



# Zoning requirements for Dairy Suppliers



# Overview

- What is zoning?
- Zoning requirements?
- Why do we need zoning?
- How Does MDLZ International Define The Different Levels of Zoning?
- Equipment examples for each Zones and Controls
- Conducting Zoning Assessment
- Zoning example
- How is the efficiency of the zoning measures verified?



# What Is Zoning?

**Identification and differentiation of the processing areas within the manufacturing facility.**

Where microbiological cross contamination by relevant spoilage or pathogenic organisms may occur during the receipt, storage, processing and packaging of products.

## Separation may include :

- Personnel and materials traffic.
- Air handling.
- Equipment.
- Effluent, drains and waste systems.
- Locker rooms.
- Others ,that could result in transfer of microorganisms.

# Zoning Requirements

All facilities which manufacture or handle MDLZ International Dairy products shall have a Zoning program to reduce the potential for environmental microbial cross contamination of materials and products through the application of proper controls.

## Requirements

- A documented Zoning risk assessment shall be conducted to identify and differentiate processing areas within the facility where potential sources of pathogen and non-pathogen (spoilage) microbial contamination exist (e.g.: air, traffic, people, equipment and materials). Adequate controls shall be identified and implemented.
- Plant Checklist for Prevention of Microbial Cross Contamination and Hygienic Zoning Map is required.

# Why Do We Need Zoning?

- To prevent microbial cross contamination and to assure product quality and safety.
- Re-contamination of processed microbiologically sensitive products after the heat process such as pasteurization, could be a major source of inadequate application of zoning principles, e.g. re-contamination of cheese after pasteurization
- Therefore areas, where processed (e.g. heat treated) products are kept, shall be separated from the non-processed/raw and/or under processed product areas



# How Does MDLZ International Define The Different Levels of Zoning?

- **Zoning definitions:**
  - **Non-manufacturing zone:**
    - Area where there is no product processed/packaged.
    - May Includes areas such as utility rooms, offices, cafeteria, locker room, laboratory, etc.
  - **Raw zone:**
    - Areas, such as raw meat/raw milk/raw agricultural receiving and storage.
    - May also include refuse/recycling, restrooms (when in manufacturing area), roof access and emergency door exits to processing
    - These zones may have dedicated employees and shall be physically separated from controlled zones or high control zones.

# How Does MDLZ International Define The Different Levels of Zoning?

## Zoning definition:

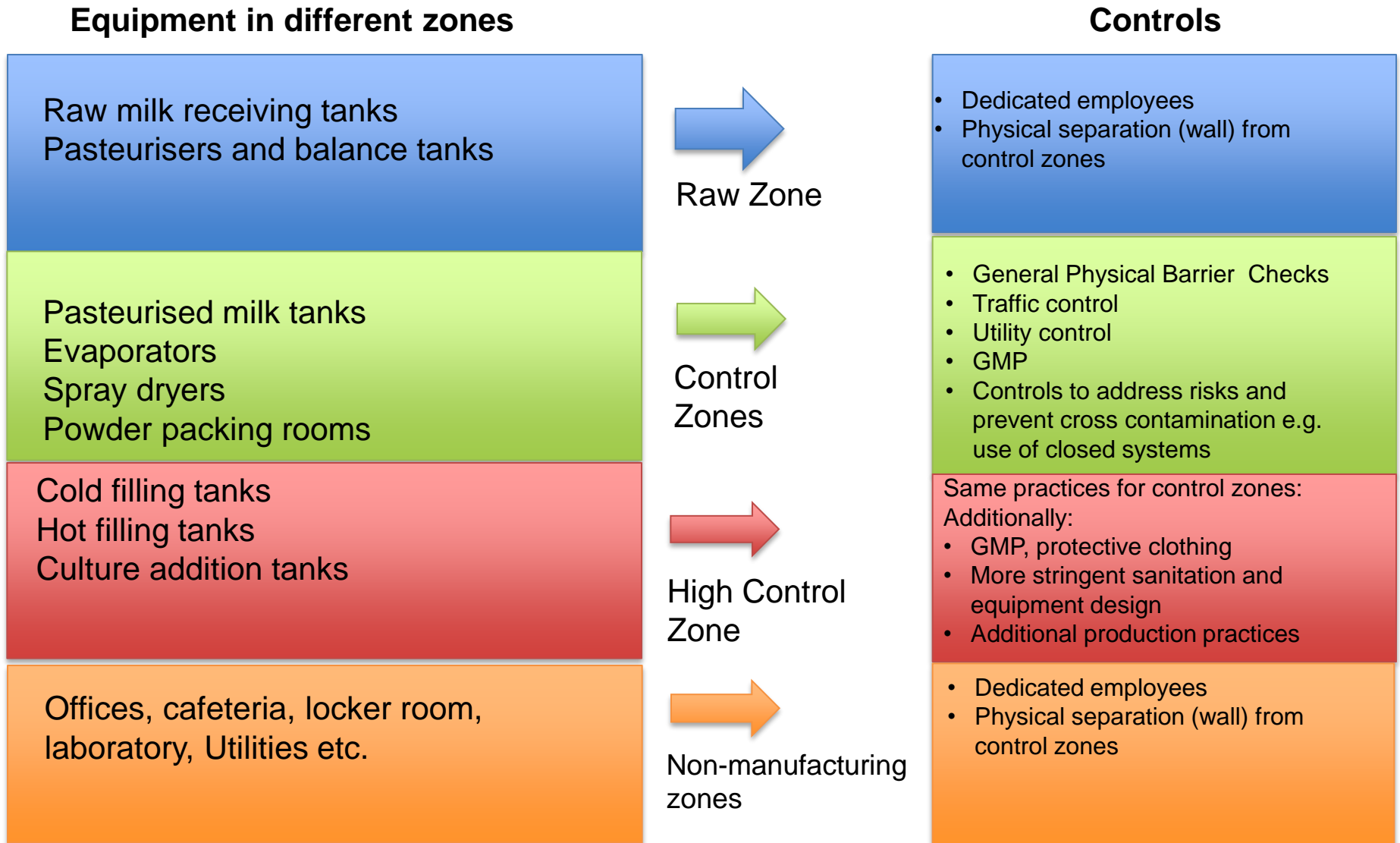
### – Controlled zone:

