NEARS: Identifying environmental factors contributing to foodborne illness outbreaks

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Environmental Health Services Branch

Presentation overview

- CDC's National Center for Environmental Health (NCEH)
- Environmental factors contributing to foodborne illness outbreaks
- Outbreak environmental assessments
- Support for environmental assessments- training
- Collection and analysis of environmental assessment data - National Environmental Assessment Reporting System (NEARS)
- Benefits of NEARS

NCEH Objectives

- **Support environmental health practitioners to prevent environmental exposures and protect health.**

- **Work with state and local health departments to identify and address environmental factors contributing to foodborne and waterborne illness outbreaks.**

NCEH Food Safety Objectives

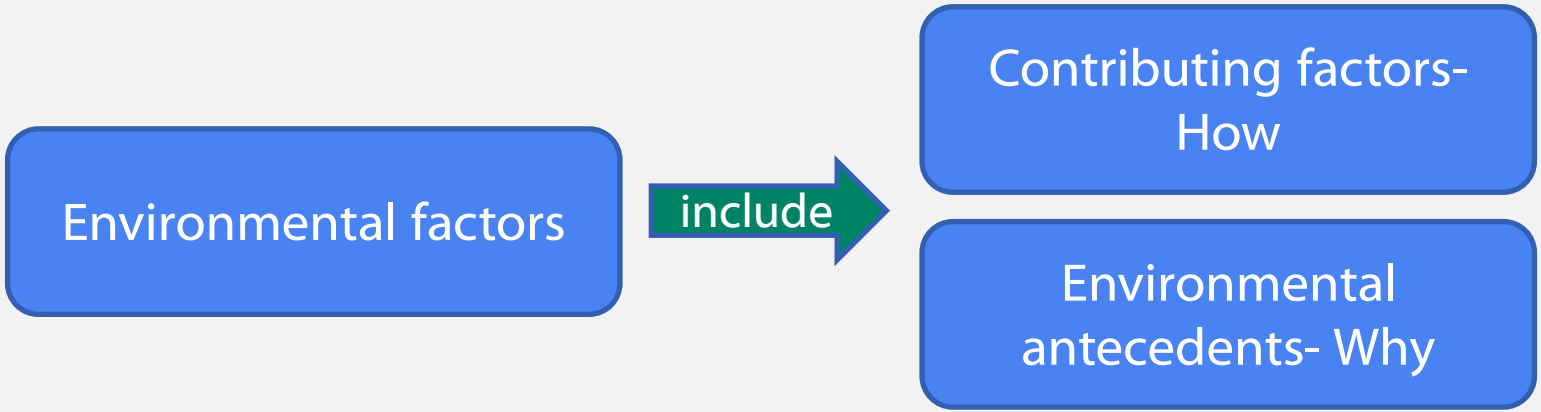
Improve identification and reporting of environmental factors contributing to foodborne illness outbreaks

through

Support of environmental assessments at the state and local level

Collection and analysis of environmental assessment data at the national level

Environmental factors contributing to outbreaks



Environmental factors contributing to outbreaks

Contributing factors

Contamination

- Cross-contamination of ingredients
- Contact by an infectious/ill worker

Proliferation

- Improper cold holding due to malfunctioning equipment
- Improper cold holding due to improper procedure

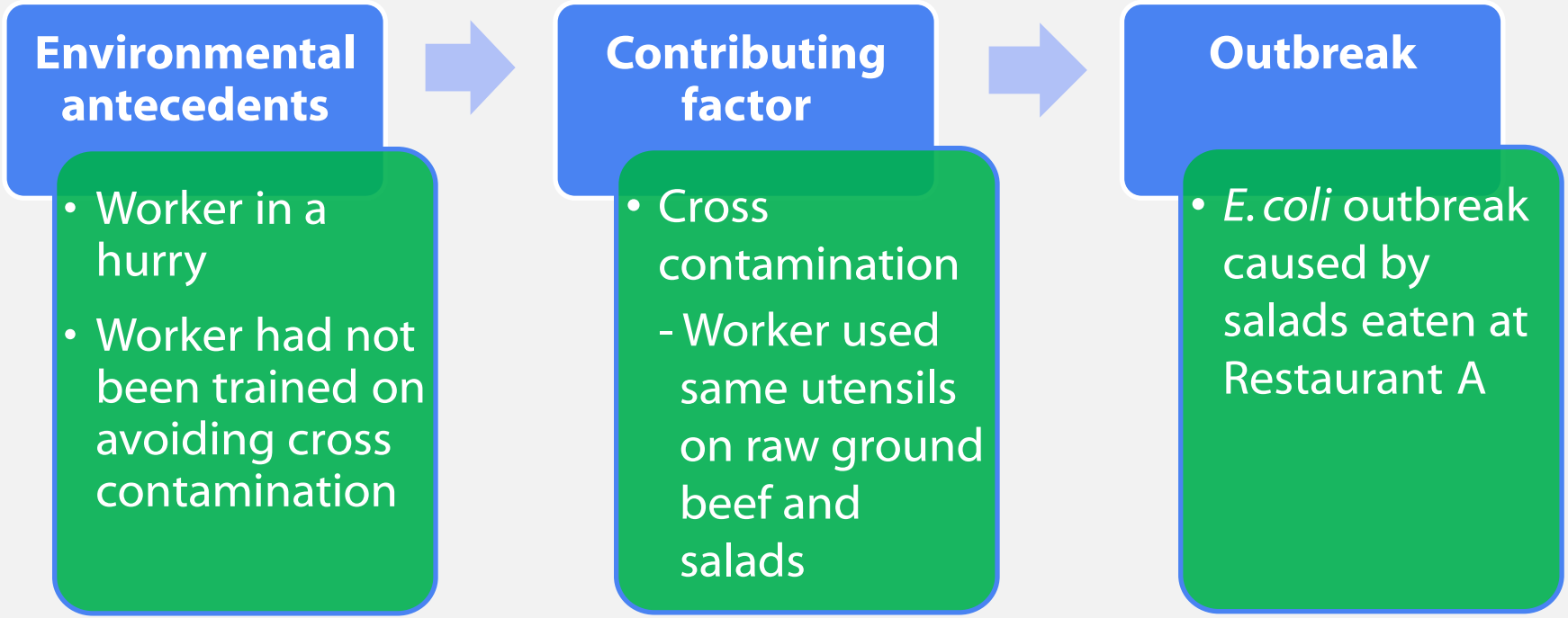
Survival

- Insufficient time/temp during reheating
- Insufficient time/temp during freezing

Environmental antecedents

- People
- Processes
- Equipment
- Economics

Environmental factors contributing to outbreaks



Outbreak environmental assessments

Describe how the environment contributes to the introduction and transmission of illness agents

Are conducted by environmental health program staff

Involve a thorough review of the processes and practices used with suspected food items

Are guided by known information about the outbreak (e.g., agent)

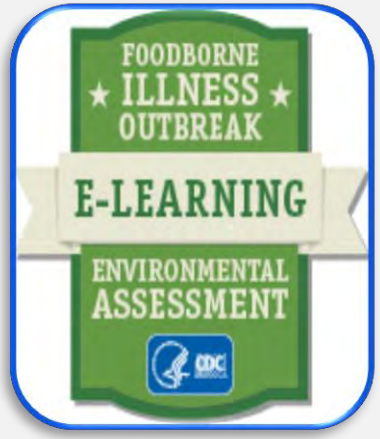
May include food flows, staff interviews, observations of food preparation, sampling

Generate recommendations for intervention

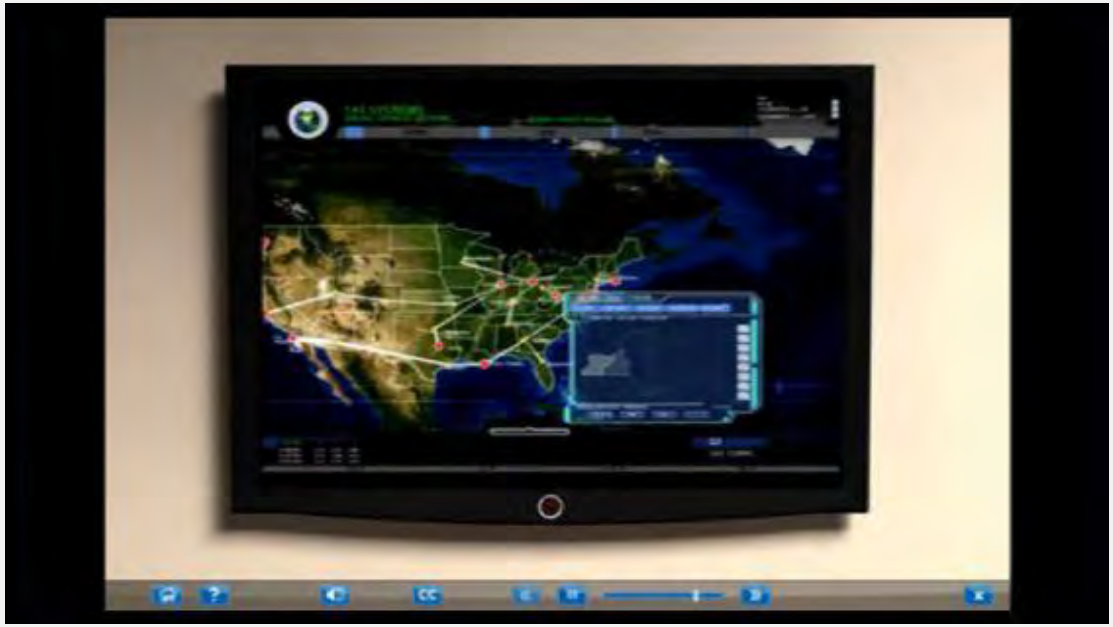
Support of environmental assessments at the state and local level

Development and launch of environmental assessment training

- Designed to improve environmental health programs' competency in conducting environmental assessments during outbreaks
- 5,100 people from over 1,200 federal, state, local government agencies have registered for the training
- Free, web-based, interactive
- Participants show a 25 percentage point increase in pre to post test scores



Environmental assessment training



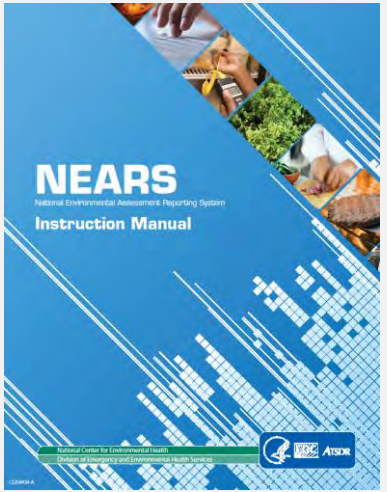
http://ow.ly/HnnxJ

Environmental assessment training

Collection and analysis of environmental assessment data at the national level

Development and launch of National Environmental Assessment Reporting System (NEARS)

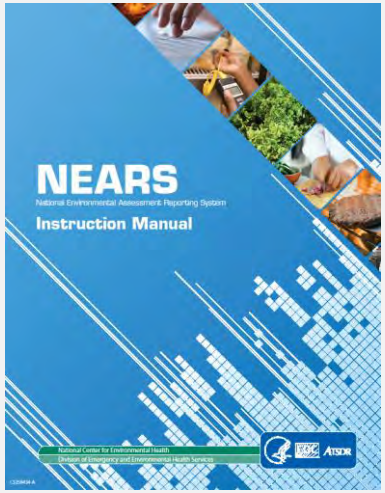
- Repository for state and local programs to report data collected from their environmental assessments
- 25 state and local agencies are currently reporting data into NEARS



Collection and analysis of environmental assessment data at the national level

Programs report data into NEARS from environmental assessment:

- **Interviews**
- **Observations**
- **Food and environmental sampling**



Short-term benefits of NEARS

- Annual report from CDC summarizing your NEARS data
- Collaboration/ communication with other states/localities participating in NEARS
- Potential scientific publication opportunities
- Ability to document and track foodborne outbreak response data

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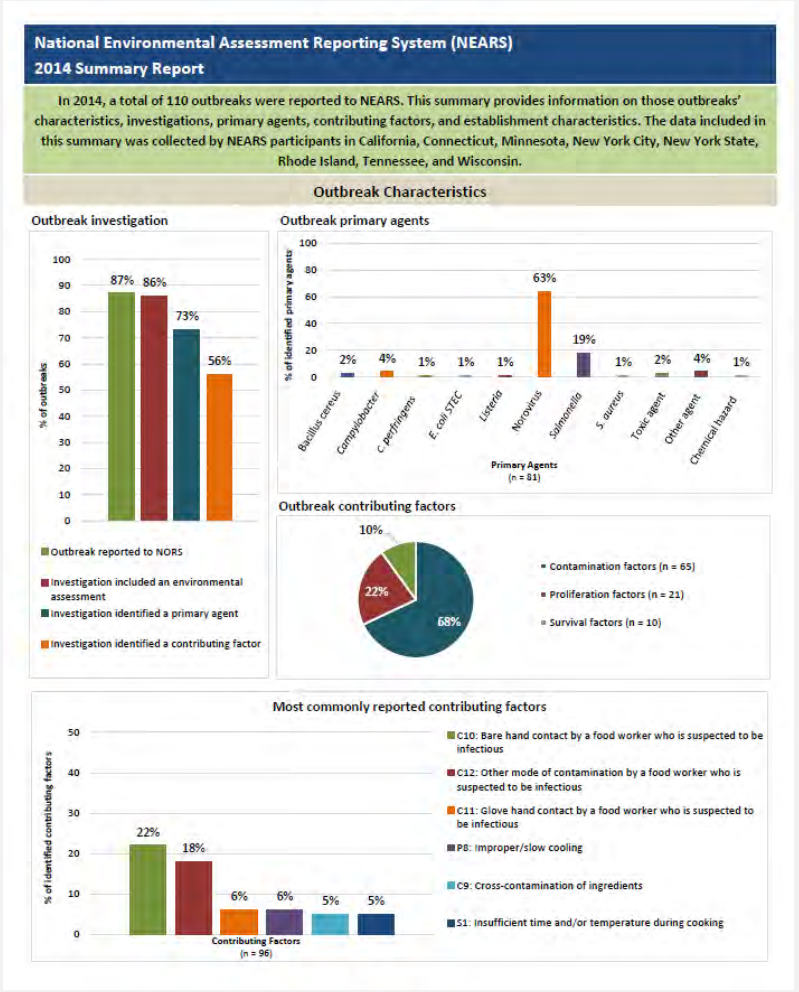
NEARS annual report



