Role of Environmental Monitoring Programs in Food Safety Program

Aaron M. Pleitner, Ph.D.
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Introduction

- Culture of Food Safety
  - Rapidly accelerated in recent years
  - Increase in regulatory guidelines
  - Holistic management approach
  - Development of testing methodologies and tools
    - Molecular assays
      - Rapid TAT/response
      - Decrease incubation times
    - Typing methods (e.g. Whole genome sequencing)
    - Facility mapping and production windows

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Approaches to Testing

- Holistic approach to Food Safety
  - Preventive controls to monitor:
    - Supply chain
    - Finished product
    - ***Environment***
      - ***Pre- and post-operation***
      - ***Cleaning and sanitization***
      - ***Intermittent***
      - ***Broad ranging throughout facility***
      - ***Frequency***
      - ***Traffic flow***
      - ***Plant design***

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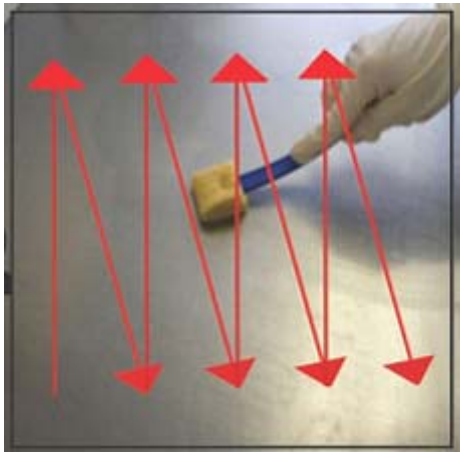
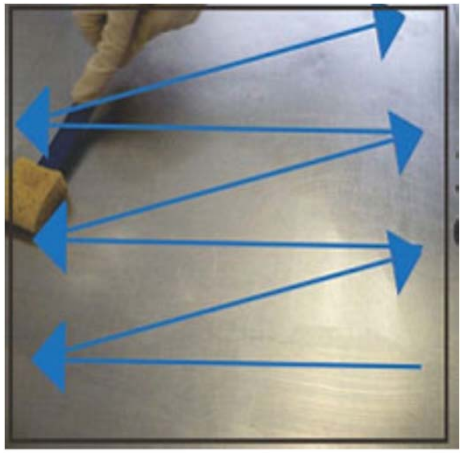
Environmental Sampling Procedure

- Procedural Considerations
  - Aseptic technique and GMP/GLPs
    - Use of gloves/provided gloves
    - Washing of hands and forearms
    - Opening and closing of sample bags
  - Sampling area
    - $10cm^2$ ($4 in^2$), $1 ft^2$, entire area of harborage/niche site, drain
    - This can effect what type of sampling apparatus is used
  - Sampling technique
    - For specific areas, 10 drags vertically followed by 10 drags horizontally
    - Coverage of drain area
    - Vigorous swabbing around harborage/niche sites due to biofilm or strong adhesion to area
    - Type of hydration buffer for (a) neutralization, (b) type of sampling apparatus and (c) type of facility





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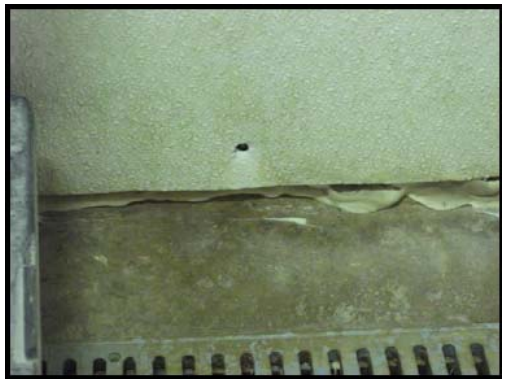
Environmental Sampling



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Environmental Sampling Procedure

- Guidance provided by USDA FSIS for *Listeria* Control Programs
  https://www.fsis.usda.gov/wps/wcm/connect/259fcaf4-ce2b-4ba1-8140-da873243040f/Chapter_3_Controlling_LM_RTE_guideline_0912.pdf?MOD=AJPERES
- Guidance provided by FDA for Control of *Listeria* in RTE
  - https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM535981.pdf
- Environmental Sampling for Poultry House in Section A
  - https://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114716.htm

