Advanced HACCP training
HYGIENIC ZONING & PATHOGEN ENVIRONMENTAL MONITORING (PEM)
7.1.4

GMP-

HYGIENIC ZONING PROGRAM
Hygienic Zoning is a prerequisite program

Applied to facilities manufacturing or handling food products to reduce the potential for pathogen contamination of materials and products from the environment or other materials

Just because it is not CCP does not mean it is not important
The hygienic zoning program shall consist of 3 parts, which shall all be documented:

1. Assessment
2. Implementation of controls, and
3. Evaluation and verification

Assessment shall consider risk of below and have necessary control measures:

1. Pathogen risk: survival / growth / no risk
2. Spoilage potential
3. Product risk
HYGIENIC ZONING

Division of areas in a food production facility to reduce the potential for environmental cross contamination of the product and other materials from the environment or other materials.

Zoning covers the following (not limited to):

- Physical and non-physical barriers
- Cleaning procedures
- Employee practices
- Traffic Control of:
  - people
  - equipment
  - materials movement

Note: The whole plant area is required to have adequate areas assigned, i.e. also separate buildings on plant premises need to be assessed.
CLASSIFICATION OF AREAS

- **Non-manufacturing area**: (still requires application of basic hygiene requirements) no open product, raw materials (excluding raw ingredients from agricultural and animal sources), intermediate or finished products or food contact packaging materials.
  - e.g. (not limited to) offices, laboratories, locker rooms, boiler rooms, wastewater treatment plants, cafeteria/break rooms/smoking areas, toilets, outside areas, utilities, tank farms / silos / warehouses (except those containing raw agricultural materials or exposed materials), palletization areas, etc

- **Raw area/Limited process area**: Areas receiving, storing or handling raw agricultural or animal products including areas of product preparation that will be thermally or otherwise processed and that are known to or have the potential to be contaminated by pathogen, usually prior to a validated pathogen reduction step (thermal or other). May also include emergency exit to outside, roof access, rest rooms in production
  - areas often require use of dedicated employees and may be physically separated from the controlled areas or high control areas
  - eg (but is not limited to): Raw cocoa bean, nuts, meat, milk and egg, vegetable & fruits reception and processing / Raw dough preparation area/ Silos containing raw agricultural materials / products / Warehouses holding raw agricultural products or ingredients
CLASSIFICATION OF AREAS

- **Controlled area**: Areas containing materials or products of low to medium microbiological sensitivity (product risk 2-3, refer to Micro susceptibility risk rating Table 23) that are not fully enclosed and therefore are exposed to the environment during routine operation or maintenance.
  - GMP practices are implemented and MDLZ air requirements are met. (Refer to Table 6 & Table 9)
  - The controlled area may also serve as transition from non-manufacturing or raw/limited process area to high control area or products of higher sensitivity may be present if they are completely enclosed.
    - e.g. (but is not limited to): Chocolate making / Cakes or muffin cooling post oven / Primary (food contact) packaging lines / ingredient weighing stations (except raw ingredients)

- **High control area**: areas containing products of high microbiological sensitivity (product risk 1 - refer to Micro susceptibility risk rating Table 23) that support growth of the pathogen of concern and can be exposed to the environment during routine operation or maintenance.
  - additional GMP practices, such as captive footwear/clothing, may be required
  - when products are exposed, additional production practices, such as prohibiting the use of cardboard, wooden pallets, etc. shall be implemented.
  - Positive air pressure may be required as an additional control (refer to Table 6 & Table 9).
    - eg (but is not limited to): Starter culture handling / Fresh cheese production Processed cheese filling- cold filling.
FOCUS ON APPROPRIATE CONTROLS

- Transition points: **interfaces and movements** between areas where the microbial profile changes:
  - Raw to Controlled area
  - Non-manufacturing to Controlled area
  - Outside areas to production areas

- Protect product, raw materials and packaging during their movement from one area to another in a facility,

- Protect the processing environment where exposed product and materials might become contaminated from higher risk areas of the factory
OPTIMAL LAYOUT FOR SUCCESSFUL ZONING MANAGEMENT

RAW MATERIALS → KILL STEP → FINISHED PRODUCT → CONSUMERS

MANUFACTURING AREA
ZONING GMP GHP

HACCP
ZONING CONTROL (1)
METHODS TO REDUCE CROSS CONTAMINATION RISK

❑ EQUIPMENT DESIGN
  ▪ Use of closed systems (e.g. tanks and pipes used for pasteurization milk, retort or aseptic systems)
  ▪ Use of enclosed filler supplied with filtered air and temperature and humidity controls.

