MONDELĒZ INTERNATIONAL MEU DAIRY SUPPLIERS WEBINAR

MDLZ MEU DAIRY SUPPLIERS WEBINAR

Quality is at the heart of Mondelēz international, it is part of our purpose and values

- Reinforce suppliers awareness on MDLZ quality and food safety requirements
- Provide guidance on quality and food safety topics specific to dairy materials & suppliers

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MDLZ MEU DAIRY SUPPLIERS WEBINAR

Souhila Ghidouche
MEU Supplier Quality

Susana Cunquero
MEU Supplier Quality

Carolina Lopez
MEU Sanitation

PRESENTERS

Peter Mc Clure
Global Food Safety-Microbiology

Marta Palac
MEU Suppliers Food Safety

Linda Nadeem
Global Food Safety-Physical hazards

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AGENDA

1) Mondelēz international suppliers portal
2) Suppliers approval process at Mondelēz International
3) Requirements for Dairy suppliers
4) Kill step requirements & Validation
5) Zoning & Pathogen Environmental monitoring (PEM)
6) Sanitation requirements for Dairy suppliers
7) Metal Detector Requirements for Dairy suppliers
8) Dairy processing expectations updates
9) Q&A

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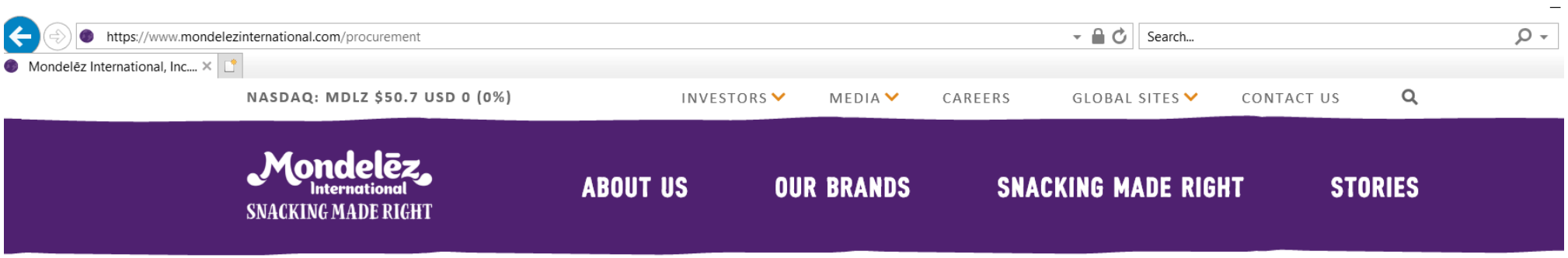
MONDELĒZ INTERNATIONAL SUPPLIERS PORTAL

Susana Cunquero
MEU Supplier Quality

MONDELĒZ INTERNATIONAL SUPPLIERS PORTAL



HOME /

SUPPLIER INFORMATION CENTER

Dear Supply Partner,

At Mondelēz International, our dream is to create delicious moments of joy. We are passionate about snacking and about driving growth through our much-loved Global Power Brands like *Milka* and *Cadbury* Chocolate, *Oreo* Biscuits, and *Trident* Gum, to name but a few.

We look to our supply partners to commit to the same dream by helping us drive extraordinary value through innovative products and services of the highest quality at competitive costs.

It's an exciting time to be working with Mondelēz International. We want to form winning relationships that create opportunities for you to help build our brands, optimize our processes, and achieve mutual growth. We want to work with only the very best and look forward to our continued partnership.

https://www.mondelezinternational.com/procurement

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MONDELĒZ INTERNATIONAL SUPPLIERS PORTAL

SUPPLIER QUALITY & FOOD SAFETY

QUALITY MANUALS

SUPPLIER MANUAL AND HACCP → Supplier Quality Expectations (SQE)
Supplier and EM HACCP Manual

PROCESSING EXPECTATION MANUALS

RE-PACKERS, WAREHOUSE AND TRANSPORTATION MANUALS

SUPPLIER AUDIT INFORMATION → Metric Stream Link
Ingredient / Packaging Supplier Audit Matrix

TRAINING → Trainings & Webinar sessions

FOOD DEFENSE & FOOD FRAUD MITIGATION → Food Defense Supplier Guidelines

OTHER QUALITY RESOURCES → Approved Pathogen Laboratories list

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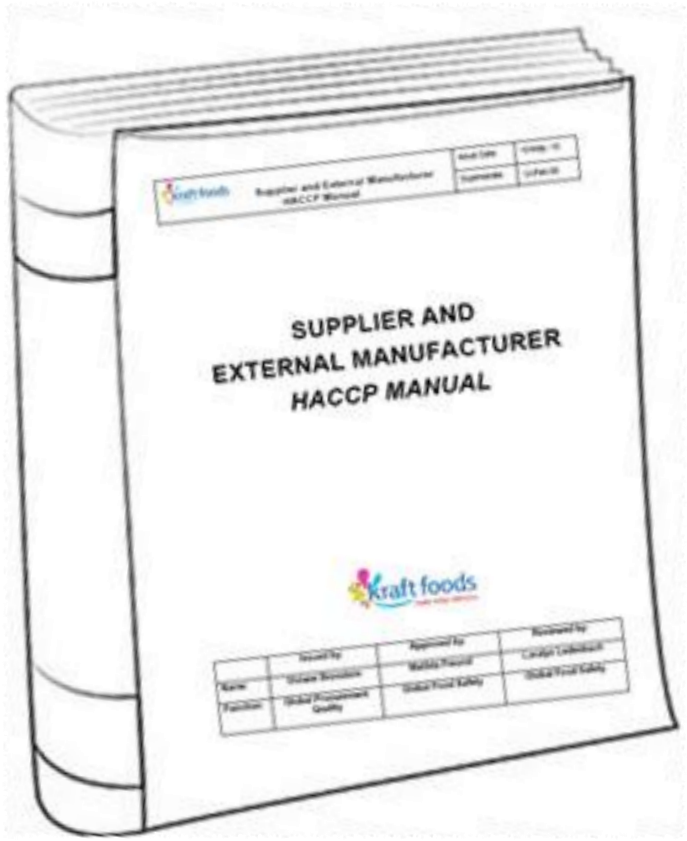
DOCUMENTS OF REFERENCE

