Verifying your sanitation program – environmental monitoring

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Environmental monitoring
Builds on Existing GMP and Sanitation Programs

Guidance Resources:
RAC’s, Fresh-cut, Dry Facilities

Published 2000

Guidelines for Controlling Listeria monocytogenes in Small- to Medium-Scale Packing and Fresh-Cut Operations

Environmental Monitoring

• A verification step
  – Verify that you are following the procedures you developed (‘compliance’)
  – Verify that the plan is working in practice.


http://www.almonds.com/processors/processing-safe-product#pem

http://www2.unitedfresh.org/forms/store/ProductFormPublic/

http://www.cdc.gov/salmonella/braenderup-08-14/

2014 Nut Butter Outbreak - Identification in Reverse

• Routine inspection of facility
  – January
  – Isolates Salmonella Braenderup
    • PFGE fingerprinting
    • Whole genome sequencing
  – Search PulseNet for cases
    – January (2), February, March, April, May
• Epidemiology
• Re-inspection, re-isolation — Salmonella Braenderup
• 6 months product recall

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http://www.almonds.com/processors/processing-safe-product#pem
Verification activities include

- **Review of**
  - written policies and procedures
  - quality systems audits, GMP self-audits, etc.
  - records that support the GMP programs
    - E.g., sanitation and training records
- **Observation of**
  - cleaning and sanitation, sanitary conditions,
  - GMP compliance, etc.

### Zone Concept for Setting Master Schedule Cleaning and Sanitation & Environmental Monitoring Programs

**Zone 1**
- **Direct or indirect** product contact surfaces
  - Direct
    - surfaces exposed to product during equipment operation
      - conveyor belts, brushes, rollers
      - ladders, hoses, tools, etc. used by workers who also handle product or touch product contact surfaces

**Environmental Testing**
- **Routine Tests**
  - Visual Inspection – is it clean?
  - Adenosine triphosphate (ATP) testing
  - Indicator organisms
    - aerobic plate count, coliform count

**Zone 1**
- **Indirect** surfaces from which liquids or dust or other material may drain, drop, diffuse, or be drawn into the product or into the container, and surfaces that touch product contact surfaces or the product container (ABC PEM manual)
  - Not universal agreement on which surfaces classify as indirect
  - A sanitation survey can be used to identify and reduce the number of indirect contact points in a facility

**Environmental Testing**
- How often is it recommended to swab food contact surfaces for APC...once week...once a month, etc.?

**Develop a Master Swab Plan**

Frequency of testing: Routine sampling may be performed weekly, monthly or quarterly depending on the amount of product produced, risk and facility history. There is no “right” answer as to frequency and number of swabs.
**Zone 1**

- **Special circumstances only**
  - Environmental Pathogens
    - *Listeria* spp., *Listeria monocytogenes*, *Salmonella*

**Environmental pathogen**

- means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen.

Proposed preventive controls rule, 2014

**Dry processes**

- **Pathogen:**
  - *Salmonella*

- **Example indicator organism**
  - *Enterobacteriaceae*

- **Infant formula**
  - **Pathogen:** *Cronobacter sakazakii*
    (formerly *Enterobacter sakazakii*)

**Wet processes**

- **Pathogen**
  - *Listeria monocytogenes*

- **Example indicator organism**
  - *Listeria spp.*

- **NOTE:** Positive for *Listeria* spp. on food contact surface may be considered equivalent to finding *L. monocytogenes*

**Testing for *Listeria* spp.**

- **Zone 4**
  - Removed from processing
    - Warehouses, bathrooms, maintenance areas, loading docks, offices, entrance

- **Why?**
  - Confirmation that tests for *Listeria* spp. are working
  - May reveal ingress points

**Testing for *Listeria* spp.**

- **Zone 3**
  - Surfaces further removed from product contact
    - Walls, walkways, phones, carts, air handling units, drains

- **Why?**
  - These areas provide niches and harborage
  - Can accumulate moisture and nutrients

  - Zone 3 contamination can move to Zones 2 and 1
    - Workers, air, water (often during cleaning)
Testing for *Listeria* spp.

- **What is the recommended frequency for swabbing drains for *Listeria* spp. in a fruit packing house?**
  
  See United Fresh guidance document for discussion

Testing for *Listeria* spp.

- **Zone 2**
  - *Immediately next* to food contact surfaces
    - Outside and under food contact surfaces
      - Exterior, under, & framework of equipment; refrigeration units, equipment housing; switches
  - **Why?**
    - More likely than Zone 3 to collect moisture and nutrients, shorter distance to transfer bacteria to food contact surfaces.

Testing for *Listeria* spp.

- **Zone 1**
  - Food contact surfaces
    - Hoppers, conveyor belts, brushes, employee hands, racks, work tables
  - *Listeria* spp. testing NOT USUALLY DONE
    - A positive on this surface may be considered indicative of product contamination
  - If/When?
    - Between production lots, when affected product can be held until results are know.
    - During in depth investigations

Pathogen Accumulation

- Microbes may survive, especially on surfaces that remain wet (brush/sponge rolls; floors)
- Contact of plant material with surfaces:
  - waxes and plant sap accumulate
- Partially decayed plant material:
  - sticks to surfaces
  - is loaded with microbes
- Use of dump tanks
  - Pathogens can accumulate during packing

Bacteria Can Hide

- Even though a surface may appear smooth, there are many places for bacteria to hide!
- This is polished stainless steel.

Where to look? “Be the *Listeria*”

http://www.asmusa.org/edusrc/s6ofilms/hiesa044h.jpg
**Listeria form biofilms**

- Biofilms can be found everywhere
- Collections of microscopic organisms which have attached themselves to a surface (and each other) in the interests of survival.
- Characterized by a sticky adhesive substance.
  - Provides protection
  - Serves as attractant

**The Making of A Biofilm**

**What about a positive finding?**

- You MUST have a written corrective action.
- Transient
  - Not found in repeated testing
- Resident
  - Repeatedly found
  - Examine the site, implement appropriate cleaning/sanitation
    - Retest the site and surrounding area
    - Increase routine testing in and around area until several negative results
- If resident Listeria spp. is suspected
  - Form a team
    - Investigate potential cause, implement corrective action, retest
  - Document all activities

**Special Events**

- Enhanced environmental monitoring should be considered when:
  - Construction
  - New equipment installation
  - Major repairs
  - Breaks in operation

**Indicator and Pathogen Testing**

- Results
  - Understand the limitations.
  - Define Critical Limits in Writing
    - What is unacceptable?
  - Define Corrective Action in Writing
    - Action for unacceptable result?
  - Written data disposition policy.

- Data processing
  - Keep good records
  - Evaluation of trends
  - Recognizing site-specific deviations
  - Recognizing equipment or practice-specific risks

- Further characterization of isolates
  - *Listeria* spp. to *L. monocytogenes* to fingerprints
Summary

• Environmental monitoring
  – Is a verification activity that can be used to assess the efficacy of GMPs and a sanitation program
  – For zone 1 surfaces assessing for indicators of reduced organic or microbial load (e.g., ATP, APC) is common
  – For zone 2 to 4 surfaces assessing for a pathogen or pathogen indicator (e.g., Listeria spp.) may be appropriate

• Written
  – Environmental monitoring plan and corrective actions
  – Documentation is critical