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

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

include

Contributing factors - How

Environmental antecedents - Why
## Environmental factors contributing to outbreaks

### Contributing factors

<table>
<thead>
<tr>
<th>Contamination</th>
<th>Proliferation</th>
<th>Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Cross-contamination of ingredients</td>
<td>• Improper cold holding due to malfunctioning equipment</td>
<td>• Insufficient time/temp during reheating</td>
</tr>
<tr>
<td>• Contact by an infectious/ill worker</td>
<td>• Improper cold holding due to improper procedure</td>
<td>• Insufficient time/temp during freezing</td>
</tr>
</tbody>
</table>

### Environmental antecedents

- People
- Processes
- Equipment
- Economics
Environmental factors contributing to outbreaks

Environmental antecedents
- Worker in a hurry
- Worker had not been trained on avoiding cross contamination

Contributing factor
- Cross contamination
  - Worker used same utensils on raw ground beef and salads

Outbreak
- *E. coli* outbreak caused by salads eaten at Restaurant A
Outbreak environmental assessments

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

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

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

- Are conducted by environmental health program staff

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

- 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
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
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

vradke@cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
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)
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)
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
NYS Foodborne Illness Outbreak Response Team

- Ill Patient
- Physician
- Local Labs
- Wadsworth Labs
- Public Health Nurses
- Communicable Disease Control
- Regional Office
- Food Protection
- Other State & Federal Agencies
- Food Traceback Possible Recall

- Patient Interview
- Food Preference
- Case Control Study
- Facility Investigation
- Enforcement Action
Number of Foodborne Outbreaks, New York State 1980 – 2015

Reporting Year

Number of Outbreaks

0 50 100 150 200


41 160 102 159 143 142 120 126 107 115 97 89 76 84 53 53 53 48 57 42 46

Updated 01/2017
Number of Foodborne Outbreaks by Etiology in New York State, 2001-2015

Total Number of Outbreaks: 794

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

Number of outbreaks by etiology:
Top 10 Foodborne Outbreaks by Agent, New York State, 2001-2015

<table>
<thead>
<tr>
<th>Agent</th>
<th>Number of Outbreaks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unknown</td>
<td>236</td>
</tr>
<tr>
<td>Salmonella</td>
<td>137</td>
</tr>
<tr>
<td>Calicivirus (Norovirus)</td>
<td>136</td>
</tr>
<tr>
<td>Scombrotoxin</td>
<td>52</td>
</tr>
<tr>
<td>E. coli: Shiga toxin positive</td>
<td>43</td>
</tr>
<tr>
<td>Clostridium perfringens</td>
<td>42</td>
</tr>
<tr>
<td>Campylobacter</td>
<td>25</td>
</tr>
<tr>
<td>Gastrointestinal virus (GI)</td>
<td>19</td>
</tr>
<tr>
<td>Listeria monocytogenes</td>
<td>15</td>
</tr>
<tr>
<td>Bacillus cereus</td>
<td>13</td>
</tr>
<tr>
<td>Vibrio parahaemolyticus</td>
<td>13</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>13</td>
</tr>
</tbody>
</table>

Updated 01/2017
Top 10 Significant Ingredient Identified in Foodborne Outbreaks, New York State 2001-2015

- Unknown: 298
- No specific ingredient: 79
- Fin fish: 73
- Infected worker: 69
- Poultry: 68
- Beef: 64
- Starchy foods: 53
- Green Leafy Vegetables: 28
- Fruits: 26
- Shellfish: 25

There were 884 instances where a significant ingredient was identified.
Top 10 Contributing Factors Identified in Foodborne Outbreaks, New York State 2001-2015

- Unknown: 391
- Contaminated ingredient: 126
- Infected person: 110
- Natural toxicant: 70
- Inadequate cooking: 57
- Improper cooling: 41
- Consumption: Raw/ lightly heated (animal origin): 41
- Inadequate refrigeration: 40
- Inadequate hot holding: 39
- Hand contact w/ implicated food: 37
- Inadequate reheating: 30

Number of Times CF was Identified
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 (%)

Updated 01/2017
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

- **Ingredients**
  - Organisms
  - Chemicals

- **Processes**
  - Receive
  - Store
  - Prep
  - Cook
  - Cool
  - Assemble
  - Hold
  - Serve
  - Reheat

- **Internal System Variables**
  - People
  - Equipment
  - Food
  - Economics

- **External Feedback to System**
  - Receive
  - Store
  - Prep
  - Cook
  - Cool
  - Assemble
  - Hold
  - Serve
  - Reheat

- **Final Food Item**
  - Customer Health
  - Customer Satisfaction
  - Profit

Source: CDC NCEH
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
ENVIRONMENTAL ASSESSMENTS AS PART OF FOODBORNE ILLNESS OUTBREAK INVESTIGATIONS

Step 1: Plan and Prepare
Step 2: Site Visit
Step 3: Assess Information
   Identify Contributing Factors
Step 4: Recommend Control Strategies
Step 5: Report
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
# DISPOSABLE GLOVES

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Missing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glove Policy*</td>
<td>193 (79.1)</td>
<td>48 (19.7)</td>
<td>3 (1.2)</td>
</tr>
<tr>
<td>Glove Supply**</td>
<td>198 (81.1)</td>
<td>41 (16.8)</td>
<td>5 (0.4)</td>
</tr>
<tr>
<td>Glove Use**</td>
<td>159 (65.2)</td>
<td>72 (29.5)</td>
<td>13 (5.3)</td>
</tr>
</tbody>
</table>

*Part III
**Part IV

2006-2008

Source: CDC NCEH
HAND HYGIENE CHARACTERISTICS

Does the establishment have a disposable glove use policy?