Supplier Quality Expectations Manual



Supplier HACCP Manual

Dairy processing expectations Manual

All MONDELEZ documents are confidential

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SUPPLIERS APPROVAL PROCESS AT MONDELĒZ INTERNATIONAL

Souhila Ghidouche-Porcher
MEU Supplier Quality

SUPPLIERS APPROVAL PROCESS AT MDLZ INTERNATIONAL

Tier	Ingredient Categories (List is not all inclusive - refer to the Raw Material Tier Assignment list for details)	Qualification Process (new)	Accepted Audits & Certifications (ongoing)	Target Freq. (years)
1	RTE Meats, RTE Cheese, RTE raw fruits and vegetables., RTE Seafood, (Strategic Tier 2 suppliers)	Mondelez SQE Audit, [1]GFSI Certification and report	[8]Mondelez SQE Audit every 2 years [1]GFSI certifications and report	2.0
2	Coconut, Retorted & Aseptic Products including seafood (Low Acid Canned Foods), Sugar Confectionary, Treated Herbs/Spices/Seasoning, Treated Tea & Tea Products; Treated Egg & Egg Products; Dairy Products, Yeast (Non baking) Enzymes, Cultures, Treated Nuts and Seeds, Cocoa Chocolate confectionery, Vegetable Products (pH>3.5), Fruit & Fruit Products pH>4	Mondelez SQE Audit, [1]GFSI Certification and report	[1]GFSI Certification and report, Supplier Food Safety Assessment	2.5 (SFSA 3 years)
3	As above (case by case decision[9]) and Retorted & Aseptic Products including seafood (Low Acid Canned Foods), Sugar Confectionary; Yeast (Non baking) Enzymes, Cultures, dried fruits; flavorings	Mondelez SQE Audit, [1]GFSI Certification and report	[1]GFSI Certification and report	GFSI 2.5year, SFSA Lethality review process: 3 Years
4	Grain & Grain Products, Emulsifiers; Prepared Sauces/Spreads/Condiments, Coffee &Coffee Products, Bread & Bakery Products; Salt Sugars & Sweeteners (Lactose); Starter Media/Culture; Fats & Oils; Food Additives; Raw Meat & Raw Meat Products, Food Chemicals Hydrocolloids & Gums, Untreated herbs/Spices/Seasoning; [4]Direct Contact Packaging Material (See packaging Audit matrix, Labeled and Unlabeled, Non-Contact Packaging Material Labeled); [5]Chemicals-Distillation ,Crystallization, Extraction, Talc , [2]Cheese for processing, [2]Liquid / Frozen Egg products, [2]Yeast For baking/Further processing, Fruit Products pH<4; Vegetable Products pH<3.5	[1]GFSI Certification and report .	[1]GFSI Certification and report	3
5	Raw Milk & Cream, [3]Nationally Branded Confections; Green Coffee Beans; Raw Cocoa, Compressed Gases; Raw Grains; Raw Nuts/Seeds/Coconut; Alcoholic Substances (Spirits, Liquors); Cream, Liquid Whey and Liquid Milk (Bulk Only), Sodium Hydroxide, Raw Agricultural Vegetables, Gum Base,	Audits may be required as result of a risk assessment by BU or Plant using the material. A Risk assessment or Audit must be on file for all approvals going forward.		4

SUPPLIERS APPROVAL PROCESS AT MDLZ INTERNATIONAL

Tier	Ingredient Categories (List is not all inclusive - refer to the Raw Material Tier Assignment list for details)	Qualification Process (new)	Accepted Audits & Certifications (ongoing)	Target Freq. (years)
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REQUIREMENTS FOR DAIRY SUPPLIERS

Souhila Ghidouche-Porcher
MEU Supplier Quality

REQUIREMENTS FOR DAIRY SUPPLIERS

➢ Tier 5 suppliers

- Dairy Materials rated as **Tier 5** are: raw milk & cream, cream, liquid Whey and liquid Milk (bulk only). These materials will undergo a thermal treatment/ kill step internally within MDLZ
- Requirements for T5 suppliers
  - Audits may be required as result of a risk assessment by BU or Plant using the material
  - A risk assessment or Audit must be on file for all approvals going forward.

➢ Tier 4 suppliers

- Dairy materials rated as Tier 4 are cheese(s) for processing. This type of materials will undergo further thermal treatment (kill step) internally within MDLZ
- Requirements for T4 suppliers:
  - Valid GFSI certification and report (for new suppliers and existing supplier to grant reapproval)
  - Meet the requirements described in Mondelez international supplier quality expectations manual
  - Meet the requirements described in the "**Dairy Products Processing Expectations**" manual

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REQUIREMENTS FOR DAIRY SUPPLIERS

➢ Tier 1 & Tier 2 Dairy suppliers

- Materials rated as Tier 1 (ready to eat cheese) & Tier 2 (dairy powders, an hydrated milk fats, Butter…) are microbiologically sensitive materials.
- Requirements for T1 & T2 Dairy suppliers
  - Valid GFSI certification and report (for new suppliers and existing supplier to grant reapproval) existing T1 suppliers are audited every 2 years by MDLZ)
  - Meet the requirements described in Mondelez international supplier quality expectations manual
  - Meet the requirements described in the "**Dairy Products Processing Expectations**" manual
- The Microbiology CCP (Kill step) to eliminate and reduce target pathogenic organisms of concern must be defined and validated
- A Detailed report of the kill step validation of must be shared with MDLZ supplier quality and Food safety
- If the process meets MDLZ expectation, MDLZ Food Safety approves the kill step. The approval is granted for each material and each line separately (i.e. per pasteurizer)

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REQUIREMENTS FOR DAIRY SUPPLIERS

➢ **New Tier 1 & Tier 2 Dairy suppliers:**

- MDLZ Supplier Quality support the qualification of the supplier to pass a MDLZ audit
- When the supplier is ready for the audit, MDLZ procurement rep uploads the audit request in MSI.
- The request goes to MDLZ Auditing and the date of the audit is scheduled.
- If the supplier passes the audit, the approval is granted per line and per material

➢ **Existing Tier 1 & Tier 2 Dairy suppliers**

- Tier 1 suppliers are audited by MDLZ every 2 years
- If a new/additional line is needed in the future (not in the scope of the initial approval), a new audit must be performed in order to approve the line
- The kill step must be re-validated :
  - At least every 2 years
  - When a major change occurs (equipment/process or installation)
- The supplier must inform MDLZ in case of any changes in the process and the kill step parameters

KILL STEP REQUIREMENTS & VALIDATION

Marta Palac
MEU Suppliers Food Safety

MONDELEZ CCP MODELS

Requirements Matrix – appropriate CCP model shall be applied for the control of biological hazards.

Dairy processing Expectations, table 5.1: Pathfinder table outlining product type and Minimum Applicable Food Safety Models and Minimum Applicable Time and Temperature:

Product	Other controls / Remarks	Minimum Applicable Food Safety Models and Minimum applicable Time/Temperature
Anhydrous Milk Fat: When the CCP is applied to the cream step.		Follow CCP1 or CCP2.
[6,15,21,37]Anhydrous Milk Fat: When the CCP is controlled at the polishing step in the process	Target organism: *Listeria monocytogenes*	Polishing step: Temperature of water/oil mix must be controlled to reach 85°C
[6,,21] Anhydrous milk fat: produced from melted butter	Target organism: *Listeria monocytogenes*	Follow CCP1 or CCP2 for melted butter but apply 72.°C/15 sec (z=6.71C°) or CCP2 65°C for 35 min (z=6.71C°)
Cream cheese	Please see section 8.5 for specific requirements	Follow CCP1 or CCP2 in addition to CCP6 and CCP9
Butter		Follow CCP1 or CCP2, and CCP 9
Fresh / Cottage cheese	Please see section 7.8 for specific requirements	Follow CCP1 or CCP2, and CCP6
Natural cheeses	Please see section 7.8 for specific requirements	Follow: Option A: CCP1 or CCP2 or CCP3, option A Option B : CCP1 or CCP2, or CCP3, option B and CCP4
Mould ripened cheese	Please see section 7.8 for specific requirements	Follow CCP1 or CCP2, and CCP6
Milk powders (produced from raw milk)	Please see section 8.1 for specific requirements	Follow CCP1 or CCP2, and CCP9
Cheese powder		Follow CCP1 or CCP2 in addition to CCP6 and CCP9
Pasteurised liquid dairy products		Follow CCP1 or CCP2 and CCP9
Quark / yoghurt		Follow CCP1 or CCP2
[24]Pre-pasteurised concentrate after transportation from another location(whey or skim milk ≤24%)	Target organism: *Salmonella* Senftenberg 775W	Follow CCP1 using 72°C/ 15sec (z=8C°)
[11,24] Pre-pasteurised concentrate after transportation from another location(whole milk <30%)	Target organism: *Salmonella* Senftenberg 775W	Follow CCP1 using 72°C /45sec (z=8C°)

- If the fat content of the milk product is > 10%, or if it contains added sweeteners, or total solids >18% the specified temperature shall be increased by 3°C (5°F).
- All Dairy material received by a plant, whether pre-pasteurized or raw must undergo a heat treatment.

VALIDATION AND VERIFICATION OF CCP HEAT TREATMENT

Validation

- Description of how the heat treatment system has been designed to ensure that it is effective =Validation.
- Provide information on design of equipment e.g. schematic diagram, type of agitation (batch)
- Description of heating process such as plate heat exchanger, steam jacketed vessel
- Position of probes and valves
- Product flow and line connections identifying that raw and pasteurized product is separated.
- Evidence of assessment of potential processing risks such as dead spots where heat treatment may not be effective.
- Theoretical calculation and system validate under worse case scenario: e.g. max flow rate, product flow type (laminar/turbulent – the type of applicable flow, based on product characteristics can be derived from the Reynolds number or from an empirical method such as salt test.)