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Environmental Sampling Procedure

- Assessment and tracking of manufacturing site microbial fingerprint
  - Insight:
    - Hygienic state
    - Effectiveness of cleaning and sanitation efforts
    - Effect of traffic flow
    - Effect of plant design
- Determination of testing sites
  - Zones:
    - Zone 1 – Food contact surface (FCS)
    - Zone 2 – Non-food contact surfaces (NFCS) directly adjacent to FCS
    - Zone 3 – NFCS that are not adjacent to FCS but pose a threat to contamination in post-processing areas
    - Zone 4 – NFCS that are remote from post-processing areas

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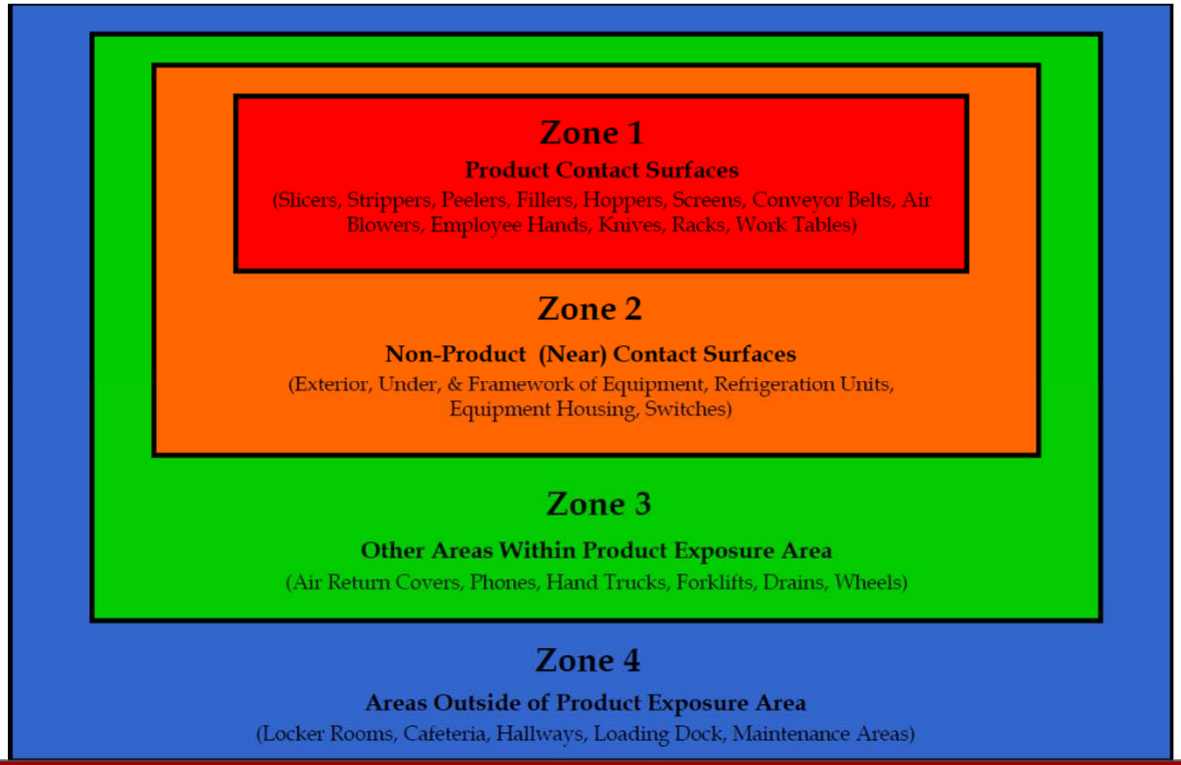
Environmental Sampling Zones



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Environmental Sampling Procedure

- Implementation of environmental sampling plan
  - Identification of zones and testing sites
  - Increased testing frequency to begin with
    - Development of baseline microflora levels
    - Baseline allows for timeline and historical comparison
  - Swabbing of locations with sponge/cotton swab with hydration solution
    - Sanitizer residue has an effect on recovery
    - Appropriate hydration buffer solution necessary[1]
    - Dey-Engley (D/E), Neutralizing Buffer (NB), Letheen Broth (LE), Buffered Peptone Water (BPW), etc.