Long-term benefits of NEARS

Data to improve retail food safety

Restaurant characteristics (environmental antecedents) linked with outbreak size

Restaurants with a policy requiring workers to tell their managers if they are sick have smaller (fewer cases) norovirus outbreaks than restaurants without this policy

Restaurants in which gloves are used have smaller norovirus outbreaks than restaurants in which gloves are not used

Restaurants with only prep and cook serve food prep processes have smaller norovirus outbreaks than restaurants with complex food prep processes

Long-term benefits of NEARS

Data to improve foodborne outbreak response

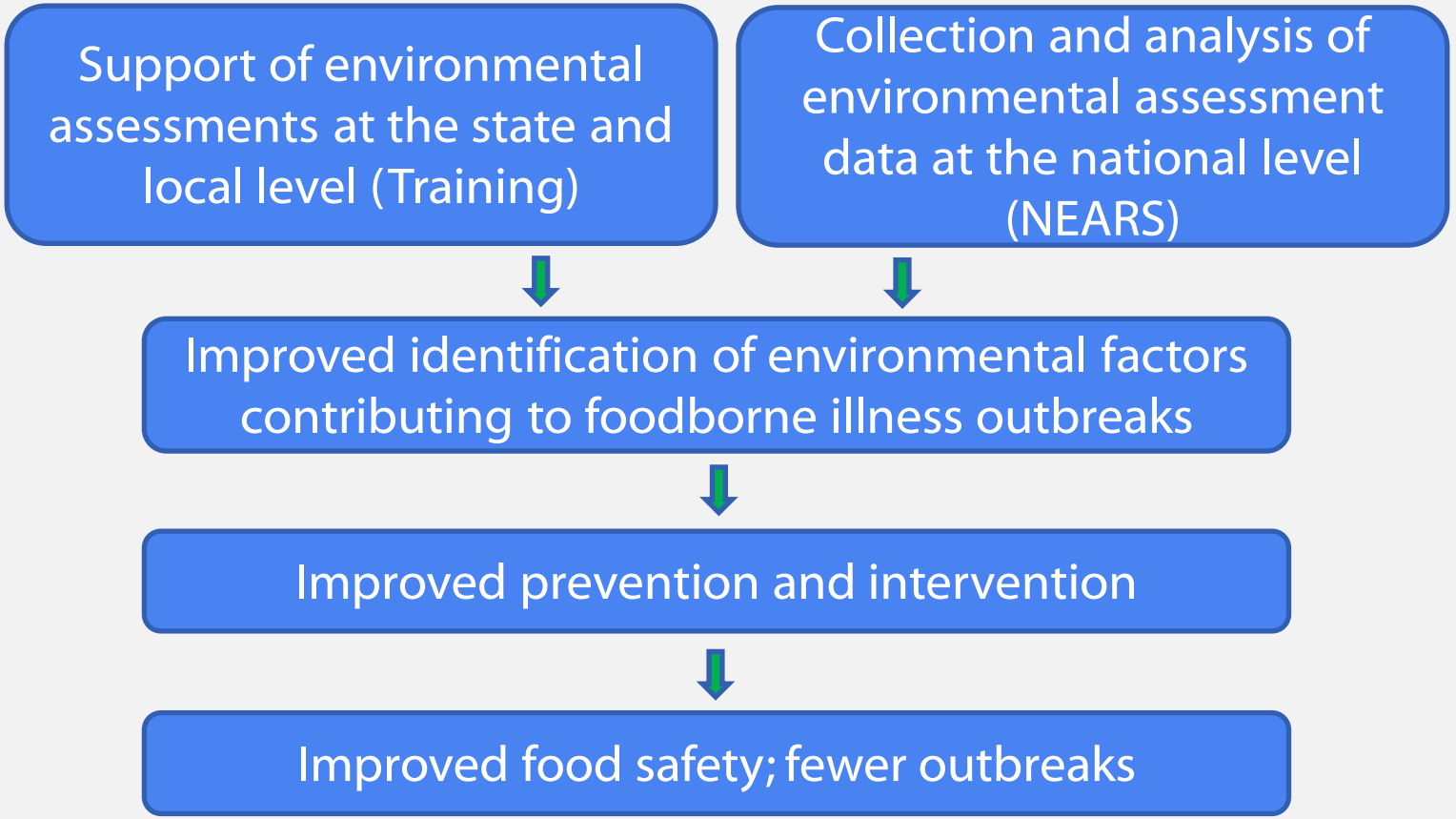
Gaps in investigation practices

- In 20% of outbreaks, the environmental assessment occurred 5 days after the outbreak was identified
- In 4% of outbreaks, the environmental assessment occurred between 6-27 days after outbreak identification

Investigation practices and outbreak characteristics linked with contributing factor identification

- Contributing factors more likely to be identified when
  - An agent had been identified
  - Environmental assessment occurred soon after outbreak identification
  - Multiple establishment visits were made to complete the environmental assessment
  - Outbreak establishment prepared all meals on location
  - Outbreak establishment served more meals a day

Summary


Support of environmental assessments at the state and local level (Training)
Collection and analysis of environmental assessment data at the national level (NEARS)
Improved identification of environmental factors contributing to foodborne illness outbreaks
Improved prevention and intervention
Improved food safety; fewer outbreaks

Thank you

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For more information, contact NCEH
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov
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New York State National Environmental Assessment Reporting System (NEARS) Perspective

Food Safety Summit
May 8-10, 2017
Rosemont Illinois

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OVERVIEW

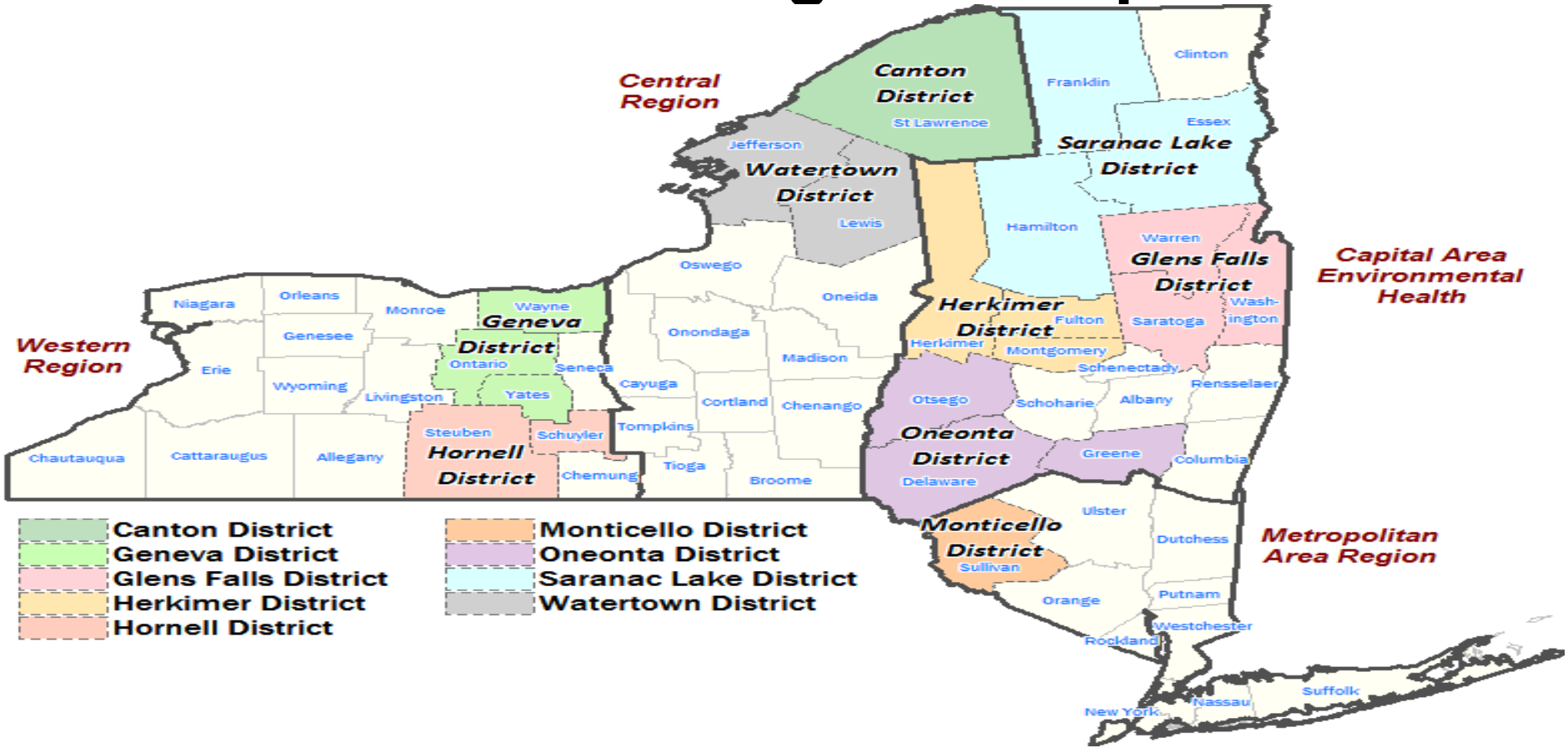
- **Background**
  - NYSDOH
  - EHS-Net in NYS
  - Foodborne Disease Outbreak Surveillance
- **Environmental Assessments: A systems approach to foodborne illness outbreak investigations**
  - Systems Theory
  - Contributing Factors
  - Environmental Antecedents
- **NEARS – Data Collection**
  - Information the data can provide

NYSDOH– LHDs

- **Home Rule State**
- **Four Regional Offices**

- **Local Health Departments (LHDs)**
  - 36 Full Service Local Health Departments
  - 9 State District Offices (21 Counties)
  - New York City DOH (5 Counties)

NYSDOH Regional Map



EHS-NET IN NYS

- EHS-Net Site since 2001
- Participate, Coordinate and Conduct EHS-Net studies and NEARS
- Provide Training to LHDs on EHS-Net Studies and Investigating Outbreaks
- Coordinate Communication for all foodborne outbreaks amongst Local and State Environmental Health and Laboratory partners
- Maintain Foodborne Disease Surveillance for NYS
- Link Outbreak Data (NORS) with Environmental Assessment Data (NEARS)

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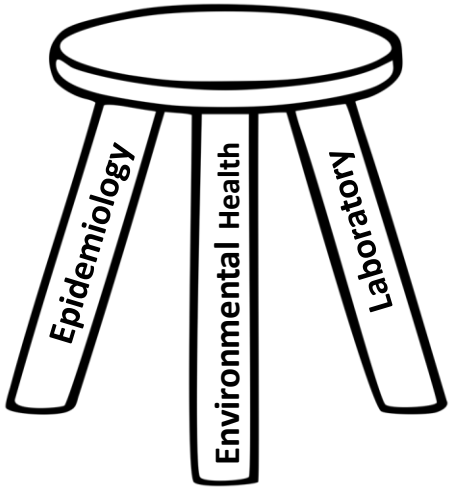
THREE LEGGEDD STOOL

- **Environmental Health**
  - Visit and conduct evaluation at site
  - Review food prep procedures
  - Conduct staff interviews
  - Collect food & environmental samples
  - Interventions
- **Epidemiology**
  - Establish case definition
  - Design questionnaire and conduct ill & well interviews
  - Calculate food specific Attack Rate (AR)
  - Epi curves
  - Stool samples
- **Laboratory**
  - Sample analysis
  - PFGE matching
  - WGS



