Operational Risk Management

Ensuring Security for Food Systems

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Background

- **Threats**
  - **Bombs**
    - Chem/Bio/Agri terrorism
      - Cat A Bio Agents-- botulinum toxin, anthrax, others
      - Cat B Bio Agents-- biotoxins, gram neg. enteric pathogens, protozoa, others
      - Chemicals--e.g., (chem warfare agents), industrial chemicals
  
  - **Possible means of dispersal in food systems**
    - Air, Food, Water, Vectors, Environment

- **Terrorist tactics**
  - Exterior attacks, forced entry, covert entry, insider compromise
Modes of Chem/Bio Terrorism

Analysis of 233 past incidents of CB terrorism concludes .... top four means of delivery:

- Food, Water
  - Chemical 89%
  - Biological 4%
- Aerosol / Vapor
- Unknown
- Other

Harvey J. McGeorge, *Weaponization and Delivery of Chemical and Biological Agents: A Terrorism Perspective*. Proceedings, Chemical and Biological Medical Treatment Symposia, Dubrovnik, Croatia, April, 2001
Chem/Bio Food Terrorism

So what are the greatest concerns of agents that might be used?

- Broad effect vs. more limited attack
- Agent choice
  - Desired effect (mortality, morbidity, fear, economic)
  - Accessibility (availability, manufacture, storage)
  - Viability/Stability in vehicle (persistence, degradation)
  - Suspicion threshold (normal pathogen vs. strange event)
  - Presence indicators (odor, taste, smell)

In 1999, the US Air Force established a task force to address a recognized lack of institutionalized procedures to prevent intentional contamination of food and water...
USAF Food & Water Antiterrorism Initiative

A collaborative effort of many groups within the Dept. of Defense and Battelle Memorial Institute
The Food and Water Security Continuum

Source/Farm

Processor

Transport/Distribution

Storage

Preparation

Serving

Attacks on food or water might occur at any point

The continuum is mapped for location-specific processes from source through serving; points are identified where security threats are greatest.
Operational Risk Management (ORM)

- An approach similar to HACCP
  - Recognizes that some risk is inevitable
  - However, accept no unacceptable risk
- Provides for more effective use of resources and can be used to improve food safety and security
ORM Components

- Hazard identification
- Assess risks
- Analyze risk control measures
- Make control decisions
- Implement risk controls
- Supervise and review
Getting Started

- Establish a team to manage the ORM process, including:
  - Operations
  - Food Safety/QA
  - Asset Protection
Hazard Identification

- Identify all points in your food system where hazards might exist
- Many tools exist to support this:
  - FDA’s Food Security Guidance for Industry
  - USDA’s Food Security Guidance
  - Third party consultants
- Example
  - No employee background checks
Assess Risk

- Example: If no employee background checks, more likely to hire employee who might contaminate product.
- Probability: Occasional
- Severity: Critical
- Risk is therefore High
Analyze Risk Control Measures

- Reject--refuse the risk
- Avoid--cancel job
- Delay--delay risk
- Transfer--spread loss to another
- Spread--increase exposure time
- Compensate--redundant capabilities
- Reduce--plan systems without hazards, develop procedures and training
- Example: Employee background checks (compensate or reduce)
Make Control Decisions

- Resources have to be allocated to control the risk, if the control is implemented.
- Decisions should be made at the appropriate level.
- Example:
  - How much do employee background checks cost?
  - How effective are employee background checks?
Implement Controls, Then Supervise and Review

- Implement controls
  - Allocate resources
  - Establish accountability and provide management support

- Supervise and review
  - Monitor effectiveness of control actions
    - Regularly audit program
      - e.g., Question screening company--how thorough is their screening?
    - Regular reviews of program (e.g., as operations change and at least annual)
# ORM in a Food Processing Environment

<table>
<thead>
<tr>
<th>Facility security</th>
<th>Assess Risk</th>
<th>Risk Control Measure</th>
<th>Rank</th>
<th>Control Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. No one is assigned responsibility for security</td>
<td>No accountability for security procedures</td>
<td>Assign person in charge of security</td>
<td>Med/5</td>
<td>Implement</td>
</tr>
<tr>
<td>b. No procedures for investigating unusual activity</td>
<td>No procedures prevents appropriate, consistent follow-up of unusual activity</td>
<td>Written procedures to document investigation and follow-up of unusual activity</td>
<td>Med/8</td>
<td>Implement</td>
</tr>
<tr>
<td>c. Unrestricted access into building</td>
<td>Access to foods and intentional contamination possible</td>
<td>Allow only controlled access to food and ingredient areas: - Locks on doors/windows, storage tanks - Secured vents, fresh air intakes, and roof openings</td>
<td>Med/2</td>
<td>Implement/1 Implement/2</td>
</tr>
<tr>
<td>d. Access to building not monitored</td>
<td>Access to foods and intentional contamination possible</td>
<td>Monitor access: - Sign in/out - Account for all keys to establishment - Surveillance cameras - Security patrols - Adequate lighting exterior and interior - Limit potential hiding places for intentional contaminants</td>
<td>Med/4</td>
<td>Implement/2 Implement/1 Implement/3 No No No</td>
</tr>
<tr>
<td>e. Employees have unrestricted access to all areas of plant</td>
<td>Access to chemicals, laboratory, and foods (ingredients, processing, and finished products) with potential for intentional contamination</td>
<td>Restrict employee access to only areas of plant related to their function</td>
<td>Hi/1</td>
<td>Implement</td>
</tr>
<tr>
<td>f. No supervision of contractors (cleaning, maintenance, construction, etc.) or visitors (tours, sales, auditors, truck drivers, regulators, mail delivery, etc.)</td>
<td>Access to foods and intentional contamination possible</td>
<td>Allow no unsupervised access to plant by contractors or visitors</td>
<td>Med/3</td>
<td>Implement</td>
</tr>
<tr>
<td>g. Contractor tools, equipment, vehicles not inspected prior to entering facility</td>
<td>Could provide concealed means to bring agents into facility</td>
<td>Inspect all tools, equipment, and vehicles entering plant</td>
<td>Med/6</td>
<td>Implement</td>
</tr>
<tr>
<td>h. Laboratory (QA/R&amp;D) chemical and culture access not restricted</td>
<td>Could provide ready source of intentional contaminants</td>
<td>- Lock up reagents and microbial positive control cultures - Restrict laboratory materials to the laboratory - Keep timely and accurate inventory of reagents and positive control cultures - Investigate missing reagents or cultures and document findings</td>
<td>Med/9</td>
<td>Implement all concurrently</td>
</tr>
<tr>
<td>i. Hazardous chemical (e.g. cleaning/sanitizing agents, pesticides) storage access not restricted</td>
<td>Could provide ready source of intentional contaminants</td>
<td>- Lock/limit access to chemical storage areas - Supervise maintenance and sanitation staff - Keep timely and accurate inventory of hazardous chemicals - Investigate missing chemicals and document findings</td>
<td>Med/7</td>
<td>Implement all concurrently</td>
</tr>
</tbody>
</table>
Food/Water Security Doesn’t Have to be Complicated
The price of food security is eternal vigilance