



# Evaluation of Food Safety Plans in Regards to Lending and Liability Insurance Decisions

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# Overview

- I. Why Does FSMA Matter to Lenders?
- II. Elements of FSMA and Potential Implications From a Lender's Perspective
  - A. Prevention
  - B. Inspection
  - C. Compliance
- III. Potential Conversations between Lenders and Borrowers
- IV. Summary of Key Points



# WHY DOES FSMA MATTER TO LENDERS?



# Food Safety Issues = Bad For (Lender) Business



- **Bankruptcy** (loan default, other lending customers in supply-chain assuming liability)
- **Permanent brand damage** (Topps Meats)
- **Industry damage** (peanut butter, cantaloupe, spinach)
- **Increased FDA scrutiny of facilities**
- **Personal injuries, deaths**
- **Criminal liability** (*Park Doctrine*)

# FSMA From 30,000 Feet (Good for Lenders?)



## + Proactive v. Reactive

- Focus on prevention
- Risk-based analysis

→ Enhanced risk management policies may lead to better inventory management and, potentially, protection of collateral

## - More FDA authority

- Recall/Detention
- Registration Revocation
- Rulemaking/Guidance
- Programs

→ Potential implications to collateral value and potential enforcement remedies

## + / - More requirements

- Inspections
- Recordkeeping
- Imports

→ Earlier warning signs of potential food/feed contamination

→ Opportunities to assess risk ratings of customers and collateral



# OVERVIEW OF FSMA AND POTENTIAL IMPLICATIONS FROM A LENDER'S PERSPECTIVE



# Basic Elements of FSMA



- **Prevention**
- Inspection
- Compliance



# Prevention: Food Safety Plan



- Develop and implement a written plan that includes:
  - ✓ Hazard Analysis
  - ✓ Preventive Controls
  - ✓ Monitoring Procedures
  - ✓ Corrective Action Procedures
  - ✓ Verification Procedures
  - ✓ Recall Plan
  - ✓ Supply-Chain Program



# Prevention: Food Safety Plan (A Lender's Perspective)



- Require copies of Food Safety Plan and other documentation as conditions to loan closing
- In addition to general “compliance with laws” representations and covenants, consider including in loan documentation specific representations and covenants that the company comply with FSMA, its rules and regulations, and the company’s own policies and procedures that it implemented to minimize risks of food/feed contamination



# Prevention: CGMPs

- Areas of Focus:
  - Personnel
  - Plant and grounds
  - Sanitary facilities and controls
  - Equipment and utensils
  - Plant operations—product labeling, raw material inspection
  - Warehousing and distribution



# Prevention: Basics of HARBPC



- **Evaluate** hazards
- Develop a written **hazard analysis**
- **Validate** preventive control
  - Justify why/how it will control hazard
- **Monitor** preventive control to ensure it is working
- **Verify** preventive control is effective
  - Review monitoring records
- **Corrective Actions**
  - Additional controls implemented if preventive control is not effective at minimizing/eliminating hazard



# Prevention: Supply-Chain Program



- **If** a lending customer has identified:
  - A hazard requiring a preventive control and
  - The customer relies on its supplier to control the hazard
  
- **Then** the lending customer is required to:
  - Verify supplier is adequately controlling hazard
  - Conduct onsite audits of supplier operations
  - Sample/test
  - Review supplier food safety practices
  
- **If** there is a reasonable probability the hazard could kill/harm humans/animals, **then**:
  - Receiving facility required to audit supplier annually by a qualified auditor

# Prevention: Supply-Chain Program (A Lender's Perspective)



- Buyers and suppliers are setting extensive documentation requirements (including guaranty/warranty agreements)
- Increase use of indemnification, pushing liability up (or down) the supply-chain





# Prevention: Recordkeeping

- Record-keeping and document management is essential
- Recordkeeping requirements
  - Monitoring records
  - Verification records
  - Episodes of material nonconformance
  - Corrective actions
  - Supply-Chain program
- Written plan and records must be kept for 2 years
- Reanalysis every 3 years unless significant change in process
- Records must be provided to FDA on written or oral request

