







#### 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.

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

Zone 1
Product Contact Surfaces
(Slicers, peelers, fillers, hoppers, screens, conveyor belts, air blowers, employee hands, knives, rades, work tables)

Zone 2
Non-Product (Near) Contact Surfaces
(Exterior, unde, & farmework of equipment, refrigeration units, equipment housing: switches)

Zone 3
Other Areas within Finished Product (RTE) Room
(Air return covers, phones, hand trucks, forklifts, drains, wheels)

Zone 4
Area Outside of RTE Room
(Locker rooms, caleferis, hallways, loading dock, maintenance areas)

#### 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



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#### 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

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#### Zone 1

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

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# **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.



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#### 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
  - May reveal ingress points





- Surfaces further removed from product contact
  - · Walls, walkways, phones, carts, air handling units, drains
- Whv?
  - These areas provide niches and harborages
  - 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.

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# Testing for *Listeria* spp.



- Zone :
  - 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

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#### Where to look? "Be the Listeria"











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

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#### Bacteria Can Hide

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



http://www.asmusa.org/edusrc/biofilms/hires/0444h.jpg

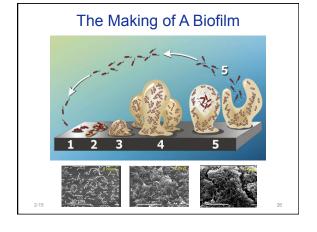
## *Listeria* form biofilms

- 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









# 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.

# **Indicator and Pathogen Testing**

- 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
- - Environmental monitoring plan and corrective actions
  - Documentation is critical