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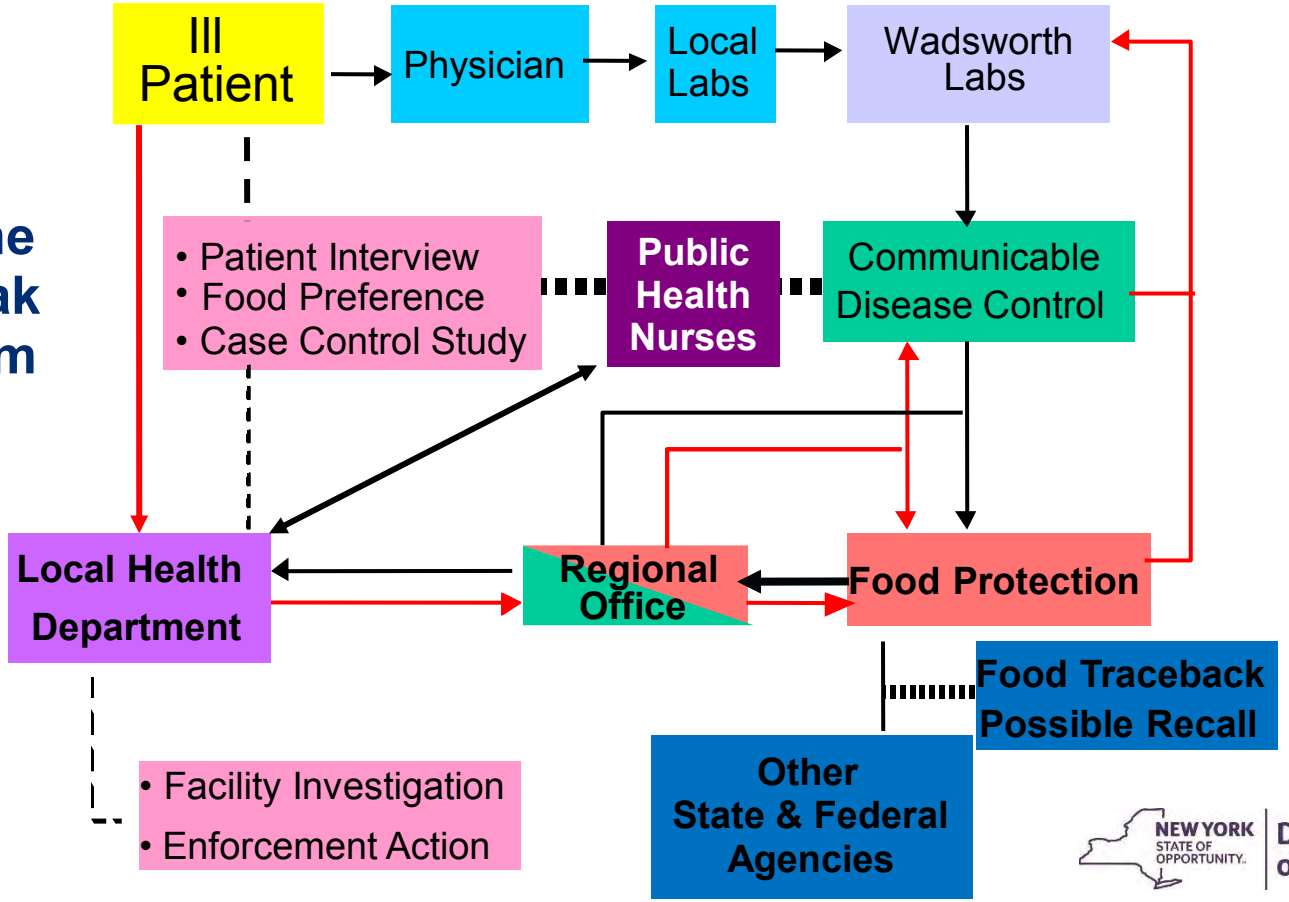
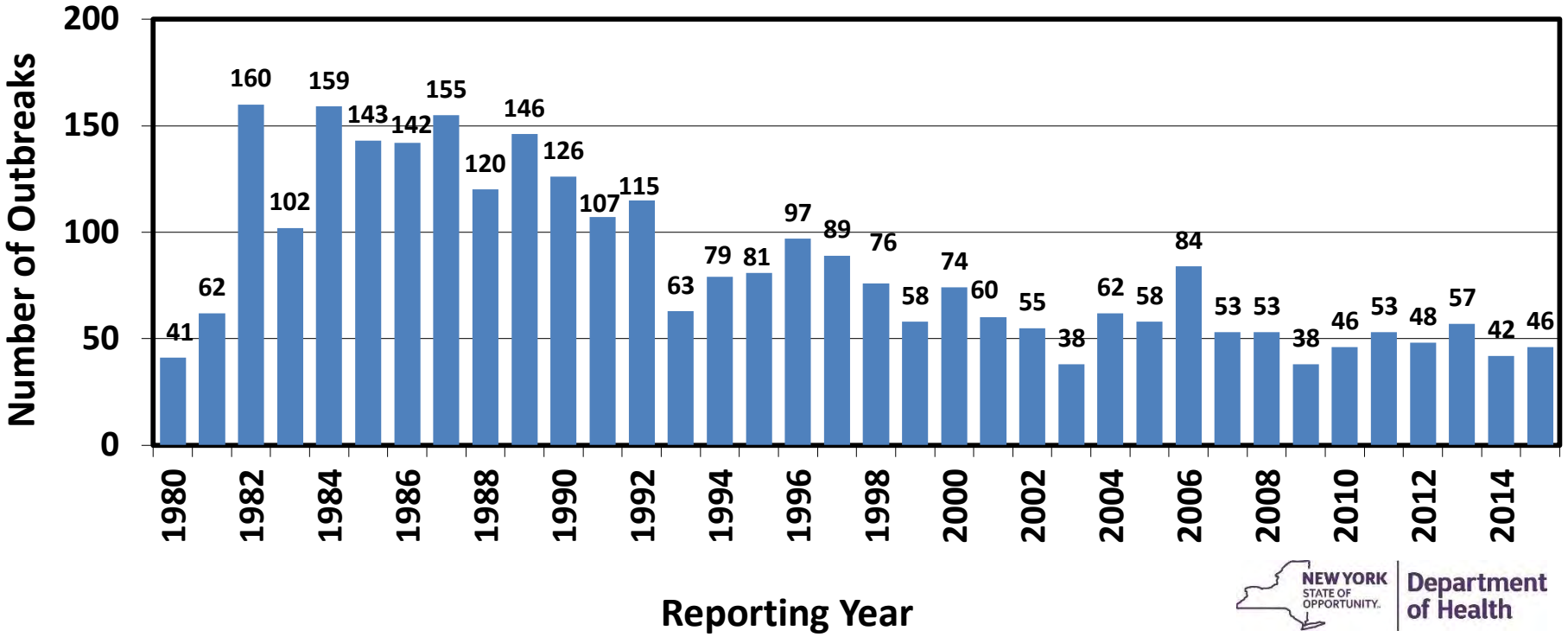
NYS Foodborne Illness Outbreak Response Team



Number of Foodborne Outbreaks, New York State 1980 – 2015



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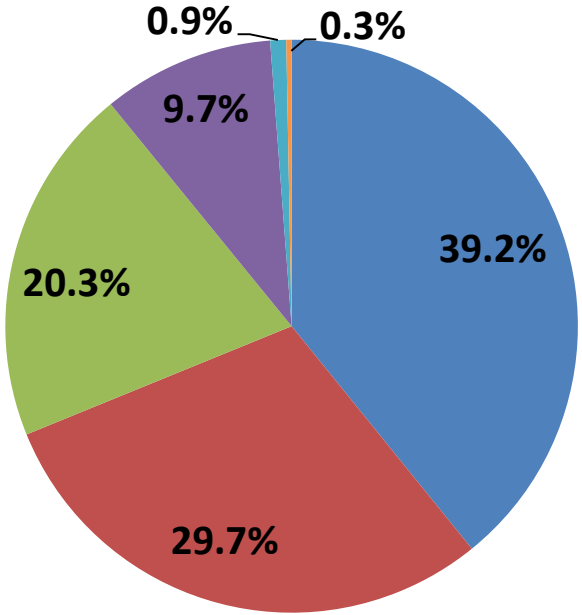
Updated 01/2017

Number of Foodborne Outbreaks by Etiology in New York State, 2001-2015



Number of outbreaks by etiology:

- Bacterial: 311
- Unknown: 236
- Viral: 161
- Chemical: 77
- Parasitic: 7
- Multiple: 2

Total Number of Outbreaks: 794

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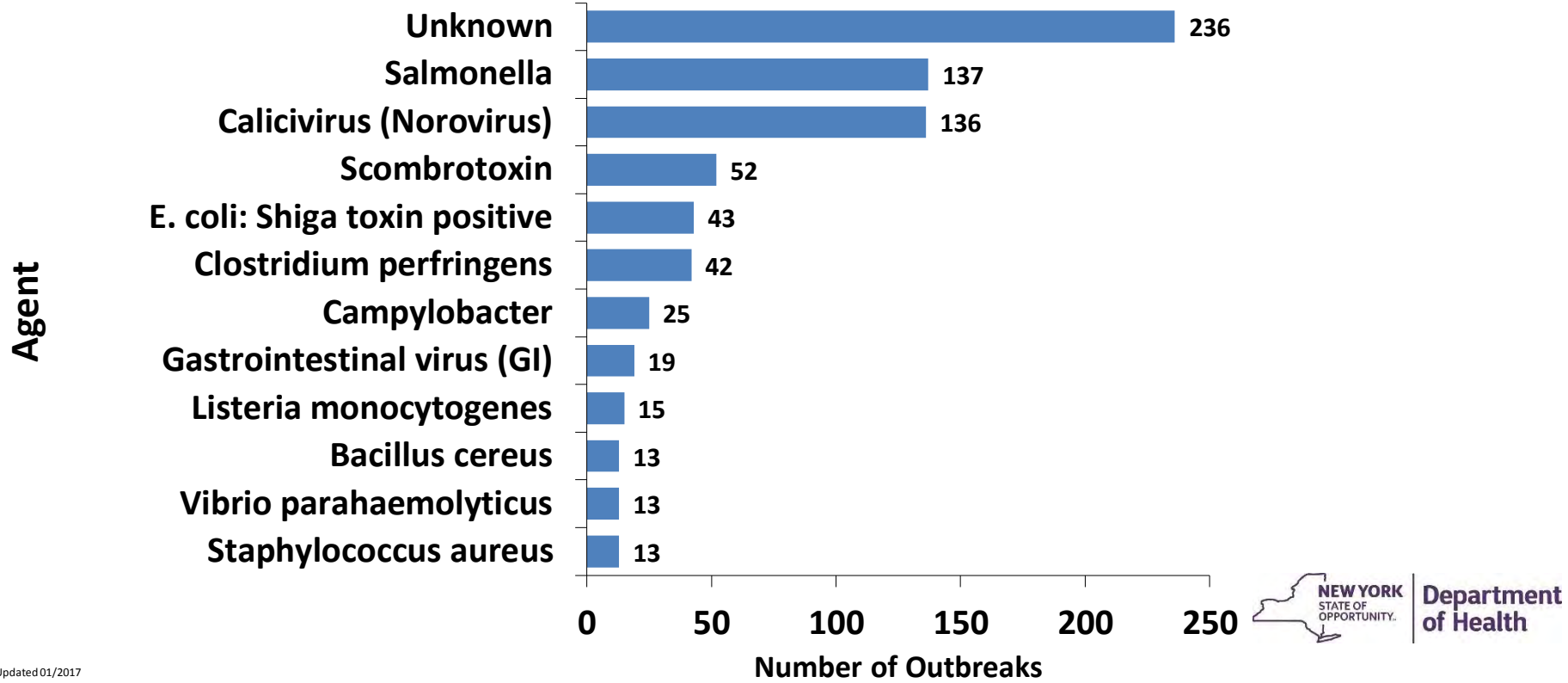
Top 10 Foodborne Outbreaks by Agent, New York State, 2001-2015



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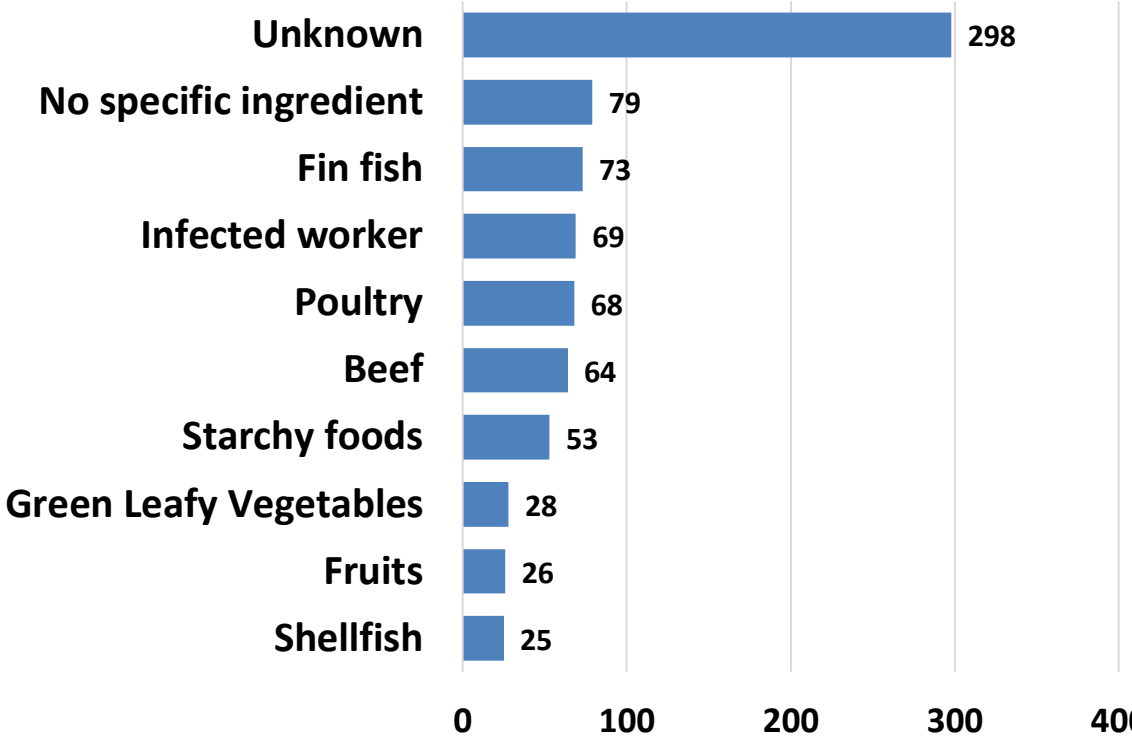
Top 10 Significant Ingredient Identified in Foodborne Outbreaks, New York State 2001-2015



There were 884 instances where a significant ingredient was identified.

