

# *E. coli* O104:H4 Outbreak in EU

Learning → Changing → Improving  
Food Safety



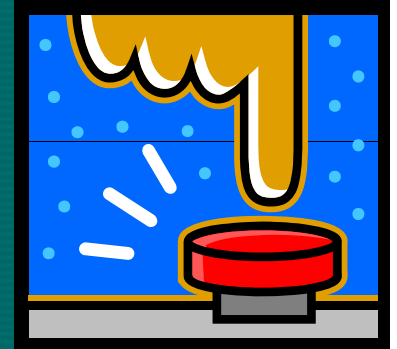
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# Outline

- Outbreak in EU
- Learning from Outbreaks
- Changes and Improvements



# Initial Media Reports



- May 23: Various Quotes

“Potentially Fatal Strain of e-coli spreading in Germany”

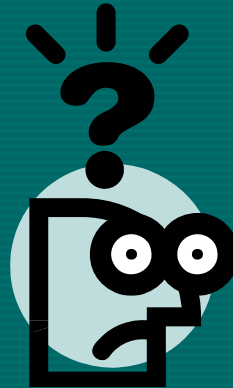
“...EHEC, hospitals across Germany report surge in infections..”

Total of 40 treated in Hamburg, mostly female, city health authority said.

“...disease experts said evidence of uncooked vegetables might have helped spread latest outbreak..”

# Timeline: May 23 - 31

- Hamburg official says detected EHEC on cucumbers likely from Spain
- German official states cucumbers (sample) not responsible for outbreak
- RFI – Advise consumers in Germany to abstain from eating raw cucumbers, tomatoes, and leafy salads



# Timeline: June 1 - 4

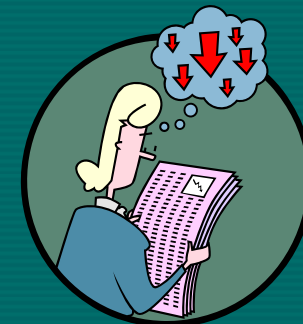
- RKI: Additional epi studies = warning stands
- FDA and CDC post statements
- “...reports said police investigating a possible deliberate act..”
- Region German authority – More than 2,000 ill
  - Festival in Germany drew 1.5 mil visitors
- WHO expert expresses skepticism that EHEC come from salad and points to beef.

“...No clear lead...”



# Timeline: June 5-7

- June 5 - Regional Ag Minister:
  - **Bean sprouts suspected as source.** Expect confirmation...
  - Different kinds (18) of sprouts from one farm traced to ill person in 5 different German states
  - Fresh herb, fruits, etc recalled. Farm shut down
  - One of farm employee infected with *E.coli*
- June 6 – German official:
  - Initial tests provided **no evidence that bean sprouts are the cause of the outbreak**
- June 7 – Reports of new cases on decline





## Timeline: June 8 -10



- June 8:
  - Cucumbers under fresh suspicion
  - Still evidence leading to sprouts from one farm
- June 9:
  - Sprouts from beans and peas as a salad garnish prime suspect
  - “May never know the cause”
- June 10: “It’s the sprouts”, President of RKI.

# Timeline: June 10-13

- All clear on cucumbers, tomatoes, and lettuce
- Sprouts implicated...3 employees of the implicated farm fell ill last month... Intense investigation at restaurant...(RKI)
- O104 detected on half used retail package of sprouts from ill consumer home
- May not be animal but human source
- Don't home grow sprouts; seed might be contaminated





# Outbreak in EU - Epidemiology

- As of June 17:
  - Total: 3604 HUS and EHEC cases, including 40 fatalities
    - EHEC – 2752 cases, 12 death
    - HUS – 852 cases, 28 deaths
  - In Germany 61% of the EHEC cases and 70% of the HUS cases are in female (as 6/3/2011).
  - Ages severely affected very unusual
  - # of reported cases of HUS/EHEC has declined significantly
  - Most cases reported or exposed in Northern Germany
    - US cases had connection to Germany



Source: WHO

# Cracking the Case

- Intensive cluster investigation
  - Travel coach group ate a restaurant
  - Patrons took lots of pictures including food
  - All affected ate sprouts
- Several case control studies
- Product tracing to link to clusters
- Teamwork by RKI, DG SANCO, Regional and local German officials, and others



# Outbreak in EU – Testing

- Thousands of samples tested
- Lack of common protocol for STEC early on
- Surge capacity
- Interpreting/Communicating lab findings
  - Open samples from ill consumer homes
  - Preliminary lab findings, not confirmed
- 300 samples from implicated farm in process



