FDA Current Thinking on Foodborne Outbreak Investigations

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FDA/CFSAN

FDA Policies & Procedures

- FDA Crisis Management Plan
- FDA Chemical & Biological Emergency Response Plan
- CFSAN Emergency Response Plan
- These include:
  - Coordination
  - Roles & responsibilities
  - Communications

FDA Roles & Responsibilities

- Office of Crisis Management
  - Office of Emergency Operations
- Office of Regulatory Affairs
  - District Offices
  - Field laboratories
- Center for Food Safety & Applied Nutrition
  - Emergency Coordination & Response Team
  - Scientific & policy experts

Anatomy of an Outbreak Investigation

- Surveillance
- Epidemiological investigation
- Laboratory analysis
- Environmental investigation
- Response/recall
- Traceback/traceforward
- Farm investigation

Surveillance

- Local & State Health Departments
  - Surveillance & detection
- Laboratory surveillance
- Consumer complaints
- CDC consultation
- Regulatory Surveillance
  - Inspections
  - Samples

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Epidemiologic Investigation

- Conducted by state and local public health agencies,
- FDA relies on CDC vetting of epi & lab investigation data & CDC's recommendations
- FDA reviews the epi and lab investigation data before we act

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Laboratory Investigation

- Clinical
- Food
- Environmental
- PulseNet

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Environmental Investigation

- Environmental investigation:
  - Point of service
  - Along the chain of distribution
    - i.e. distributor, manufacturer, re-packer, farm
  - Identify possible sources of contamination
    - not your normal inspection

Environmental Investigation

- Critical to identifying where the contamination occurred and at which point(s) in the distribution chain
- FDA won't be involved if contamination occurred at point of service; that's within a state's jurisdiction
- Usually involves sample collection

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Response/Recall

- Response
  - Criteria:
    - Epidemiological association
    - Laboratory association
    - Negative environmental at point of service
    - Population still at risk?
- Recall
- Press

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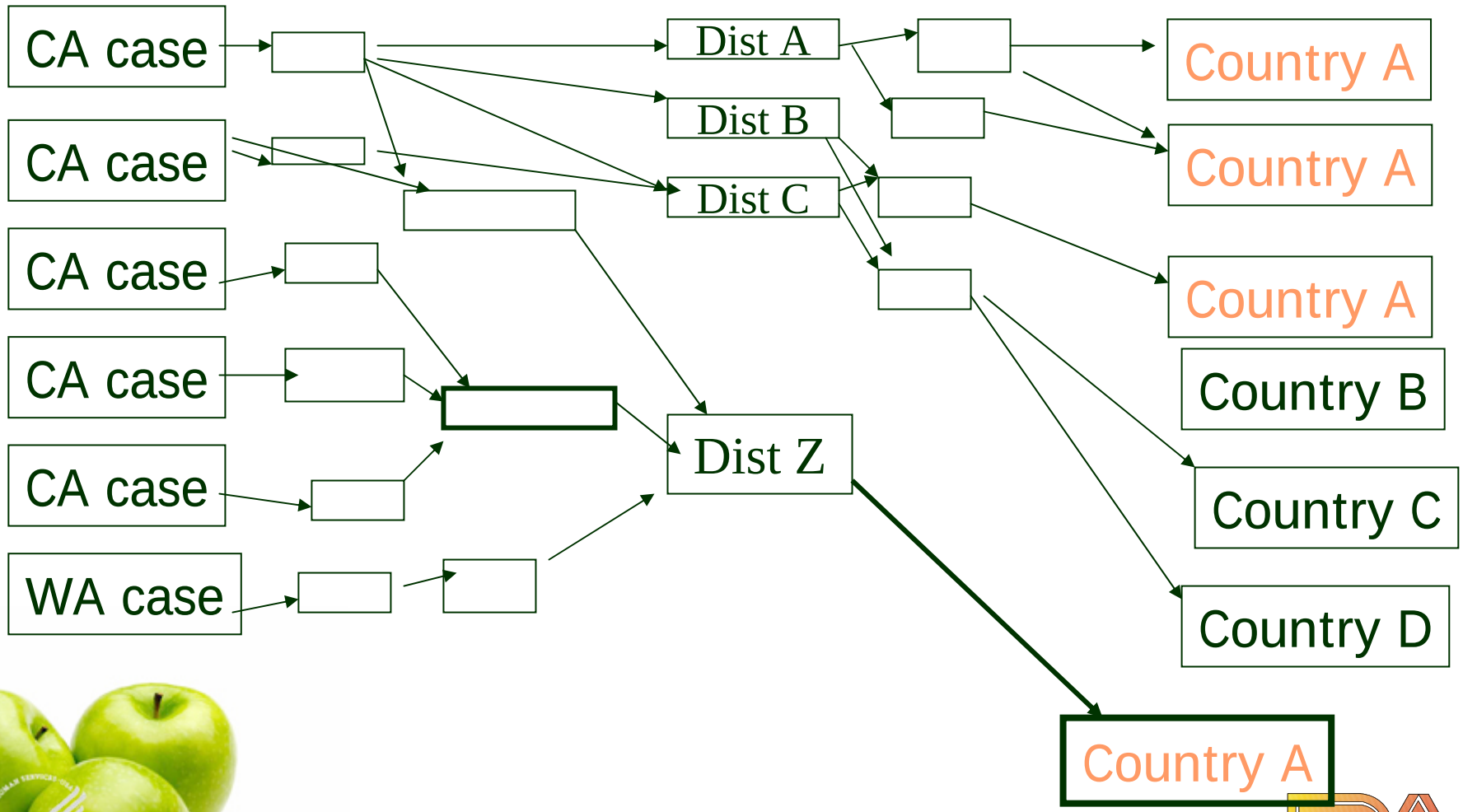
Traceback Diagram