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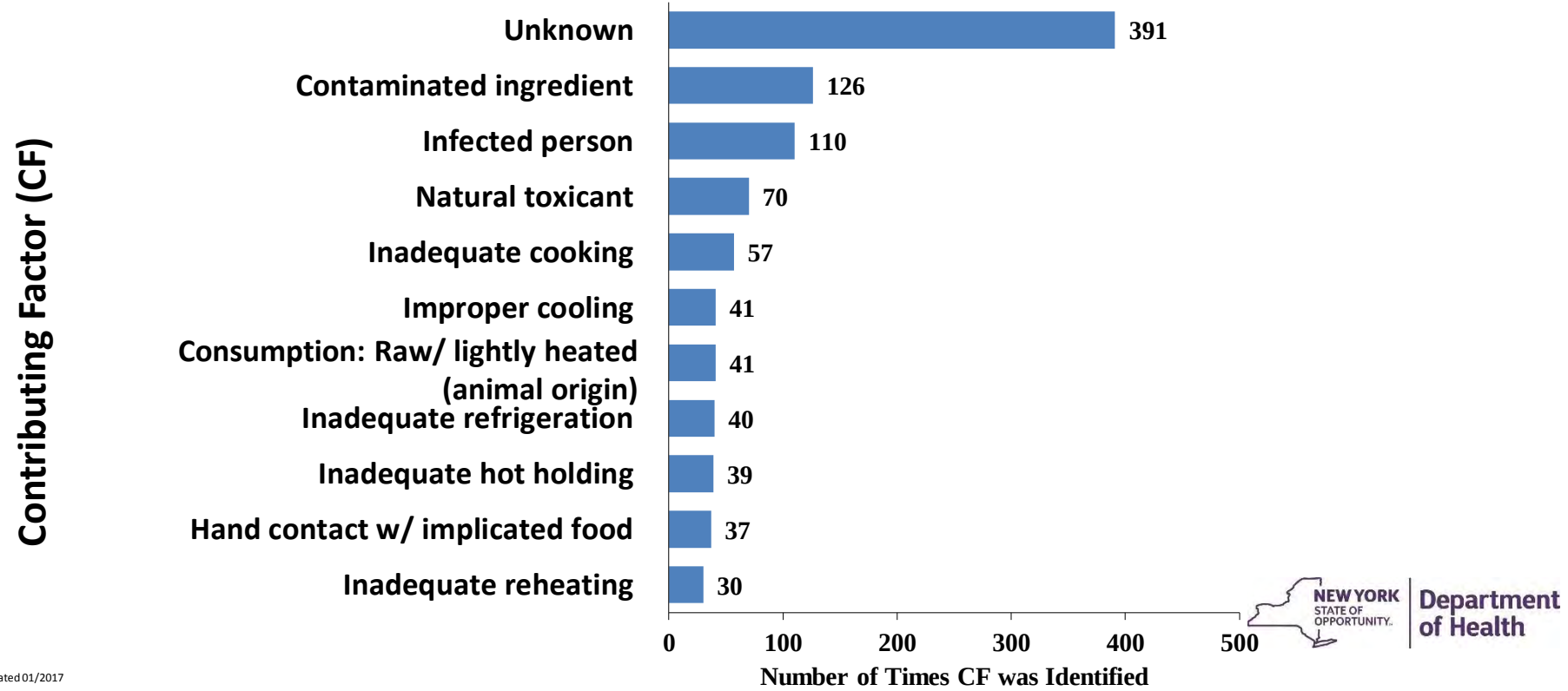
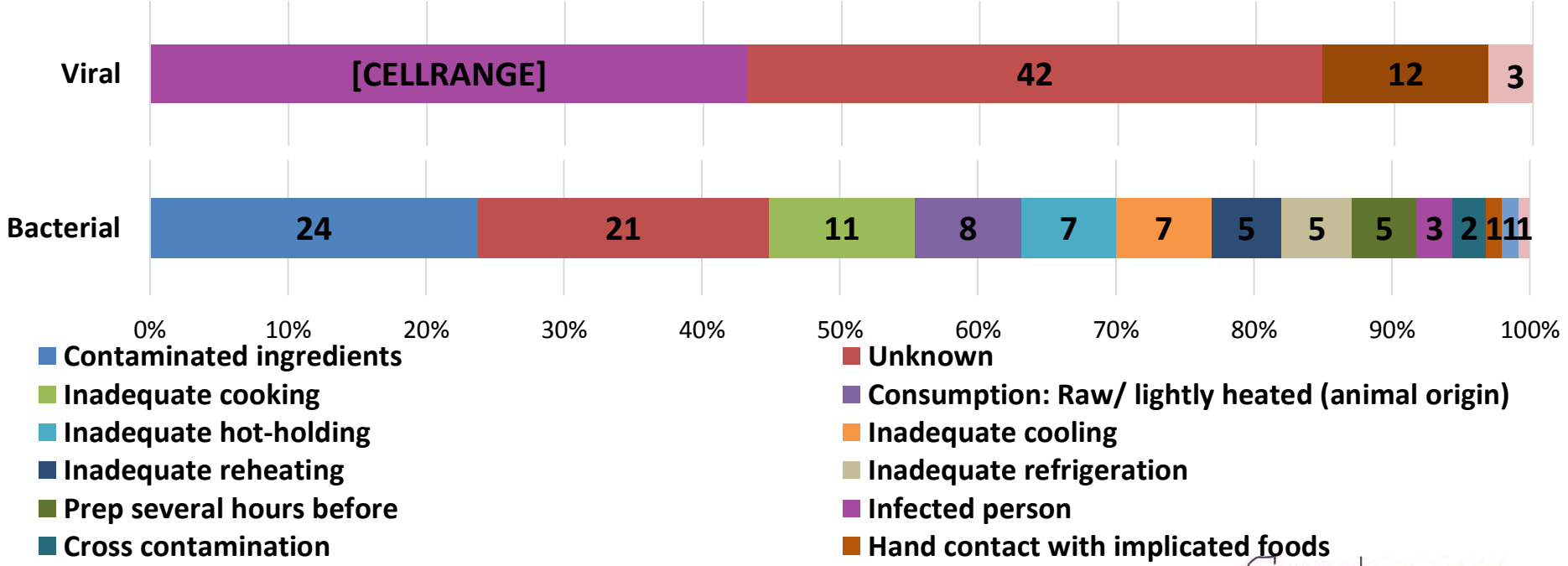
Top 10 Contributing Factors Identified in Foodborne Outbreaks, New York State 2001-2015



Distribution of Contributing Factors Identified in Bacterial and Viral Outbreaks, NYS, 2001-2015



183 Contributing Factors identified in 160 Viral Outbreaks

508 Contributing Factors identified in 311 Bacterial Outbreaks

*Above numbers indicate percent (%)

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WHAT REALLY CAUSED THE OUTBREAK?

ENVIRONMENTAL ASSESSMENTS AS PART OF FOODBORNE ILLNESS OUTBREAK INVESTIGATIONS

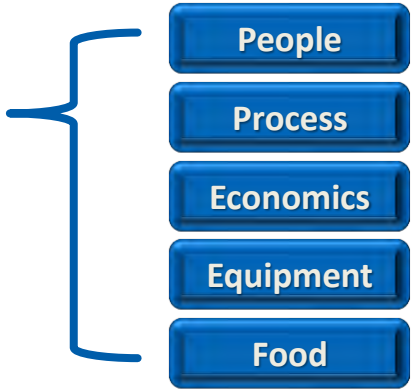
- **Environmental Assessment**
  - Describes how the environment contributes to the introduction and/or transmission of agents that cause illness
    - **NOT A ROUTINE INSPECTION**

- **Objectives of an environmental assessment**
  - Identify contributing factors
  - Identify environmental antecedents
  - Generate recommendations for informed interventions

NATIONAL ENVIRONMENTAL ASSESSMENT REPORTING SYSTEM

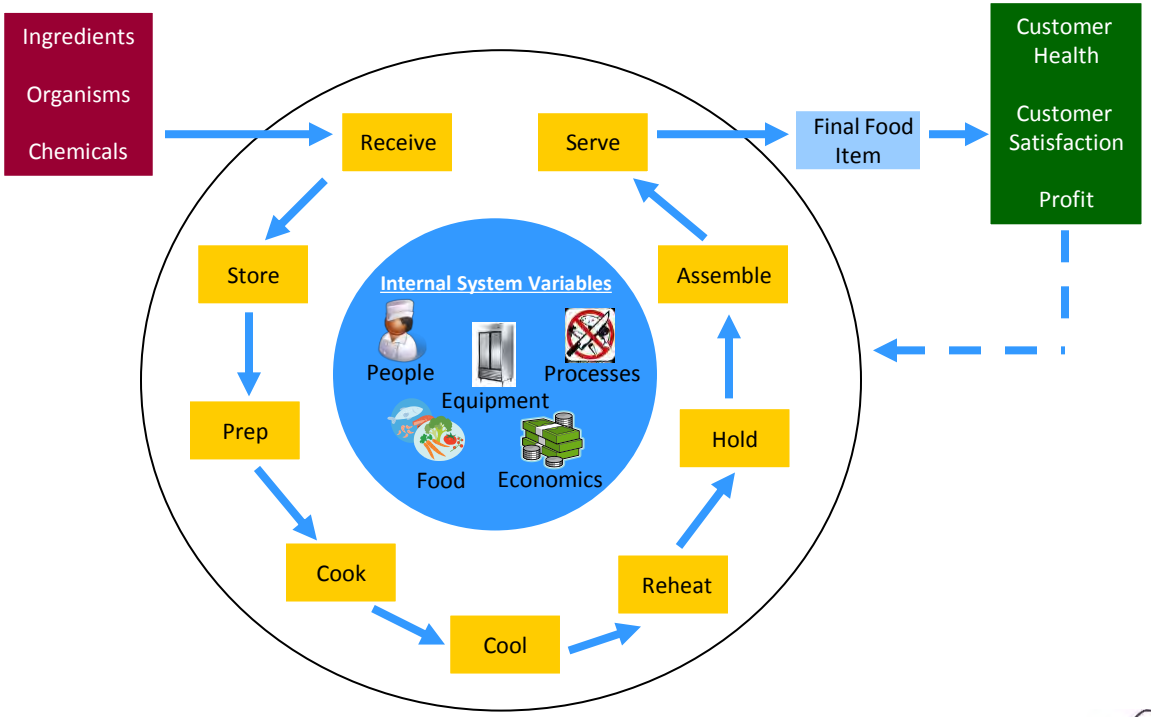
- Captures environmental factors through environmental assessments

- Serves as a companion surveillance system to the National Outbreak Reporting System (NORS)



Source: CDC NCEH

THE FOOD ESTABLISHMENT SYSTEM



Source: CDC NCEH

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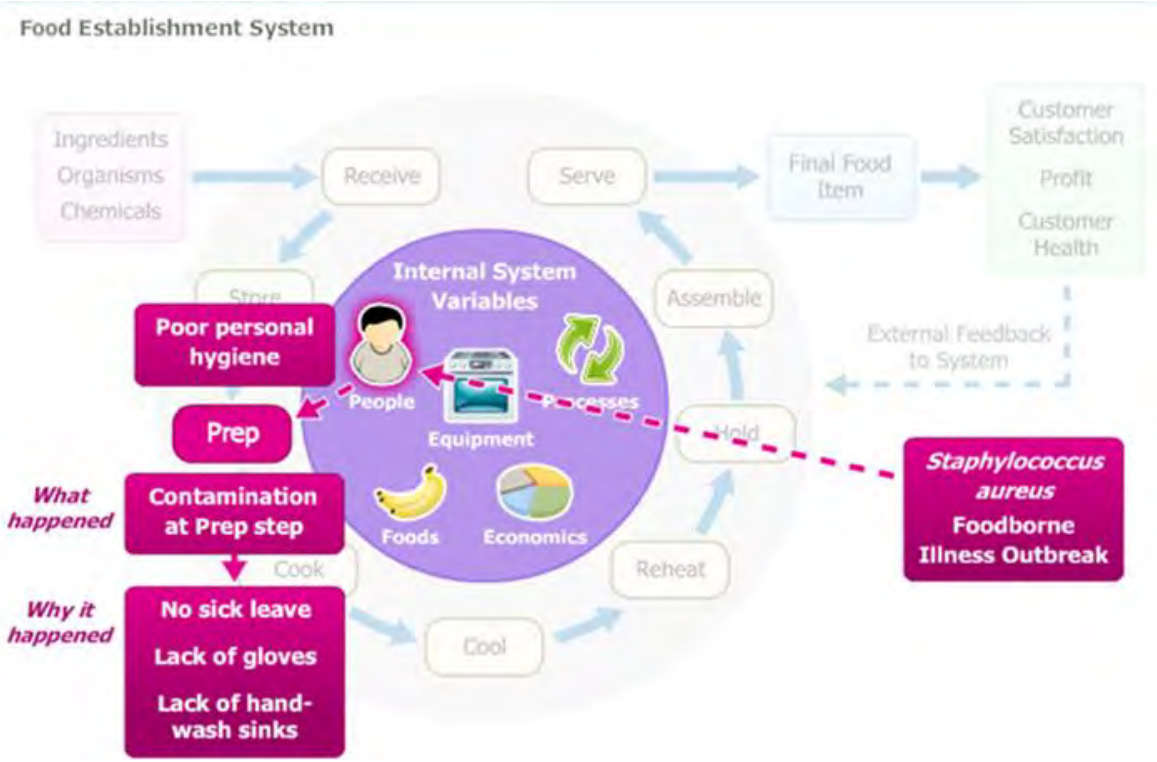
EXAMPLE