# Outbreak in EU - Investigation


- Global food supply
- FDA actions – Increased and adjusted sampling, communication with EU and CDC, consumer reassurance, shared sprout resources
- How sprouts became contaminated remains under investigation by EU officials



# Outbreak in EU - Communications

- Pressure of finding the answer fast
- Consequences of releasing unconfirmed information
  - Consumer trust and confidence
  - Appear not to be transparent
  - Interpretation by others of significance/meaning
  - Economic/trade





# Some Challenges Not Unique to Outbreak in EU

Lessons from US Outbreaks

# Similar Challenges

- Delays in illness reports
- Pinpointing the food causing illnesses
- Traceback
- Laboratory testing, particularly with STEC
- Determining how contamination occurred
- Interagency coordination
- Responding to information requests



# Managing the Incident

- Urgency to solve
- Communications
  - Sharing info with stakeholders
  - Information management
- Multiple officials making public announcements
  - Who's the official voice
  - What do consumers believe





# Lessons from US Outbreaks

- *E.coli* O157/Spinach
- Salmonella Saintpaul
- S. Montevideo/Peppered deli meats
- *E.coli* O145 in shredded lettuce
- Deep Horizon Oil Spill
- SE in shell eggs



# Evaluation of Response

Emergency Plans  
and Procedures

Evaluate  
Modify

Train  
Practice



# Lessons

- Epidemiological investigation
  - Clusters are key
  - Still need new approaches when clusters small
- Laboratory
  - Common methods, confirmatory results, subtyping
- Environmental assessments – intensive but key
- Communications/Leadership
- Managing the incident



# Changes → Improvements

- NIMS/ICS
- CORE  
Network
- FSMA



# NIMS Overview

- NIMS Components

- Preparedness

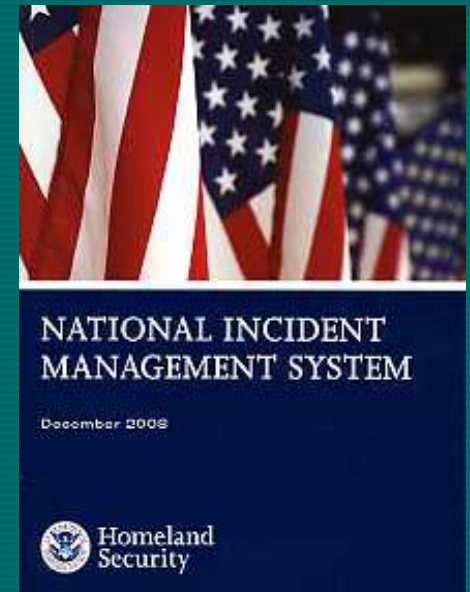
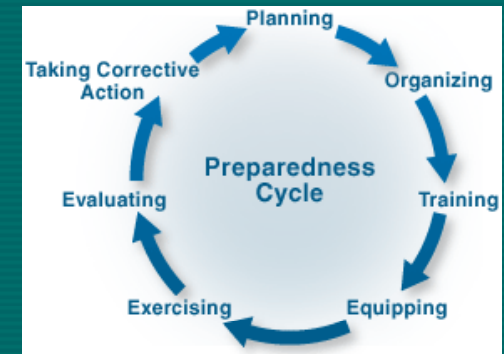
- Communications and Information Management

- Resource Management

- **Command and Management**

- Incident Command System (ICS)
    - Multiagency Coordination Systems
    - Public Information

