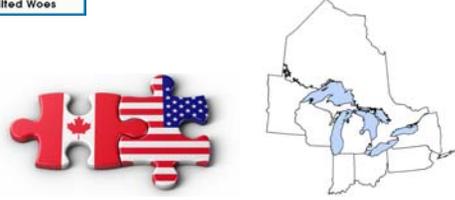




**Wilted Woes**  
Tabletop Exercise



Michigan & Great Lakes Region  
Tabletop Exercise of April 23, 2012




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**Special Thanks To Our Funding Agencies**

- U.S. Food and Drug Administration
  - Food Protection Task Force Conference Program Grant
  - Food Related Emergency Exercise (FREE-B) Toolkit Grant
- U.S. Department of Health and Human Services—Assistant Secretary for Preparedness and Response Grant (provides EWIDS grant to fund GLBHI Program)
- U.S. Department of Homeland Security—State Homeland Security Grant

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**For Your Information**

**Safety / Comfort** -- Note exits; restrooms just down corridor

**Name Tags** -- Those with duties for today's TTX identified on their name tags -- Facilitator, Observer/Recorders, Evaluators

**Primary Participant Groups** --

- Michigan Food & Ag Protection and Defense Work Group (Lead: Brad Deacon)
- Michigan Food Safety Alliance (Lead: John Tilden)
- Great Lakes Border Health Initiative (Lead: Diane Krueger)

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**Introduction**

**Purpose and Scope**

- It is crucial that we ensure that food products are safe for consumption
- Everyone involved in the food chain, from farmer through consumer, has a responsibility to keep the food supply safe
- At any point during production or distribution, food can be contaminated either accidentally (food safety), or on purpose from sabotage, fraud or terrorist activities (food defense)

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**Introduction**

**Purpose and Scope**

- FDA, CDC, USDA FSIS, CFIA, PHAC, and others, work closely to safeguard the food supply
  - Continuously seek new ideas and strategies to reduce the incidence of human health incidents and to support food defense-related innovation
  - It is incumbent that local, State/Provincial and Federal governments and industry partners understand the roles and responsibilities of all participating entities

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**Introduction**

**Goal**

- This tabletop exercise provides participants with an overview of what happens at the local, State/Provincial and Federal levels during a food related incident
- Focus on the role that key personnel play in containing the problem and protecting consumers

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### Introduction

Goal

- Assess plans, policies, and procedures and think about how you would realistically apply them in the event of an incident
- Facilitate discussion among various participating entities, such as medical doctors, State/Provincial and local entities, and the private sector



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### Exercise Structure

- This exercise is a highly interactive facilitated exercise with two learning modules:
  - **Module 1 – Identification of Outbreak**
  - **Module 2 – Identification of Food**

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### Exercise Structure

- Tabletop exercise reflects the policies and procedures currently in use and is accurate as of May, 2011
- FDA has developed five FREE-B exercises, and today's scenario follows 'Wilted Woes,' as well as incorporating questions from other scenarios
- Initially developed by Consolidated Safety Services and revised by IFT on behalf of FDA CFSAN Food Defense Oversight Team; also produced in cooperation with CDC
- Scenario is hypothetical - don't fight the scenario

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**Exercise Guidelines**

- Open, low-stress and non-public learning environment, and is not intended to set precedents
- Listen to and respect the varying viewpoints of all of the other participants
- Scenario is plausible and the events occurred as presented
  - Suspend your disbelief, and feel free to discuss differing policies and procedures during the breakout discussion
- SITMAN (Situation Manual) copies at each table – details on scenario, acronyms used (last page)

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**Exercise Guidelines**

- Work with each other to provide the expertise needed to ensure that our discussion is accurate and thorough
- You have been split into work groups, by table (refer to Table Work Group Assignment handout) – representing:
  - Epis / Investigators / Public Health / Communicable Disease
  - Food / Feed Industry
  - Food / Feed Regulatory Agencies
  - Federal Agencies
  - Laboratory
  - Border Personnel / Law Enforcement / Legal

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**Exercise Objectives**

- Commit to applying learnings from today's activities to your job/function and sharing key learnings with colleagues
- After the conclusion of this exercise you will be able to:
  - Understand how an epidemiological investigation unfolds and the roles that various public health agencies play
  - Clearly state your role and contribution to an epidemiologic investigation of a foodborne public health incident
  - Obtain an awareness of the specific roles each participant group / agency plays when engaged in this investigation

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### Exercise Objectives (cont.)