- **Thorough understanding of the problem**
  - On the ground assessment by Environmental Health Specialist or Environmental Engineer

- **Identification of underlying causes of problems (not just symptoms)**
  - Contributing Factors
  - Environmental Antecedents



Source: CDC NCEH

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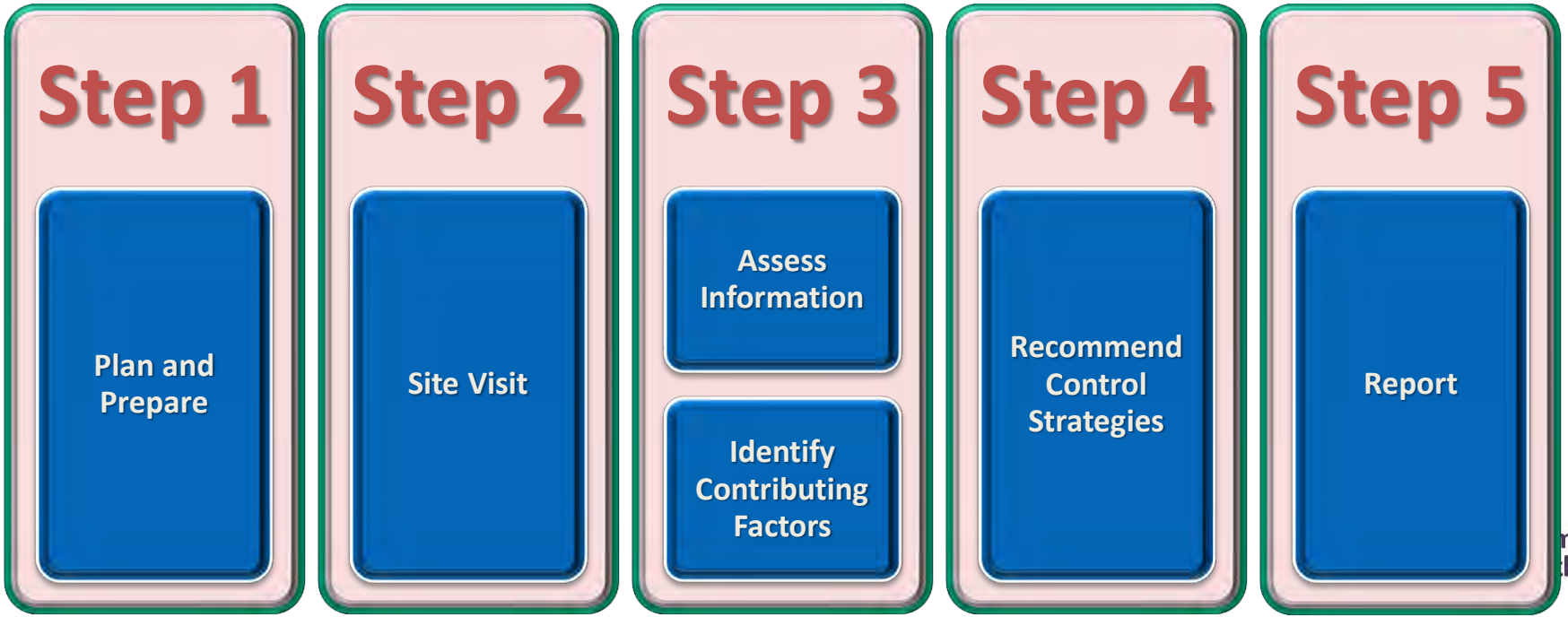
ENVIRONMENTAL ASSESSMENTS AS PART OF FOODBORNE ILLNESS OUTBREAK INVESTIGATIONS

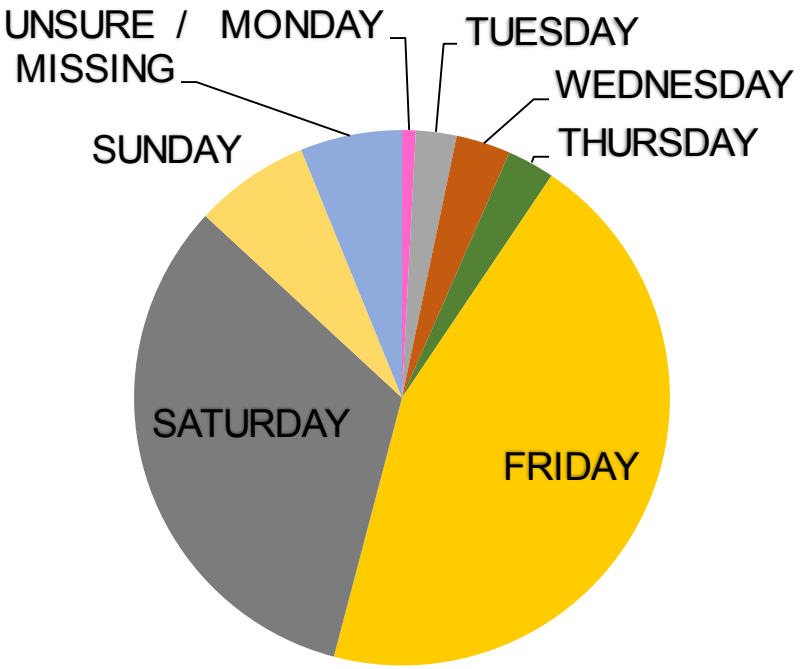


ENVIRONMENTAL ASSESSMENTS IN NYS

- Incorporated in the Investigation of a FBDO
- Conducted by LHDs at Regulated Food Service Establishments
  - Submitted by LHDs to Central Office
  - Reviewed and feedback provided by Central Office
  - Data entered by Central Office
- EHS-Net Administrator = NORS Reporting Site Administrator
  - Allows for improved data quality and verification of data between NEARS and NORS

INFORMATION NEARS DATA CAN PROVIDE

PART III- BUSIEST DAY



2006-2008

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Source: CDC NCEH

DISPOSABLE GLOVES

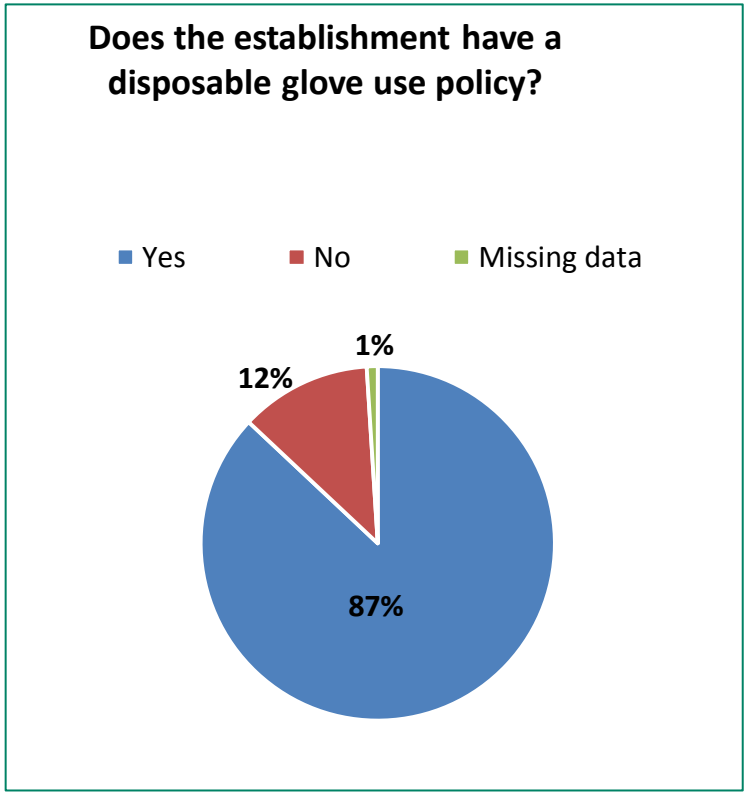
	Yes	No	Missing
Glove Policy*	193 (79.1)	48 (19.7)	3 (1.2)
Glove Supply**	198 (81.1)	41 (16.8)	5 (0.4)
Glove Use**	159 (65.2)	72 (29.5)	13 (5.3)

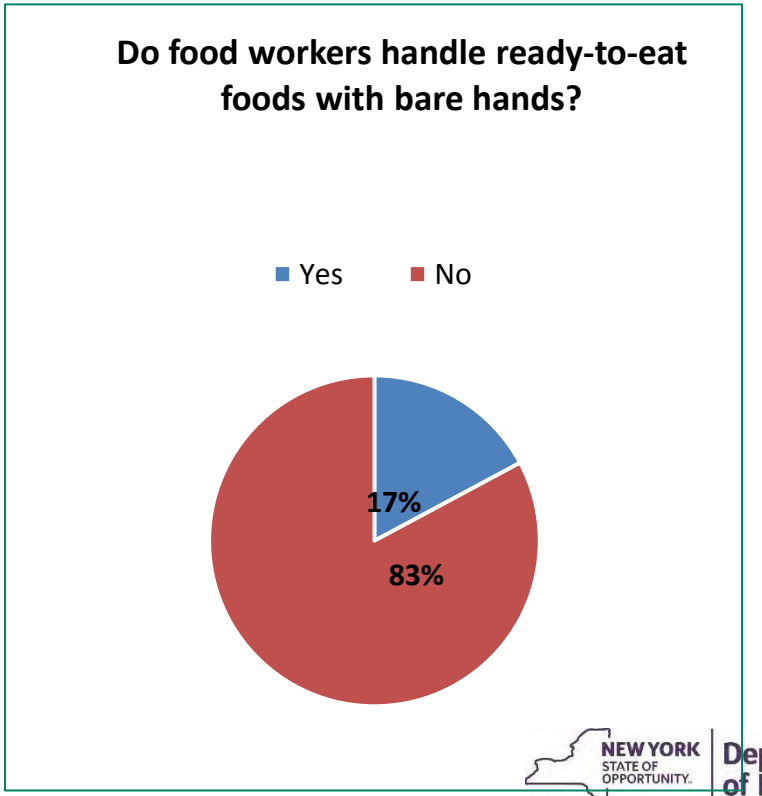
2006-2008

*Part III
**Part IV

Source: CDC NCEH

HAND HYGIENE CHARACTERISTICS





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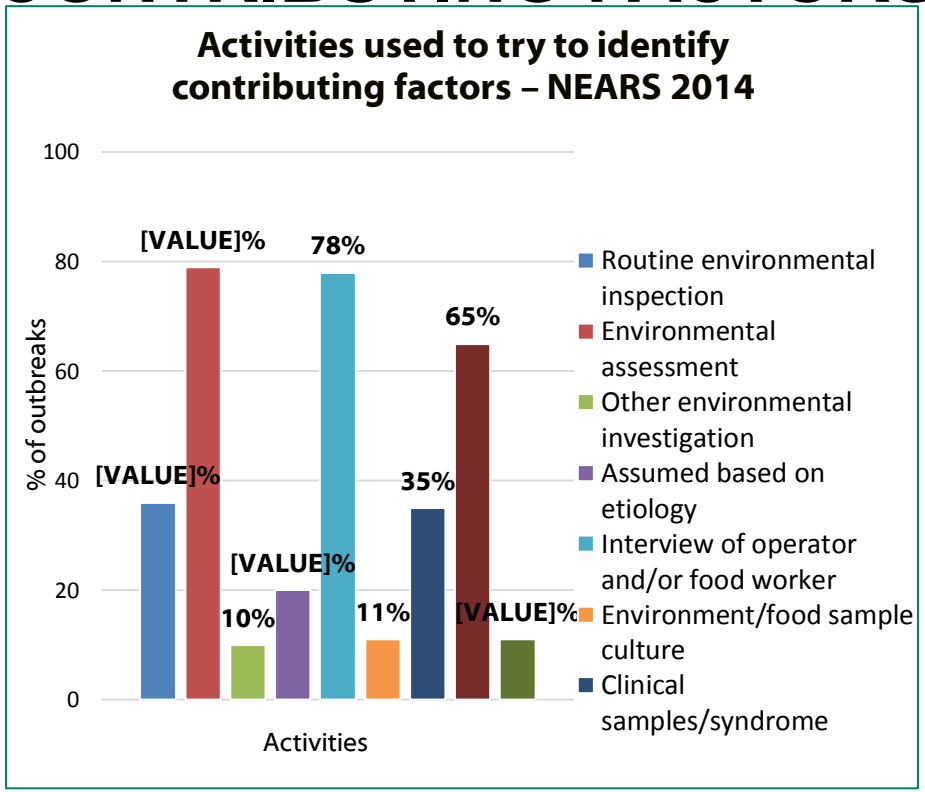
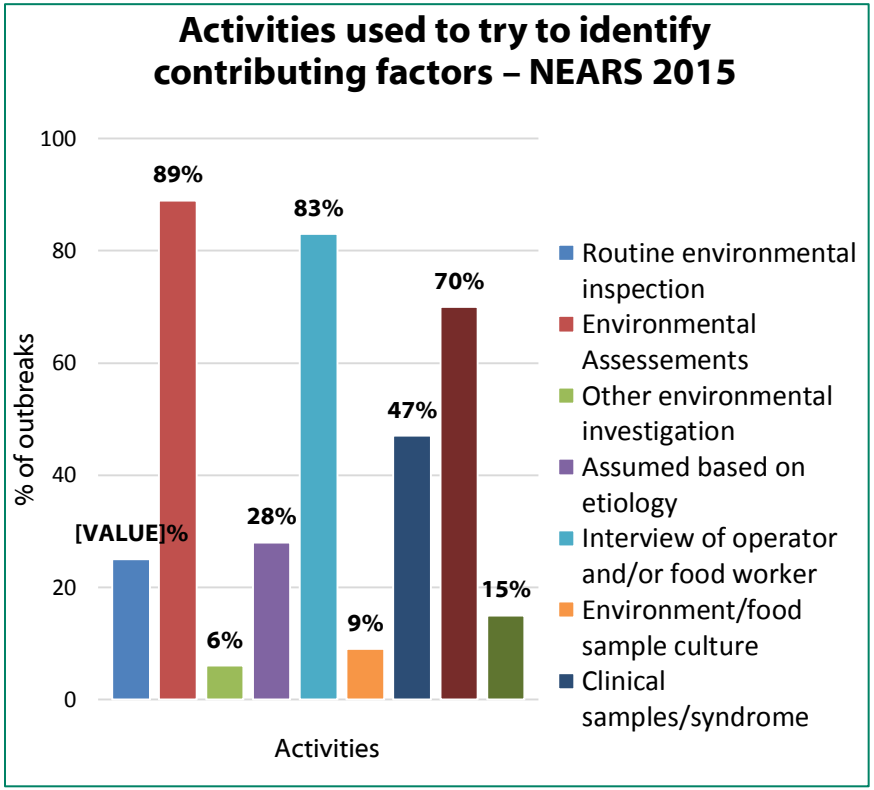
Source: CDC NCEH