- Product of low to medium microbiological sensitivity can be exposed to the environment and the operators.
- The controlled zone may also serve as transition from non-manufacturing zone or high risk zone to high control zone.

### – High hygiene zone:

- Product of high microbiological sensitivity can be exposed to the environment and/or the operators.
- Additional GMP practices, such as captive footwear/clothing, may be required and more stringent equipment/building sanitary design requirements are followed.
- When product of very high sensitivity are exposed, additional production practices, such as preventing cardboard, wooden pallets, etc. from this area may be implemented

# Equipment examples for each Zones and Controls



Note: Separation between “control zones” e.g. wet separated from dry control environments



# Conducting the Zoning Risk Assessment

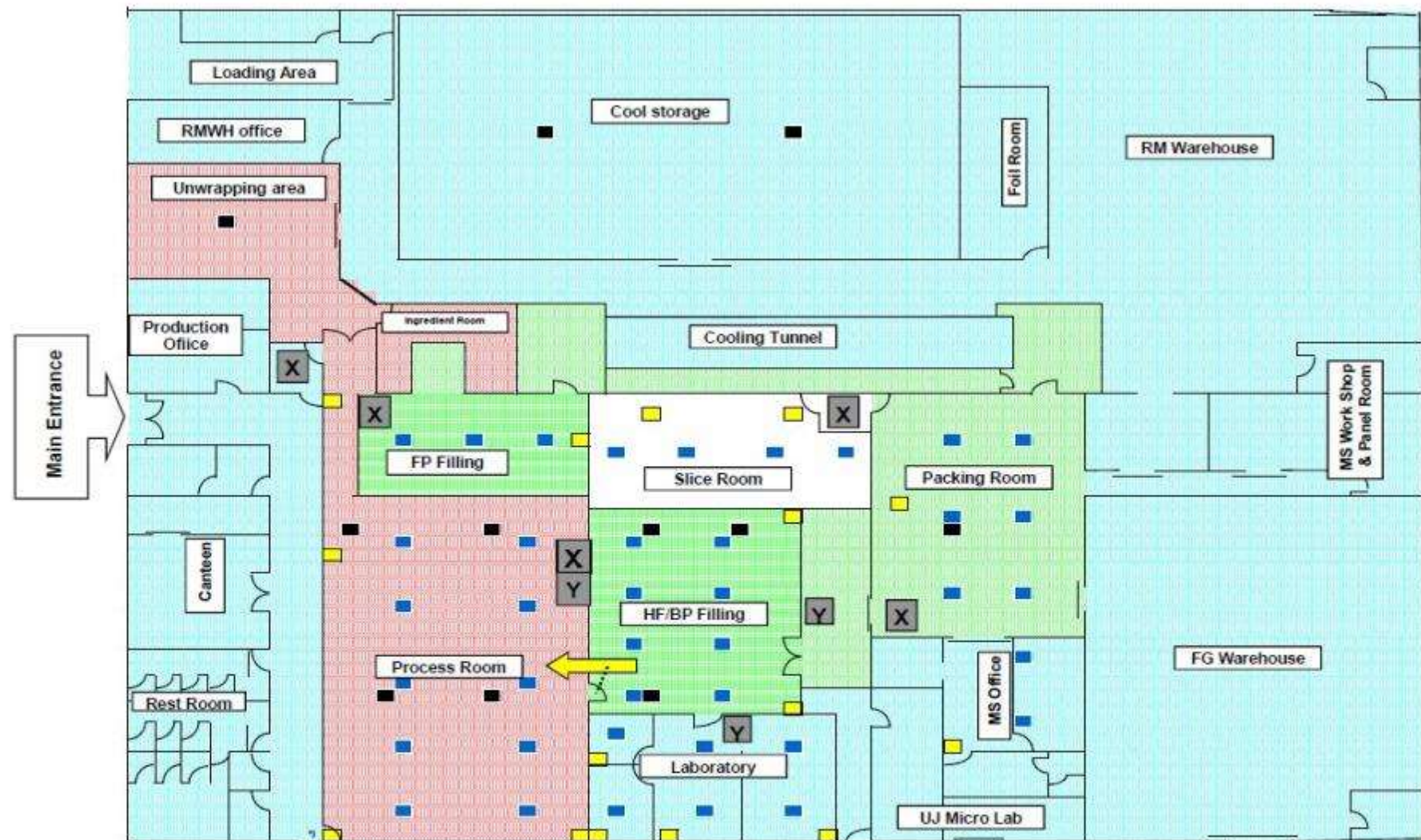
- **Identification of potential cross-contamination between different processing environments and/or products**
- Categorization of zones at the plant
- **The following control mechanisms shall be taken into consideration:**
  - Usage of closed systems
  - Structural separation of the respective area by design (raw/RTE, wet/dry environments)
  - Utilities control (air, water) e.g. air filters in tanks e.g. crystallisation tanks if located outside.
  - Control of traffic patterns of people, materials/supplies flow and equipment movements, internal transports
  - Use of a vestibule as entrance and exit with personnel hygiene and changing measures
  - Sanitation

# Zoning Assessment

- Personnel hygiene practices of employees
- Use of designated and/or coded tools and equipment
