

HOLLAND & HART<sup>LLP</sup>



# FOOD SAFETY

**A Regulatory Overview and  
Considerations for Risk Management**

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# Why is Food Safety Important?

## Foodborne Illness

48 million illnesses per year  
128,000 hospitalizations  
3,000 deaths

## Financial Losses

Recall expenses  
Lost sales  
Lawsuits



# **Food Safety Modernization Act**

**Written “Hazard Analysis & Preventative Controls” plan**

**Significant increases in FDA authority**

**Mandatory recalls**



# Hazard Analysis & Preventative Controls

## Science-based standards for:

Evaluating hazards

Implementing preventative controls

Monitoring performance

Corrective actions

## FDA regulations in process



# Who is subject to FSMA?

## Any facility engaged in:

Manufacturing

Processing

Packing

Distributing

## Limited “very small business” exemption

Less than \$500,000/year in revenue



# **Small Producer & Organic Recalls**

**Organic spinach in California**

**Organic eggs in Minnesota**

**Organic energy bar manufacturer in California**

**Peanut Butter recall**



# **Risk Management**

**Regulatory compliance for all facilities  
and operations**

**Consider additional preventative  
measures**

**Contractual commitments from partners**

**Diligent recordkeeping**

**Traceability system**

**Liability insurance**



# **Non-Food Companies**

**Good Manufacturing Practices (GMPs)**

**Recordkeeping & traceability**

**Contractual commitments from partners**

**Examine issues and risks specific to your products**





**QUESTIONS?**