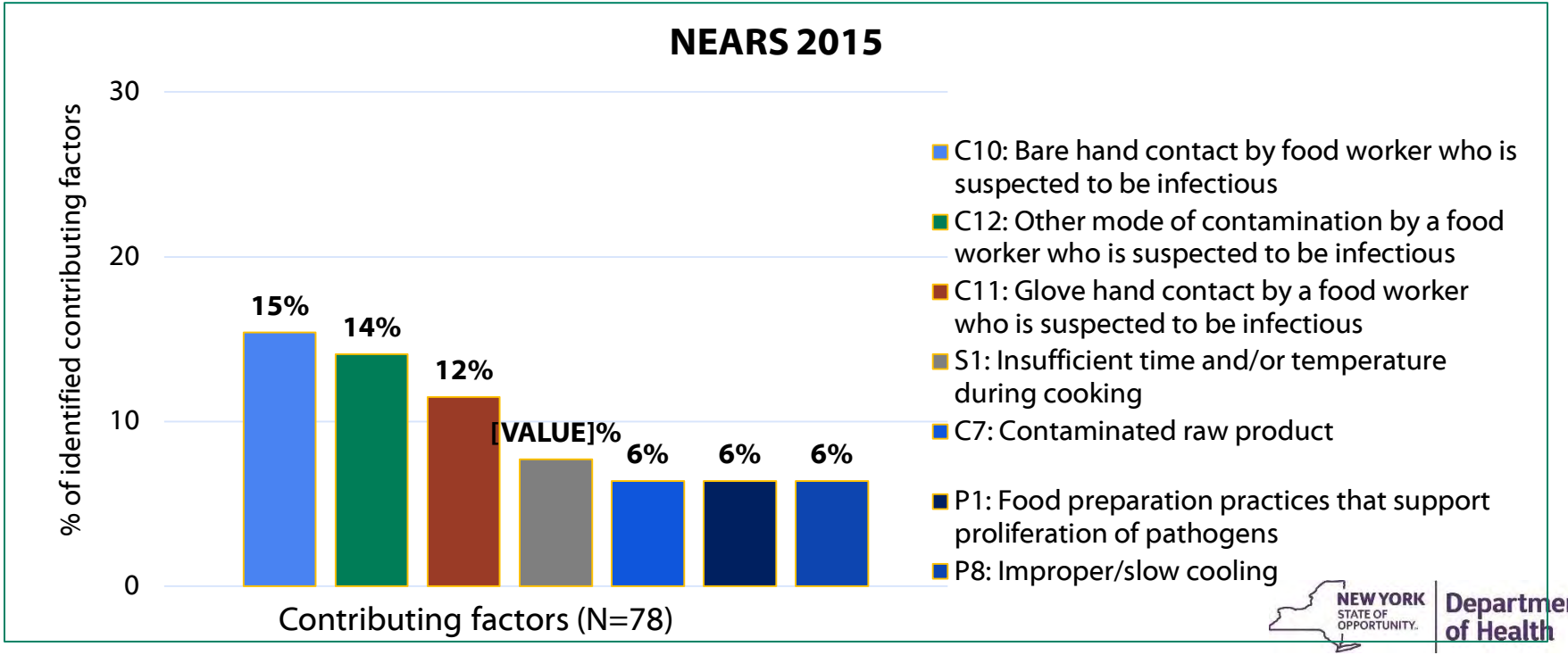
ACTIVITIES USED TO TRY TO IDENTIFY CONTRIBUTING FACTORS





Source: CDC NCEH

MOST COMMONLY REPORTED CONTRIBUTING FACTORS



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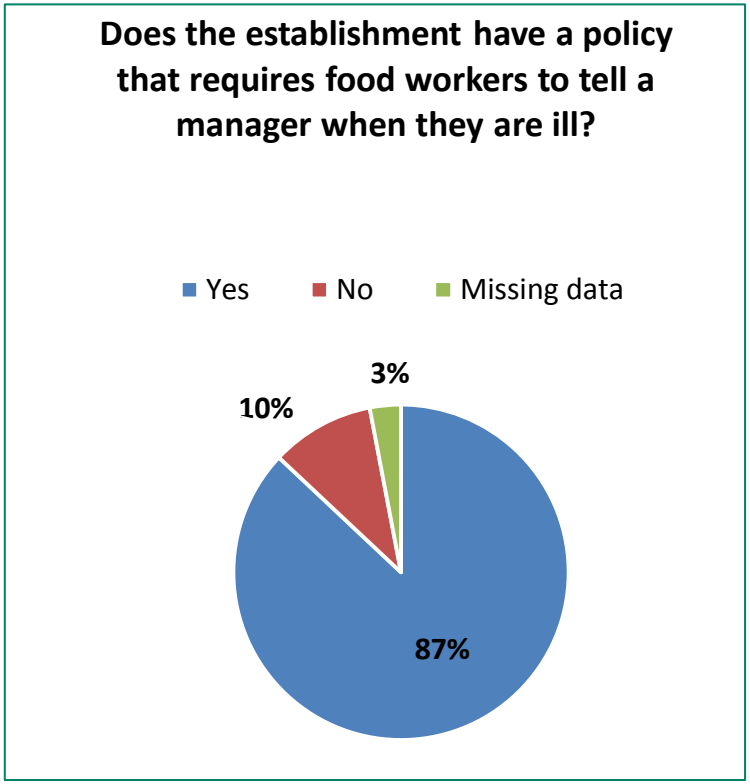
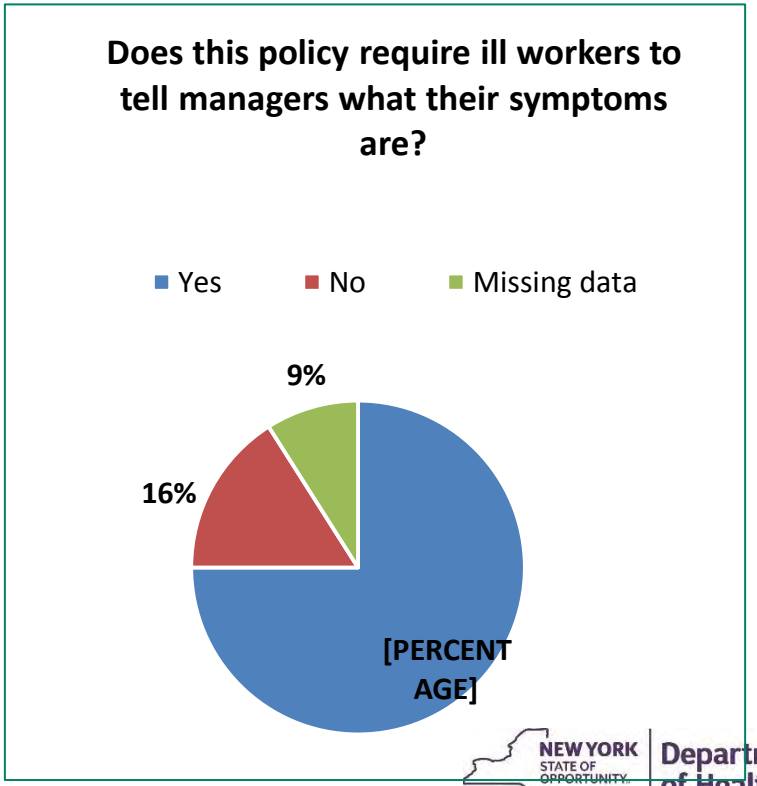
ILL WORK CHARACTERISTICS





Source: CDC NCEH

NYS 2016 PRELIMINARY DATA

- **Reviewed 5 Norovirus Outbreaks**
  - 5/5 Infected Food Handler Primary CF
  - 4/5 Had a Certified Kitchen Manager
  - 4/5 Exposure Date was on Busiest Day
  - 5/5 Had a Glove Policy, **1/5 Written Glove Policy**
    - 5/5 Glove Supply Observed, **3/5 Used Gloves Properly**
  - 5/5 Ill Worker Policy , **2/5 Written Ill Worker Policy**
    - **2/5 Required Ill Worker to Report Illness to Manager**
    - **2/5 Specified Sx Worker was to Report to Manager**
    - **1/5 Offered Paid Sick Leave**

WHAT ELSE

- Manager Interview
  - Food Worker
    - Number of workers
    - Food safety training and certification
    - Language
- Policy
  - Cleaning
  - Glove use
  - Health policies

WHAT ELSE

- Observations
  - Physical Facilities
  - Food Handling Practices/ Food preparation
  - Storage
  - Food worker behavior
- Food Vehicle
- Contributing Factors
- Etiology

ACKNOWLEDGEMENTS

- **Centers for Disease Control and Prevention**
  - Erik Coleman
  - Adam Kramer
  - Vince Radke
  - Laura Brown
- **EHS-Net Site Partners**
- **Local Health Departments**

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THANK YOU!

QUESTIONS

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Session 11
The Importance of the Environmental Component of Foodborne Illness Outbreak Investigations

In-Factory Investigations and Risk Assessments: The Two Foot level

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Food Safety Summit
Donald Stephens Convention Center
Rosemont, IL

May 10, 2017

KORNACKI MICROBIOLOGY SOLUTIONS, INC.

Why Are We Here?

Galaxies NGC 2207 and IC 2163

Hubble Heritage

NASA and The Hubble Heritage Team (STScI) • Hubble Space Telescope WFPC2 • STScI-PRC99-41

Why Do We Care About Food Safety?

- Illness / death

  48 million cases, 128,000 hospitalizations, 3000 deaths per year[1,2,3]

- Recalls-public exposure & lost market share
- Lawsuits -stricken individuals / class action
- Lawsuits-shorted customers

1www.cdc.gov/foodborneburden **December 2010**

[2]Scallan, E., R.M. Hoekstra, F.J. Angulo, R.V. Tauxe, M-A. Widdowson, S.L. Roy, et al. 2011. Foodborne illness acquired in the United States—major pathogens. Emerg Infect Dis. 2011 Jan; [Epub ahead of print]

[3]Scallan, E., R.M. Hoekstra, F.J. Angulo, R.V. Tauxe, M-A. Widdowson, S.L. Roy, et al. 2011. Foodborne illness acquired in the United States—major pathogens. Emerg Infect Dis. 2011 Jan; [Epub ahead of print]

Microbiological Risks - Food Safety *(continued)*

- Down time until contamination sites determined and eliminated and food safety system overhauled
- Costs of repairs / modifications
- Costs to remanufacture product
- Insurance issues

Principal Source of Microbial Contamination in Processed Foods:

Processing Environment

Often related to unhygienic equipment design

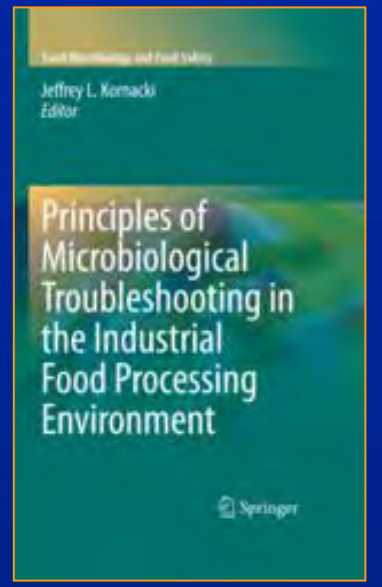
Approaches to Food Contamination Investigation

- Initial review of factory concerns and data
- Review of Food Safety/HACCP plans (including validation)
  - Review of process on paper
  - Question the CCP's and CL's – based upon solid science or tradition or "logic"
- Review of factory generated data
  - (pre-operational, post-operational, in-line and finished product sample test results, etc.)
- "Scoping the Problem"

Food Contamination Investigation – Approaches (Cont.)