Verification

- To verify the effectiveness of the heat treatment operational monitoring and testing procedures must be followed.
- Provides evidence that the specifications set through validation continue to be met during processing.

CCP VERIFICATION - CONTINUOUS SYSTEM

Parameter	Verification frequency	Monitoring
• Temperature difference between recording and indicating device	Daily, to verify that the difference is not >0.5 °C, important when working close to critical limits	Continuously
• Cut in cut out test of FDD	Daily, to verify that the valve activates at an instructed set temperature (does not have to be at critical limit)	Position of DV continuously monitored
• Time/Flow rate when managed by timing pump	Daily, verify that flow has not been increased, which could compromise residence time, or check seal	Flow meter: Flow continuously monitored /Timing pump: once per shift
• Pressure difference	Daily, to verify that pressure is 1PSI higher on pasteurized side compared to raw, ensuring no cross contamination occurs over the production – applicable for heat plate exchanger	Continuous is preferred
• Pasteurization records	Daily to verify that pasteurization was not compromised	N/A

All measuring devices used to monitor critical control parameters shall be calibrated on a yearly basis.

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CCP VERIFICATION - BATCH SYSTEMS

Parameter	Verification frequency	Monitoring
• Temperature of heat treatment	Daily to verify correct heat treatment was applied	Continuous or manual recording (Coldest spot study is required, updated when changes are made to product formulation or equipment)
• Headspace temperature	Daily, to verify temperature in the air space is 3°C higher than product temperature, to avoid contamination from condensation forming and milk/foam spatters on tank ceiling	Continuous
• Time	Daily to verify that the correct time for a particular recipe was used, ensuring correct heat treatment parameters were applied	Correct for recipe in use
• Pasteurization records	Daily to verify that pasteurization was not compromised	N/A

All measuring devices used to monitor critical control parameters shall be calibrated on a yearly basis.

CORRECTIVE ACTIONS CCP MANAGEMENT – HEAT TREATMENT

- Under pasteurized product found by documentation review = Category 1 hold.
- Hold and release required and corrective actions to be documented

Continuous systems:

- Cleaning in place must be carried out when:
  - When the FDD is positioned after the cooling section
  - When the FDD is positioned after the evaporator section
  - When FDD function is covered by a combination of valve systems leading to dead areas during divert

Batch systems:

- Pasteurization step must be restarted in cases where:
  - Product temperature drops below pasteurization temperature during the hold period or inlet piping was not disconnected.
  - Time was not achieved

Microbiological testing of finished product and release is not acceptable for MDLZ International.

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STORAGE MILK BEFORE PASTEURIZATION – CCP 10

Holding time and temperature in order to prevent more than 10 multiplications of *Staphylococcus aureus*.

- Holding time and temperature for each batch must be monitored and recorded
- If critical limit for time/temperature is exceeded, then the batch has to be discarded and the appropriate shall be cleaned and sanitized before preparing the next batch.
- Designated responsible employee (usually the Supervisor) reviews and signs processing records at least daily
- All measuring devices used to monitor critical control parameters shall be calibrated in a yearly basis

STORAGE TEMPERATURE	MAXIMUM STORAGE TIME (HOURS)**
< 8 °C (< 45 °F)	only for product quality
>8°C - 10°C (45 - 50 °F)	60
>10°C - 12ºC (50 - 54 °F)	42
>12°C - 14°C (54 - 57 °F)	30
>14°C - 16°C (57 - 61 °F)	23
>16°C - 18°C (61 - 64 °F)	18
>18°C - 20°C (64 - 68 °F)	15
>20°C - 22°C (68 - 72 °F)	12
>22°C - 24°C (72 - 75 °F)	10
>24°C - 26°C (75 - 79 °F)	8
>26°C - 29°C (79 - 84 °F)	7
>29°C - 31°C (84 - 88 °F)	6
>31°C - 34°C (88 - 93 °F)	5
>34°C - 50°C (93 - 122 °F)	4
>50 °C (> 122 °F)	Only for product quality

HYGIENIC ZONING & PATHOGEN ENVIRONMENTAL MONITORING (PEM)

Marta Palac
MEU Suppliers Food Safety

WHAT IS ZONING?

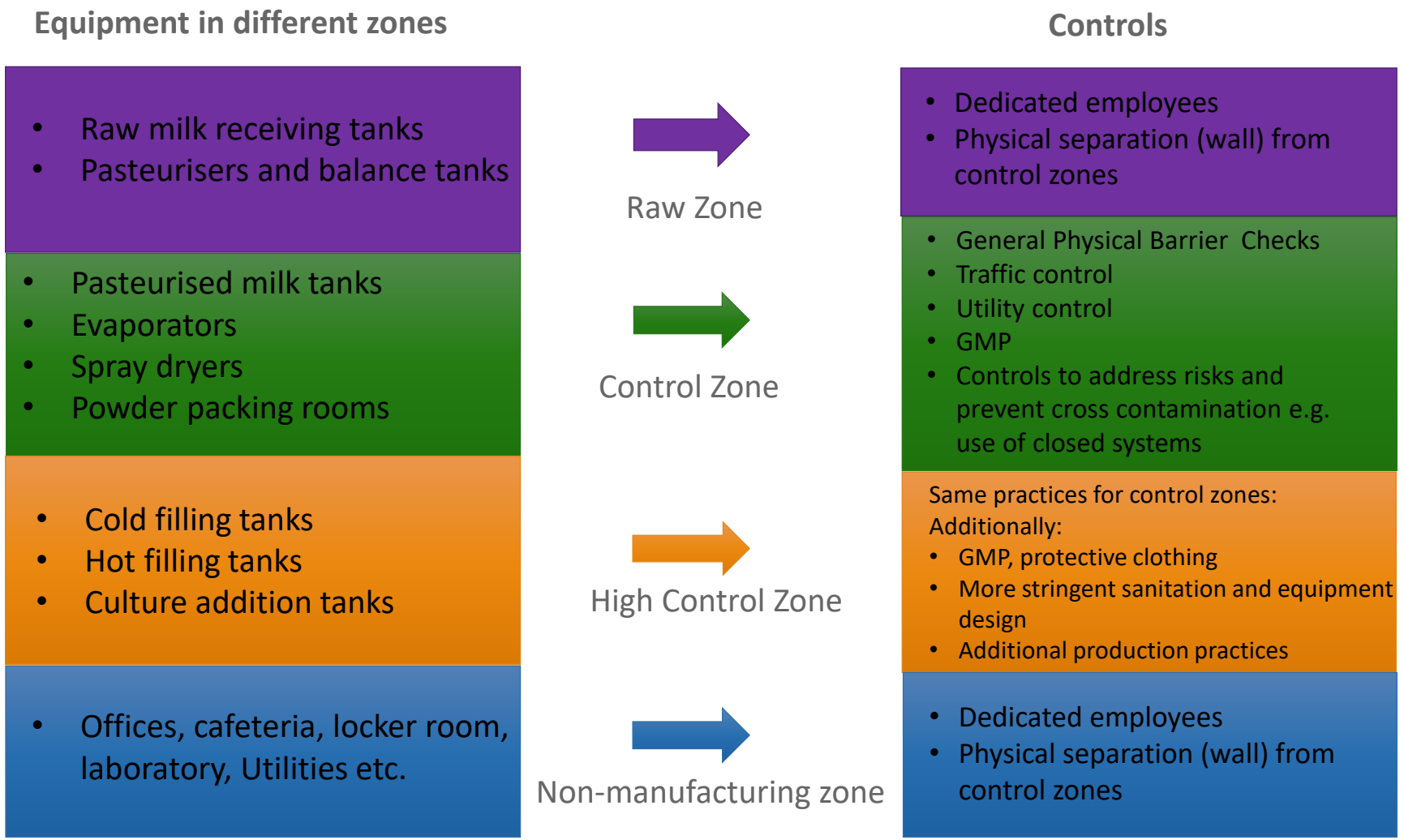
Identification and differentiation of the processing areas within the Manufacturing facility based on microbiological risk

- The purpose is to protect products from potential microbiological hazards originating from the manufacturing environment and its surroundings.
- 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.

