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together

Recalls and Beyond:

The Changing Regulatory and Risk Environment for the Peanut Industry

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FDA Basics

- Adulteration and/or Misbranding + Commerce = Violation
- Adulteration – multiple definitions but:
  - Condition of Product
  - Condition of Facility
- Maintenance of Sanitary Conditions
- Compliance with Good Manufacturing Practices (GMPs)

FDA Inspections

- Credentials
- Written notice
- Authorized to enter
- To inspect at reasonable times in a reasonable manner
- Report in writing
- Sampling Issues
- Record Access Issues
- Copy of results of analysis shall be furnished

Inspections

- Review credentials
- Assign a company representative
- Company's inspectional policies
- Ask the purpose of the inspection

Inspections

- Inspector's Exit Interview
  - Form FD-483 List of Observations
  - Explain (professionally) for the record where you agree or disagree
  - Request a copy of the Establishment Inspection Report (EIR)

Inspections

- After the Inspection
  - 483 Response in writing
  - Per “new policy”:
    - *“Significant out of Compliance” – 15 days to respond or “Warning Letter” or other action*

Recalls

- Voluntary removal or correction of marketed violative products against which FDA would initiate legal action

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Recall Alternatives

- Stock recovery – product not marketed or has not left control of firm
- Market withdrawal – removal or correction of distributed product against which FDA would not take action or which involves no violation
- Reportable Food Registry Issues

Recall Classification

- Class I – Reasonable probability that use or exposure to product will cause serious adverse health consequences or death
- Class II – Temporary or medically reversible health consequences
- Class III – Not likely to cause adverse health consequences

Recall Basics

- Have a team and know it
- Lotting and Recordkeeping – recall friendly
- Knowledge is power – bluffing can be fatal
- Company Stress Test
- More can be less
- Document everything
- Not just a Recall

Food Safety Modernization Act (FSMA)

- Bi-Annual Registration – foreign and domestic
- Hazard analysis and preventative controls
- Related recordkeeping requirements
- Import verification
- Fees on imports and reinspections
- Mandatory recall authority
- Detention on “reason to believe” basis
- Foreign certification
- Traceability

FSMA Implementation

- Potential issuance of regulatory proposals
- Current force of statute
- Guidance materials
- Budget and resource issues
- Private/Public partnerships

Sun Land, Inc. Action

- Suspension of registration – first time under FSMA
- Consequences of suspension
- Allegations –
  - Evidence of outbreak
  - Sole source of implicated product
  - Records of violative test results
  - Shipments of implicated product

Sun Land, Inc. Action (cont.)

- Positive environmental samples
- PFGE matches with outbreak (environment and product)
- GMP and sanitation issues
- Opportunity for hearing and appeal

Peanut Industry Issues

- PFGE + CDC + State Public Health = Recall and related FDA activity
- Law, Regulation and Guidance
- FDA Guidance:
  - Five log reduction target
  - Process – specific validation
  - Creates rebuttable presumption of validity.

Types of Insurance Coverage for Contamination Recall Losses and Liabilities

- Comprehensive General Liability Policies First Party Property/Business Interruption
- Policies
- Specialty Recall and Contamination Policies

Comprehensive General Liability Policies

- Generally provide defense and indemnity to policyholder against third-party claims and lawsuits alleging bodily injury or property damage caused by policyholder's products
  - Typically exclude coverage for damage to "impaired property" or property that has not been physically injured by a defect or danger in "your property"
    - *But may cover situation where defective or injurious food product is integrated into another entity's product in a way that it cannot be separated and removed from the entire product*
  - Typically exclude coverage for costs incurred for "loss of use, withdrawal, recall, inspection . . . removal or disposal
    - *But may cover recalls initiated by a third party and not the policyholder*

First-Party Property/Business Interruption Policies

- Generally provide coverage for losses of or damage to the policyholder's own property
  - Typically exclude losses caused by contamination, including pollution, and specifically fungus, mold or mildew
    - *Fungus, mold or mildew may be defined as "fungus, including but not limited to, mildew and mold . . . Or bacterium"*
  - Covered lost profit must result from direct physical loss or damage of the type insured by the policy, and to property not otherwise excluded
  - May cover fungus clean-up or removal costs by endorsement, unless fungus caused by moisture, e.g., leaking process pipes

Specialty Recall and Contamination Policies

- Provide coverage for costs of recall, rehabilitation, crisis response and lost profit arising from accidental product contamination or product tampering
  - Coverage began to be offered within last decade
  - Usually offered as stand-alone policy, with separate terms and conditions and premium
  - To date, coverage disputes over this type of policy have not resulted in limited precedents
  - No duty to defend or to pay defense costs

Specialty Recall and Contamination Policies (cont.)