- Apply the step-by-step process used to investigate a public health situation that starts with a few cases of clinical illnesses through to the ultimate identification of the food vehicle
- Define the process for collecting and applying the epidemiologic data related to the identification of the contaminated food product
- Assess the limitations of the public health, regulatory sectors, industry, and emergency preparedness / law enforcement groups and take necessary actions to address these limitations

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### Roles and Responsibilities



- **Participant:** responds to events based on knowledge and experience
- Some participants will assist by taking a role at their table:
  - **Group Leader**
  - **Group Reporter**
  - **Group Recorder**
  - **Group Time Keeper**
- **Evaluator and Observer:** record events and capture the essence of the dialogue best practices
- **Facilitator:** leads the exercise and moderates large group discussions

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### Roles and Responsibilities



- **Table Discussion Leader:** representative from each table (volunteered by/within the group) who will lead the group as they explore discussion questions and the breakout activities
- **Table Recorder:** representative from each table (volunteered by/within the group) who will record the key themes discussed
- **Table Reporter:** representative from each table (volunteered by/within the group) who will be responsible for reporting out during the large group dialogue
- **Group Time Keeper:** representative from each table (volunteered by/within the group) who will ensure that the group discussions are kept on time

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**Personal Learning Inventory (PLI)**

- Designed to provide you with a document to capture questions, improvement ideas and action items
- For your use only; PLI's will not be collected; however, you are encouraged to share your PLI with others as a record of your learning experience
- Add to your PLI throughout the day and refer back to it as needed

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**Module 1: Identification of Outbreak**

- Presentation of Scenario
- Work Session (in breakout groups)
  - Answering Questions – 25 minutes
- Module Debrief (whole group) – 45 minutes

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**Module 1: Identification of Outbreak**

- Between January 15<sup>th</sup> and January 22<sup>nd</sup>, three individuals in state "A" and four individuals in state "B" had acute onset diarrhea, nausea and vomiting and sought medical attention
- Stool specimens were sent to clinical laboratories, which isolated *E. coli* O157:H7
- Specimens were also sent to state public health laboratories for "DNA Fingerprinting" (PFGE – or Pulsed Field Gel Electrophoresis pattern)

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### Module 1: Identification of Outbreak

- February 8<sup>th</sup>, CDC officials reviewed the PulseNet data
  - Spike in the number of reported infections due to *E. coli* O157:H7 above expected background
  - Several of the strains of *E. coli* O157:H7 entered into the database in the past few weeks from various states had matching PFGE patterns



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### Module 1: Identification of Outbreak

- February 9<sup>th</sup>, the CDC coordinated a call with the epidemiologists in the states where at least one case with this strain of *E. coli* had been reported
  - Likely foodborne transmission
    - Spread over several states
    - History of being foodborne
  - CDC summarized total number of cases reported with the matching PFGE pattern
  - Each state reported status on their cases, laboratory results, and investigation efforts to date
    - States with 1 case lack resources to follow up

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### Module 1: Laboratory status in affected states to date

State	Male	Female	Confirmed O157:H7 match	O157:H7 with PFGE subtype
A	1	2	3	3
B	0	4	4	4
C	0	1	1	1
D	2	5	7	5
E	1	2	3	1
F	1	0	1	0
G	0	2	2	0
H	2	2	5	3
I	0	1	1	1
J	1	1	2	2
K	1	2	3	0
L	0	2	2	0
M	0	1	1	0
<b>TOTAL TO DATE (Feb. 9)</b>	<b>9</b>	<b>25</b>	<b>35</b>	<b>20</b>