- Filtration of the room air to protect the food against pathogens and/or spoilage organisms
- Packaging material treatment (e.g. for clean cold filling or aseptic packaging)
- Separation of effluent and water waste drains coming from zones with potentially higher contamination risk
- Consider refuse /recycling, restrooms, roof access and emergency door exits to processing that maybe a risk

# Zoning Example

Plant Lay Out



- Note
- X Foot bath and Hand washing Station
  - Y Hand Sanitizer
  - One way traffic
  - Raw area
  - Controlled area, products are exposed to air
  - Control Area, products are not exposed to air
  - High Hygiene Area
  - Non manufacturing

- Drain
- Air Supply
- Air Return
- \*) Emergency Exit

1. All personnel entering a controlled area, esp if entering via raw area must pass through the footbath and Hand wash station
2. Personnel exiting from laboratory, must sanitize her/his hand by hand sanitizer
3. Personnel entering BP/HF Filling from packing area, must must passing through the footbath and hand wash station
4. Personnel entering MP Filling, must passing through the footbath and hand wash station
5. Personnel from Process Room is not allow entering BP/HF Filling/Packaging Room

# How is the effectiveness of the zoning measures verified?

The following tools should be used:

- Pathogen Environmental Monitoring
- Air /Water monitoring
- GMP audits
- Sanitation controls





# Pathogen Environmental Monitoring For Dairy Suppliers



# Overview

What is PEM and why do we need it?

How Do Bacteria Spread and potential sources of pathogens in the plant.

Controlling the Environment

General Approach to Pathogen Environmental Monitoring

What pathogens and indicators are in scope of the program?

