Environmental Monitoring

Types of Biological Contaminants

Transient Microorganisms

- Introduced via raw materials, personnel, packaging materials
- Removed through normal cleaning and sanitizing
- Typically do not become established in the environment

Resident Microorganisms

- Become established in the environment
- May persist for long periods
- Normal cleaning and sanitizing may control numbers but may not eliminate

Facility Hygienic Zoning and GMPs

- Documented assessment of the facility, considering:
  - Infrastructure
  - Personnel, materials and other traffic flow
  - Cross over areas
  - Room air
  - Compressed air, if used in direct product contact
  - Adjacent and support areas

Assessing the Need for Zoning and Environmental Monitoring

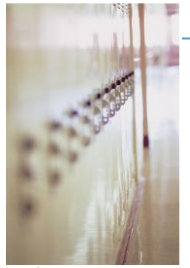
1. Does the product formulation have an intrinsic property that would kill the environmental pathogen of concern (e.g., a high acid level)?
2. Is the product or ingredient associated with pathogen contamination?
3. Does the product receive a validated process control designed to kill environmental pathogens?
4. Is the product exposed to the environment after the kill step and before packaging?
5. Are ready-to-eat ingredients used to produce a ready-to-eat product?
6. Does a refrigerated ready-to-eat product support the growth of *Listeria monocytogenes*?

Hygienic Zoning

Useful to differentiate facility hygiene requirements to minimize product cross-contamination, e.g.,

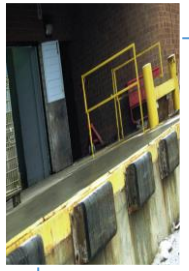
Non-manufacturing areas

- Maintenance shop, offices, employee areas, waste disposal



Transition areas

- Entry rooms, locker rooms that enter onto basic GMP areas, etc.



Basic GMP areas

- Raw, receiving and storage

Primary pathogen control area – CONTROLLED ACCESS

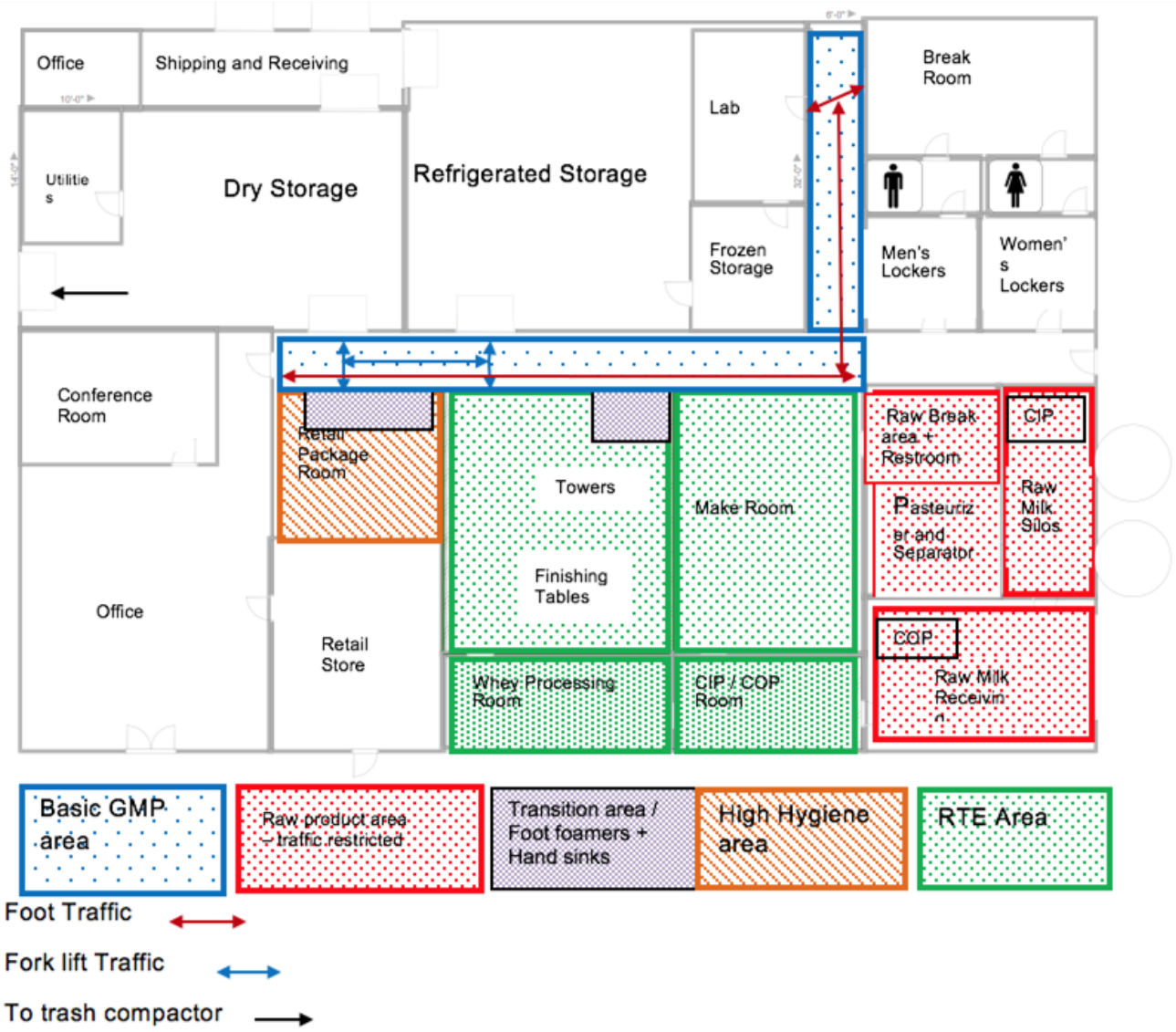
- Cooked, pasteurized or RTE products exposed to the environment

Sensitive/high hygiene area – RESTRICTED ACCESS

- Products for sensitive populations such as infants

Images from Microsoft clip art

Example Hygienic Zoning Map



Pepper Jack Example

Who: All employees are required to follow Hygienic Zoning protocols.