- **Walk-through**, understand the process, pre-selection of sampling sites ("Risk Assessment-walk through")
- **Taking samples** (often expanded; Op, Post-Op, Pre-op)
- **Evaluation of investigator generated data**
- **Further sampling** if necessary
- **Re-validation of CCPs/Preventive Control** (if corrective actions fail or if CCP's not certain to destroy pathogens)

Importance of GMPs, HACCP, Finished Product Testing



- None by themselves get us to microbiological food safety (Kornacki, 2009)
- Tomatoes (HACCP Verification)
- Testing statistics

Test Number Needed to Detect One or More Positives per Lot

Percent positives	Number of analytical units to be tested (n)		
% Positive	90 % confidence	95 % confidence	99 % confidence
100	3	4	4
10	23	30	46
1	230	299	461
0.1	2,303	2,996	4,605
0.01	23,026	29,963	46,052

Adapted:Compendium of Methods for the Microbiological Examination of Foods 3rd ed.

Kornacki, J.L. 2009. The missing element in microbiological food safety inspection approaches, Part 1. February-March, Food Safety Magazine, Glendale, CA.

Kornacki, J.L. 2009. The missing element in microbiological food safety. inspection approaches, Part 2. April-May, Food Safety Magazine, Glendale, CA.

Examples of Outbreaks Attributed to Environmental Contamination

Product	Pathogen	Comment	Reference
Ice Cream	*S.* Enteritidis	Pasteurized ice cream mix in tanker truck previously used for transporting raw liquid eggs	Hennessy *et al.* (1996)
Infant formulae	*S.* Eealing	Contamination from the processing environment, insulation material of the drying tower	Rowe *et al.* (1987)
Soft cheese	*S.* Berta	Cheese ripening in buckets previously used for chicken carcasses	Ellis *et al.* (1998)
Cooked sliced ham	*S.*Typhimurium	Cooked ham placed into containers previously used for curing raw pork	Llewellyn *et al.* (1998)
Chocolate	S. Napoli	Possibly contaminated water used in double-walled pipes, tanks,	Gill *et al.* (1983)
Chocolate	*S.* Eastbourne	Contamination from the processing environment	Craven *et al.* (1975)
Butter	*S.* Eastbourne	Contamination from the processing environment	Lyytikainen *et al.* (2000)
Hot dogs	*L. monocytogenes*	Contamination from the processing environment	Anonymous (1999)
Canned salmon	*C. botulinum*	Contamination from the processing environment, cooling water	Anonymous (1984);Stersky *et al.* (1980)
Lasagna	*S. aureus*	Growth of *S. aureus* in the processing equipment, improper cleaning	Woolaway *et al.* (1986);Aureli *et al.* (1987)

Examples of Outbreaks Attributed to Environmental Contamination *continued*

Product	Pathogen	Comment	Reference
Different foods	*E. coli* O157:H7	Contaminated meat grinder and equipment at retail level	Banatvala *et al.* (1996)
Chocolate milk	*Y. enterocolitica*	Probably during manual mixing of pasteurization milk and chocolate or contaminated chocolate syrup	Black *et al.* (1978)
Canned meat	*S.* Typhi	Use of non-potable water for can cooling	Ash *et al.* (1964); Stersky *et al.* (1980)
Crabmeat	*S. aureus*	Contamination during manual picking of cooked meat	Bryan (1980)
Canned mushrooms	*S. aureus*	Possible growth of *S. aureus* in the brine bath before canning	Hardt-English *et al.* (1990)
Flavored Yogurt	*E. Coli* O157:H7	Pump previously used for raw milk	Morgan *et al.* (1993)
Pastry	*S.* Enteritidis PT4	Equipment previously used for raw eggs or insufficiently cleaned piping and nozzles used for cream	Evans *et al.* (1996)
Yeasts	*S.* Műnchen	Contamination from the processing environment	Joseph *et al.* (1991
Pasteurized milk	*S.* Typhimurium	Possibly cross-connection between raw and pasteurized milk	Lecos *(1986)*
Pasteurized milk	*E. coli* O157:H7	Contamination from pipes and rubber seals of the bottling	Upton & Coia (1994)
Mexican type cheese	*L. monocytogenes*	Contamination from the processing environment	Linnan *et al.* (1988)

Environmental contamination increases the risk of post-process contamination, *if the product is not biocidally treated in the end-use container*

Environmental Contamination

"… *cross contamination* ...was mentioned as the *most important factor* relating to the presence of pathogens in prepared foods"[1]

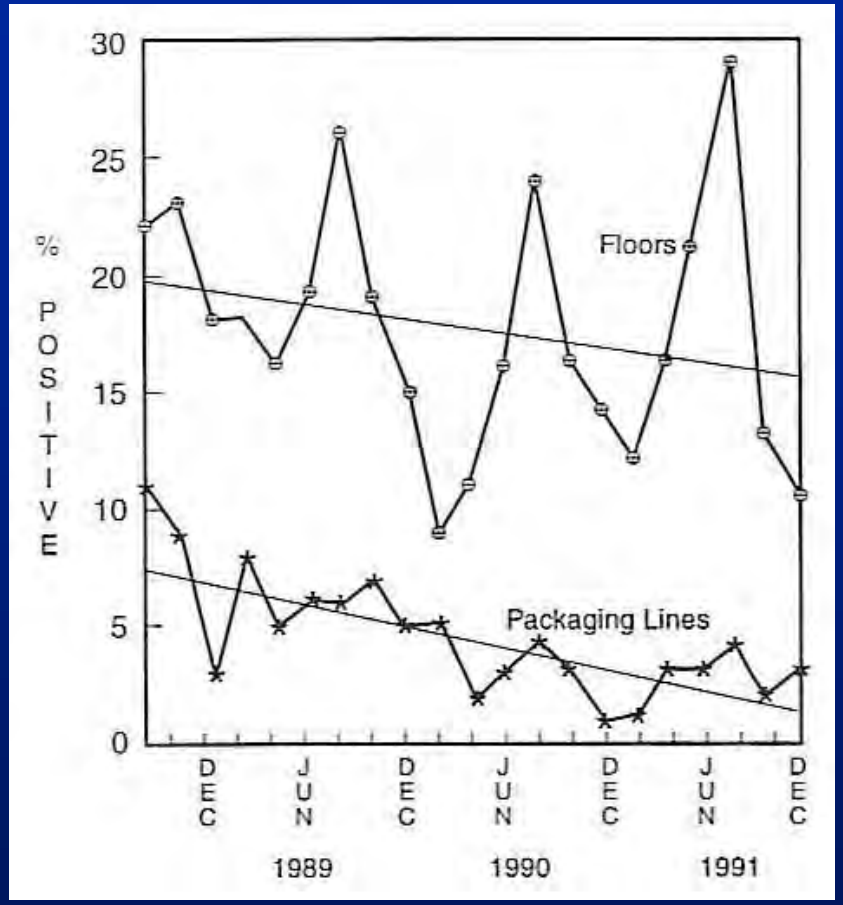
Environmental contamination is the principle source of contamination of processed foods

It is from the post-processing (post-CCPm) environment[2]

[1]Riej, et al. 2005. *Recontamination as a source of pathogens in processed foods-A literature review*. ILSI. Quoting, Rocourt, J., et al. 2003. Present state of foodborne disease in OECD countries. WHO, Food Safety Department, Geneva.

[2]Kornacki, J. L. 2009. The missing element in microbiological food safety inspection approaches, Part I. Food Safety Magazine. February / March.

Correlation of % *Listeria spp.* Isolated from Packaging Lines and Floors to RTE Meat



Lead to in-plant risk assessment concept

Tompkin, R.B., L.N. Christiansen, A.B. Shaparis, R.L. Baker, and J.M. Schroeder. 1992. Control *of Listeria monocytogenes* in processed meats. Food Australia 44:370-376

Kornacki, J. L. and J. B. Gurtler. 2007. Incidence and control of *Listeria* in food processing facilities, Chapter 17. In, E. T. Ryser and E. H. Marth (eds.), Listeria, listeriosis and food safety, 3rd ed. CRC Press, Taylor & Francis Group, Boca Raton, FL. Pp. 681-766.(see page 729).

Correlations of % Environmental to % Finished Product Contamination

Smoked fish plant: Correlation of environmental *L. monocytogenes* to finished product ($p<0.0001$)

Thimothe et al. 2004. Tracking of *Listeria monocytogenes* in smoked fish processing plants. J. Food Prot. 67(2):328-341.

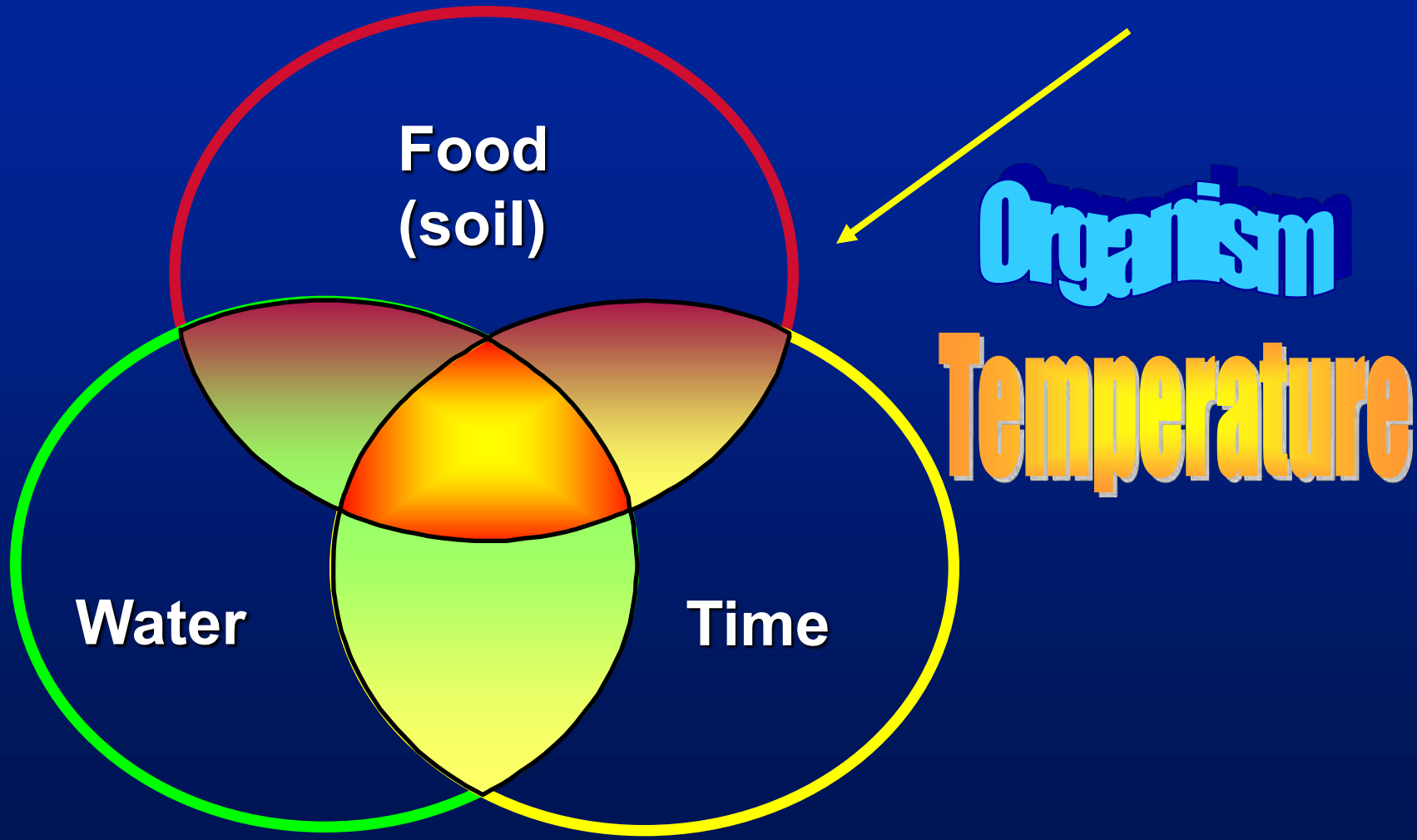
Variables Affecting Likely Contamination From the Processing Environment

"The probability of product contamination from the environment is dependent upon a number of variables…"

1. ***Proximity of microbial growth niches to the product stream***
2. ***Number of niches in the factory***
3. ***Spatial relationships of niches and product stream***
4. ***Microbial population in niches***
5. ***Degree of niche disruption during operations***
6. ***Exposure of the product stream to the environment***

Gabis, D. A. and R. E. Faust. 1988. Controlling microbial growth in the food-processing environment. Food Technol. Dec. pp. 81-82.; 89.

