



# The Role of FDA

AFDO Foodborne Illness Workshop

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# Overview

- FDA's role
- Lessons learned from past outbreaks
- Improvements at FDA
- Coordinating surveillance and response
- Coordinating communications
- The importance of stakeholders



# Why do we do Investigate Outbreaks?

- Take prompt control actions –  
    Take the handle off the pump!
- Identify and interpret trends in foodborne disease
- Determine the consequences of foodborne illness
- Identify emerging problems and stimulate actions to address them
- Evaluate intervention programs
- Set goals and priorities for food safety
- Adjust reg. policies, philosophy, training, etc.



# FDA's role

- Investigation and coordination in multi-state outbreaks
- Review of epidemiological and environmental data
- Tracebacks of implicated foods
- Investigation at site of contamination and sample collection



# FDA's role

- Provide investigational and laboratory assistance
- Monitor recalls
- Take other appropriate regulatory actions
- Evaluate data to identify trends and make recommendations to prevent similar problems



# Investigation Lessons

- FDA depends on epidemiology to identify outbreaks and to identify the vehicle
- FDA responds to what the epidemiology is telling us
- Many public health agencies lack epi and lab resources to effectively do their jobs
- FDA is limited in its ability to share findings with public health agencies and industry



# Investigation Lessons

- Federal, state and local public health agencies need to improve detection, response and coordination
- FDA investigations have often been hampered by lack of epi and trace information from state and local agencies
- More efforts for outreach to industry and consumer groups
- PulseNet has had a tremendous impact on foodborne disease surveillance. It detects most of these interstate outbreaks. CDC monitoring 30 – 40 clusters at any time.



# Investigation Lessons

- We have to be fast and we have to be right in these investigations
- Tremendous media, public and legislative attention
- Major task developing and issuing public messages
- Stealth ingredient vehicles make investigations even more complicated





# Improvements at FDA

- CORE
- Partnership for Food Protection: Response Workgroup
- FDA/CDC/FSIS workgroup
- Environmental assessment
- FSMA: partnerships and capacity building with state and local partners
- Rapid Response Teams
- Traceback: speed, accuracy
- Recalls: speed, coordination



# Improvements at FDA

- Retail Food and Manufactured Foods Voluntary Program Standards 5
- FDA / FSIS / AMS reviewing and updating MOUs
- FDA / CDC/ FSIS / State / Local Outbreak Brainstorming workgroup
- Produce Safety Alliance



# FDA Coordinated Outbreak Response and Evaluation Network (CORE)

- In July 2011, FDA will launch the CORE Network
- Mission: to coordinate, conduct and improve FDA's preparedness, response and post response efforts involving **human and animal** food **and feed** related outbreaks of illness, both within the Agency and in collaboration with its partners.
- Structure: CORE will have a Chief Medical Officer (CMO) who will direct all outbreak related activities and will act as spokesperson during outbreaks. A Senior Advisor will report to the CMO.

# CORE Structure (cont'd)

- Two managers will lead the Response and Prevention/Post-Response sides of CORE.

## **Prevention side:**

- Surveillance (signals) Detection, trending
- Post-Response (reports, environmental assessments, lessons learned)

## **Response Side:**

3 multidisciplinary outbreak investigation teams

Communications specialists will be “imbedded” within the CORE Network structure



# Partnership for Food Protection: Emergency Response Workgroup

- Co-Chairs:
  - Ben Miller – state
  - Susan Palchick – local
  - Jack Guzewich / Roberta Hammond – Federal
- Charges being worked on:
  - Traceback white paper
  - Communications



# FDA / CDC / FSIS Collaboration Group

- Cluster calls
- Exchange / orientation / cross training
- Building relationships
- Risk communication workgroup



# Environmental Assessment

- Environmental assessment
  - how the food was contaminated (contributing factors)
  - what conditions/practices permitted the contributing factors to happen (environmental antecedents)
- To identify preventive controls



# Environmental Assessment Implementation Plans at FDA

- Outbreaks and contamination events
- FDA work group
- Documents:
  - One pager: overview of EA objectives at FDA
  - SOP outline
  - Case study: E coli O157:H7 cookie dough
  - Concept paper for ELT
- Training
- Stakeholder outreach
- Data collection system:
  - Contributing factors & environmental antecedents
  - Preventive controls





# Rapid Response Teams

- Nine states: WA, MN, FL, MA, NC, TX, VA, CA, MI
- RFR recently issued for 6
- Playbook



# Traceback

- Working closer with states (FoodShield)
- Contacting industry earlier and more often
- More use of electronic records
- Pilots – were waiting for money



# Recalls

- Working with CDC and others to improve outbreak investigations
- FDA is in the process of automating the recall audit check process
  - When completed states will be able to access a list that contains consignees for food / feed recalls affecting their state



# Coordinating Surveillance and Response

- CIFOR: Guidelines and Toolkit
- Training courses
  - Epi-Ready – NEHA
  - Industry – Foodborne Illness Training – NEHA
  - Free – B
  - ICS
  - Foodborne Illness Investigation
  - Produce Farm Investigations



# Coordinating Communications

- Press releases: federal, state, local & epi  
VS regulatory: who goes first & what is the message, consistent messages
- Communicating within and among agencies
- Industry: needs to know info in order to act
- Consumers: giving them actionable information



# Produce Safety ALLIANCE

- A broad-based partnership charged with developing a national education and training program for farmers, packers, and regulatory personnel
- Launched in Fall 2010, the Alliance is a public-private partnership with Cornell University, USDA and FDA, under a cooperative agreement between USDA/AMS and Cornell University
- In anticipation of FDA's issuance (late 2011) of a proposed rule for the production, harvesting and on-farm packing of fresh produce, the Alliance has created 10 working committees, each focused on a specific aspect of produce safety.
- Committees will: review existing educational and instructional materials; identify gaps where current information is lacking; and develop and continuously update multi-formatted educational programs on produce safety, as well as how to co-manage food safety and environmental concerns.
- To view a complete list of working committees and details of the scope of work of each, visit <http://producesafetyalliance.cornell.edu/working.html>



# The Importance of Stakeholders

- Everyone is a stakeholder
- Playing nice in the sandbox
- Importance of transparency
  - Transparency web page:
    - <http://www.fda.gov/AboutFDA/Transparency/default.htm>
  - FSMA Web Page
    - <http://www.fda.gov/Food/FoodSafety/FSMA/default.htm>
- Reach out and touch someone
  - Do so before the emergency!



# Questions?