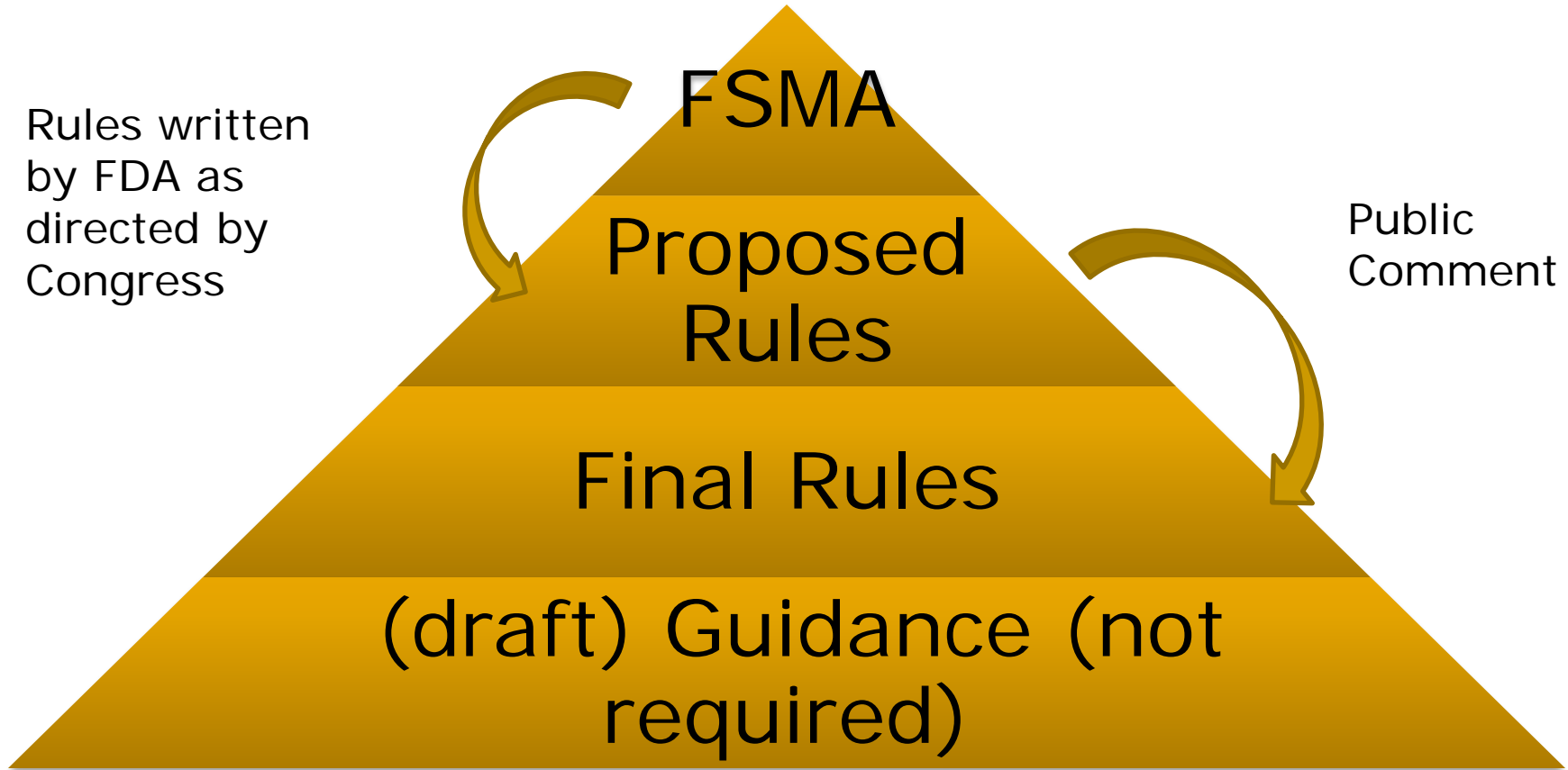
Each rule is different:

- Impacts a different part of the supply chain
- Has different requirements
- Has different exemptions
- Has different compliance dates

# How a Law Becomes Regulations



# How a Law Becomes Regulations



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# White House oversight of FDA

- Reviews proposed/ final rules for
  - Alignment with other rules
  - Alignment with international standards
  - Economic impact

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# 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<sup>rd</sup> 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
    - 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](http://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



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# 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)
  
- 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  $\neq$  FSVP QI

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# 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 3<sup>rd</sup> 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, 3<sup>rd</sup> 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