Mondelez 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.
- A Hygienic Zoning map must be documented and shall be reviewed in the event of changes to plant layout and/ or introduction of new lines and processes.

EQUIPMENT EXAMPLES FOR EACH ZONES AND CONTROLS



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MAIN CONSIDERATIONS REGARDING ZONING

- Structural separation of the respective area by design (raw/RTE, wet/dry environments)
- Filtration of the room air and adequate pressure/flow of room air to protect the food against pathogens and/or spoilage organisms in area where post-pasteurized material is handled
- Utilities control (air, water) i.e. F7 air filters in tanks after pasteurization located outside e.g. crystallization tanks and in the areas where products exposed
- Use of a vestibule as entrance and exit with personnel hygiene and changing measures between different zones
- 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 areas that may be a risk
- Restricted access to microbiology susceptible product areas (applies to employees not working in the area, visitor, etc.);
- Maintenance tools should be dedicated to each zone or cleaning and disinfection procedure shall be in place in case of passing from a low care zone to a high care zone

PATHOGEN ENVIRONMENTAL MONITORING (PEM) - WHAT AND WHY?

PEM is a programme aimed at:

- Detection of pathogens
- Detection of organisms that indicate potential presence of pathogens in the processing environment

The purpose of PEM is to:

- Verify that the controls put in place for during the Hygienic Zoning assessment is effective at preventing cross-contamination
- Tool to provide information to improve environmental controls for prevention of potential cross-contamination

Assessment of controls of post processing environment; Raw areas receiving further processing are not included

Critical evaluation of process flow and identify areas of greatest risk; Sampling plans need to be flexible, sampling is randomised

Review historical environmental and sanitation swab data; Unique events should be monitored

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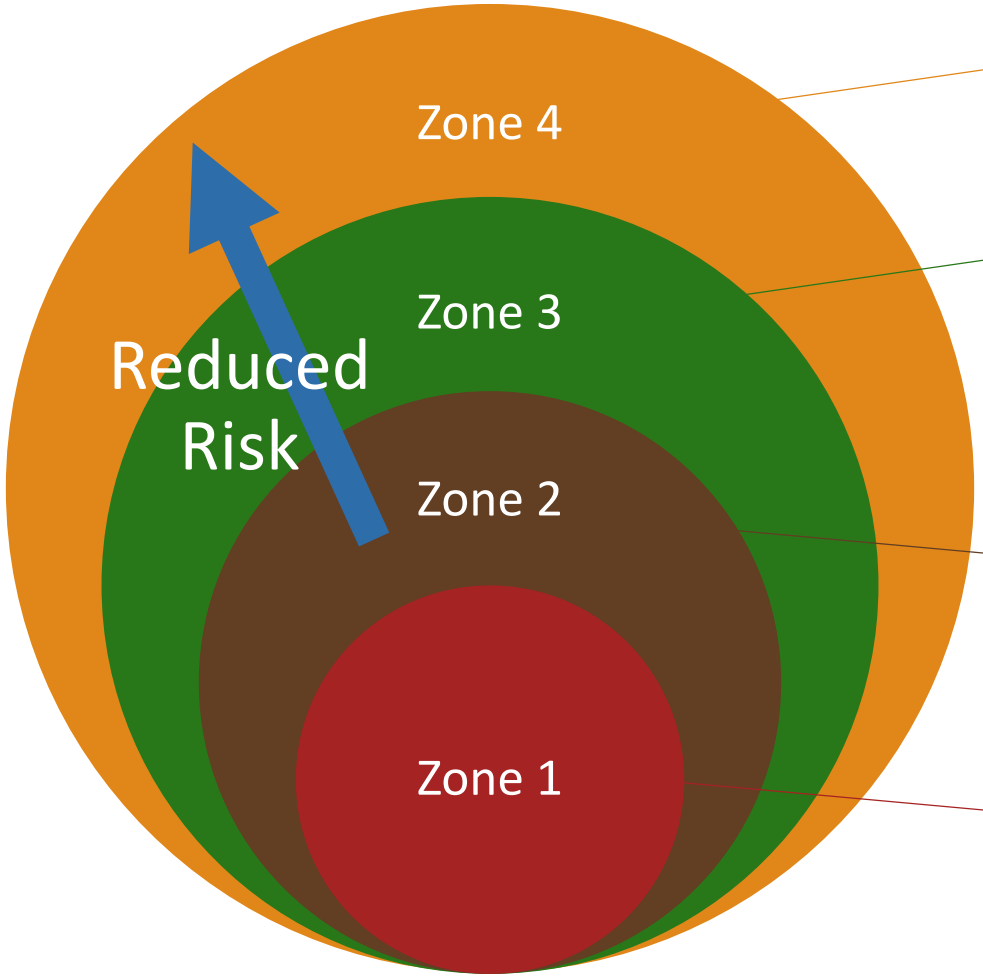
PEM SAMPLING PLAN – GENERAL RULES

- Swabs should be taken during production and at least 3-4 hours into a run including rotation between shift and different days during the week.
- PEM sample size changes for large areas. Large surface areas shall be sampled for qualitative analyses. A sponge is more effective for sampling large surface areas. For smaller hard to access or irregular shaped areas, a cotton swab is more effective. Sanitise the site after swabbing
- Composite – Take individual sponges for each site to form composite sample versus using same sponge (only when minimum one year history built up). Drains samples shall not be composited (allowed only if sampling locations are part of one long drain or if drains are collecting water from the same area)
- 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.
- *Listeria spp*. testing should be done for wet area instead of *Listeria monocytogenes.*

ZONE CONCEPT FOR PEM



Areas remote from product contact surfaces outside the processing room

Sites that are non-product contact; environmental surfaces within the processing room that are more remote from product contact surfaces

Sites that are non-product contact; environmental surfaces immediately adjacent to product-contact surfaces.

Sites that are direct or indirect product contact surfaces (MDLZ do not recommend Zone 1 sampling)

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PEM PLAN FOR DAIRY SUPPLIERS

Testing Plan	PEM zone	Test organisms	Minimum test frequency	Products
PLAN B Dedicated for low moisture products which *Salmonella* may survive and/or grow	2,3	*Salmonella*	Once per week	Milk powders
	4	*Salmonella*	Once per month	
	2,3	*Listeria* spp.	Once per month	
PLAN C Dedicated for product in which *Listeria Monocytogenes* may grow and *Salmonella* may grow or survive	1	*Listeria* spp. and coliforms (optional *E.coli*)	Once per week	Natural Cheese and RTE Fresh Cheese supporting Listeria NOTE: Zone 1 testing for coliforms exempt for Natural Cheese
	2,3	*Listeria* spp. & *Salmonella* or optional indicators	Once per week	
	4	*Listeria* spp. & *Salmonella* or optional indicators	Once per month	
PLAN E Dedicated for product that support pathogen survival	1	Indicators	Once per week	Cheese Products, Cold filled RTE Cream Cheese and Process cheese All Cheese Products Hot filled RTE (minimum filling temperature 145°F or 62,8°C) - Zone 1 testing exempt Natural Cheese and RTE Fresh Cheese not supporting Listeria growth - Zone 1 testing exempt for Natural Cheese only Dairy, Sweet Condensed Milk Dairy and Cheese Cultures, Frozen, Non-RTE
	2,3	*Listeria* spp. & *Salmonella* or optional indicators	Once per week	
	4	*Listeria* spp. & *Salmonella* or optional indicators	Once per month	
Plan I	2,3	*Listeria* spp. and/or *Salmonella*	Once per month	Butter/Margarine, AMF (for any reason when the plants can expect possibility or growth/survive pathogens, they should follow plan C)
	4	*Listeria* spp. and/or *Salmonella*	Once per quarter	

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POSITIVE PATHOGEN FINDINGS

- Root cause 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 within a 3-week time frame
- 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. This requirements is valid for all zones.
- Root cause analysis and documented corrective action report must be provided to MDLZ, even if specific lot is not for MDLZ