Procedure: Employees entering the described areas must follow the protocol for the area.

1. Raw product areas

   a. Traffic in these areas is limited to dedicated personnel. Dedicated personnel must wear a clean, gray uniform stored in lockers in Raw Area. Only employees working in this area wear gray uniforms. Employees in gray colored uniforms may not enter the common areas of the plant.
   b. Upon entering the area, employee changes into uniform and steel toe, slip resistant boots.
   c. Employee dons hairnet and beard net (where applicable) and red bump cap. Employee then washes hands and continues into the work area.
   d. Occasional employees may enter this area only if authorized. They must don Tyvek (disposable) suits and rubberized yellow shoe covers upon entrance to the area.
   e. Employee removes bump cap, discards hair covering and changes into street clothes and shoes OR removes Tyvek suit and shoe covers (if applicable) before leaving the raw area.
   f. Tools in this area are dedicated and must remain in the area.

2. RTE areas

   a. Employees working in RTE or High Hygiene (HH) areas change into a clean white uniforms each day and clean, dedicated slip resistant, steel toed footwear. Temporary employees use blue shoe covers.
   b. Employee dons hairnet and beard net (where applicable) prior to entering basic GMP, RTE or HH areas.
   c. Employees designated to work in the make room don green bump caps.
   d. Employees must wash hands in the gang sink located in the same hallway prior to entry into the plant.

3. High Hygiene area

   a. Employees entering the HH area must don a clean apron and arm guards upon entry to the HH area. They must wash their hands and wear gloves to handle product.
   b. Aprons and arm guards must be left in the HH area when employees go on break. At the end of the shift aprons must be placed in the soiled apron bins. Arm guards must be discarded.
   c. Gloves should be discarded as employee exits room, when non-food contact surface has been touched or if glove is torn and replaced with new prior to resuming packaging activities.
   d. Tools in this area are dedicated and must remain in the area. Tools must be cleaned and sanitized after use.

Pepper Jack Example

Environmental Monitoring

- Purpose
  - Verify the effectiveness of sanitation programs
  - Verify that hygienic zoning is working to:
    - Protect product from cross-contamination or recontamination
    - Prevent microbial harborage
  - Understand “normal” environmental conditions vs. something has changed or something unusual is going on
- Must be tailored to each facility
- May include pathogens or indicator organisms
- A useful program diligently *tries to find* the organism!