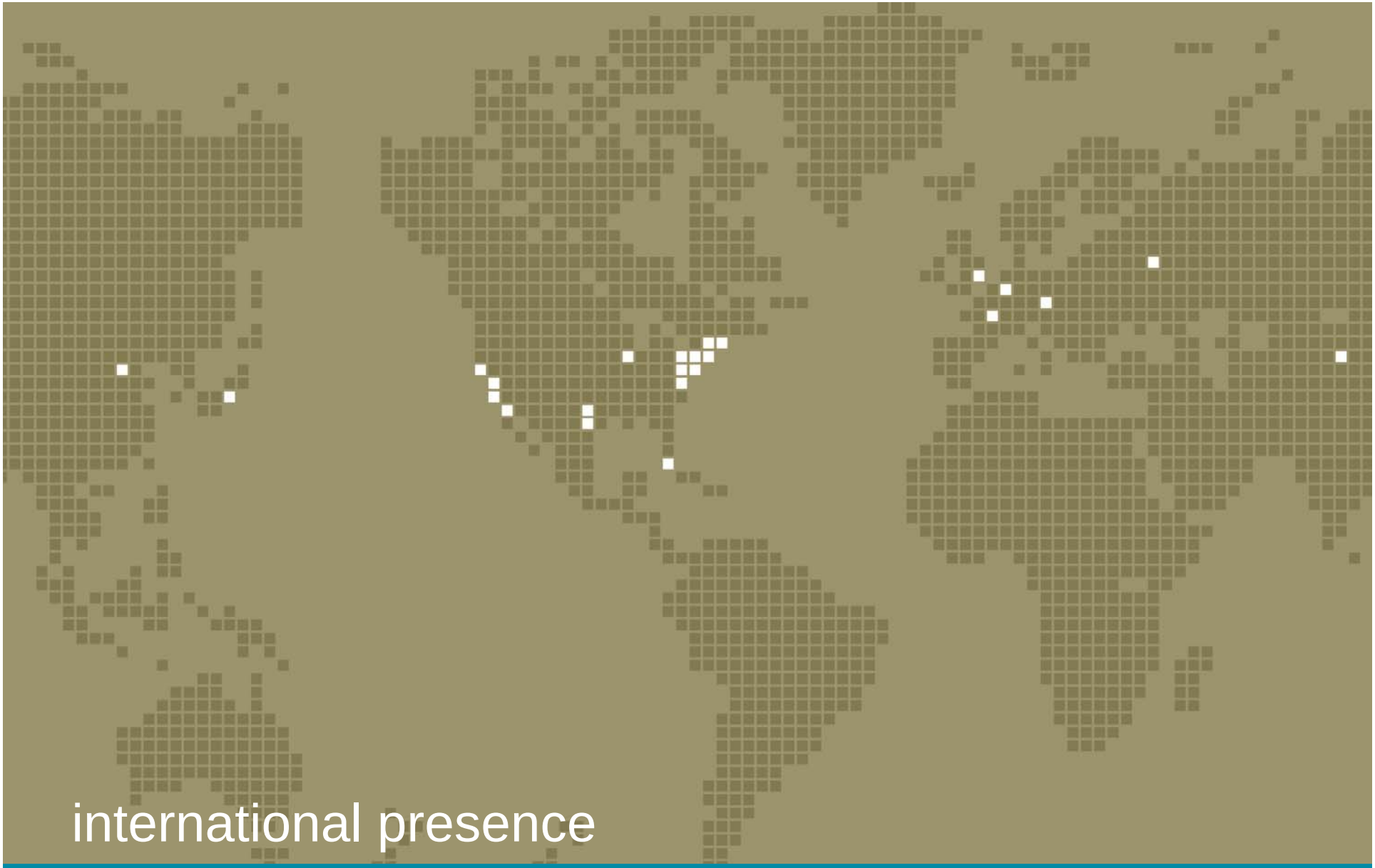
- Covered recall costs typically include:
  - Repair or replacement and disposal of “your product”
  - Recall notifications
  - Employee overtime
  - Temporary workers and independent contractors
  - Transportation, shipping and packaging of affected product
  - Warehouse/storage of affected product

Risk Management Issues

- Letters of Guaranty and related documents – incoming and outgoing
- Review and integrate with insurance coverage
- Strict liability in tort
- Reasonable standard of care

Conclusions

- Risks cannot be eliminated – they can be effectively managed and reduced
- Recalls can be company destroying or company enhancing event – preparation is critical
- FSMA is already here
- Regulatory compliance is a must but often only the starting point
- Critical to keep pace with the rising standard of care and enhanced sciences
- Document everything



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