

FDA & Food BioSecurity

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**CVDPA and NCDPA
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Requested Information

- **Laboratory Reaction & Capability for Emergencies**
- **Availability & Accuracy of Rapid Test Kits**
- **Multi-State Cooperation on Security concerns**

September 11, 2001

- **Wake Up Call**
- **U.S. Food Supply is at Risk**
- **How Do We Protect the Food Supply?**

Identifying Potential Threats

Threat Equation

Threat = Capability + Intent + Vulnerability

Identifying Potential Threats

Strategies for Threat Reduction

- **Reduce capability – not our responsibility**
- **Anticipate Intent – Very Difficult**
- **Identify & decrease vulnerability - ORM**

ORM

Operational Risk Management

- **Six step process to identify and prioritize hazards and preventive measures to reduce risk**

ORM

- **Identify hazards**
- **Assess the risks**
- **Analyze risk control measures**
- **Make control decisions**
- **Implement risk controls**
- **Supervise and review**

Protecting the Food Supply

- **Personnel**
- **Product**
- **Property**

Prevention vs. Protection

- **Prevention is NOT 100%**
- **Can We Prevent an Attack on Food?**
- **Protect to Prevent**
- **Protect to Deter**

Deterring an Attack

- **3 L's**
 - **Limit Access**
 - **Light It**
 - **Lock It**
- **Cannot be Done Alone**
 - **Security & Law Enforcement Specialists**

Laboratory Preparedness

- **Biological Agents**
 - Clostridium botulinum
 - Bacillus anthracis (anthrax)
 - Yersinia pestis (plague)
 - Francisella tularensis (tularemia)
 - Brucella sp. (brucellosis)
 - Salmonella
 - Ricinus communis – ricin toxin (castor bean)

Laboratory Preparedness

- **Bacteriological or viral agents**
 - Not an effective way to contaminate large volumes of milk
 - Might be used to contaminate retail products
 - Limited deaths
 - Widespread panic

Laboratory Preparedness

- **Chemical Agents**
 - Heavy Metals
 - Pesticides
 - Drugs
 - Radionuclides
 - Poisons
 - Industrial chemicals

Laboratory Preparedness

- **Major Concern**
 - **Chemical Contaminants**
 - Low concentrations lethal
 - Labs don't look for these agents
 - Methodologies for chemical agents are expensive
 - **CDC**
 - Setting up four or five regional labs (State?) to test for chemical contaminants
 - These labs will probably test clinical rather than environmental samples

Laboratory Preparedness

- **Contingency Plans**
 - Alternate locations
 - Shifting of personnel
 - Alternate labs

Laboratory Preparedness

- **Biological Safety Levels**
 - BSL 1
 - Milk Lab
 - BSL 2
 - Minor Pathogens
 - BSL 3
 - Pathogens (Ebola)
 - Most States don't have a BSL 3

Laboratory Preparedness

- **Main efforts**
 - Additional BSL 3 laboratories
 - Obtaining equipment & test kits
 - Obtaining personnel
 - Training personnel
- **Front line laboratories**
 - Public health labs

Laboratory Preparedness

- **Test Kits**
 - Military
 - Private
- **Test Kits**
 - Rapid?
 - Need high concentrations of bacteria to work
 - Present kits test for standard food pathogens

Louisiana

- **\$16 million grant**
- **Epidemiology program**
 - Rapid response teams (epi & lab staff)
- **Pharmacy**
 - Stock piling drugs
- **Preparedness training**
- **Networking**
 - State lab/private labs
 - Training
 - Improve communication
- **New instrumentation**
 - DNA testing in 4 OPH labs

California

- **Incorporated ORM in GMP inspections**
- **Provided ORM training to State & local agencies**
- **Developing 'strike teams'**
- **Augmenting lab capacity**
- **Secure website for improved communication among agencies**

Texas

- **ORM guidance to industry**
- **Training staff in biosecurity**
- **Bioterrorism work group**
- **State emergency mgt plan**

Oregon

- **Developing guidance documents for industry**
- **Updated emergency contact numbers for agencies**

Minnesota

- Updated emergency contact database
- Videoconferences on biosecurity
- Proposed legislation to give Health, Agriculture, & Animal Health additional authority regarding the movement of people, animals & commodities

Other States

- Some are doing more than others, but all are focusing more attention on food security
- Better coordination among agencies
- Developing new programs

FDA Emergency Operations

- **Nationwide, 24 hour emergency telephone number**
 - (301) 443-1240
- **Local FDA District Office**
 - www.fda.gov

FDA Emergency Operations

- **Provide coordination and immediate response to foodborne illnesses, product tampering, counterfeit products, threats, bioterrorism events**
 - FDA field staff, Centers, and labs
 - CDC, USDA, EPA, FBI, FEMA, state & local health regulatory agencies
 - Industry

Multi-State Cooperation

- **5 C's**
 - **Communication**
 - **Consultation**
 - **Coordination**
 - **Collaboration**
 - **Cooperation**

Multi-State Cooperation

- **Contact/meet with neighboring States**
- **Coordinate activities/efforts with other agencies within your State**
- **Meet, consult, coordinate NOW—Don't wait until an attack occurs.**

Everyone Must Work Together

- **Government**
- **Academia**
- **Public health agencies**
- **Industry**
- **Media**
- **Consumers**

- **The Nation Must Not Lose Confidence in the Food Supply**
- **The Nation Must Not Lose Confidence in the Government**

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