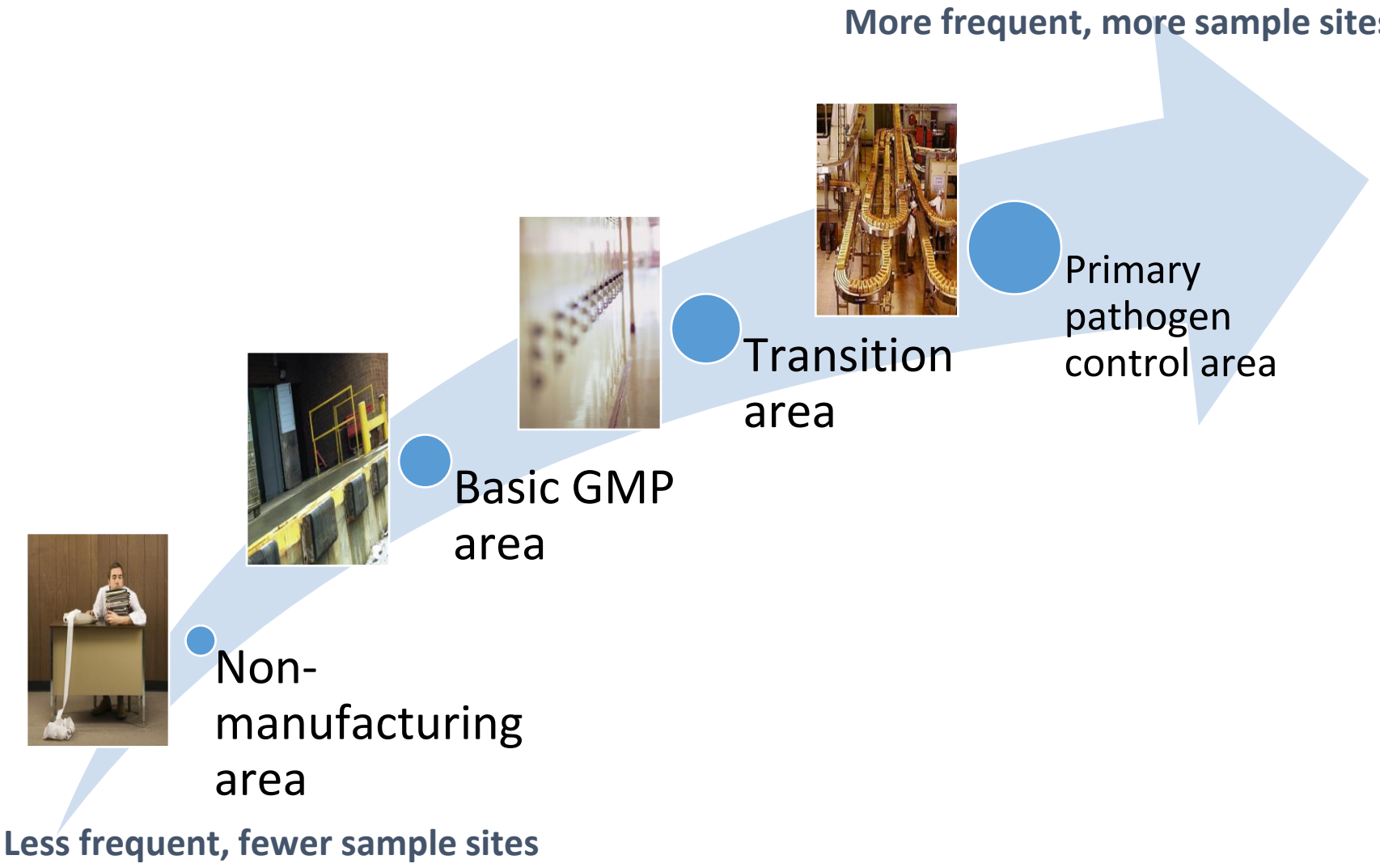
Environmental Monitoring Development

- Biased targeted to the specific facility, equipment, history, products, ingredients and final product

- Low moisture foods – *Salmonella*

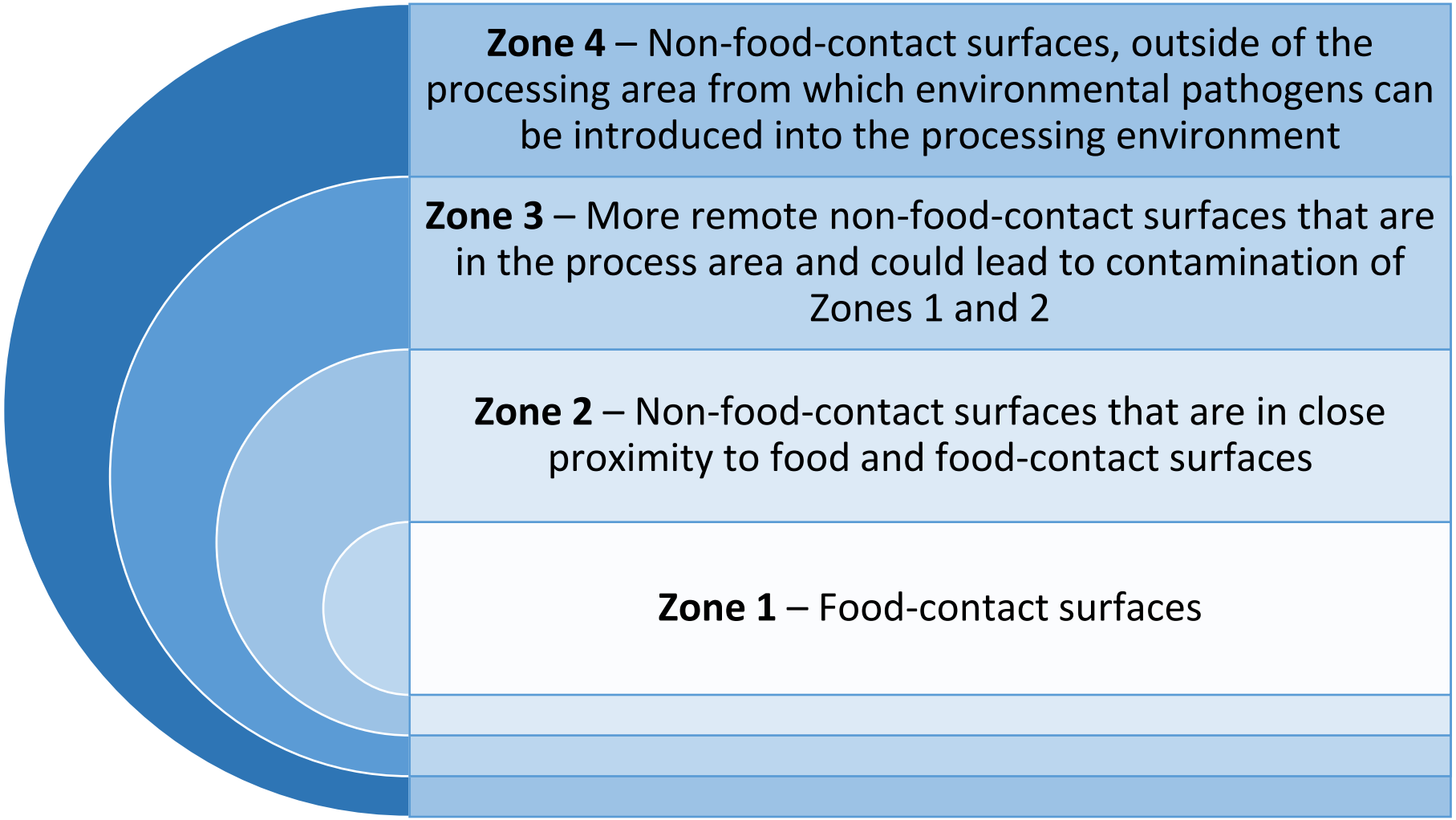
- RTE refrigerated foods - *Listeria monocytogenes* or *Listeria* spp.

Frequency of Environmental Sampling



Images from Microsoft clip art

Environmental Monitoring Sampling Zones



Sample Zones 2, 3 and 4 to prevent contamination in Zone 1.