PEM- Where and when shall samples be taken?

Zone Concept for PEM and PEM plan

Additional PEM monitoring

What has to be done zone 1 is tested?

What could Out of Specification indicator results indicate.

What type of corrective actions have to be in place in the event of a positive pathogen finding?

Summary: What Your PEM plan should include





# Why do we need PEM ?

- Verify the effectiveness of controls for preventing cross-contamination, including Sanitation, GMPs, preventive maintenance, and plant traffic controls.
- Tool to provide information to improve environmental controls for prevention of potential cross-contamination.
- Use data to correct problem areas before they pose a risk to product.
- Enable detection of pathogens, and/or organisms that indicate potential presence of pathogens.





# How Do Bacteria Spread?

**People  
Handling**



**Air-Water-Soil**



**Equipment, and  
Sanitation**



**Ingredients**

# Potential Pathogen Sources in the Plant

- Raw product without product separation/zoning.
- Resident population.
- Traffic (trucks, people - move it from raw to pasteurized/cooked to packaging/RTE areas).
- Inadequate sanitation/hard to clean equipment.
- Product movement on line.
- Vacuum cleaners

# Controlling the Environment

Air, Water,  
Controls  
& Traffic  
Patterns + GMPs + Dry, Un-  
cracked,  
Clean Floors, + Sanitary  
Walls, Design + Sanitation  
Ceilings Procedures

**= Pathogen Control**

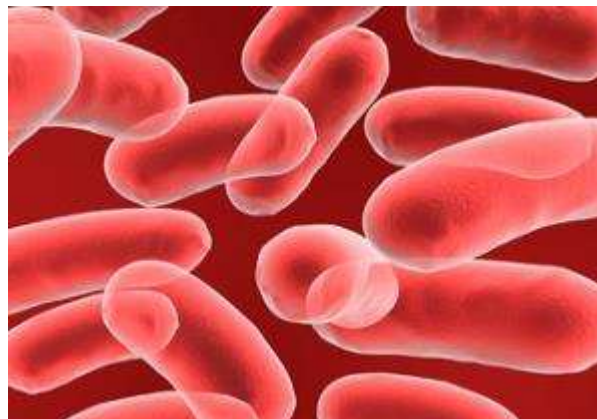
To validate / improve the robustness of environmental control programs and testing protocols in plants that supply, manufacture, and package microbiological sensitive products.

# General Approach to Pathogen Environmental Monitoring

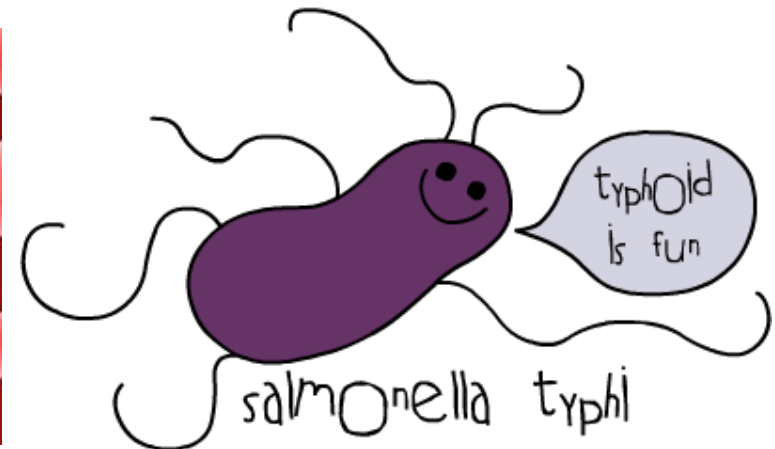
- PEM team (QA, Sanitation, Maintenance, etc) review blueprints/flow diagrams
- Timely assessment of control of post processing environment.
- Environmental testing requires a high level of sampling.
- Dairy Environments- Large surface areas sampled for *Listeria* genus and *Salmonella* or Coliform indicators.
- Sampling is randomized.
- Sampling plans need to be flexible.
- Review historical environmental and sanitation swab data.
- Critical evaluation of process flow – identify areas of greatest risk
- Raw areas receiving further processing are not included.
- Zone concept and sample site selection
- Unique events (e.g., construction) should be monitored

# PEM for Dairy suppliers- What pathogens and indicators are in scope of the program?

- *Salmonella sp.*
- *Listeria monocytogenes*
- Indicator organisms (e.g. coliforms, *enterobacteriaceae* and *Listeria spp.*)



## Meet the microbes



# Indicator Organisms

## •What are Indicator Organisms?

–An organism whose presence, in certain numbers is reflective of both sanitary and quality conditions that could lead to the entry and proliferation of pathogens.