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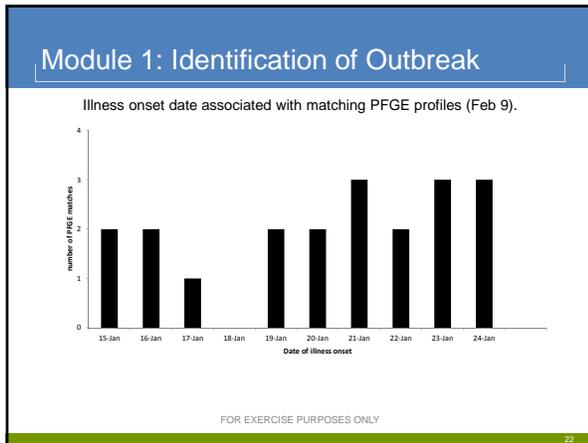
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- ### Module 1: Identification of Outbreak
- CDC contacted the FDA and USDA FSIS
  - CDC sent a notification to all 50 state health departments
  - State health departments begin/continue conducting hypothesis-generating interviews
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- FOR EXERCISE PURPOSES ONLY
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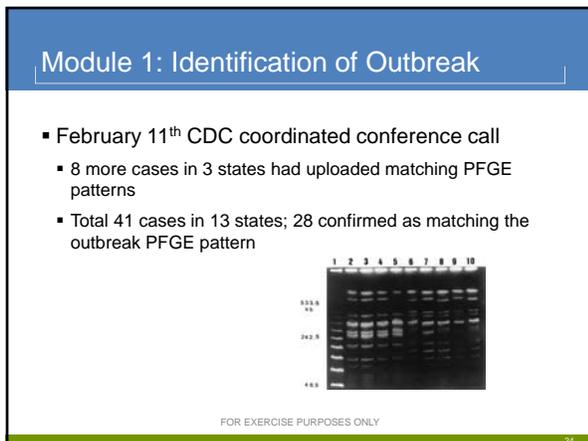
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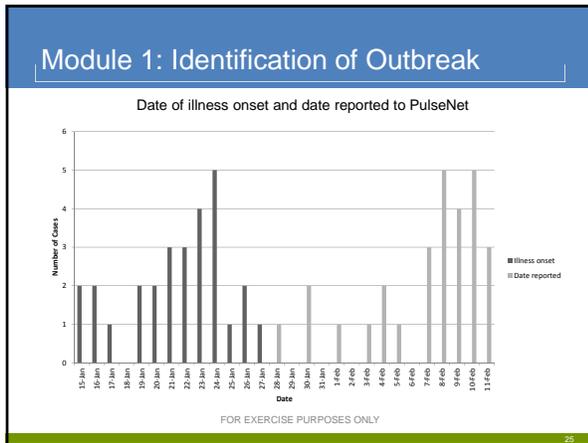
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### Module 1: Identification of Outbreak

- States "A", "B", "D", and "H" completed questionnaires and states "A" and "B" had analyzed the data on food histories from their cases
- Information from the interviews in states "A" and "B" was collected to generate a "short list" of those foods the ill people has consumed in common

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### Module 1: Identification of Outbreak

- Short lists:
  - State "A": eggs, yogurt, fresh spinach, beef and tortilla chips
  - State "B": eggs, yogurt, lettuce, spinach, chicken, cheese, and cereal/granola
  - State "D": fresh spinach salad, bread, minestrone stoup

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**Module 1: Identification of Outbreak**

- Preliminary hypothesis: fresh (raw) spinach
- FDA and USDA reviewed historical information and all the states conducting interviews agreed to share data with the CDC

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**Module 1: Identification of Outbreak**

- Multi-agency call on February 12<sup>th</sup>
  - 6 additional PFGE matches, bringing total number of matching PFGE patterns to 34
- Additional states reported analysis of food history questionnaires
  - Continued to support fresh spinach as hypothesis

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**Summary of Developments**

- CDC notices unusual increase in matching *E. coli* O157:H7 PFGE patterns in several states
- Multi-state conference call
- CDC notifies state health departments; FDA and USDA FSIS engaged
- Cluster of illnesses in one state + food histories of other cases = hypothesis of fresh spinach

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**Table Activity Session** 

1. Consider the developments while answering assigned questions
2. Identify any additional requirements, critical issues, decisions, and questions you think should be addressed at this time
3. Record any unanswered assigned questions or participant questions

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**Breakout Session**

25 Minutes to discuss questions

45 Minutes for all groups to report out

Plan to report out briefly:

- Your roles / responsibilities to date in this scenario
- One to three main points gathered at your table, from the assigned questions

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**Lunch Break**

45 Minutes

(Be ready to begin again at 12:45 p.m.)

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**Module 2: Identification of Food**

- Presentation of Scenario
- Work Session (in breakout groups)
  - Answering Questions – 30 minutes
- Module Debrief (whole group) – 45 minutes

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**Module 2: Identification of Food**

- February 13<sup>th</sup> multi-agency call
  - 10 more PFGE matches (total now 38, still in 13 states)
- Additional state data supports hypothesis of spinach
  - Three states identified fresh *bagged* spinach
- CDC and states begin case control study
- FDA press release associates bagged spinach with outbreak

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**Module 2: Identification of Food**

- February 14<sup>th</sup> conference call
  - One brand of spinach identified in 3 states
    - Open bag collected from consumers home
  - Different brand identified by 3 other states
- FDA warning limited to bagged spinach
- Traceback showed both brands were processed by ABC Processing Company
  - Company announced a voluntary recall

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**Module 2: Identification of Food**

- February 15, a joint investigation team of FDA investigators and State health inspectors arrived at ABC Processing Company
- FDA also collected 22 retained samples of fresh bagged spinach from the plant (produced from Jan. 26 onward), and samples of incoming spinach for *E. coli* analysis