Environmental Monitoring – People and Tools

- Requires training in technique
  - Identify likely sampling spots

- Tools vary by facility and product type
  - Swabs, sponges, gauze and other options
  - Contact plates
  - Floor sweeps
  - Dust accumulation
  - Air samplers

- Environmental monitoring courses are available for different product categories

Where and When To Sample

- Clearly define where and when the samples to take samples
  - To evaluate cleaning and sanitizing effectiveness
    - After cleaning but before sanitizing
    - Prior to start of operations
    - After cleaning and sanitizing
  - During production operations
    - No less than 3 hours after the start of production
    - At end of run / end of operational shift
    - At shut-down before cleaning
  - During special events
    - During construction periods
    - New process area, equipment or line
    - Following major maintenance activity

Target and Action Limits

- Establish a baseline to monitor trends
  - Requires more sampling than needed for ongoing monitoring
  - Attempt to capture a snapshot of the stable/routine operation
  - Several sets of data may be collected to cover seasonal variability

- Detection of a pathogen in Zone 1 requires immediate action as product may be contaminate

Investigation of a Positive Finding

- Review infrastructure and equipment in the area
- Targeted cleaning
- Review records
  - Cleaning
  - Environmental data
  - Maintenance and mechanical down time
- Test samples from composites individually
- Corrective action depends on:
  - Location (zone) of positive finding
  - Trends – single isolate or repeated finding

Environmental Monitoring for Sanitation Preventive Control Verification

Pathogen Environmental Monitoring Program

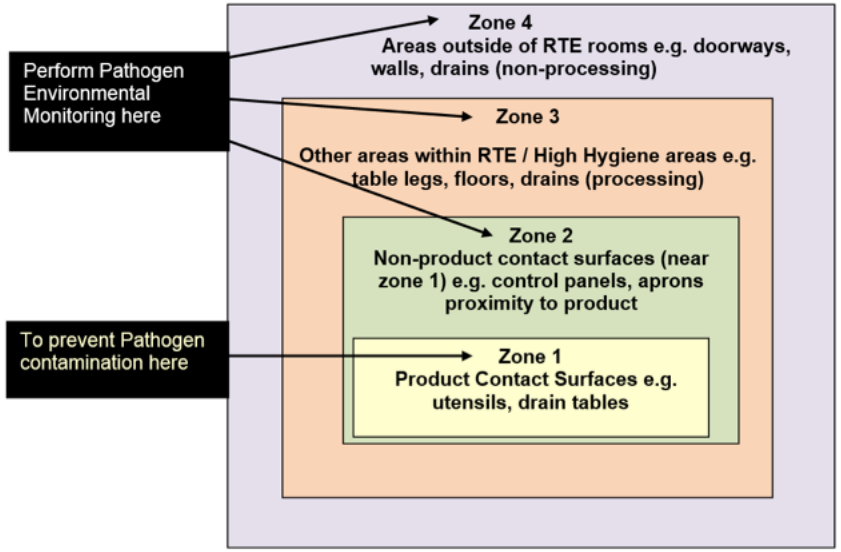
Purpose: Pathogen Environmental monitoring is conducted to verify the effectiveness of sanitation and hygienic zoning procedures in the primary pathogen control zones to control environmental pathogens such as *L. monocytogenes* and *Salmonella.*

Sample identification: Based on observation when sampling, "worst case" areas are sampled; e.g., standing water or product residue, around table legs, crevasses, and major traffic areas. Samples identification should include the specific location sampled and the date and time the sample is taken.

Sampling procedure: The primary pathogen control area is tested weekly for the presence of *Listeria* species. Sponge swabs are collected during production at least 3 hours after production starts. Sampling time is not uniform to avoid bias of results. Samples are shipped to the laboratory using the sampling kit provided by the laboratory. Samples are refrigerated and shipped in an insulated cooler with a gel pack with next day delivery. Samples are NOT frozen.

Samples are collected by trained personnel in zoned areas (see diagram). Most samples are taken in zones 2 and 3 and include pre-identified sites as well as random sites based on observed conditions. Total number of samples collected each week:

- Zone 2 – Minimum 6 samples
- Zone 3 – Minimum 6 samples
- Zone 4 – Minimum 2 samples
- Minimum 8 other samples (Zone 2 or 3) based on observed conditions



Test conducted: For routine samples, the contract lab composites sponges from the same area to run as one test for *Listeria* species. *Investigation samples must be run individually.*

Five separate swabs are taken once per month in the High Hygiene area and are tested for *Salmonella*.

Laboratory: Superior Laboratory (987 Dairy Drive, Hometown, USA) conducts the analysis using approved procedures. Analysis is started within 48 hours of sampling. The test result report identifies the specific method number used.

Interpretation of results:

Acton for a negative result – continue routine operations.

Corrective action for a positive result:

1. If a composite is positive, the areas implicated by the composite are re-sampled within a day of notification and prior to implementing intensive sanitation procedures. Additional samples (number depends on size of area) are taken in adjacent problem areas (vector sampling) in an attempt to identify a source of contamination. All samples are run individually, without compositing.
2. Intensive sanitation procedures are implemented after sampling is complete.
3. Production can continue after sanitation is complete and product can be shipped.
4. Suspect area should be sampled and test negative 3 consecutive times before resuming the normal sampling frequency.
5. If one or more re-samples are positive, perform corrective action investigation to resolve the issue. Implement a hold and finished product testing procedure per the Product Testing for Verification corrective action protocol.