❑ FACILITY
  ▪ Structural separation of area (e.g. separate building, physical barriers, traffic controls or distance).
  ▪ Restricted access to sensitive product areas.
  ▪ Use of vestibules as entrance/exit with personnel hygiene and changing measures (e.g. hand washing station, footbath/shoe change, additional garments/coat change).
  ▪ Air filtration and pressure.
ZONING CONTROL (2)
METHODS TO REDUCE CROSS CONTAMINATION RISK

- **GMP/TRAFFIC PATTERNS**
  - Restricting people and equipment traffic flow between raw areas and other parts of the facility.
  - Use of designated/color coded tools and equipment for sensitive product areas.
  - Prevention of entry/exit from outside directly into the production area.

- **SEPARATION IN TIME**
HANDLING OF RAW AGRICULTURAL COMMODITIES

- in separate floor/room of production building
- dedicated people working there
- dedicated tools available (also for cleaning)
- separate raw material deliveries (no common lifts, forklifts – warehouses)
- separate air filtration systems
- separate drain systems
- procedure in place for maintenance people/visitors to prevent contamination of other processing areas
BISCUIT PLANT - EXAMPLE

Oven area

Filling preparation
EXAMPLES OF POTENTIAL ZONING CONTROL MEASURES (APART FROM PHYSICAL SEPARATION)

- Time separation
- Dedication of people/tools/equipment to specific areas
- Cleaning Practices (includes hand wash/disinfection)

When People are moving outside buildings and going back to production:
- Shoe change or cleaning (Note: Alcohol-based sanitizer showed highest effectiveness, Quaternary ammonium based sanitizer, much less effective)
- Coat change
- Hand wash/disinfection
8.2.1 MICROBIOLOGY: PATHOGEN ENVIRONMENTAL MONITORING (PEM)
PATHOGEN ENVIRONMENTAL MONITORING

- **PEM** is a **verification activity of effective zoning** in place

- It has been extended beyond product containing sensitive ingredient(s) to **include all products exposed to the manufacturing environment.**

- **Note:** PEM is not a control
  - Samples taken during normal production (typically 3h into production)
  - PEM is not meant to be a verification of cleaning practices!
  - Special considerations i.e. moving/removing equipment
REASONS FOR DOING ENVIRONMENTAL MONITORING

- Provide an early warning of environmental contamination
- Tool to verify other control programs e.g., Hygienic Area Designation (Zoning), GMPs and traffic controls
- Aid root cause investigation
- Verify the effectiveness of corrective actions i.e. confirm removal of contamination.
- Identify harbourage sites
- Verification of sanitation within a production facility (use of indicators)
- To check for the introduction and spread of contamination following incidents, activities
MONITORING NEEDS & REQUIREMENTS

- Sampling site locations and time-frame for taking samples shall be changed on a periodic basis i.e. sampling at different times and days.

- Sampling site locations and frequencies should verify sanitation practices following specific events such as start-up following a shutdown, or maintenance or other events that could affect the environment or equipment hygiene.

- Testing may be reduced when areas are not in use (idle). In all cases, testing must be resumed once production recommences.

- Pathogen survival/growth studies and historical data may be used in conjunction with HACCP validation data to determine the testing plan or frequencies.

8.2.1.3 MONITORING REQUIREMENTS AND INSTRUCTIONS

An Environmental Monitoring plan shall be in place and define the following:

<table>
<thead>
<tr>
<th>Target organism(s) (Refer to Table 12)</th>
<th>Applicable products or processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sampling location (includes zones), frequency and method</td>
<td>Testing methodology</td>
</tr>
<tr>
<td>Test results acceptance criteria (action limits)</td>
<td>Corrective Actions and Preventive Actions (CAPA) plan, including modified verification requirements</td>
</tr>
<tr>
<td>Training needs and status for personnel conducting sampling</td>
<td></td>
</tr>
</tbody>
</table>


• For raw areas (e.g., raw agricultural commodities) sampling is not routinely required. However, a transition area from a raw area to controlled shall require verification in the part of the controlled side.

• Floor drains located in relevant areas shall be included in any sampling plan.