# Prevention: Recordkeeping (A Lender's Perspective)



- Recordkeeping requirements
  - Monitoring records
  - Verification records
  - Episodes of material nonconformance
  - Corrective actions
  - Supply-Chain program
  
- Consider adding disclosure schedules (at closing) and reporting covenants (for future disclosure) of any previous recalls, other episodes of material nonconformance and any corrective actions
  
- If material nonconformance, consider addressing in risk rating, underwriting, borrowing base advance rates and/or borrowing base reserves

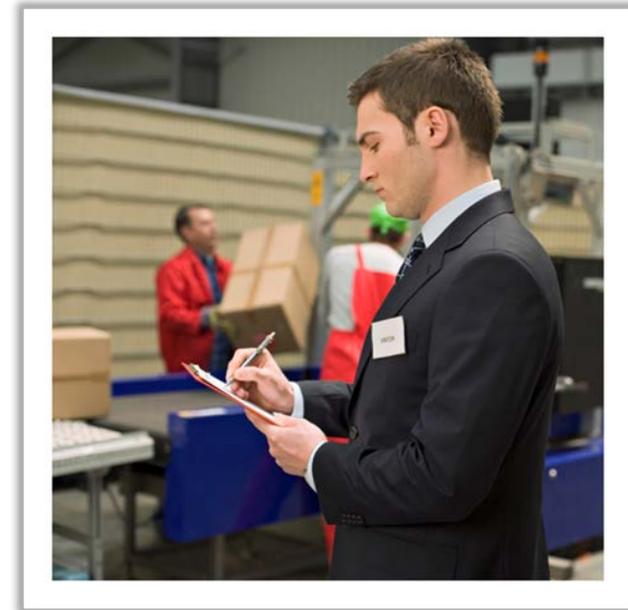
- Prevention
- **Inspection**
- Enforcement





# Inspection: FDA Authority

- Inspections move from being a snapshot in time to being more like an IRS audit
- Prior to FSMA: very limited access to records
- Now have access to:
  - Food Safety Plan
  - Monitoring/verification records
  - Validation records
- Inspection authority given to FDA upon enactment of FSMA





# Inspection: Frequency

- Target FDA's limited inspection resources to **high-risk** facilities/foods
- **Risk Profile:** Identify high-risk facilities/foods, both domestic and imported



# Inspection: Frequency (A Lender's Perspective)



- If identified as high-risk facility/food by FDA, consider when underwriting the loan
- Incorporate into disclosure schedules, reporting covenants and representations that, except as disclosed, neither the borrower nor any of its facilities or products have been identified by FDA/USDA/DHS as “high-risk”
- Expand reporting covenants to require copies of any FDA warning letters or inspection reports promptly upon receipt

- Prevention
- Inspection
- **Enforcement**



# Enforcement: FDA's Powers



- **Administrative Detention of Food**
  - FDA can detain food if it has “reason to believe” the food is “adulterated or misbranded.”
  - Normally no more than 20 days
  
- **Mandatory Recall**
  - FSMA gives FDA authority to issue a mandatory recall when a company fails to voluntarily recall unsafe food/feed, after being asked to do so
  
- **Suspension of Registration**
  - FDA has new powers to suspend registration if FDA determines that the food/feed poses a reasonable probability of serious adverse health consequences or death to humans or animals

# Enforcement: FDA's Powers (A Lender's Perspective)



- Include administrative detention, large recalls and the suspension of registration as specific Events of Default under loan agreement (rather than relying on general “MAE” clause)
- Non-inventory collateral may take on greater importance



# Enforcement: FDA's Powers (A Lender's Perspective)



- Potential implications for enforcement of remedies:
  - May not be able to sell contaminated product
  - If registration is revoked, no person can sell “or otherwise introduce” into commerce products that were produced during period of suspected contamination. Violations lead to penalties, prison, fines.
  - Foreclosing lender may not be willing to provide supplier indemnities, guaranties or warranties required by downstream purchasers; may affect sale price and potential market for sale of inventory