Pepper Jack Example

Additional Monitoring for Adverse Events

- Adverse Event – a situation known to be associated with increased potential for environmental contamination

- Examples
  - Roof leak
  - Floor drain back-up
  - Construction or new line installation

Environmental Monitoring Records

- Track and trend environmental data

- Collect and record data to provide actionable information, e.g.:
  - Use spreadsheets to identify trends
  - Show positive results on a facility map

- Ultimate goals:
  - Demonstration of a controlled environment
  - Demonstration of responding to positive findings

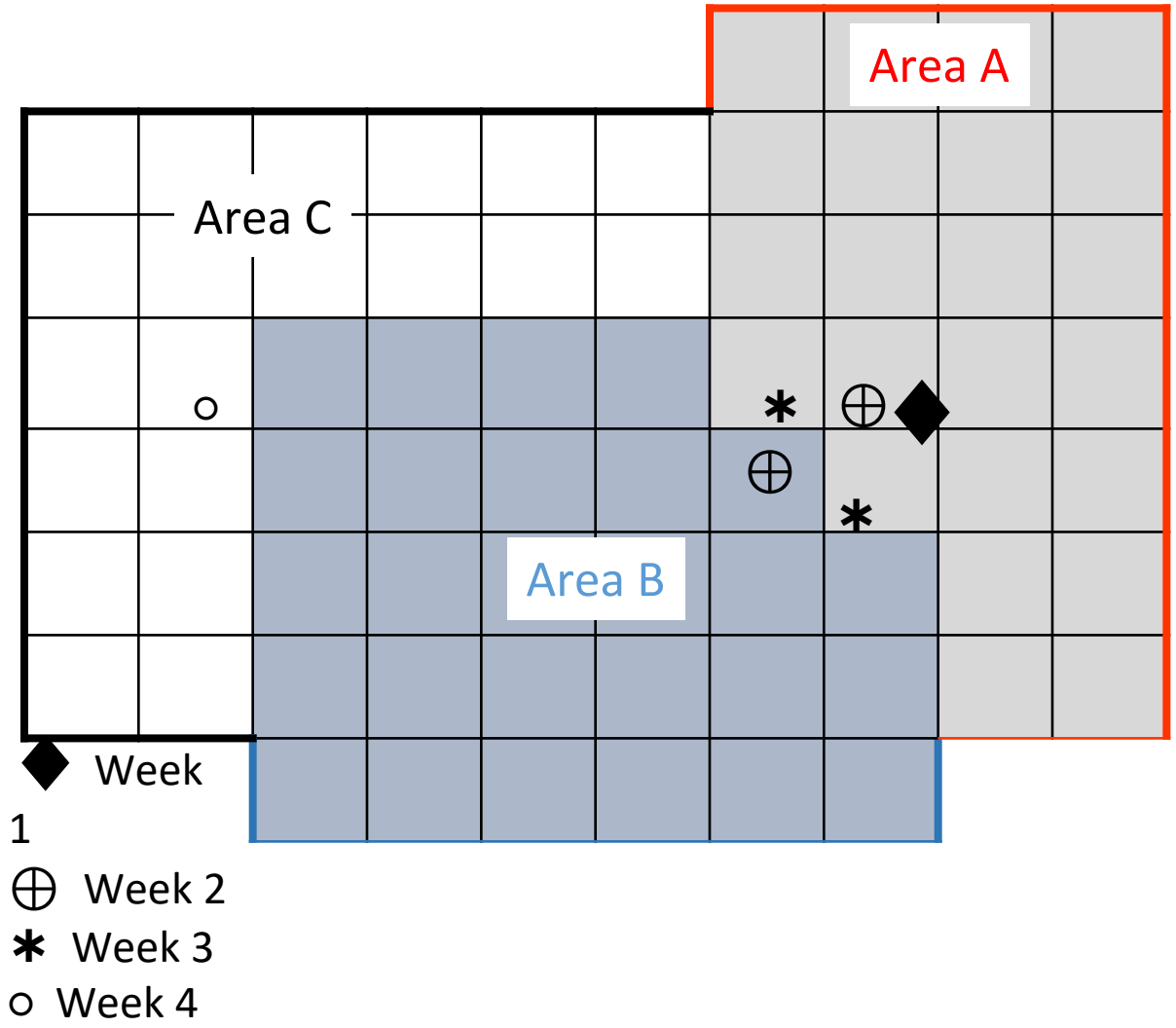
Tracking Results Example

Week	Week 1	Week 2	Week 3	Week 4	Total
Area A	1/25*	0/25	1/25	1/25	3/100
Area B	0/25	1/25	1/25	0/25	2/100
Area C	0/25	0/25	0/25	1/25	1/100