• The number of sampling locations for each zone shall be in accordance with the complexity of the site. The sites should be selected based on the potential to harbor pathogens. Sample site locations should be changed on a periodic basis.

• Every sampling location under Zone 1, 2 and 3 shall be spread out so that they are tested within a maximum of 6 weeks in rotation. It can be up to 8 weeks provided there are no positives in the last 2 years in any zone.

• It is recommended to try and cover each area every week, as an example if there are 4 areas – try to have at least 1 sample from each area. For Zone 4, the rotational frequency shall be set to be covered within a quarter.

• It is recommended that routine sampling should be varied to represent the entire production schedule, (e.g., 2nd or 3rd shift, and different weekdays).
# SAMPLE REQUIREMENTS

<table>
<thead>
<tr>
<th>Parameters</th>
<th>PEM</th>
</tr>
</thead>
</table>
| **Sampling location**                   | • Zone 2, Zone 3, Zone 4.  
• Zone 1: when testing zone 1 or product for pathogens *Salmonella* or *Listeria monocytogenes*, all product and associated rework manufactured since the last clean break shall be placed on hold until a negative/satisfactory test result is obtained – consult your Regional TML Quality Coordinator. |
| **Sampling Method**                      | • Sponges - Large surface  
• Swabs/ debris – Small surfaces, crevices.  
• Neutralizing broth shall be used prior to sampling where appropriate. |
| **Time before sampling**                | Routine 3-4 hours after the start of the production.                                                                                                                                 |
| **Time between sampling and testing**   | Maximum 48 hours (best within 24 hours).                                                                                                                                                   |
| **Temperature for storage of samples**  | 1-8 °C                                                                                                                                                                                   |
| **Recommended frequency of rotation**   | As aligned and recommended by *MDLZ TML Quality Coordinator*.                                                                                                                              |
| **Tor**                                 | • Swab flat surface: An area of 100 cm² (10x10 cm) shall be sampled with one swab each.  
• Sponge: The sampled area shall be as large as possible to increase the probability to detect microorganisms (1000 cm² to 3000 cm²), however a minimum area of 10x10 cm shall be sampled. |
| **Sampling in raw Zone**                | Not required.  
• Only samples from the same PEM zone and location and surfaces in close proximity. See Guidance for more details and examples.  
• PEM samples may be pooled by combining up to 5 swabs / sponges (maximum) into one sample.  
• Samples from different drains network shall not be pooled.  
Pooling can be done independent of the zone and areas. The sample shall be pooled only after pre-enrichment of individual samples. Sampling shall be done separately for each location. Single swab or sponge shall not be used for sampling multiple locations. Please consult the respective *MDLZ TML Quality Coordinator* for alignment. |
| **Compositing (dry pooling) of samples**| Before enrichment  
• Only samples from the same PEM zone and location and surfaces in close proximity. See Guidance for more details and examples.  
• PEM samples may be pooled by combining up to 5 swabs / sponges (maximum) into one sample.  
• Samples from different drains network shall not be pooled.  
Pooling can be done independent of the zone and areas. The sample shall be pooled only after pre-enrichment of individual samples. Sampling shall be done separately for each location. Single swab or sponge shall not be used for sampling multiple locations. Please consult the respective *MDLZ TML Quality Coordinator* for alignment. |
| **Pooling of samples**                   | After enrichment (Wet Pooling)  
(Only with methods that are validated for wet pooling)  
Pooled samples may be pooled post-enrichment into one sample. The number of samples pooled (this is typically between 2 and 10) will be dependent on the method used based on an external validation and an evaluation done in consultation with the respective *MDLZ TML Quality Coordinator* for alignment. |
Variations to Table 12 are permitted where approved by TML Quality Coordinators.