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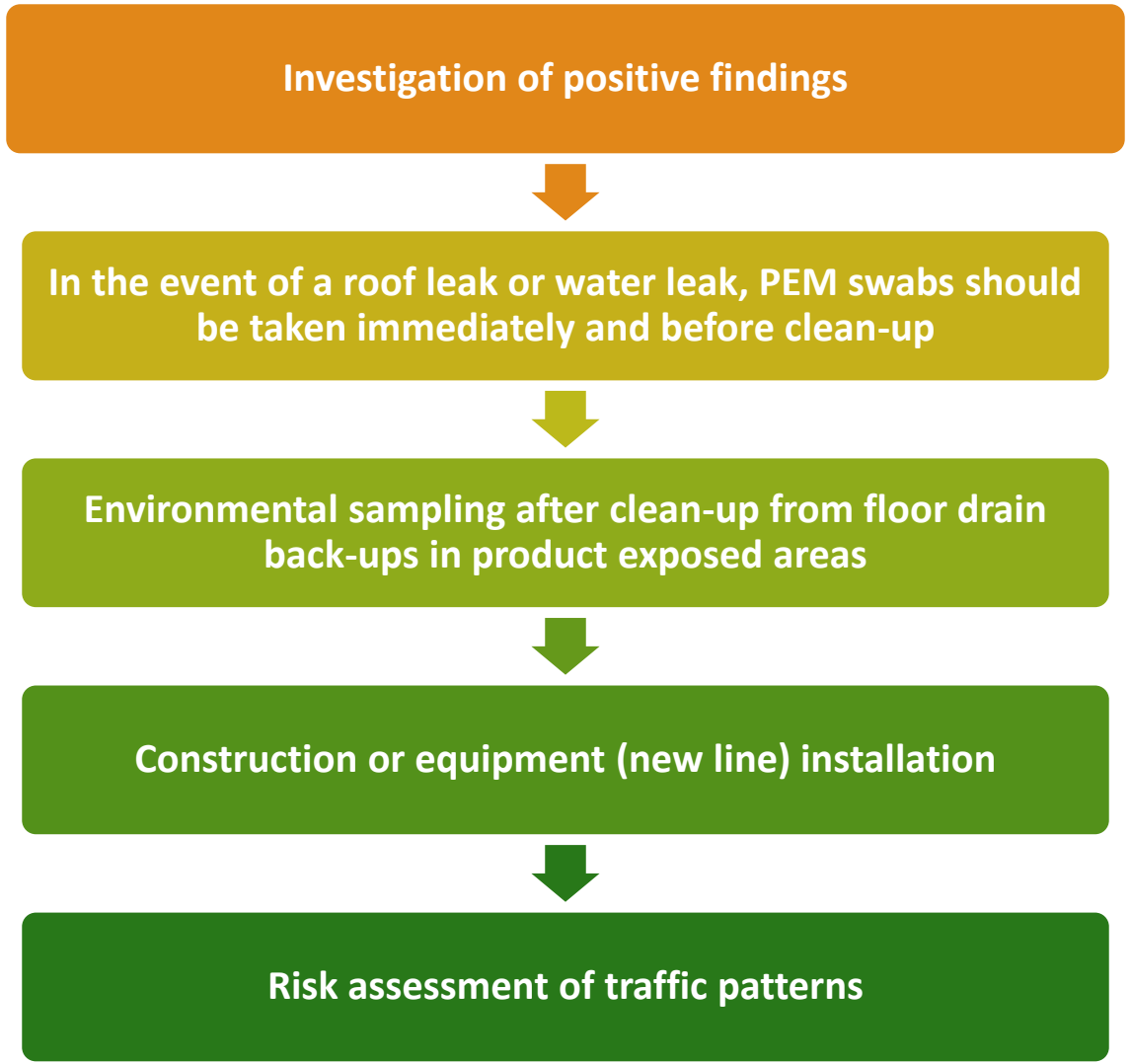
ADDITIONAL PEM SAMPLING - WHEN AND WHY?



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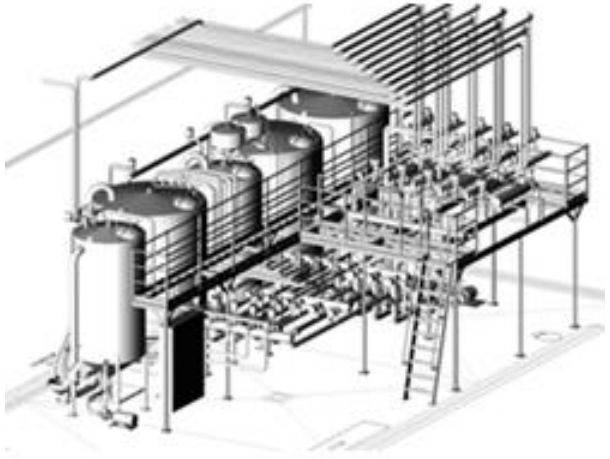
SANITATION REQUIREMENTS FOR DAIRY SUPPLIERS

Carolina Lopez
MEU Sanitation

CIP SYSTEMS - TYPES OF CIP INSTALATIONS



1. Custom built CIP station

2. Pre-Fabricated CIP station

3. Mobile Skid

4. Existing process tank as a CIP tank

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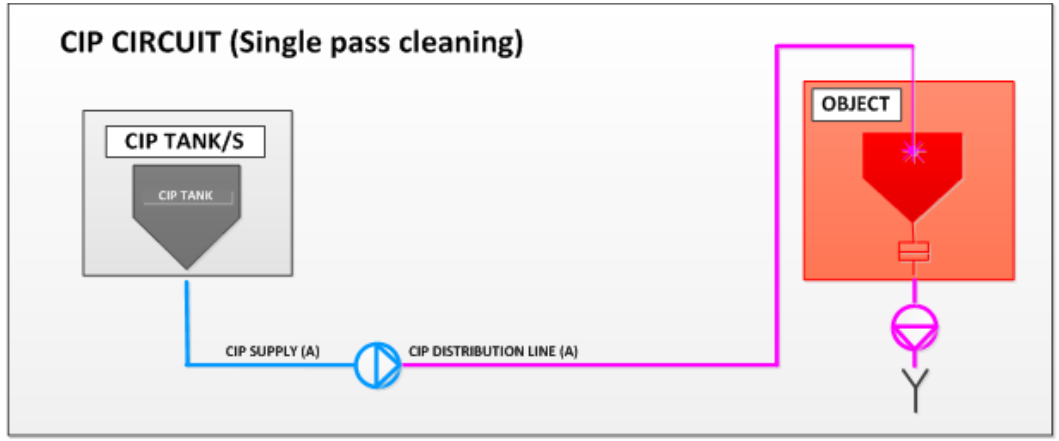
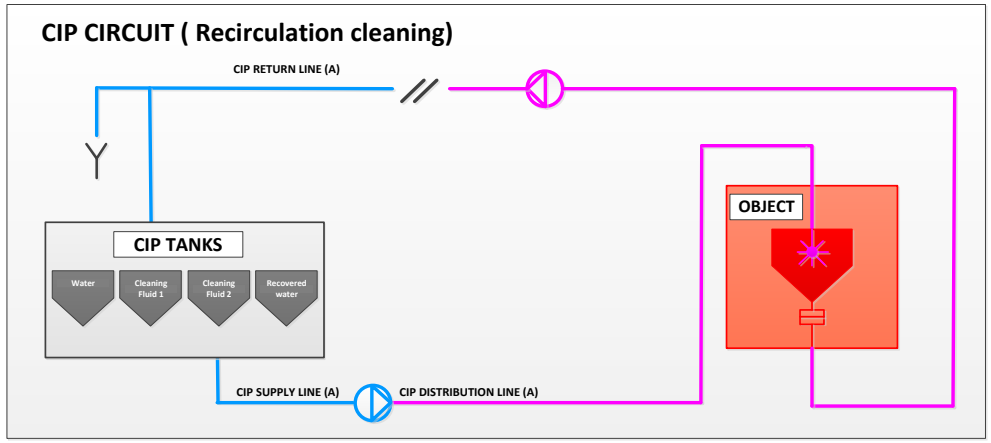
CIP SYSTEMS- CIP CONCEPTS