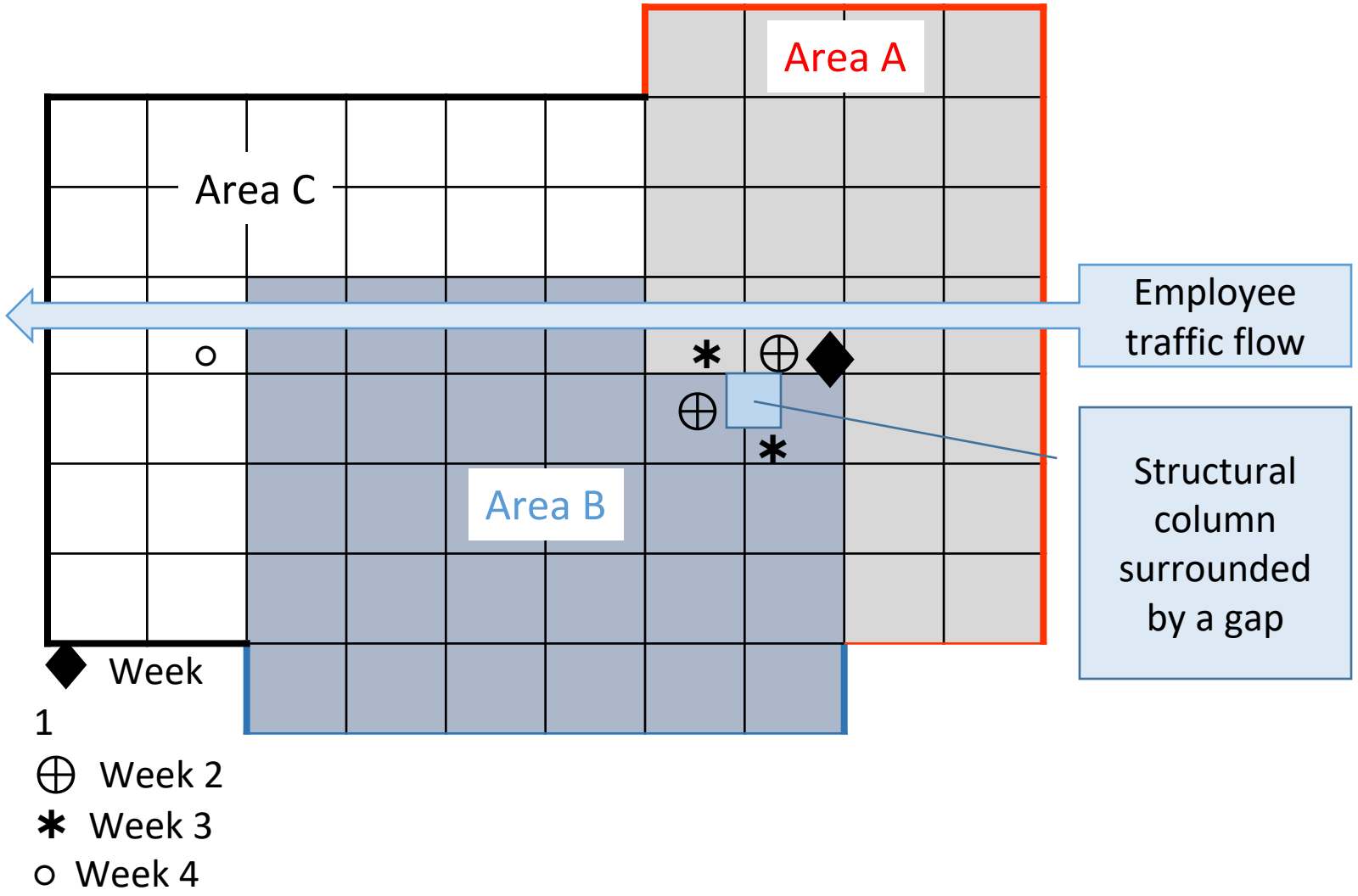
* Number of samples positive / Number of samples taken

NOTE: Numbers represented are **hypothetical**. Some facilities will take many more samples a week, others will take fewer. This could represent samples taken to establish a baseline or to identify a potential source of an issue identified with less intensive routine sampling.