- Ongoing Management and Maintenance



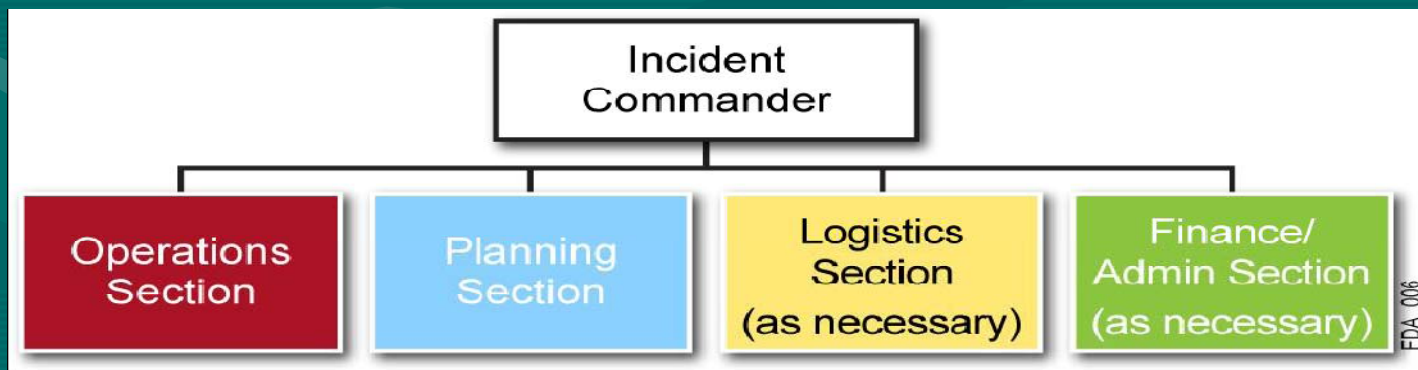
# ICS Benefits

- Meets needs of incidents of any kind or size.
- Allows personnel from a variety of agencies to meld rapidly into a common management structure.
- Provides logistical and administrative support to operational staff.
- Is cost effective by avoiding duplication.



# NIMS at FDA - IMT

- Incident Management Team (IMT)
  - Field level response structure
  - Planning for five FDA IMTs
    - One team from each of the five FDA Regions.
  - IMTs were mobilized:
    - 2010 *Salmonella* Montevideo outbreak
    - 2010 Deepwater Horizon oil spill incident