# Enforcement: FDA's Powers (A Lender's Perspective)



- Potential implications for enforcement of remedies (cont'd):
  - Any owner, operator or agent in charge of a facility engaged in manufacturing, processing, packing or holding food/feed needs to have facility registered with FDA (with some exceptions). Assuming no revocation by the FDA of any of the company's facility registrations:
    - Foreclosing lender may need to have food/feed stored in registered facilities
    - If foreclosing lender for some (unlikely) reason takes title to facility and becomes an owner, operator or agent in charge of a facility, would need to comply with facility registration requirements



# POTENTIAL CONVERSATIONS BETWEEN LENDERS AND BORROWERS





# Potential Conversations

- **Have you had a food safety recall or received an FDA warning letter in the last 5 years?**
  - If so, when did the recall(s)/warning letter(s) occur?
  - What classification was each recall?
  - What was the cause of each recall/warning letter? Due to internal issue or caused by supplier?
  - What steps were taken to mitigate reoccurrence?
  - Was there any publicity regarding the recall?



# Potential Conversations

- **Does your facility have a Food Safety Plan in place and are you validating it?**
- **If any of your facilities were to be shut down due to a food safety event, would you be able to shift production to another facility?**
- **What procedures do you have in place to verify the safety of your incoming ingredients?**



# Potential Conversations



- **What kind of recall insurance does your facility have?**
  - In addition to comprehensive general liability insurance, companies may be able to obtain contamination / recall insurance (as well as business interruption insurance)
  - Has become the “coverage cornerstone”, addressing majority of risks resulting from a contamination event
  
- **Note: Policies aren’t standardized**
  - Some cover only “actual” contamination
  - Others cover “reasonable probability” of existence of contaminants
  - Insurance company may alter basic form or issue a separate endorsement for recall coverage
  - Know which risks have been retained or self-insured by company

# Potential Conversations



**Depending on outcome of conversations, lender could consider:**

- **Strengthening Due Diligence Deliverables:**
  - Copies of current Food Safety Plan
  - Documentation as to whether facilities are certified under a food safety certification program, such as GFSI, SQF, BRC, FSSC 22000 GlobalGap
  - Information on whether the company imports any ingredients and, if so, its current FSVP; any domestic supplier verification programs
  - FDA website for warning letters, form 483s, recalls, compliance history
  - Disclosure as to whether identified as “high-risk” facility or food by FDA
  - Insurance policies

# Potential Conversations



- **Potential Additions to Loan Documents:**
  - Representations and covenants regarding compliance with FSMA and company's own Food Safety Plan and other policies and procedures
  - Reporting requirements for recalls (whether mandatory, recommended or voluntary), administrative detention, suspension of registration, other episodes of material nonconformance, FDA warning letters
  - Specific events of default for administrative detention, large recalls and the suspension of registration



# Potential Conversations



- **Potential additions to loan documents (cont'd):**
  - Insurance representations and covenants (commercial general liability, property, flood, recall and business interruption insurance)
  - Assignments of recall and business interruption insurance signed by insurance company
  - Lender loss payable endorsements





# Potential Conversations

- **Companies (and lenders) may want to review insurance coverage to see whether the insurance:**
  - Covers only government-ordered recalls, or whether it also includes government-requested recalls, voluntary recalls and administrative detentions by FDA
  - Provides only “first-party” coverage, or whether it also provides “third-party” coverage for: (1) lost profits of downstream business partners resulting from the recall for which the company may be liable (i.e., claims by purchasers) and (2) losses resulting from recalls of ingredients used in the company’s products that were purchased by other suppliers (i.e., losses resulting from suppliers)
  - Covers class II or class III recalls when lower likelihood of bodily injury
  - Requires any deductible (and the amount of the deductible)



# SUMMARY



# Summary



- FSMA requires steep learning curve for borrowers and lenders alike
- Increased lender risk may require additional disclosure and insurance requirements on behalf of borrower
- Lenders encouraged to engage in key conversations with borrowers to help minimize the costs and risks to business disruptions due to FSMA compliance



# QUESTIONS?

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