## •Why test for indicators?

–It is unrealistic to examine foods and the environment for ALL pathogens due to:

- Cost
- Complicated Test Methods
- Time Restraints
- A higher prevalence than the target pathogen
- Have a reasonably strong correlation with the detection of the target pathogen

# *Salmonella* and Indicators –Wet verses dry environments

- The target organism is *Salmonella*. Not a spore former, but is resistant to dry conditions, can survive for extended periods of time without water in the environment.
- *Salmonella* can create a niche anywhere. When facilitated by water, it will even establish a harborage point deep within concrete.
- Indicator organisms such as *Enterobacteriaceae* and *Coliforms*, do not survive for long in a dry environment. The presence or absence of these organisms is not always a good indicator for the presence or absence of *Salmonella*.
- These organisms can be tested: monitoring drains or other frequently wet areas, entryways, water leaks, etc. as indicators for conditions that will allow growth of pathogens or demonstrate sanitation efficiency. *Enterobacteriaceae* testing is recommended for monitoring these conditions but has not been widely implemented yet.

# *Listeria spp* –Wet Environments

*Listeria sp.* that indicate potential presence of *Lm.* Exhibits the same growth parameters as *Listeria spp.* And will inhabit the same niches in the plant environment.

*Listeria* is most frequently found in moist environments or areas with condensed or standing water or milk, including drains, floors, coolers, conveyors and washing areas.

*Listeria* can be spread from processing equipment and table tops to food products through the ventilation system, from dripping and splashing when cleaning with high powered hoses, and by workers themselves.



# PEM for Wet and Dry Environments

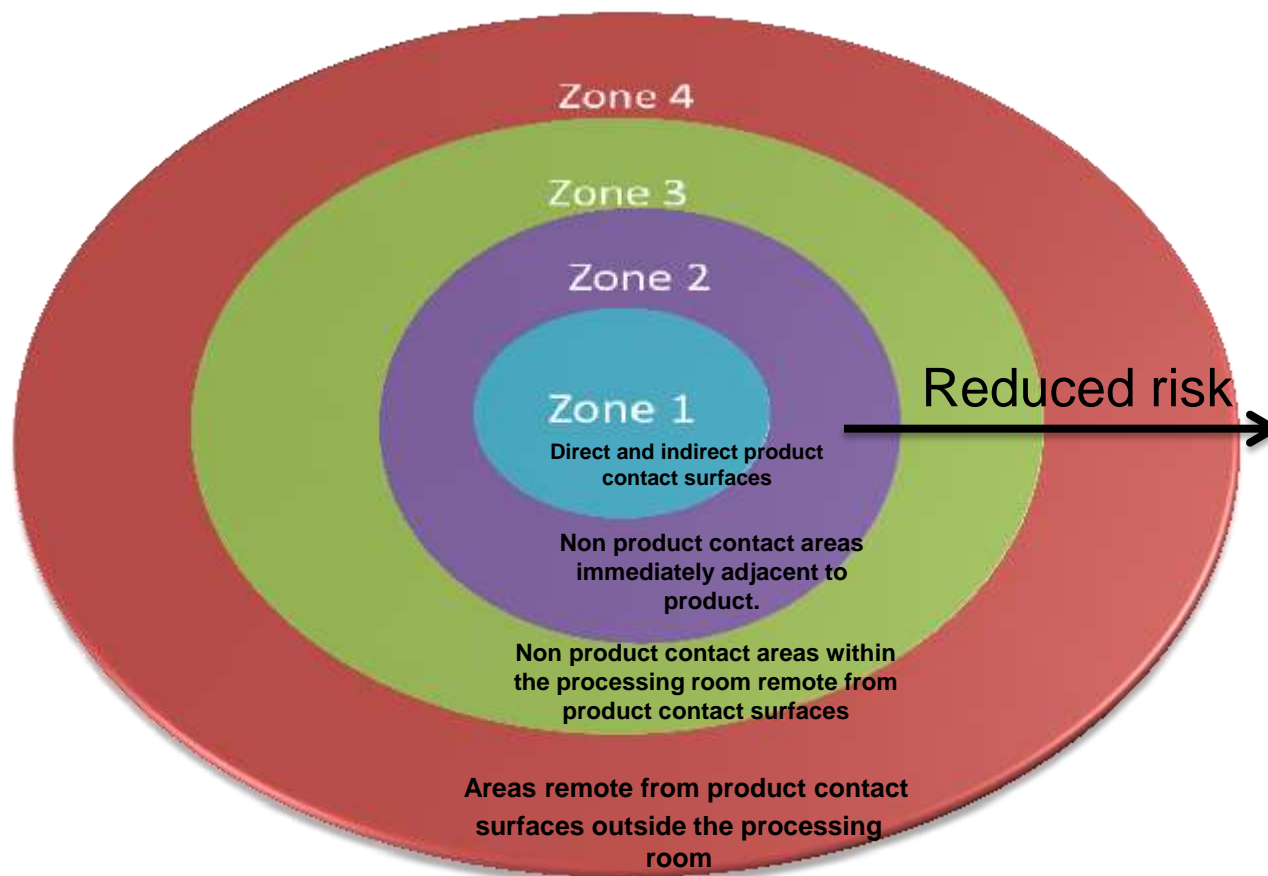
**Table 1: Pathogens and indicators relevant in dry verses wet environments**