Map with Areas and Positive Swabs



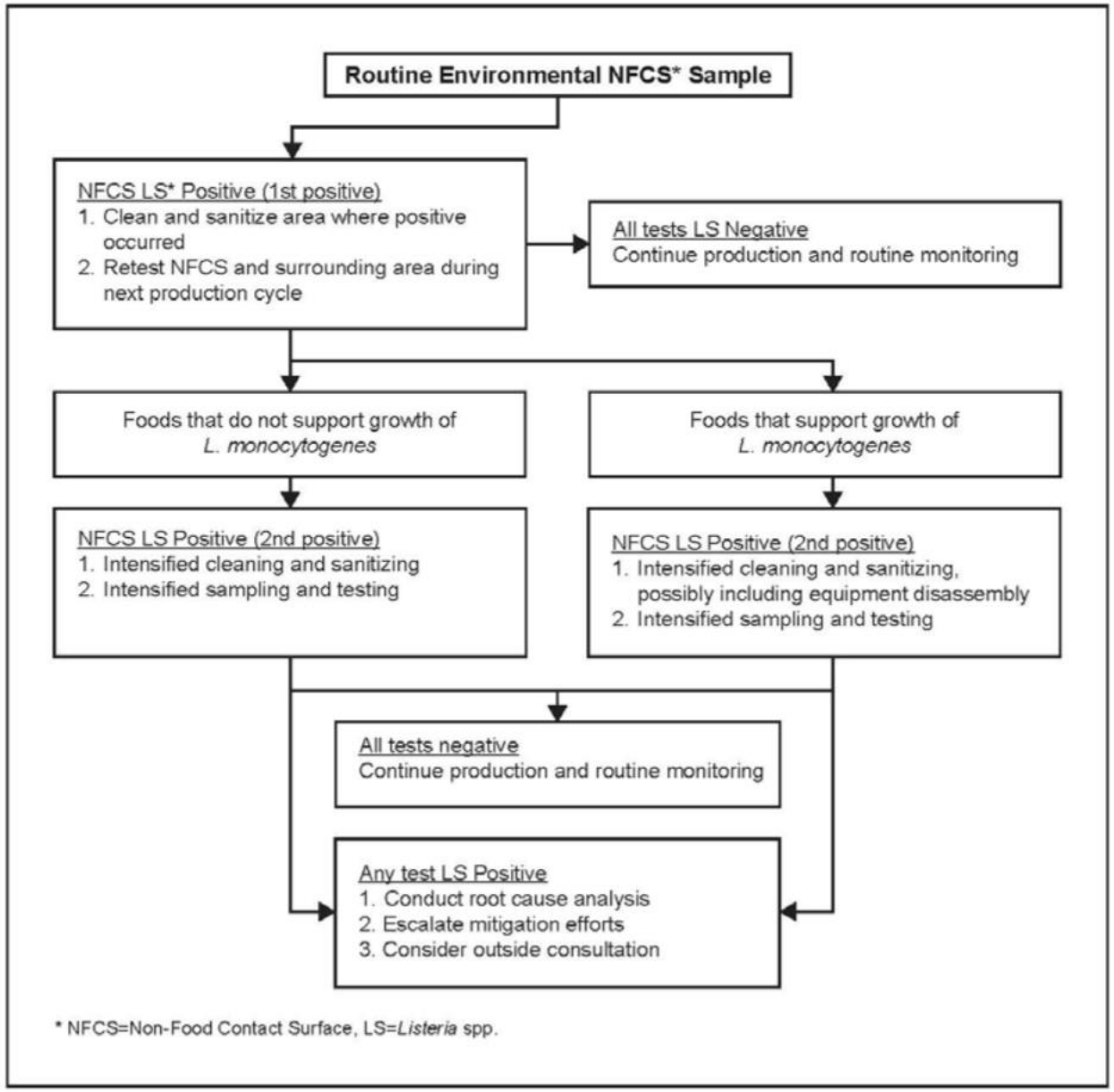
Map with Areas and Positive Swabs



Interpreting Environmental Results

- Assemble data from all sources
- Reconstruct what was happening with swabs were collected
- Develop potential interpretations from results
- Conduct additional testing to confirm conclusions
- Document root cause, take action to correct
- Take more samples to demonstrate effectiveness

https://www.fda.gov/RegulatoryInformation/Guidances/ucm073110.htm



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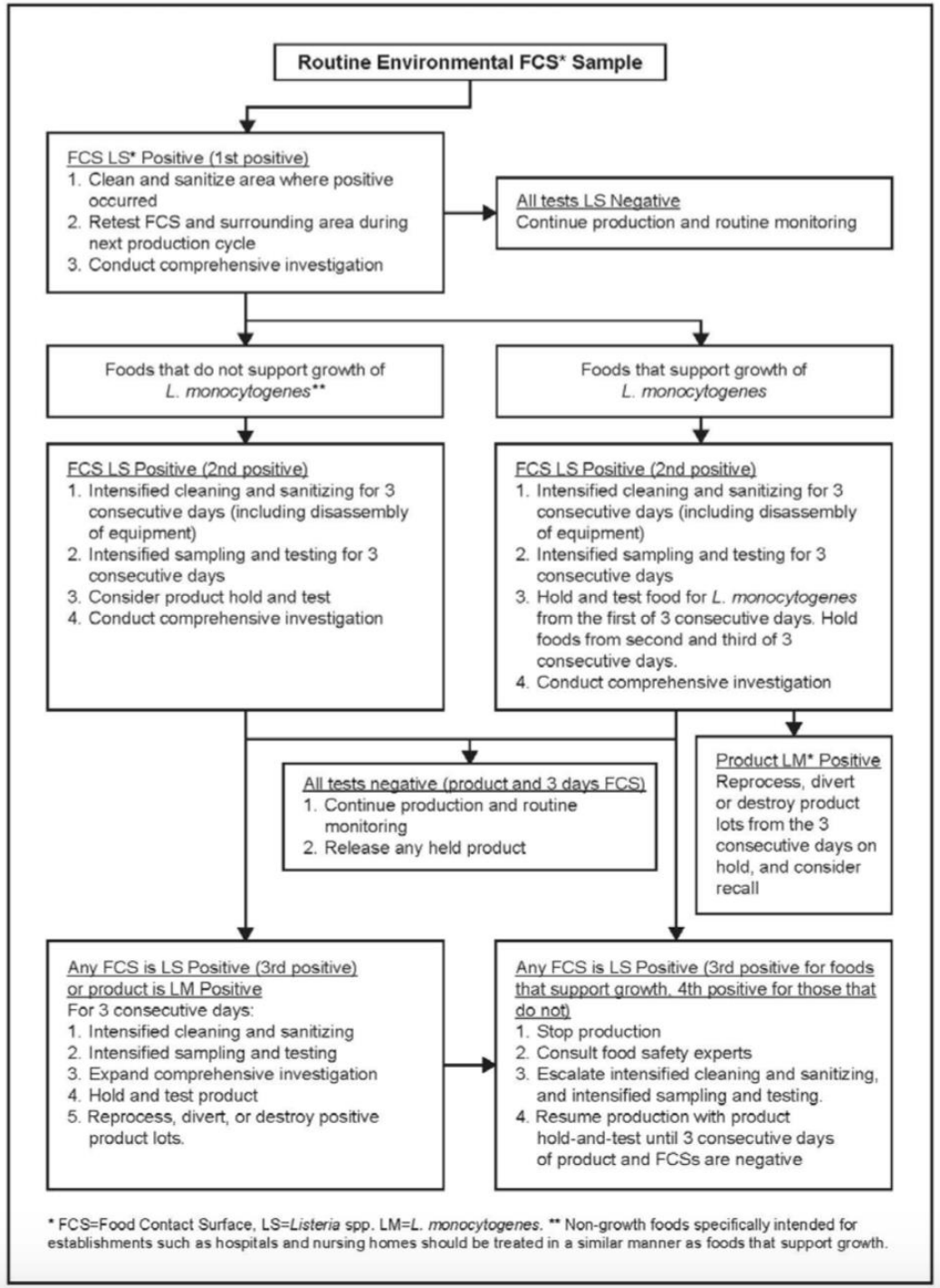


Environmental Monitoring Program Revisions

- Review the program at least annually and modify as necessary when:
  - Indicated by corrective actions
  - When ingredients and processing changes are made
  - Following adverse events
  - When equipment modification, repairs, replacements are made
  - When there are consistently no positive findings

Search for FDA Guidance Documents

FDA Guidance Documents: General and Cross-Cutting Topics

Advisory Committee Guidance Documents

Clinical Trials Guidance Documents

Combination Products Guidance Documents

Import and Export Guidance Documents

International Council for Harmonisation (ICH) Guidance Documents

Veterinary International Conference on Harmonization (VICH) Guidance Documents

Draft Guidance for Industry: Control of Listeria monocytogenes in Ready-To-Eat Foods

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

Contains Nonbinding Recommendations
Draft - Not for Implementation

Please Note: This guidance is being distributed for comment purposes only.