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1. J. Food Pro. 75(3): 580

Environmental Sampling

- Testing targets
  - Indicator organisms
    - Aerobic plate count/Total plate count
    - Yeast/Mold
    - *Enterobacteriaceae* (EB)
    - *Listeria* spp.[1]
      - *Listeria innocua*
      - *Listeria grayi*
      - *Listeria welshimeri*
      - *Listeria seeligeri*
  - Target pathogens
    - *Salmonella*

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1. Int. J. Food Microbiol. 238:274

Environmental Sampling

- Testing methodologies
  - Surface sampling using either sponge, spongesicle or cotton swabs to specific surface area
  - Indicator organisms
    - Culture based methods (Quantitative)
    - Molecular based assay for *Listeria* (Qualitative Presence/Absence)
  - Target pathogens
    - Molecular and culture based assays
      - Enzyme-linked fluorescent immunoassay
      - Gene targets unique to target
      - More rapid than culture based qualitative methods
    - USDA MLG or FDA BAM culture based methodologies

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Environmental Sampling

- Testing methodology results
  - Quantitative method provides overall general population in the surface area samples (CFU/mL, CFU/g, CFU/cm^2)
  - Qualitative method provides presence/absence of target bacteria
    - Stages to positive include:
      - Potential positive
      - Presumptive positive
      - Confirmed positive
      - Negative
      - False positive

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Environmental Sampling

- Further suggested steps:
  - ***Quantitative indicator organisms increase*** suggest increasing cleaning/sanitation interventions and intensified sampling
  - ***Qualitative method*** identifies either target indicator organism or presence of pathogen of concern
    - Suggested to halt production, deep clean, place product on hold
    - Typing of isolates from positive results determine if same species and possibly strain is tracking throughout facility/harboring at specific site
  - Intensified sampling to identify source[1]
  - Rotation of sanitizer and cleaning agents
  - Biofilm identification

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1. J. Food Pro. 65(4):709

Environmental Sampling

- Historical data collection and facility mapping
  - Defining of baseline, comparison with employee traffic flow, implementation of new GMPs, SSOPs, introduction of new vendors
  - Further typing of bacterial isolates
    - Pulsed-field gel electrophoresis
    - Whole genome sequencing
    - VITEK

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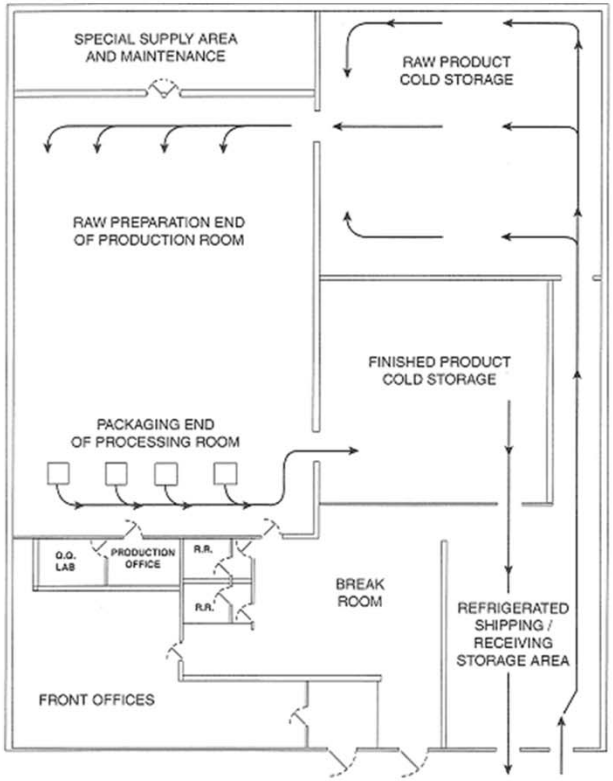
Environmental Sampling