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# Intentional Adulteration

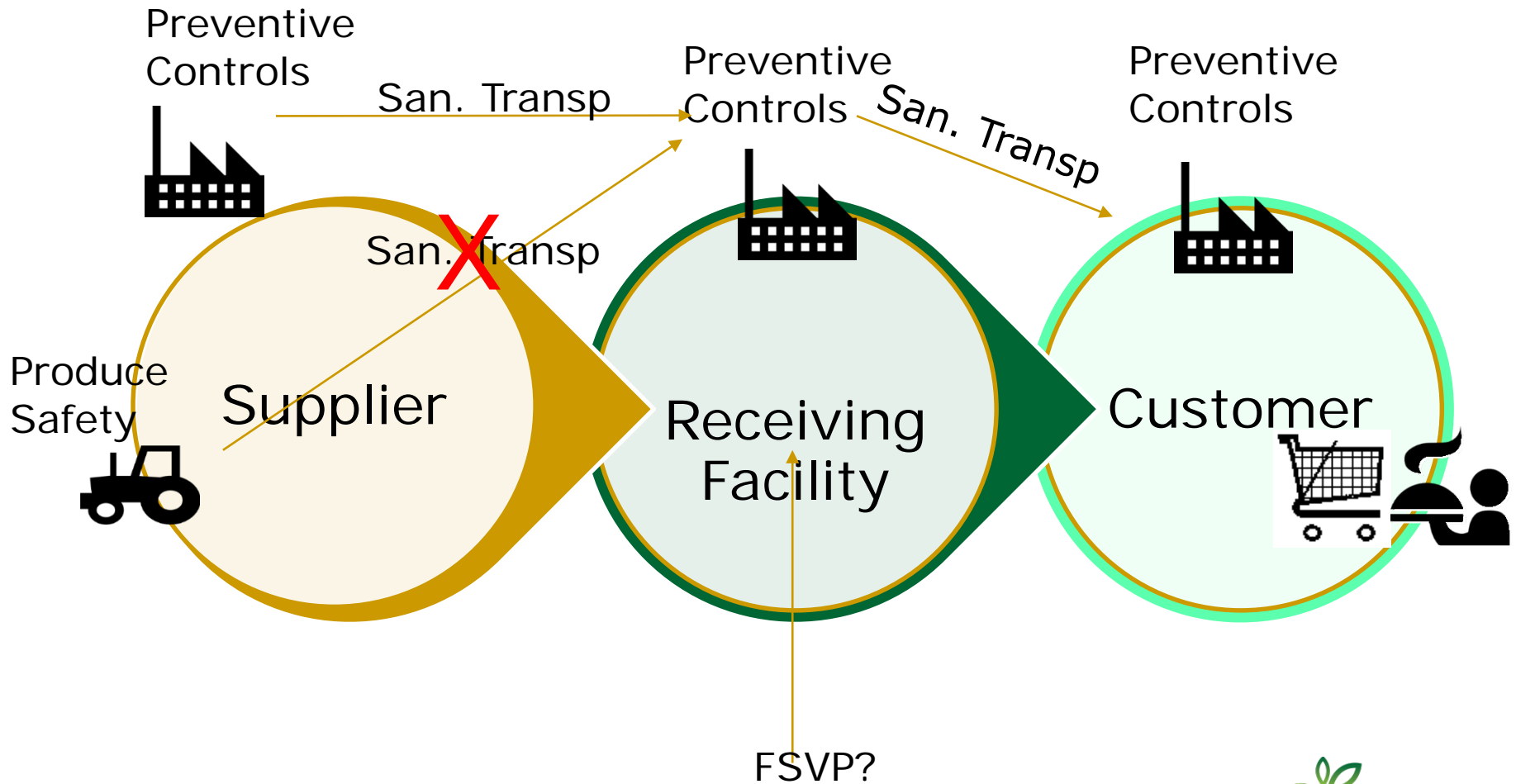
- AKA food defense
- Only applies to registered facilities (not farms)
  - With <\$10M annual revenue
- Similar approach to Preventive Controls
  - Identify vulnerabilities
  - Put in mitigation steps
  - Monitoring, corrective actions, etc.

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# But Wait... There's more!

- Traceability
  - “high risk foods” list
- Laboratory Accreditation
- And more!

# Continuum of regulation





# 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.unitedfresh.org/food-safety/food-safety-modernization-act/](http://www.unitedfresh.org/food-safety/food-safety-modernization-act/)
- [www.unitedfresh.org/fsma-faqs](http://www.unitedfresh.org/fsma-faqs)
- [www.Fspca.net](http://www.Fspca.net)
- <https://producesafetyalliance.cornell.edu/>

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# Questions?

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