This guidance is intended for those persons ("you") who are subject to our regulation, in 21 CFR part 117 (part 117), entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" and who manufacture, process, pack, or hold ready-to-eat (RTE) foods. This guidance is intended for you regardless of whether you are only subject to the current good manufacturing practice requirements for human food of part 117 (CGMP requirements), the requirements for hazard analysis and risk-based preventive controls for human food in part 117 (PCHF), or both the CGMP requirements and the PCHF requirements. See section II.A of this guidance for additional information about the CGMP and PCHF requirements. This guidance is intended to help

https://www.fda.gov/RegulatoryInformation/Guidances/ucm073110.htm

minimize or prevent the contamination of RTE food with L.

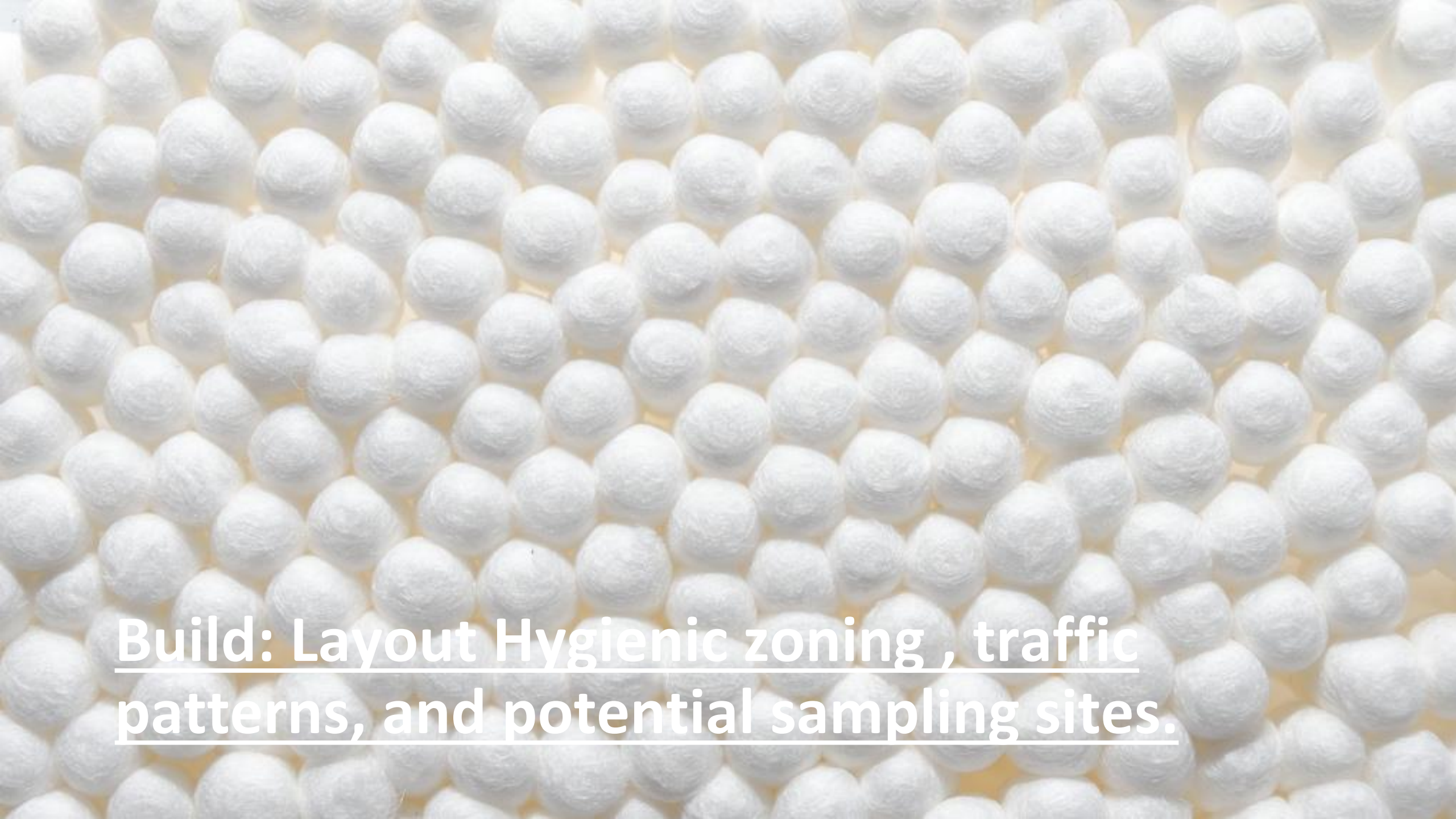
Resources

- Download the Draft Guidance (PDF: 1,336KB)
- Federal Register Notice

How to Comment

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, **submit either electronic or written comments on the draft guidance through July 17, 2017.**

Division of Dockets Management (HFA-305),
Food and Drug Administration,


Build: Layout Hygienic zoning , traffic patterns, and potential sampling sites.