|                     | Pathogen of concern   | Limits   | Indicators                          | Limits        |
|---------------------|-----------------------|----------|-------------------------------------|---------------|
| Dry sampling points | <i>Salmonella spp</i> | negative | <i>Listeria spp</i>                 | n/a           |
|                     |                       |          | <i>Coliforms/Enterobacteriaceae</i> | n/a           |
| Wet sampling points | <i>Salmonella spp</i> | negative | <i>Coliforms/Enterobacteriaceae</i> | <20cfu/100cm2 |
|                     |                       |          | <i>Listeria spp</i>                 | negative      |
|                     |                       |          |                                     |               |

# PEM- Where and when shall samples be taken?

- Determine a site list for plant, ensure all critical swabbing locations have been identified
- Swabs should be taken during production and at least 3-4 hours into a run.
- PEM Sample size changes for large areas –Swabbing video available for plant training.
- Composite – Take individual sponges for each site to form composite sample versus using same sponge (only when minimum 1 year history built up)
- Increase sampling focusing on water harborage and high traffic areas and sites more likely to be a source based on equipment and plant infrastructure conditions
- Raw areas not included
- Focus on cross-contamination after the kill step.
- Sanitize the site after swabbing.

# Zone Concept for PEM



# Example of a PEM plan for Dairy suppliers and Zone Concept

| Areas          | Sampling points   | Pathogens and Indicators  | Frequency      |
|----------------|---|---|----------------|
| <b>Zone1</b>   | E.g. Conveyor surfaces and product chutes<br>Pipeline interior, Nozzles ,Cut & wrap equipment,<br>Product scrapers/utensils, Product contact gloved hands, dust collected beneath processing line.  | Indicators- to monitor conditions that could lead to Salmonella presence) e.g. <i>enterobacteriaceae</i>            | <b>Weekly</b>  |
| <b>Zone 2:</b> | E.g. Exterior of equipment, framework, buttons, brush handles, non-product contact gloves, handles of maintenance tools., outside of tunnels, outside/below filling equipment, control panels, weight scales, motor housings, catwalks, scrap carts, vacuum cleaners if used near product contact surfaces, air filters, etc.                         | Listeria genus & Salmonella (or optional indicators to monitor conditions that could lead to Salmonella presence)   | <b>Weekly</b>  |
| <b>Zone 3:</b> | E.g. Hand trucks; forklifts; walls; drains; floors, equipment legs, ductwork, ceilings, fork truck and cart wheels, tools, brooms, squeegees, floor scrubbers, debris from vacuum collection points, floor debris, trash cans, traffic pathways into process area, ceiling drain pipes, wall/floor junctures, wash stations, ingredient storage areas | Listeria genus & Salmonella (or optional indicators, to monitor conditions that could lead to Salmonella presence). | <b>Weekly</b>  |
| <b>Zone 4:</b> | E.g. Warehouses, hallways, break areas, locker rooms, mechanical rooms, offices, cafeteria, restrooms, coolers, floors, wheeled vehicles and materials, and trash/recycle collection areas  | Listeria genus & Salmonella (or optional indicators, to monitor conditions that could lead to Salmonella presence). | <b>Monthly</b> |

**Note:** Each plant should customize their PEM's after careful evaluation of microbial risk of their product and in respect to compliance with their regulatory guidance/standards. The sample frequency, and number of samples per zone may be modified after reviewing the results and assessing the effectiveness of the corrective action plan.

