

FSMA: A Legal View

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PC Implementation Challenges Today – Substantive

- 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

- 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

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