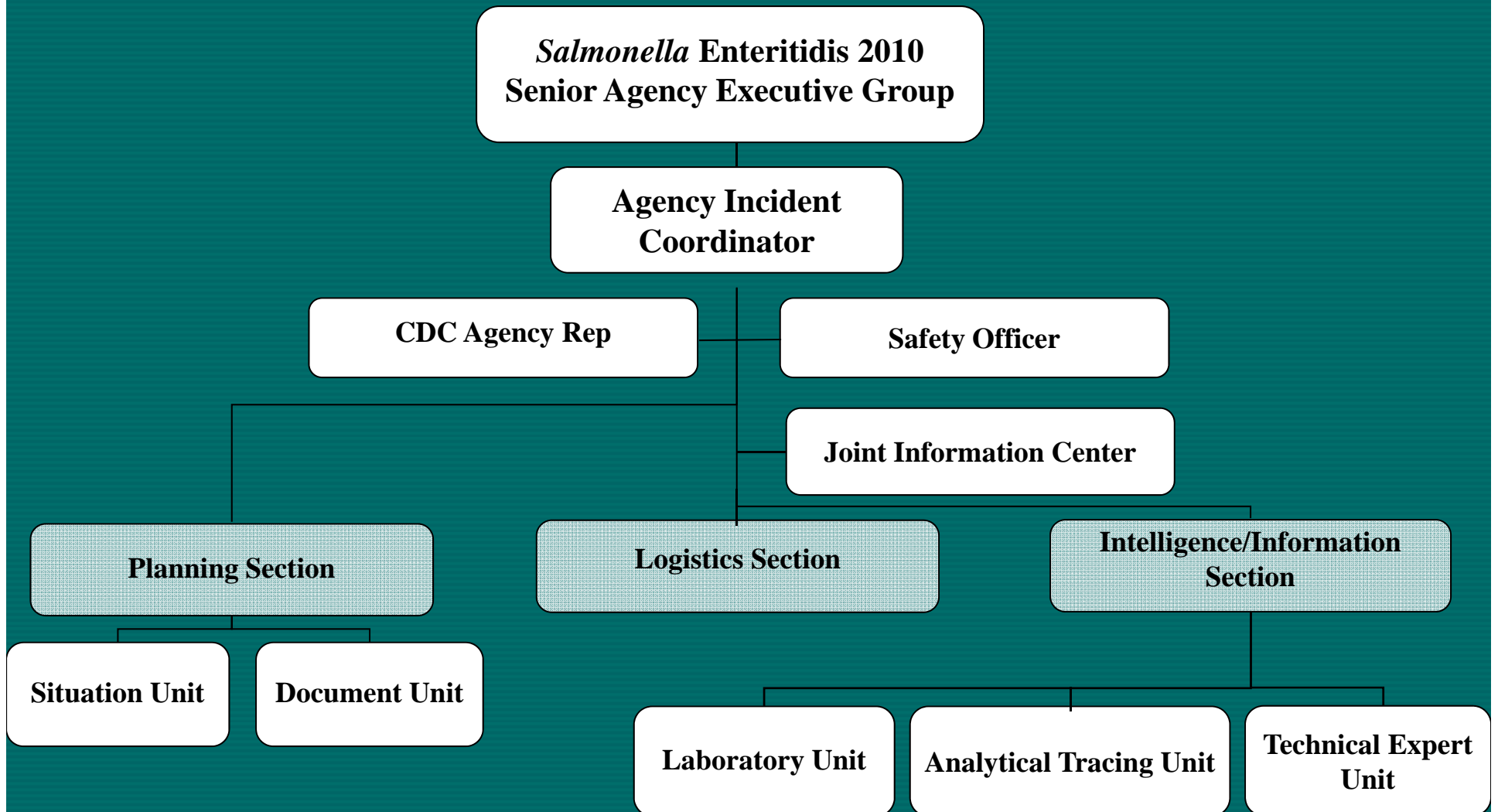
# NIMS at FDA - IMG

- Incident Management Group (IMG)
  - Headquarters level response structure
  - IMGs were utilized during several recent responses including:
    - 2010 *Salmonella* Montevideo spiced meat rub (salami) outbreak
    - 2010 Deepwater Horizon oil spill incident
    - 2010 *Salmonella* Enteritidis in eggs incident
    - 2011 Japan Earthquake/Tsunami/Nuclear Reactor Response