1. By Re-use of Cleaning Solutions

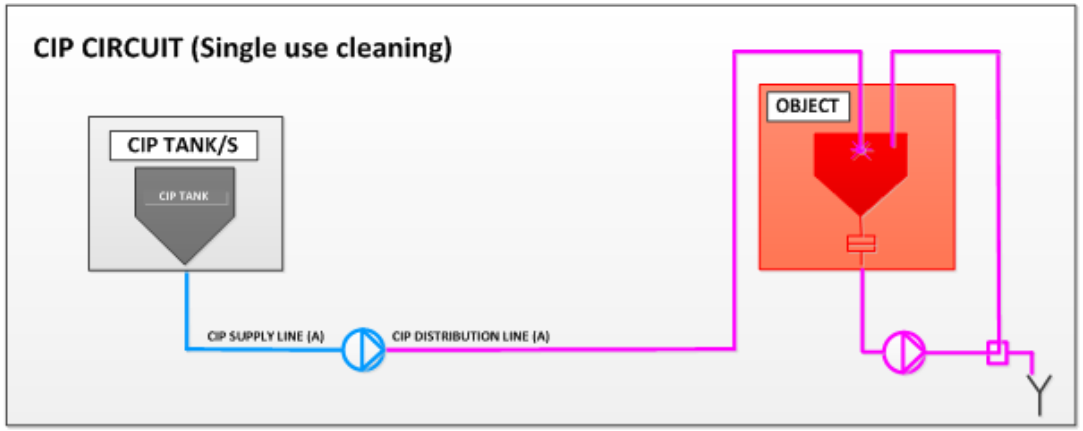
Single pass cleaning or single use
w/o recirculation



Recovery cleaning



Single use cleaning with recirculation



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CIP SYSTEMS- CIP CLEANING PARAMETERS

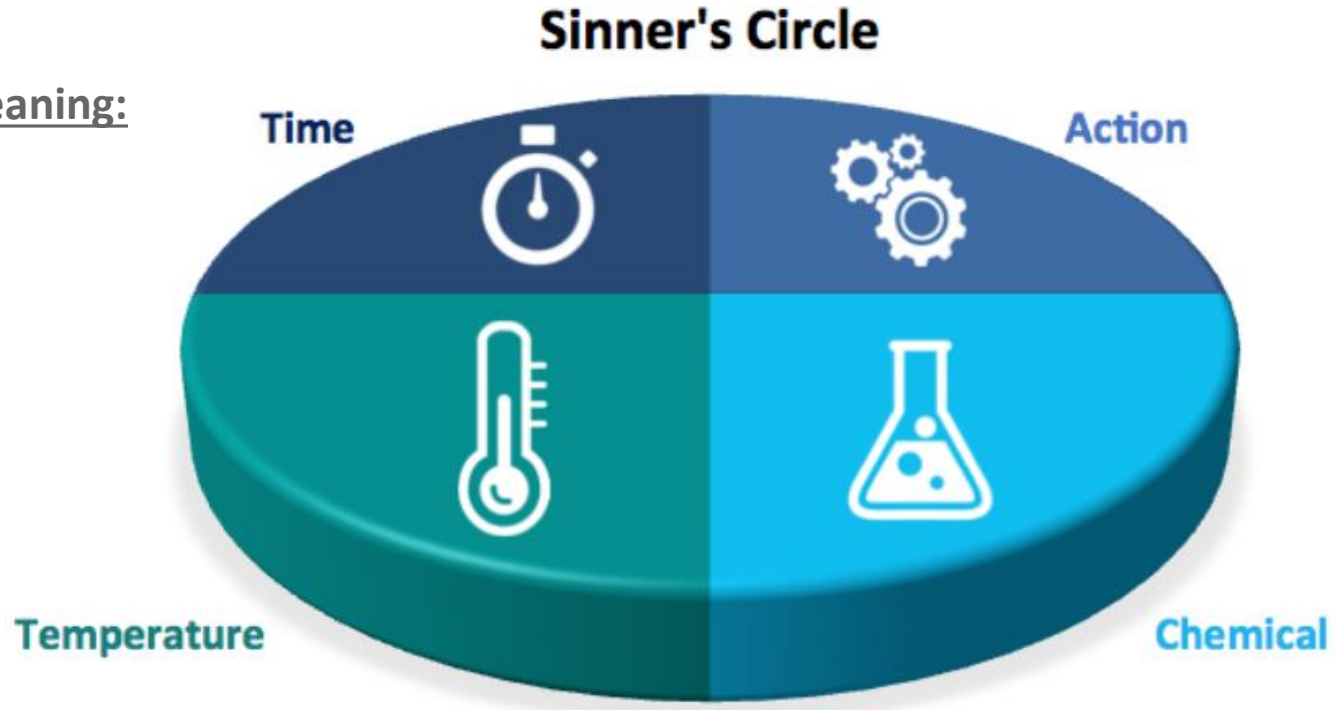
What do we need to know to set the CIP parameters

Our dirt, and **our process**,

Process parameters and running time of the line will affect how the equipment will be soiled

There are four parameters that make up cleaning:

1. **Mechanical** action
2. **Temperature** action (heat)
3. **Chemica**l action
4. **The time** these 3 forces are in action.



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VALIDATION

+

VERIFICATION

+

MONITORING

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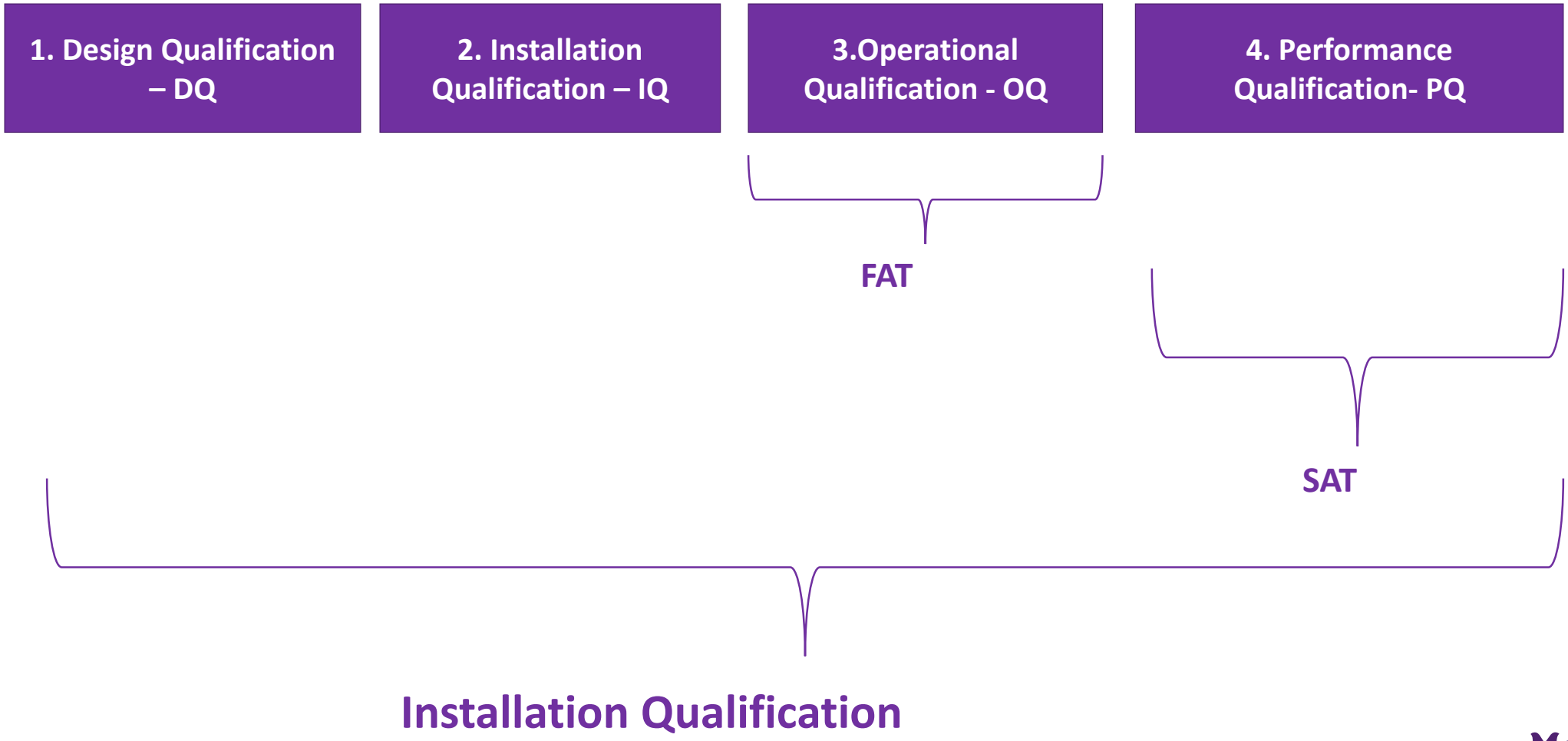
CIP VALIDATION PROTOCOLS- PHASES