- Historical data collection and facility mapping



- Location examples:
  - Employee smocks/boots
  - Equipment surfaces
  - Floor locations
  - Drains
  - Doorways
  - Refrigerated storage
  - Carts
  - Breakroom
  - Drains

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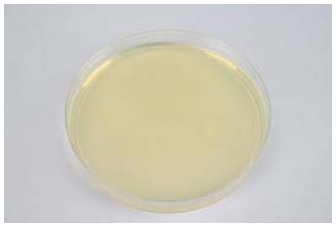
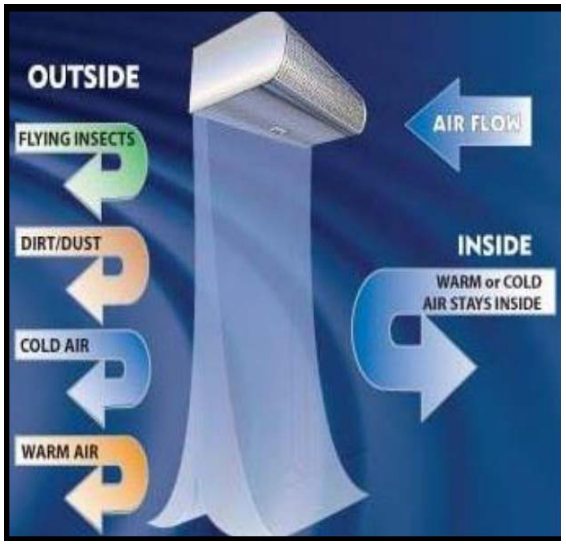
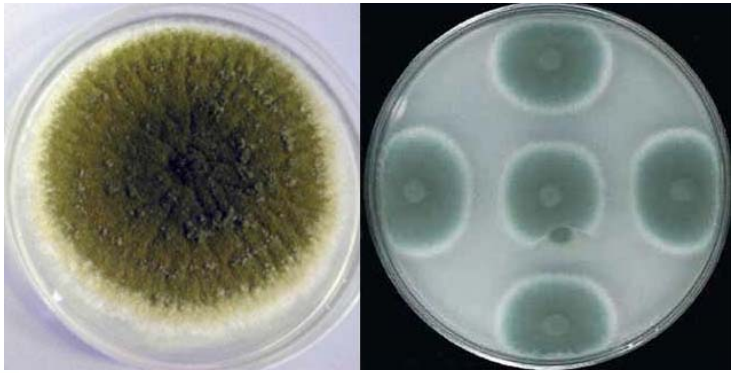
Air Sampling

- Place of an open plate in processing environment
- Use of sampling equipment
- Considerations
  - Room placement
  - Airflow in area
  - Traffic flow in area
  - Time during production
  - Velocity of collection translates to volume of air tested







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Conclusions

- Sampling procedures and considerations are pivotal
- Environmental monitoring program is dependent on:
  - Identification of sites
  - Size and traffic of facility
  - Frequency and type of testing
- Environmental monitoring programs provide heartbeat of microbial presence
- Environmental monitoring programs and follow-up steps can provide insight into route of introduction and transmission and harborage points

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Questions?

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Appendix Slides

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Culture Based for Qualitative and Quantitative Methods

- FDA Bacteriological Analytical Manual (BAM)
  - Chapter 3 for APC
  - Chapter 4A for Diarrheagenic *Escherichia coli*
  - Chapter 5 for *Salmonella*
  - Chapter 10 for *Listeria monocytogenes*
- USDA Microbiological Laboratory Guidebook (MLG)
  - 3.02 Sanitary Indicators
  - 4.09 for *Salmonella*
  - 5.09 for *Escherichia coli*
  - 8.10 for *Listeria monocytogenes*
- 3M Petrifilm
  - APC
  - Rapid APC
  - *Enterobacteriaceae*
  - *Listeria*
- For non-FDA and USDA methods, identify AOAC validation status of methods for specific surfaces

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