The Bioterrorism Act and Food Security

Department of Grain Science and Industry
Kansas State University
Fourth Heat Treatment Workshop
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We’ll Discuss…

- The Bioterrorism Act
- Threats to Food Security
- Risk Management Tools
- Incident/Crisis Response Plan
- Informal Survey of the Industry
- Resources
The Bioterrorism Act

The Bioterrorism Act

– Title III, Subtitle A: Protection of the Food Supply

– Four provisions require regulations
  • Section 303, Administrative Detention
  • Section 305, Registration of Food Facilities
  • Section 306, Establishment and Maintenance of Records
  • Section 307, Prior Notice of Imported Food Shipments
The Bioterrorism Act

• Section 303, *Administrative Detention*
  – Authorizes detention of food presenting a threat of serious adverse health consequences or death to humans or animals
  – No time frame specified
The Bioterrorism Act

• Section 305, *Registration of Food Facilities*
  – Requires registration of facility with FDA
    • Facility is any factory, warehouse, or establishment, including importers
    • Exempts farms, restaurants, retail food establishments, nonprofit food establishments (food prepared/served directly to consumer), and fishing vessels
  – December 12, 2003 facility & reg. deadline
The Bioterrorism Act

- Section 306, *Establishment and Maintenance of Records*
  - Requires establishment of requirements for the creation and maintenance of records needed to determine the immediate previous sources and the immediate subsequent recipients of food
    - Exempts farms and restaurants
  - December 12, 2003 regulation deadline
The Bioterrorism Act

• Section 307, *Prior Notice of Imported Food Shipments*
  – Requires that prior notice of food shipments be given to FDA
    • Prior notice: no less than 8 hours and no more than 5 days
  – December 12, 2003 regulation deadline
Threats to Food Security

• Biological warfare against livestock and crops
  – Iraq admittedly researched wheat smut rust as a biological agent

• Contamination of imported foodstuffs
  – FDA spot-checks less than one percent of imported foods
Threats to Food Security

• Contamination of water supply
  – Be alert to changes in potability profile
• Tampering of food
  – Certain bacteria and viruses could be deliberately added
Risk Management Tools

- ORM (Operational Risk Management)
- TEAM (Threat Exposure Assessment & Management)
- HACCP (Hazard Analysis Critical Control Points)
1. Identify Hazards/Threats
2. Assess the Risk
3. Analyze Risk Control Measures
4. Make Control Decisions
5. Implement Risk Controls
6. Supervise & Review
Step 1.

- **Hazard/Threat**
  - Any real or potential food security condition that can cause illness, injury or death, property damage or business degradation

- **Systemic Causes (5M)**
  - Man root
  - Machine
  - Means
  - Management
  - Mission
Step 1.

- **ID Tools**
  - Operations analysis
  - Scenario process
  - Site reviews
  - What if
  - Logic diagrams
  - Cause and effect

1. Identify Hazards/Threats
2. Assess the Risk
3. Analyze Risk Control Measures
4. Make Control Decisions
5. Implement Risk Controls
6. Supervise & Review
Step 2.

- **Risk**
  - The probability and severity of loss from exposure to the hazard/threat
  - Exposure expressed in terms of time, proximity, volume, or frequency
## Step 2.

### Probability Table

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<th></th>
<th>Frequent</th>
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### Severity Levels

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### Risk Levels

- **Extremely High**
- **High**
- **Medium**
- **Low**
Step 3.

- Control measures reduce or eliminate the exposure, probability, or severity of risk

- Action steps
  - Identify control options
  - Determine control effects
  - Prioritize control measures
Step 3.

- Principal Control Options
  - Reject
  - Avoid
  - Delay
  - Transfer
  - Spread
  - Compensate
  - Reduce

- Supporting control activities
  - Train & educate
  - Engineer
  - Improve task design
  - Guard
  - Warn
  - Motivate
  - Limit exposure
  - Selection of personnel
  - Reduce effects
  - Rehabilitate
Step 3.

- Control effects
  - Estimate the impact on exposure, probability, and severity
  - Consider control costs

- Understand the interaction of control options
Step 3.

- Prioritize control measures
  - Focus risk control measures where they have maximum impact
  - Involve operators
  - Benchmark existing risk control options
Step 4.

• Make control decisions
  – Right time
  – Right level
  – Mission supportive
Step 5.

- Make implementation clear
  - Be specific
  - Determine metrics
  - Integrate
  - Frame within culture
  - Document

- Establish accountability

- Provide resources
  - Standards
  - Tools
  - Training
  - Feedback
Step 6.

- Supervise like any other leadership action
- Review by conducting a risk assessment after controls are in place to ensure risks are reduced
- Apply the process as a cycle
  - Tie back to step one
HACCP

- Conduct a hazard analysis
- Identify critical control points (CCP)
- Establish critical limits for each CCP
- Establish monitoring procedures
- Establish corrective actions
- Establish record-keeping procedures
- Establish verification procedures
Food Security HACCP

- Ingredients and products entering plant
- Individuals and vehicles entering plant
- Facility (external and internal) and processes
- Products leaving the facility
Incident/Crisis Response Plan

- Reporting procedures
- Emergency evacuation plans
- A plant plan at the local fire department or in a secure location outside the plant
- Strategy for continued production
- Effective recall policy
- Relationship with qualified forensic lab
- Prepared press and customer statements
- Designated spokesperson
Informal Survey of the Industry

• The “Act” has impacted food security practices across the industry
  – “tightened-up things that needed to be done for years”
  – “lots more documentation”
  – “more focus on seals and transportation security”
  – “created structured food security programs and training”

• The majority is working on paperwork, but has not yet registered facilities
Informal Survey of the Industry

• Larger companies implemented more of the FDA voluntary guidelines than smaller ones
  – Key-pads at facility entrances
  – Lighting
  – Employee screening
  – Water supply programs
  – Non-employee identification

• Threat assessment tools
  – “HACCP and common sense”
  – Numerical scoring system using probability and severity of incident values
  – Cross-functional teams
Informal Survey of the Industry

• Challenges exist
  – Capital outlay
  – Railcar and truck integrity
  – Controlling water supply
  – “Prior Notice” regulation is a logistical nightmare, especially with LTLs
  – Securing and/or defining perimeter
  – Maintaining safe exits (in case of fire) while securing entrances
  – Training
  – Employee commitment
Resources

- FDA food security guidance documents
  - [www.cfsan.fda.gov/~dms/secguid.html](http://www.cfsan.fda.gov/~dms/secguid.html)
- The Bioterrorism Act
  - [www.fda.gov/oc/bioterrorism/bioact.html](http://www.fda.gov/oc/bioterrorism/bioact.html)
- GAO report on food processing security
- July 23, 2003, FDA progress report
- Industry Associations
- Universities
Help Keep Our Nation’s Food Supply Secure!

- Prior planning is crucial
- Keep the risk in perspective
- Collectively, our successful efforts to thwart bioterrorism will ensure consumer confidence in food products