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Farm Investigations

- What we look for:
  - *Note*: Not your typical inspection
  - Sources of Microbial Contamination
- What we've found:
  - Team approach is critical (investigator, sanitarian [water], microbiologist, wildlife biologist, epidemiologist)
  - Planning and Coordination is key

Lessons Learned From Past Investigations

- Detection
  - Variable capacity in different state and local public health agencies
  - Some states and locals do not notify FDA or CDC
- Epidemiologic Investigation
  - How good is the epi data and who decides?
  - What if CDC is not involved?
  - How do we use local investigations in enforcement?
  - Locals need to keep data. We may need it years later.

Lessons Learned From Past Investigations

- Traceback
  - Poor and incomplete record keeping
  - Slow response in providing records
  - Multiple sources of the same product at the same time at various steps in the system
  - Records from one point do not line up with records from the next point
  - Processors can not match finished product with incoming raw ingredients
  - Tracebacks often require huge amounts of resources

Lessons Learned From Past Investigations

- Response
  - Need to be fast and right
  - Legal review requirements
  - Use of Incident Command/NIMS
- Information Technology
  - Servers crash, Blackberries fail
  - Communicating with field investigation teams
  - Information management
    - eRoom
    - Emergency Operations Network

Lessons Learned From Past Investigations

- Communication
  - Information overload (phone, e-mail)
  - Need for early notification of consumers
  - How to keep everyone informed inside and outside government, domestic and international?
  - Secondary and tertiary distribution, how to keep everyone informed?
  - Need for clarity on roles and responsibilities
  - Coordinating public statements within and among agencies
  - Restrictions in what can be shared

Lessons Learned From Past Investigations

- Decision Making
  - Criteria for FDA to get involved
  - Criteria to initiate traceback, recall, press
  - When is perishable product out of distribution so press is not warranted?

Lessons Learned From Past Investigations

- Environmental/Regulatory Investigation
  - Standardized protocols and forms
  - Investigation VS Inspection
  - Multi-organization coordination
    - CalFERT
- Recalls
  - Effectiveness checks show that some products remain in the system e.g., food pantries
  - How to coordinate with industry, states and locals?