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CIP VALIDATION PROTOCOLS- PHASES

1. Design Qualification – DQ	2. Installation Qualification – IQ	3.Operational Qualification - OQ	**4. Performance Qualification- PQ (≃One month after start up)**

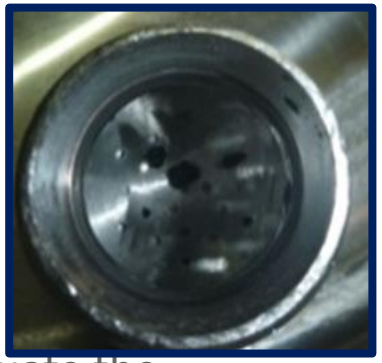
Will determine if the object is cleaned according to the acceptance criteria:

Tear down the line for visual examination: **clean surface + no odour + no stagnant water.**

Functions involved: *Supplier + Process engineering + Sanitation*







- During PQ partial tear downs (at least 2 for critical points) must be done to evaluate the performance of the installation.

- One month after start up a full teardown of the line must be done (*micro cleaning is required ; visual inspection + swabbing surfaces/ last rinse).*

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CIP RE-VALIDATION PROTOCOL- WHEN CIP VALIDATION IS REQUIRED?

Cleaning parameters changed / new chemicals, ingredients

STEP REQUESTED

Performance Qualification–PQ

- ❑ Full Tear down of the line for visual examination: clean surface + no odour + no stagnant water
- ❑ Tear down for critical areas

Micro cleaning is required (visual inspection + swabbing surfaces/ last rinse)

Installation modification

STEPS REQUESTED

Design Qualification–DQ

- ❑ P&ID and FDS review of the modification + operational parameters (flow, temperature, conductivity, time).

Installation Qualification–IQ

- ❑ Physical inspection of the modifications (CIP station, circuits, objects)

Operational Qualification - OQ

Testing the CIP installation is operating according to the FDS
Flow, temperatures and conductivity profile of the modification

Performance Qualification - PQ

- ❑ Tear down of the modification (clean surface + no odour + no stagnant water)

Micro cleaning is required (visual inspection + swabbing surfaces/ last rinse)

Every two years

STEP REQUESTED

Performance Qualification–PQ

- ❑ Tear down the critical parts of the line for visual examination: clean surface + no odour + no stagnant water

Micro cleaning is required (visual inspection + swabbing surfaces/ last rinse)

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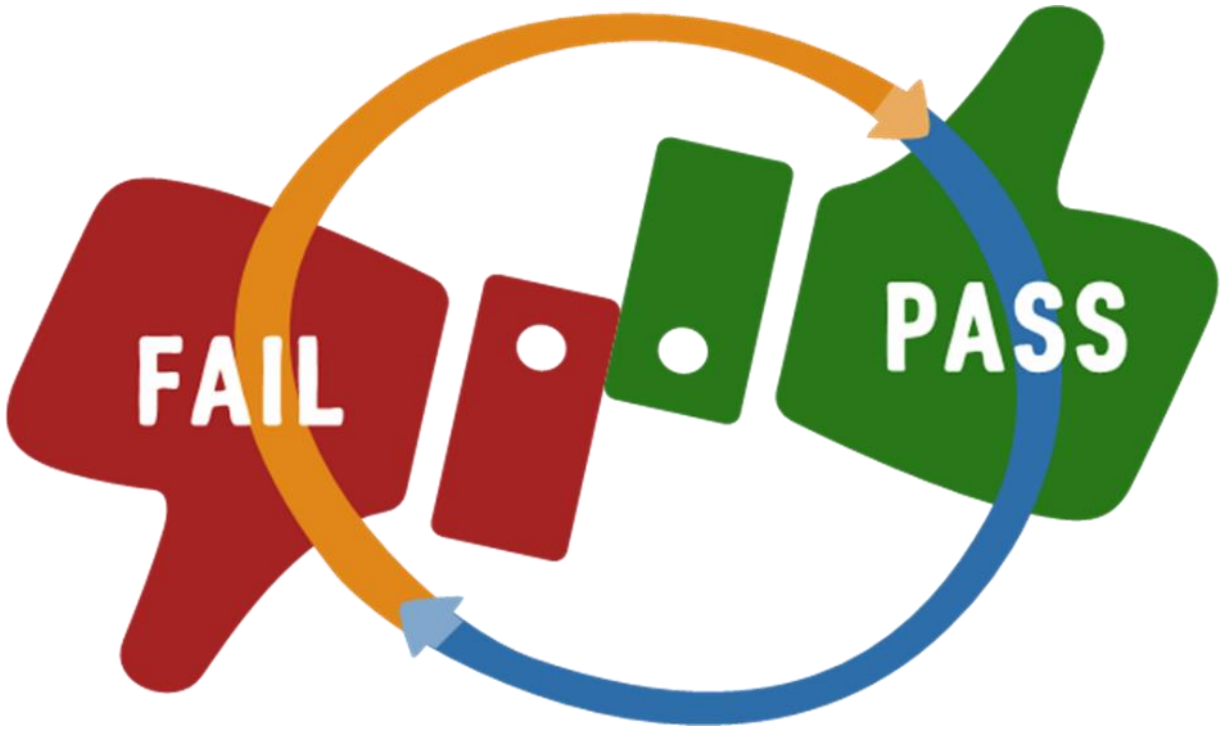
TO INCLUDE IN THE VALIDATION REPORT

- Equipment name, date, responsible person for validation
- Product produced on the line before validation (worse case selected e.g. stickiest product)
- P&ID of the circuit
- Cleaning parameters
- Program Steps
- Interlocks , Alarms
- Tear down inspection (Pictures)
- Micro testing
- Action Plan
- Trending



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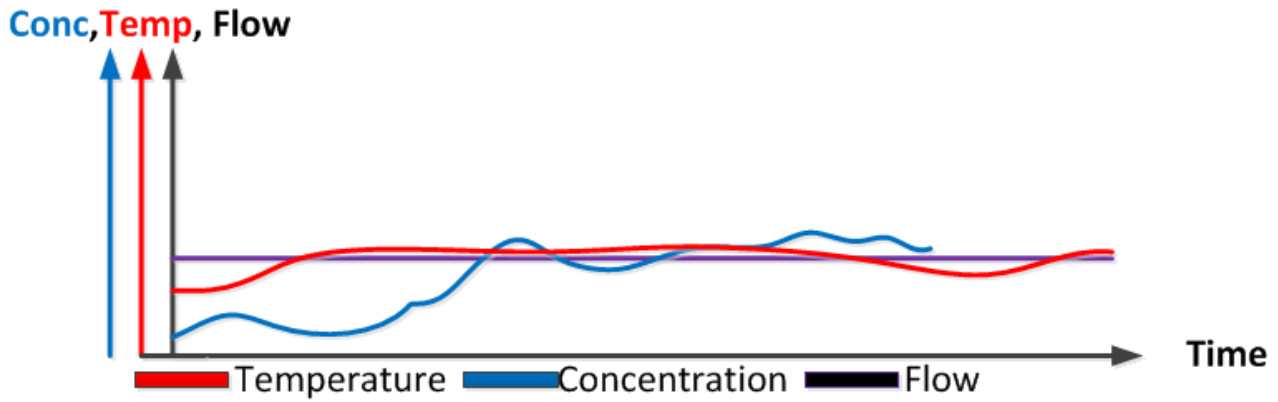
"DAILY WORKING" WITH CIP INSTALLATIONS- CIP MONITORING