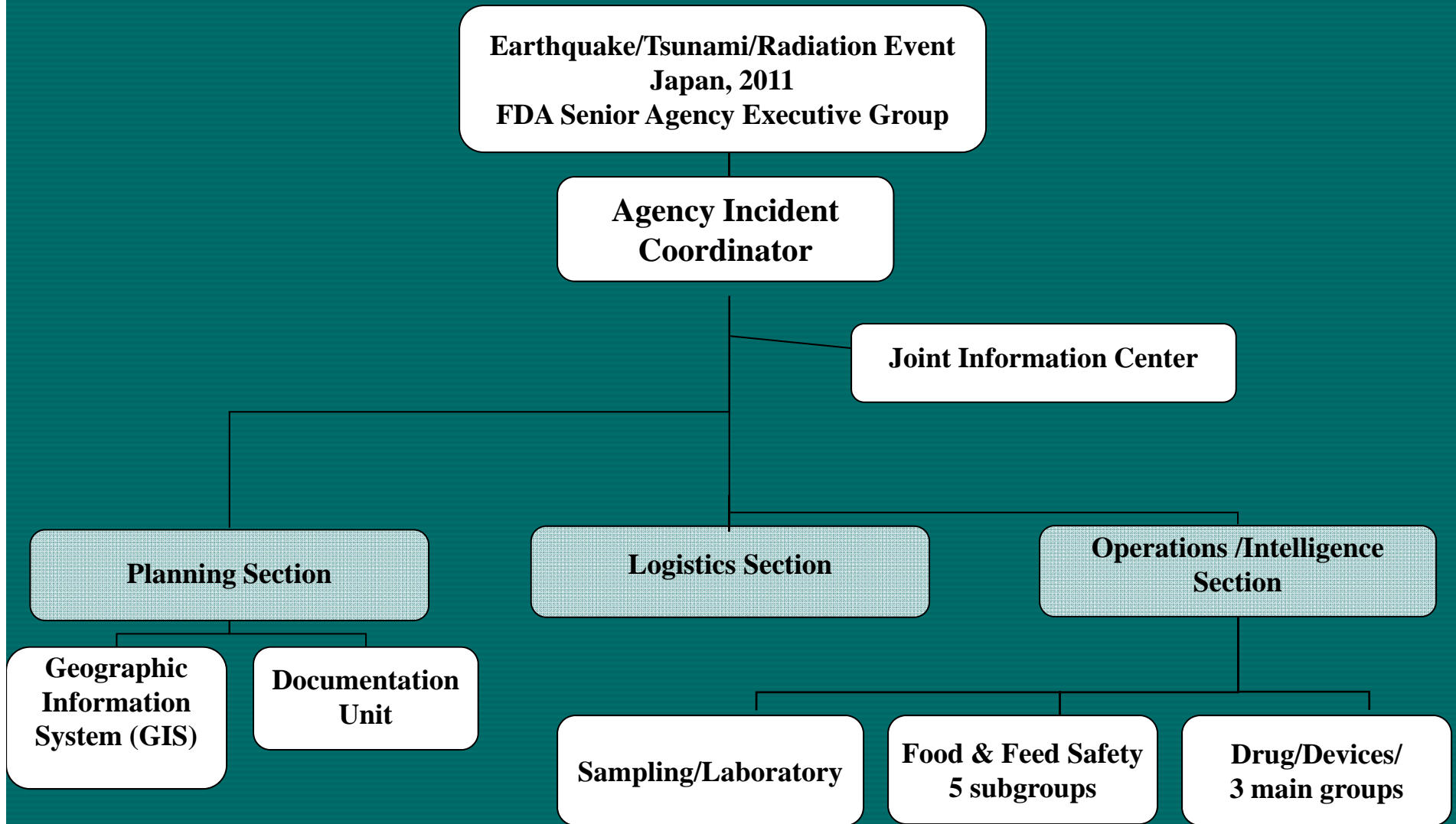




# S.E./Egg Outbreak – FDA IMG 2010



# Earthquake in Japan- FDA IMG 2011



# Multi-Agency Coordination

- Incident crosses agency jurisdictional lines may use MAC to support a unified coordination of operations.
- Primary function:
  - coordinate activities above the field level
  - prioritize incident demands for critical or competing resources.
- Representatives from each agency set goals and decide how each agency can contribute to the achievement of the goals



# Best Practices

## Oil spill – Deep Water Horizon

- Coordinated Interagency Response
- FDA activated an IMG and AEG
- Extended activation – 4 months
- Interagency development sampling plans
  - NOAA and FDA – levels of testing, capacity
- Scientific tools to inform risk management
  - GIS mapping - over 200 maps



# Best Practices - FDA perspective

- Engage stakeholders early
- Activate the ICS structure early
  - Establish triggers
  - Train with stakeholders including industry
- Establish process for managing requests for information
- Communicate often, consistently and in a **coordinated manner**
- **Clear decision maker/leader**





Created to manage surveillance, response, and post-response activities related to incidents of illness linked to FDA-regulated human and animal food.

# What's CORE about?

- Build upon the best of what we currently do across FDA in outbreak response
- Clear leadership/spokesperson in outbreak
- Goal of the CORE network:
  - streamline incident-related processes, which were previously dispersed throughout the FDA
  - enhance transparency and working relationships with our internal and external stakeholders.



# What does it mean to you?

- It may not feel a lot different but there will be changes
  - some changes more visible than others
  - some changes sooner than others...
- What's not changing:
  - District remains your point of contact.
  - RRTs continue with District/Region as point of contact. DFSR role remains as it is now.





# CORE – what it means to you

- What is changing?
  - More emphasis on prevention
  - Increased outreach to states via Districts to collaborate during an outbreak and examine data
  - Emphasis on environmental assessments
  - Communicating FDA's findings more frequently; collaborating on reports.



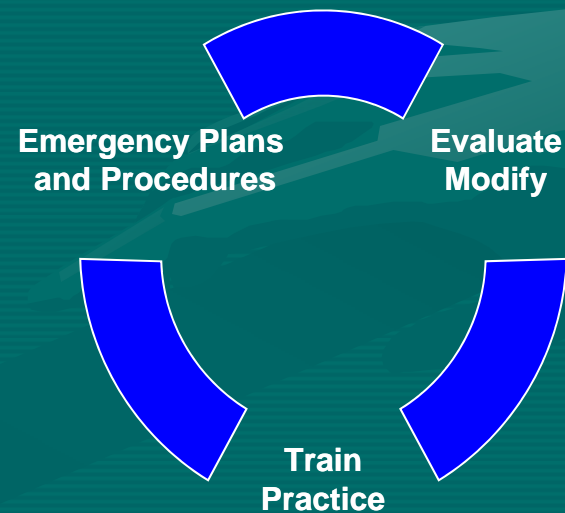
# New Food Safety Authorities

- Food Safety Modernization Act 2011
  - Preventive controls
  - Risk based inspection strategy
  - Imported Food Safety
  - **Build capacity**
  - **Surveillance, Product Tracing, Mandatory Recall**



# Overview Summary

- Prevention First
- Detection and Response
- Learn from Outbreaks
- Implement improvements
  - food safety practices and polices
- Update plans and exercise together



# Key Points to Close Regulatory Collaboration

- Global food safety system
  - Global AFDO?
  - Competing issues and sensitivities
- Nationally Integrated Food Safety System
- Proactive and informed steps lead to prevention



# Credits and Sources

- Acknowledgements
  - FDA Office of Crisis Management
  - FDA CFSAN ECRT:
- Sources
  - CDC
  - WHO, Eurosurveillance
  - RKI, DG SANCO
  - Open source media