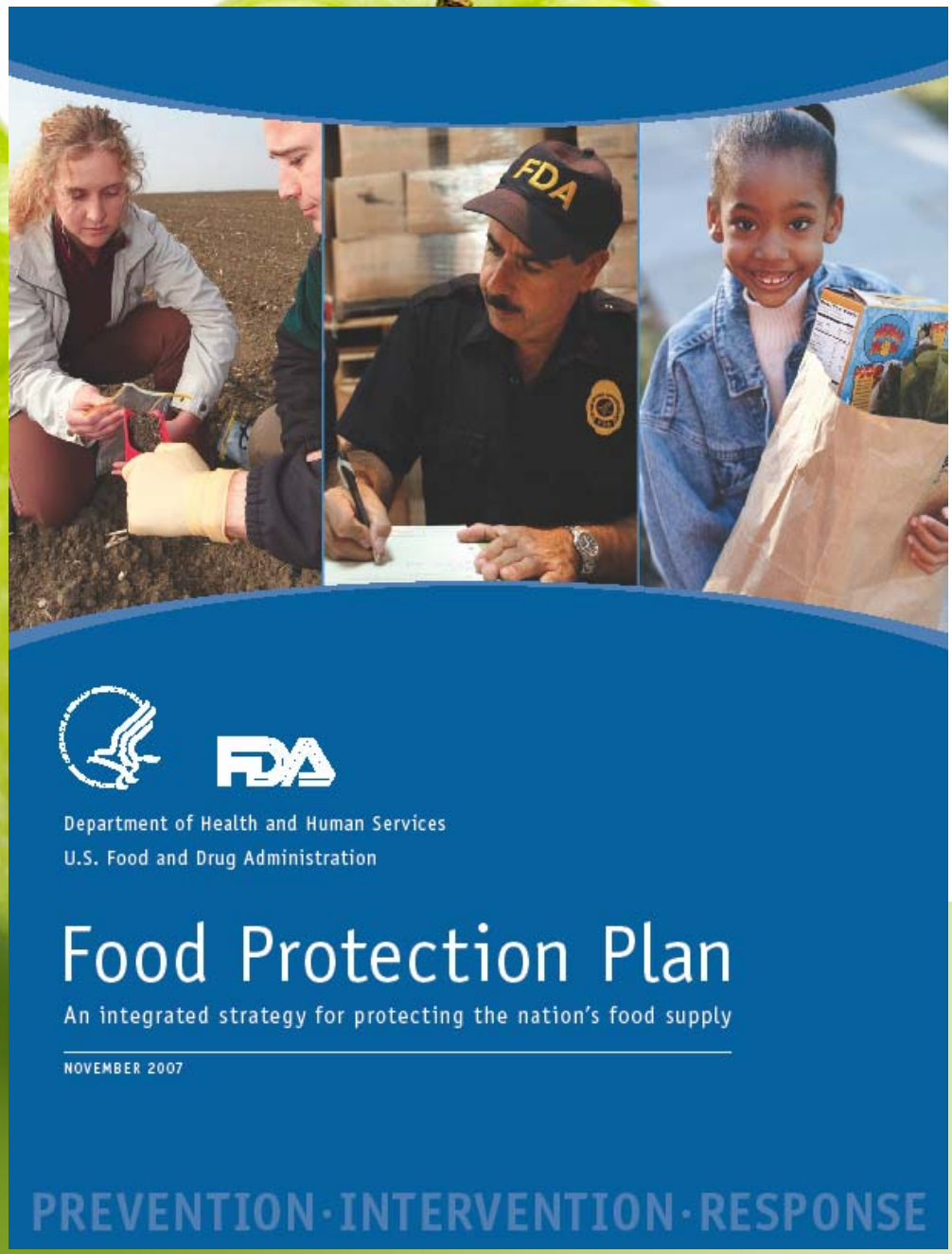
Lessons Learned From Past Investigations

- General Comments
  - Staff burn out
  - Staff does best in emergencies those things that they are familiar with
  - Exercises and training are always needed
  - Tracebacks do take time
  - Environmental investigations take time
  - Laboratory analysis does take time

Questions?

U.S. Food and Drug Administration

Food Protection Plan



Changes and Challenges
New Foodborne Pathogens Since 1977

- *Campylobacter jejuni*
- *Cryptosporidium parvum*
- Shiga toxin-producing *E. coli*
- Noroviruses
- *Vibrio cholerae* O139
- *Vibrio parahaemolyticus*
- *Campylobacter fetus*
- *Cyclospora cayetanesis*
- *Listeria monocytogenes*
- *Salmonella* Enteritidis
- *Vibrio vulnificus*
- *Yersinia enterocolitica*
- *Enterobacter sakazakii*
- *Salmonella Typhimurium* DT104

The Food Protection Plan

Food Protection
Cross-Cutting Themes

- Focus on risks over a Product's life cycle –
- Target resources to achieve maximum risk reduction
  - Gather the science
  - Rank products based on risk
  - Focus prevention and intervention
- Integration of food safety and food defense
- Use science and modern technology systems

Food Protection Plan

- Three core elements:
  - Prevention
  - Intervention
  - Response
- Under each element
  - Key steps
    - FDA actions
    - Legislative proposals

Response
Core Element No. 3

- Improve Immediate Response
- Improve Risk Communication to the Public, Industry, and Other Stakeholders

Response
Immediate Response

Agency Actions:

- Enhance capabilities of FDA's Emergency Operations Network Incident Management System
- With stakeholders, develop an action plan for more effective traceback (process/technologies) of contaminated food and feed
- Enhance IT networking for real-time lab communication

Response
Immediate Response

Legislative Proposals:

- Mandatory Recall of Food Products
  - Reasonable belief the food is adulterated and presents a risk of serious illness or death
  - Used only when firm refuses or delays a voluntary recall
- Enhanced Access to Food Records during Emergencies
  - Current access requires reasonable belief that a food is adulterated AND presents a risk of serious illness or death
  - Would allow access when specific adulterant has not been identified
  - Expand access to records for *related* foods, such as food produced on the same production line

Response
Risk Communication to Stakeholders

Agency Actions:

- Design and conduct consumer communications and behavior response studies
- Use study information to update Food Protection Risk Communication Plan with strategies to effectively communicate with consumers
- Website for food protection information
- In a food emergency, implement Food Protection Risk Communication Plan to get appropriate information to consumers, retailers, industry, healthcare community, public health officials, and other stakeholders