# Additional PEM monitoring

- In the event of a roof leak or water leak, PEM swabs (e.g. *Salmonella*) should be taken immediately and before cleanup
  - Roofs can be a *Salmonella* source (i.e. birds)
- Environmental sampling after clean-up from floor drain back-ups in product exposed areas
- Construction or equipment (new line) installation
  - Increased monitoring should be implemented between construction and production areas in order to prevent possible cross contamination.
  - Dust and traffic should be controlled in the area.
  - Upon completion of construction activities; the area should be cleaned/sanitized and swabs should be taken before production begins again
- Risk assessment of traffic patterns (ex: supplementary swabbing)

# What has to be done when product contact surfaces are swabbed?

- MDLZ do not recommend swabbing zone1 for pathogens:

## However

- If due to any valid reason (requirements of other clients) PEM is taken from direct contact surfaces, has to stay under supplier control up to time of results.

## What has to be done in case of a positive finding in Zone 1?

In the event of a pathogen-positive result the MDLZ International Contracting Representative must be notified immediately, even if the specific lot is not for MDLZ International.

- Should not be perceived as having a negative business impact with MDLZ International.
- We need to know which products could be potentially affected
- We can often help with root cause analysis

# What could Out of Specification results could indicate.

- High *Coliform* or *Enterobacteriaceae* counts may indicate:
  - Food handlers not washing hands after restroom use.
  - Contaminated raw materials.
  - Improperly cleaned and sanitized equipment and utensils.
  - Aerosols produced by high pressure hoses.
  - Faulty/inadequate, pasteurizing, baking.
  - Recontamination after the kill step.

# What type of corrective actions have to be in place in the event of a positive pathogen finding in the Environment ?

- Investigate within 24 hours of reporting results
- Corrective action plans, including increased control procedures and verification requirements.
- A minimum of three consecutive negatives or in-standard results must be achieved prior to returning to the routine testing and sampling schedule.
- This must be completed within a 3-week time frame.
- Root cause analysis and documented corrective action report.



## If repeated positive results occur (Zone1)continue corrective action:

- Reinforce GMP training/awareness
- Attention to sanitation procedures/practices
- Vector swabbing of adjacent areas
- Concentrate on zoning weakness: e.g. traffic pattern, equipment and people
- Targeted equipment tear-down & “deep cleaning” procedures
- Increased period cleaning
- Equipment modifications/ maintenance checks
- Review sanitary design of equipment/line

# Summary: What Your PEM plan should include

- a) Target organism e.g. Salmonella and/or *enterobacteriaceae*
- b) Target organism e.g. *Listeria spp* (wet areas)
- c) Sampling Locations, are critical sampling points determined and recorded .
- d) Sampling points representative of potential contamination areas and niches.
- e) Sampling frequency (Weekly?, Monthly, random rotation of sampling points)
- f) Change the day of the week and time of day for PEM sampling, e.g. shift, mid week, end of week, different shifts, 3-4hrs into production?
- d) Sampling method specified.
- e) Sampling method suitable (i.e. sponges for large areas such as floors and swabs for other sampling locations, neutralisers used).
- h) Acceptance criteria, and acceptable limits defined, and corrective actions for positive findings
- i) Training
- j) Applicable products and/or processes.
- k) Testing (detection/isolation) methodology

# Swabbing techniques

VIDEO 1 and 2

**Thank you very much!**

# **Questions & Answers**



# Mondelēz International Supplier Quality Web Site

The Mondelēz International Supplier Quality web site is designed to facilitate the communication between Mondelēz International and our suppliers.

Here you will find all of the Quality Requirements and Guidelines for Suppliers to Mondelēz International, as well as the slides used in our Supplier Forums.

## The web site includes:

- Supplier Quality and Food Safety Contractual Requirements

- Supplier Forum presentations

- Quality Support Material

- Contact email address

- eLearning modules

## Browser Address:

<http://www.mondelezinternational.com/procurement/index.aspx>