

# FSMA: A Legal View

Association of Food and Drug Officials  
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# PC Implementation Challenges Today – Substantive

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- Written assurances under 21 CFR 117.136
- Which hazards require a preventive control
- Supply chain programs
  - How do we identify the supplier?
  - Co-mans / sister plants
  - Allergens
  - And for FSVP: Who is the “importer”?
- Validation
- Testing programs
- Recordkeeping
- Co-manufacturer education and oversight
- Foreign facilities

# PC Implementation Challenges Today – Policy

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- Inspections:
  - State / Federal inspection consistency
  - How the rule will be enforced at week 10 vs. year 10
  - Escalation and appeals of technical/scientific issues (e.g., challenges to hazard analysis determinations; identification of preventive controls)
- Pending guidance
  - Timing
  - How will it be applied?
- TAN
  - Timing
  - Public access

# Contact Information

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