Microbial Growth Requirements



Microbial Growth Niches

- Operating practices (e.g. sanitation)
- Maintenance / repair practices
- Design / fabrication of factory / equipment

Site Specific Risk: High, Medium and Indirect Risks

- *High risk* - an area or practice which may directly contaminate the product
- *Medium risk* - similar to “high risk”, but mitigating factors (such as further heat processing) *may* reduce risk by an undetermined amount
- *Indirect risk* - any situation or condition (such as standing water) which potentially may contaminate product under certain but not defined conditions

An Example of Site Specific Risk Assessment Frame Work (Salad Dressing)

	Suggested			
Risk	Priority	Site	Comments/Observations/ Data	Recommendations

Unsanitary Maintenance/Repair Practices

ILL fitting / protruding gasket at bottom of mix tank

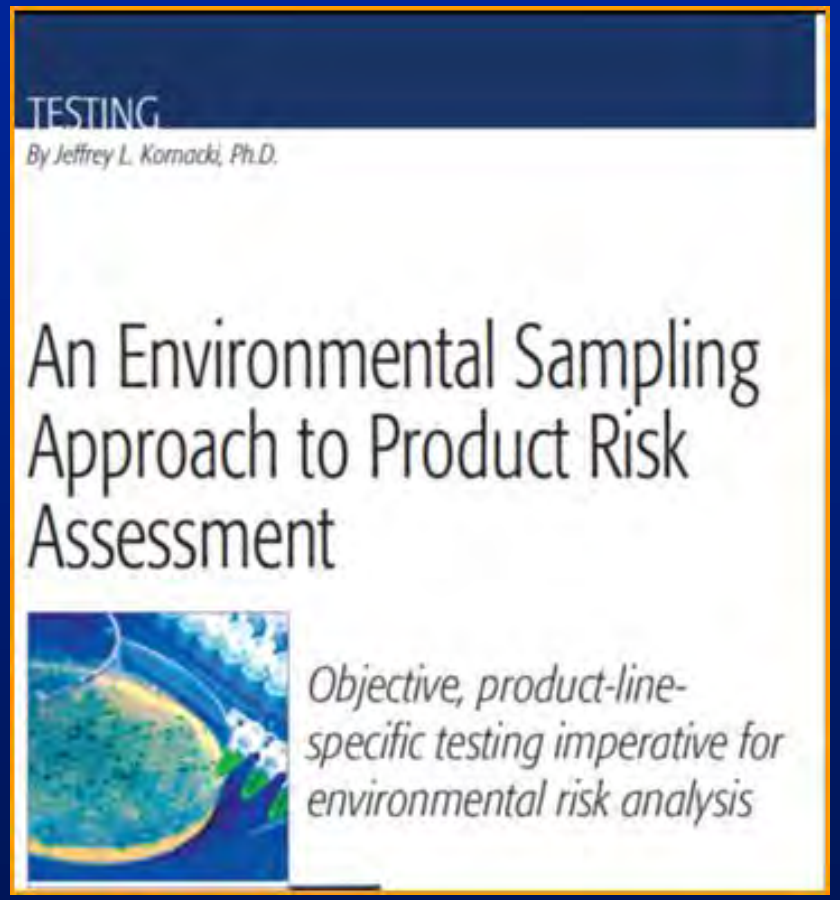
Unchanged gasket at bottom of mix tank

A chance to drill into the specifics

Parking Tickets Vs. Parking Permits

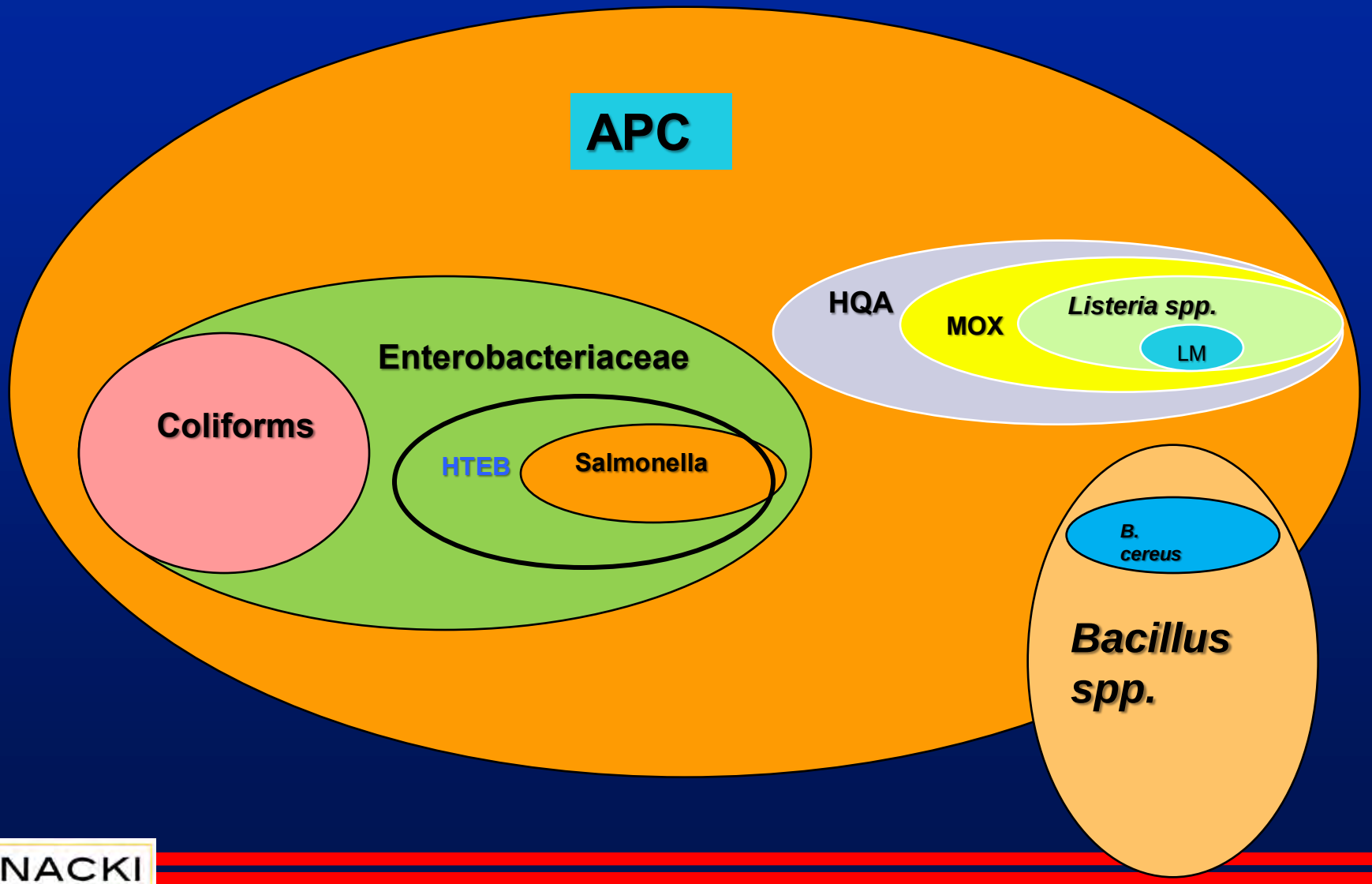
Direct vs indirect approaches

Line Specific Risk Assessment -Use of Indicators: An Industrial Approach



Kornacki, J. L. 2014. An environmental sampling approach to product risk assessment. February/March issue.

Relationship of Selected Microbiological Tests/Organisms



Food Safety Microbiological Risk Assessment

In-Line **product testing at key points**

Assess risk, build up, potential for growth, etc. ***Hygienic Indicators, a_w, pH***

Environmental **testing**

Zone 1-2: ***Hygienic indicator microbiological assays***

Zone 3-4: ***Indicators and selected pathogens***

Generalized Risk Assessment Matrix

In-light of recent experiences this should ≤1% wrt to Listeria spp.

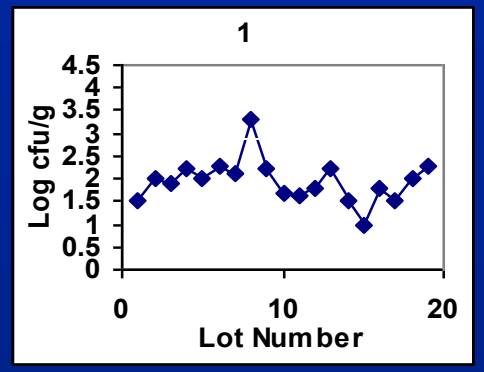
Case No.	Environmental	Environmental	Product-Associated Zone	In-Line Testing	Risk Ranking
	Zones 3–4, *Salmonella* or 5% *Listeria* spp.	Zones 3–4, 5% HTEB or 5% EB, APC or coliforms with 100,000 or more per ft²	Zones 1–2 product proximity-associated, any *Listeria* spp.-, MOX- or HQA-positive or any EB or coliforms (100 if dry cleaned) or APC >1,000	In-line or product (EB >100 per gram if a dry product)	
1	Positive	Positive	Positive	Positive	4.0
2	Positive	Positive	Positive	Negative	4.0
3	Positive	Positive	Negative	Positive	4.0
4	Positive	Positive	Negative	Negative	2.5
5	Positive	Negative	Positive	Positive	4.0
6	Positive	Negative	Positive	Negative	4.0
7	Positive	Negative	Negative	Positive	4.0
8	Positive	Negative	Negative	Negative	2.5
9	Negative	Positive	Positive	Positive	3.5
10	Negative	Positive	Positive	Negative	3.5
11	Negative	Positive	Negative	Positive	3.0
12	Negative	Positive	Negative	Negative	2.0
13	Negative	Negative	Positive	Positive	2.5
14	Negative	Negative	Positive	Negative	2.5
15	Negative	Negative	Negative	Positive	2.0
16	Negative	Negative	Negative	Negative	2.0

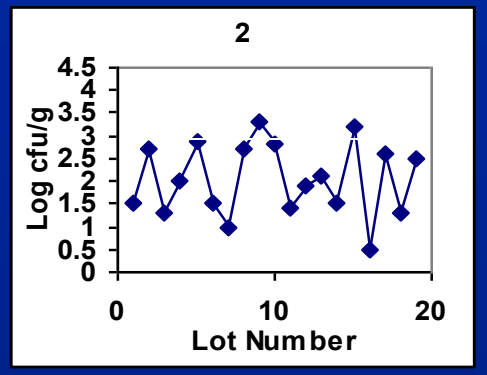
HTEB, hydrogen-sulfide-producing thermoduric Enterobacteriaceae; EB, Enterobacteriaceae; APC, aerobic plate count; MOX, modified Oxford agar; HQA, hygienic quality assay.

Kornacki, J. L. 2014. An environmental sampling approach to product risk assessment. Food Safety Magazine. February/March issue.

Hypothetical examples of using data from an assay for a microbiological Indicator to verify the effectiveness of a food safety system

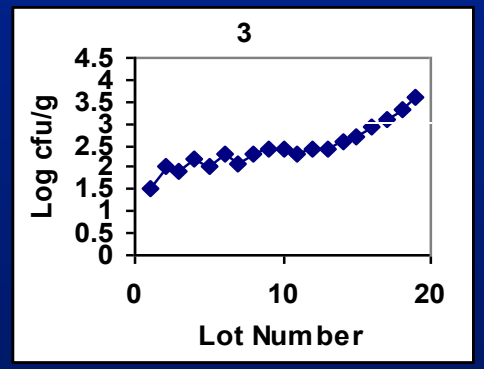
1. System under control

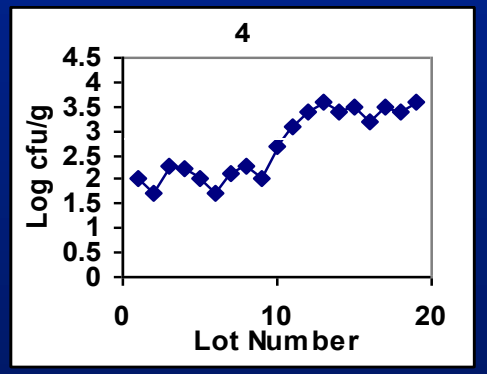




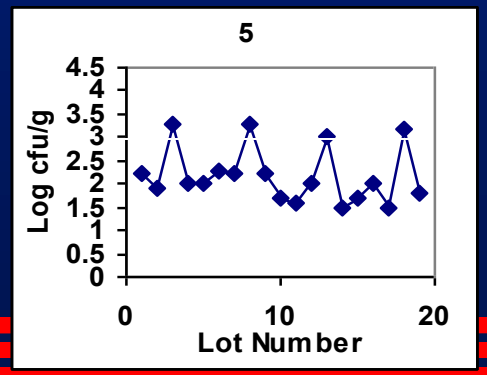
2. Lack of control due to excess variability

3. Loss of control due to gradual process failures





4. Loss of control due to abrupt process failures



5. Loss of control due to a reoccurring, transitory failure

Putting It Together: What Is Needed

- GMP audits and controls (including sanitation preventive controls)
- HACCP verification (process preventive controls)
- Appropriate product testing (Verification)
- All other preventive controls (supply chain and allergen preventive controls)
- And Approaches to monitoring, assessment and controlling *the environment* (sanitation verification)

Summary

- GMP audits, HACCP verification audits, and finished product hold and test programs are not enough by themselves to assure food safety

- The processing environment is a significant source of contamination to processed products

Summary (continued)

- Companies neglect monitoring and control of the processing environment to their own harm and to that of the public.
- There are new tools that can be used to control risk (e.g. HQA, HTEB; risk assessment matrix)
- Be aware of false paradigms in your investigations and sampling of the processing environment
- Tracking and trending is important, as is some finished product testing

Summary (Continued)

- Diligence and vigilance are essential!