### Table 12: Pathogen Environmental Monitoring Sampling Plan

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Definitions</th>
<th>EXAMPLES</th>
<th>Refrigerated products / Frozen</th>
<th>Non refrigerated</th>
<th>Plan Number</th>
<th>Zone</th>
<th>Salmonella spp.</th>
<th>Listeria spp.</th>
<th>Minimum Test Frequency</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meals Product Type A1</td>
<td>Products in which Listeria monocytogenes may survive and/or grow; typically, in wet and cold environments</td>
<td>Lunchables &amp; Processed Meat</td>
<td>Yes</td>
<td>NA</td>
<td>A1</td>
<td>Zone 1</td>
<td>NA</td>
<td>Yes</td>
<td>Weekly</td>
<td></td>
</tr>
<tr>
<td>Meals Product Type A2</td>
<td>Products in which Listeria monocytogenes &amp; Salmonella may survive and/or grow.</td>
<td>Cheese, Hummus, Cookie Dough (as finished product)</td>
<td>Yes</td>
<td>Yes</td>
<td>A2</td>
<td>Zone 1</td>
<td>NA</td>
<td>Yes</td>
<td>Weekly</td>
<td></td>
</tr>
<tr>
<td>Biscuits, Chocolate, Powdered Beverages</td>
<td>Products in which Salmonella may survive, typically in a dry environment such as low moisture food manufacturing sites.</td>
<td>Biscuits &amp; chocolate</td>
<td>NA</td>
<td>Yes</td>
<td>B</td>
<td>Zone 1</td>
<td>NA</td>
<td>NA</td>
<td>Weekly</td>
<td></td>
</tr>
<tr>
<td>Gum and Candy, Meals - Sauces</td>
<td>To monitor hygienic conditions of Controlled Hygienic Areas.</td>
<td>Candy, Sauces (excluding acid sauces)</td>
<td>NA</td>
<td>Yes</td>
<td>I</td>
<td>Zone 1</td>
<td>NA</td>
<td>NA</td>
<td>Monthly</td>
<td></td>
</tr>
</tbody>
</table>

**NOTE:** "Minimum test frequency" refers to the specific production area, not the frequency of sampling of each individual site specified in the plant PEM program frequency.

This requirement does NOT apply to the following raw ingredients handling areas:

- Raw Milk and Cream, Green Coffee Beans, Roast, and Ground coffee facilities
- Compressed Gases
- Raw Grains
- Raw Nuts/Seeds/Coconut
- Sugar: Oils and Fats (except Dairy, and Cocoa)
- Food Additives (not containing microbiologically sensitive sub-ingredients and/or not processing microbiologically sensitive ingredients at the plant):
  - Raw Meat and Raw Meat Products
  - Food Chemicals
  - Commercially Sterile Food and Beverage Products – aseptic / UHT / retort.

Any changes that can affect the plant Pathogen Environmental Monitoring program (e.g., change of products, recipe, equipment, new lines, transfer of lines, facility infrastructure damage, etc.) shall be discussed and aligned in advance (prior to implementation) with the respective TML Quality Coordinators.
USE OF APPROPRIATE HYGIENE INDICATORS

Relationship of selected microbiological test/organisms

**TVC**, Total Viable Count; **LM**, *L. monocytogenes*; pathogens marked in red
OBSERVATIONS TOWARDS POTENTIAL ROOT CAUSES

- Contaminated equipment
- Recent water event (leaks, drain damage)
- Water/condensation
- Poor cleaning practices
- Gaps in floors, porous floor materials
- Cracks/bad infrastructure (cracks in columns can allow for water rinsing down & spreading contaminations)
- Emergency Doors/Roof Access
Zone 3: Non-product contact surfaces; environmental surfaces within the processing room that are more remote from product contact surfaces. Examples include but are not limited to: hand trucks and forklifts (including their wheels); walls; drains; floors (>1 meter from exposed product/zone 1), equipment legs, ductwork, ceilings, 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, exterior of equipment, wash stations, ingredient storage areas, transitional areas to zone 4, etc..

Indirect product contact surfaces are 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 container. Direct or indirect product contact surfaces - surfaces exposed to product during normal equipment operation. Zone 1 surfaces shall not be routinely sampled for pathogens but testing for Enterobacteriaceae can be carried out. In cases of testing zone 1 or product for pathogens (Salmonella or Listeria monocytogenes), all product and associated rework manufactured since the last clean break shall be placed on hold. Examples include but are not limited to conveyor surfaces and product chutes, pipeline interior and storage fill hoppers, nozzles, formers, cut & wrap equipment, product scrapers/utensils, product contact gloved hands, etc.

Zone 2: Environmental surfaces immediately adjacent to product contact surfaces that under normal operating procedures do not directly contact the product or the product contact surfaces of the container, including the exterior of processing equipment. Examples include but are not limited to non-product contact gloves, equipment supports, frames, outside of tunnels, outside of enclosed filling cabinets or below filling equipment, control panels and buttons, weight scales, motor housings, scrap carts, transitional areas to zone 3, etc. Floors and walls close to (i.e., less than 1 meter) exposed product/zone 1 shall be regarded as Zone 2.