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**Module 2: Identification of Food**

- February 18, FDA determined that ABC Processing contracts for 100% of the spinach production on three large farms with 13 individual fields
- Spinach produced by these farms is only sold to ABC Processing



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**Module 2: Identification of Food**

- February 24, 9 packages of spinach were collected from case households in 3 states, 8 of which had been opened by consumers, were analyzed for *E. coli* O157:H7
  - ABC Processing manufactured 7 of the bags collected
  - 3 bags began with code P007
- 2 bags were positive (both code P007)

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Module 2: Identification of Food

- FDA provided a clarification to the press release and informed consumers that only spinach processed by ABC Processing Company was implicated in the outbreak
  - Fresh bagged spinach processed by other firms was not implicated and could be consumed
- Case control study implicated fresh spinach

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Module 2: Identification of Food

- February 28<sup>th</sup>, a total of 183 persons infected with the outbreak strain of *E. coli* O157:H7 had been reported to CDC from 26 States
- Among the ill people, 95 (52%) were hospitalized, 15 (8%) had hemolytic uremic syndrome (HUS), and one person died



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Module 2: Identification of Food

- P007 production code traced to 3 fields
- Environmental samples from 1 field were positive for *E. coli* O157:H7

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Summary of Developments

- Fresh, *bagged* spinach was implicated as a vehicle
- A case control study commenced
- FDA publically announced that bagged spinach was implicated in the outbreak
- Two brands of spinach were implicated, and samples were taken from consumers' homes for analysis; 2 opened bags were positive for *E. coli* O157:H7 matching the outbreak strain

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Summary of Developments, cont.

- The brands of spinach were processed in the same facility, and FDA and state regulators visited the facility; FDA updated the public announcement to focus only on spinach from this processor
- FDA collected retained bags of spinach from the plant, but none were positive for *E. coli* O157:H7
- The processor recalled all fresh spinach in distribution

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Summary of Developments, cont.

- The positive open bags of spinach had the same production code, and the traceback investigation showed that spinach used in those bags originated in three farms
- Investigation at the farms yielded a positive sample matching the outbreak strain at one farm

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**Table Activity Session** 

1. Consider the developments while answering assigned questions
2. Identify any additional requirements, critical issues, decisions, and questions you think should be addressed at this time
3. Record any unanswered assigned questions or participant questions

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**Breakout Session**

30 Minutes to discuss questions

45 Minutes for all groups to report out

Plan to report out briefly:

- Your roles / responsibilities to date in this scenario
- One to three main points gathered at your table, from the assigned questions

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**Break**

15 Minutes

(Be ready to begin again at 1:45 p.m.)

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### Exercise Objectives

- Recapping learning objectives:
  - Understand how an epidemiological investigation unfolds and the roles that various public health agencies play
  - Clearly state your role and contribution to an epidemiologic investigation of a foodborne public health incident
  - Obtain an awareness of the specific roles each participant group / agency plays when engaged in this investigation

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### Exercise Objectives (cont.)

- Apply the step-by-step process used to investigate a public health situation that starts with a few cases of clinical illnesses through to the ultimate identification of the food vehicle
- Define the process for collecting and applying the epidemiologic data related to the identification of the contaminated food product
- Assess the limitations of the public health, regulatory sectors, industry, and emergency preparedness / law enforcement groups and take necessary actions to address these limitations

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### Wrap-up Activities

- Wrap-up Questions
  - Please discuss the wrap-up questions

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### Wrap-up Activities

- After Action Report and Improvement Plan (AAR/IP)
  - Will be generated
  - Your feedback from evaluations and wrap-up questions will be incorporated
  - Consider this For Official Use Only and share only with those with a "need to know"
- Review your PLI and add final thoughts (do not turn it in; the PLI stays with you)
- **PLEASE** complete [feedback survey](#) – link provided for online evaluation survey in email (2 or 3 days)
- Pick up your Certificate of Participation as you exit today

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### Resources

- For more information, see <http://www.fda.gov/fooddefense>
- For scenario specific resources, see the list in the SITMAN
- SITMAN used today will soon be available on the GLBHI website, at [www.michigan.gov/borderhealth](http://www.michigan.gov/borderhealth)

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### Thank you

Special thanks for our funding agencies and partners:

- U.S. Food and Drug Administration
- U.S. Department of Health and Human Services–Assistant Secretary for Preparedness and Response
- U.S. Department of Homeland Security–State Homeland Security Grant
- Michigan Food & Ag Protection and Defense Group
- Michigan Food Safety Alliance
- Great Lakes Border Health Initiative

and thank YOU for participating!



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