- Yes: 87%
- No: 12%
- Missing data: 1%

Do food workers handle ready-to-eat foods with bare hands?

- Yes: 17%
- No: 83%

Source: CDC NCEH
ACTIVITIES USED TO TRY TO IDENTIFY CONTRIBUTING FACTORS

Activities used to try to identify contributing factors – NEARS 2014

[VALUE]% 78% 65% 35% 11% 10%

Activities

Routine environmental inspection
Environmental assessment
Other environmental investigation
Assumed based on etiology
Interview of operator and/or food worker
Environment/food sample culture
Clinical samples/syndrome

% of outbreaks

Activities used to try to identify contributing factors – NEARS 2015

89% 83% 70% 28% 9% 6% 15%

Activities

Routine environmental inspection
Environmental Assesments
Other environmental investigation
Assumed based on etiology
Interview of operator and/or food worker
Environment/food sample culture
Clinical samples/syndrome

% of outbreaks

Source: CDC NCEH
MOST COMMONLY REPORTED CONTRIBUTING FACTORS

Contributing factors (N=78)

<table>
<thead>
<tr>
<th>Factor Description</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>C10: Bare hand contact by food worker who is suspected to be infectious</td>
<td>15%</td>
</tr>
<tr>
<td>C12: Other mode of contamination by a food worker who is suspected to be infectious</td>
<td>14%</td>
</tr>
<tr>
<td>C11: Glove hand contact by a food worker who is suspected to be infectious</td>
<td>12%</td>
</tr>
<tr>
<td>S1: Insufficient time and/or temperature during cooking</td>
<td>6%</td>
</tr>
<tr>
<td>C7: Contaminated raw product</td>
<td>6%</td>
</tr>
<tr>
<td>P1: Food preparation practices that support proliferation of pathogens</td>
<td>6%</td>
</tr>
<tr>
<td>P8: Improper/slow cooling</td>
<td>6%</td>
</tr>
</tbody>
</table>
ILL WORK CHARACTERISTICS

Does the establishment have a policy that requires food workers to tell a manager when they are ill?

- Yes: 87%
- No: 10%
- Missing data: 3%

Does this policy require ill workers to tell managers what their symptoms are?

- Yes: [PERCENT AGE]
- No: 16%
- Missing data: 9%
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
Manager Interview
  - Food Worker
    - Number of workers
    - Food safety training and certification
    - Language
  - Policy
    - Cleaning
    - Glove use
    - Health policies
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
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
Why Are We Here?

Galaxies NGC 2207 and IC 2163

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

\(^1\text{www.cdc.gov/foodborneburden} \text{ December 2010}\)


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

<table>
<thead>
<tr>
<th>Percent positives</th>
<th>90% confidence</th>
<th>95% confidence</th>
<th>99% confidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>3</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>10%</td>
<td>23</td>
<td>30</td>
<td>46</td>
</tr>
<tr>
<td>1%</td>
<td>230</td>
<td>299</td>
<td>461</td>
</tr>
<tr>
<td>0.1%</td>
<td>2,303</td>
<td>2,996</td>
<td>4,605</td>
</tr>
<tr>
<td>0.01%</td>
<td>23,026</td>
<td>29,963</td>
<td>46,052</td>
</tr>
</tbody>
</table>

Test Number Needed to Detect One or More Positives per Lot

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


### Examples of Outbreaks Attributed to Environmental Contamination

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

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

Environmental contamination is the principle source of contamination of processed foods

It is from the post-processing (post-CCPm) environment


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

Lead to in-plant risk assessment concept

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Correlations of % Environmental to % Finished Product Contamination

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

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**

Microbial Growth Requirements

- Food (soil)
- Water
- Time

Organism
Temperature
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)

<table>
<thead>
<tr>
<th>Suggested</th>
<th>Risk</th>
<th>Priority</th>
<th>Site</th>
<th>Comments/Observations/Data</th>
<th>Recommendations</th>
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</table>

### 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
Relationship of Selected Microbiological Tests/Organisms

- **Enterobacteriaceae**
  - Coliforms
    - HTEB
    - Salmonella
  - APC

- **Bacillus spp.**
  - B. cereus

- **Listeria spp.**
  - HQA
  - MOX
  - LM
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
In light of recent experiences this should be \( \leq 1\% \) wrt to *Listeria* spp.

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Environmental</th>
<th>Environmental</th>
<th>Product-Associated Zone</th>
<th>In-Line Testing</th>
<th>Risk Ranking</th>
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HTEB, hydrogen-sulfide-producing thermolubric Enterobacteriaceae; EB, Enterobacteriaceae; APC, aerobic plate count; MOX, modified Oxford agar; HQA, hygienic quality assay.

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
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!