Zone 4: Areas remote from product contact surfaces outside the processing room but could impact processing areas through the movement of people, equipment or materials. Examples include but are not limited to warehouses, hallways, break areas, locker rooms, mechanical rooms, offices, cafeteria, restrooms, coolers, floors, wheeled vehicles and materials, and trash/recycle collection areas.

Remote areas outside of the RTE room:
warehouses, break areas, locker rooms, offices, cafeteria,
ADDITIONAL PEM

- Contaminated equipment
- Water/condensation
- Poor cleaning practices
- Gaps in floors, porous floor materials
- Cracks/bad infrastructure (cracks in columns can allow for water rinsing down & spreading contaminations)
- Emergency Doors/Roof Access

Additional PEM
Additional sampling locations and frequencies shall follow specific events such as:
- Start-up following a shutdown, or maintenance
- Other events that could affect the environment (e.g., infrastructure changes, water ingress/leakages from roof/floor/walls etc).
- Where annual preventative maintenance program is taking place, if there is potential to impact other areas that remain in production, then PEM is needed for transition areas.
- Construction/civil activity etc especially when it is done within the production area and shall ensure that dormant micro is not reactivated during building works, especially involving drainage.

Table 15

<table>
<thead>
<tr>
<th>Conditions</th>
<th>PEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Lines / new sites / new projects or Major infrastructural modification.</td>
<td>PEM clearance of the area before the area is released for production.</td>
</tr>
<tr>
<td>Major infrastructural changes are those which have an impact on the processing environment and equipment.</td>
<td>Zone 1, Zone 2, Zone 3, Zone 4.</td>
</tr>
<tr>
<td>Installation of new equipment like storage tanks, enrobers, etc.</td>
<td>PEM Zone 1 clearance prior to use.</td>
</tr>
<tr>
<td>Minor modification in existing line or manufacturing area e.g., installations which do not have an impact on the processing environment and equipment.</td>
<td>Increased PEM during installation around the area. PEM sampling of the area after 3 hours through production.</td>
</tr>
</tbody>
</table>
SAMPLING LOCATIONS - EXAMPLES

PEM Zone 2
- Control Button
- Handle (intake jam)

PEM Zone 3
- Footbridge
- Floor under sink

Pooling possible

Pooling possible
SAMPLING LOCATION CONSIDERATIONS

- Check potential harbourage areas: gaps, cracks, damaged flooring

Traffic route used by staff
SAMPLING LOCATION CONSIDERATIONS
Drains must be monitored

- check for trapped water/poor condition
SAMPLING LOCATION CONSIDERATIONS (2)
SAMPLING LOCATION CONSIDERATIONS

- Water
  - from leaks and sinks permits growth and spread of contamination in dry food environments!
SAMPLING LOCATION CONSIDERATIONS

- Foot bridges and steps
  - check floor contact (PEM Zone 3) and hand rails (PEM Zone 2)
SAMPLING TOOLS

Dust and other product (residue) sampling devices, e.g. spoons, scrapers

Swabs / tips

Sponges
SPONGES VS SWABS

- Large surface areas should be sampled for qualitative analyses using sponges (recommendation).

- The intent is to locate harborage areas.

- Use of a sponge is more effective than use of a swab.
  - **Exception:** For smaller hard to access or irregular shaped areas, a cotton swab is more effective.
SPONGE OR SWAB FOR SAMPLING?

Area covered by Sponge vs. Swab
Q: This picture (arrow) represents Zone 1

A: FALSE

This picture represents Zone 2.
Q: This picture (arrow) represents Zone 1

A: TRUE
**Q:** Would you use a stick swab or sponge to sample the following location?

**A:** B (Floor)
Q: Would you use a stick swab or sponge to sample the following location?

A: [Image of a stick swab]  

B: [Image of a sponge]

Gaps and cracks in the floor (potential harbourage location!)
THINK ABOUT SAMPLING AND CORRECTIVE ACTIONS

Impact of pooling

- Lines affected?
- Can lines be kept running?

Mobile equipment - floor cleaners, forklifts, cleaning tools

- Where has the contaminated equipment/item been used?
- Do I need to take equipment out of use?
- Can I dedicate the equipment/item to a restricted area/location?
THANK YOU FOR YOUR ATTENTION!

Questions?