Objective: Confirm CIP cleaning parameters are the same that the ones stablished during the CIP validation in order to detect possible interference that might arise in the course of the CIP cycle and lead to correct the process before reaching the final result

Frequency: During each CIP circuit
Management: Must be similar to the method applied during the validation

Automatic



Manual

Date:							
Circuit name	Detergent A			Detergent B			Last rinse pH
	Time (min)	Temp (ºC)	Conc (%)	Time (min)	Temp (ºC)	Conc (%)	
TK 001	---	----	-----	----	----	----	------

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DAILY WORKING" WITH CIP INSTALLATIONS- CIP VERIFICATION

Definition: Proof, checking, testing

Objective: Provide objective evidence to confirm the effectiveness of the CIP system. Verification will confirm that the parameters set during the validation phase meet the cleaning requirements

1. Frequency: After each CIP cycle

Management: Post cleaning inspection + Micro testing

2. Frequency: at a frequency to demonstrate control (not exceeding 1 year)

Management: Flow, temperature and conductivity verification, spray balls functionality (visual) and strainers integrity

MONITORING + VERIFICATION , ENSURE CIP WAS CARRIED OUT IN AN EFFECTIVE WAY

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METAL DETECTOR REQUIREMENTS FOR DAIRY SUPPLIERS

Linda Nadeem
Global Food Safety

END-POINT METAL DETECTOR

REQUIREMENT:

- Validated to detect and reject spherical test piece standards equal to or smaller than
  - 1.5 mm ferrous,
  - 2.0 mm non-ferrous (e.g. brass),
  - 2.5 mm stainless steel (Recommended 316 grade, minimum same grade as used in production equipment).
- Where the minimum test piece standards cannot be detected (e.g. due to the product matrix, metalized foil or size/bulk) alternative control measures such as magnets, filters, screens and/or line modifications to prevent extraneous matter introduction shall be considered and their effectiveness be verified. The detection sensitivity under production conditions **must be better than 5.0mm for all metal**

VALIDATION

Purpose:

To ensure Metal Detector is at its most sensitive detection limit with a

- **Probability of Detection (POD) of 100%**
- **and False Reject Rate (FRR) <0.1%**

POD

Pass 30 times each Validation Sample
The POD limit is defined by the smallest dimension achieving a POD of 30/30 (detected & rejected)

Calculation:- $POD = 100 \times \frac{\text{Rejected Test Samples}}{\text{Total Test Samples Inspected}}$

FRR

Measured during production by adding/ not adding known amount of contaminants with product amount equivalent to (200 – 2000 SKU). Evaluate each rejected product and classify it as a False Reject or not
Recommended target: not more than 0.1%

Calculation:- $FRR = 100 \times \frac{\text{(Total Reject – Correct Reject)}}{\text{Total Inspected}}$

MONITORING

- To assure 100% detection and rejection of every pass of each of the test pieces used
  - positioning of the test pieces is controllable, they should pass through the centre of the metal detector aperture
  - Ideally in product flow, can be without product (in Test Mode) but this needs to be documented with a yearly verification in product flow
- Where a validation has been completed and a False Reject Rate (FRR) <0.1%,
  - 1 passes of each test piece
  - If no validation or MD is unreliable 2 passes of each test piece

Frequency – This is to be determined based on

- Ability to retain on hold the product produced during the time frame selected
- Historical data from the line (frequency of confirmed rejects/findings, reliability of MD/X-ray, age of equipment)

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DAIRY PROCESSING EXPECTATION UPDATES

Peter McClure
Global Food Safety

DAIRY PROCESSING EXPECTATION UPDATES

S.No	Area for review/update	Discussion
1.	Pasteuriser – Holding tube slope importance and requirement as per PMO	Review criticality of slope requirement
2.	Requirements related to sanitary design of pasteuriser (fail safe design)	Checklist update on the design requirements of the pasteuriser Add information on fail safe design
3.	Milk cooling curves	Review time/temperature conditions for cooling and transport of raw milk Reference/source for storage time advised in expectations – need to clarify Clarify text to address confusion among suppliers in relation to the storage time as per Mondelez model 26 (high moisture material holding)
4.	Salt Test	Review need for salt test – current expectations do not mandate use of Salt test – currently only focuses on calculation The procedure for Salt test is not harmonized across the regions and need to determine if conversion from water to milk is required (if water meets requirement, then milk will also do this due to higher viscosity).

DAIRY PROCESSING EXPECTATION UPDATES

S.No	Area for Review/Update	Discussion
5.	Antibiotic and Adulterant testing e.g. chemical residues	Current processing expectations mentions antibiotic negative for each delivery of incoming milk however there is no clear guidance on - Lists/classes of antibiotic - MRLs - Test method recommended There is also no list of chemical contaminants and adulterants – need to clarify limits and basis of these
6.	Particle size of pasteurised material and difference in the time temperature monitoring	Some of the regulatory documents/guidance docs take into consideration particle size of the material and impact on pasteurisation. Review need to evaluate if the particle size criteria update needs to be updated in Mondelēz processing expectations.
7.	Ice cream category	Ice cream mixes to be added as a category in dairy processing expectation
8.	Additional clarity on following: • Crack test • Cut in and cut out requirements • Flow rate, pressure differentials etc	Current processing expectations does not provide clarity on the acceptable procedure for crack test and divert requirements during mentioned cases . This needs to be updated in expectations

Q&A

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QUESTIONS & ANSWERS

1. **What is the headspace temperature probe calibration frequency? what if headspace temperature was not monitored?**

   A: The calibration frequency for temperature probe should be once a year. For batch systems, the headspace should be monitored daily, to verify temperature in the air space is 3°C higher than product temperature, to avoid contamination from condensation forming and milk/foam spatters on tank ceiling. If headspace is not monitored, then a new temperature probe should be fitted.

2. **For cream cheese production, does holding time & temp identified as CCP besides CCP pasteurization?**

   A: In the Dairy Processing Expectation, there is a table 5.1, which is a pathfinder table outlining product type and Minimum Applicable Food Safety Models. There you can find appropriate CCP models which should be applied to control of biological hazard to process in your site. There are also described CCP models intended for cream cheese production.

3. **Fermentation tank area is classified as control zone or high control zone?**

   A: Fermentation tank area is classified as a high control zone.

4. **PQ tear down requirements captured in which MDLZ document?**

   A: these requirements are not captured in the current documents but will be included in the new revisions of these documents

QUESTIONS & ANSWERS

5. **POD must be done with 30 samples or it can be less?**

   A: POD to be done on 30 samples - you can start with 10 to find the lowest test pieces size, but 30 is required as a min to ensure it is Statistically sound.

6. **FRR required to pass 10% with contaminated product as per MDLZ validation excel file, correct? means if the total sample is 1000, then it should have 100 product with contaminant?**

   A: FRR - As a minimum it should be 30 test pieces passed through as product flows, but more can be used to take in to account the quantity put through.

7. **Is FRR to be done with mixture of Fe, non-Fe, and SS contaminant or individually? 30 is only for dairy or for other categories as well?**

   A: FRR this should be conducted on each test type - so for Fe, Non Fe, SS, (for a Metal Detector, only 1 type for X Ray) this is for all, not just Dairy.

   Note – a Validation PoD and FRR can be done internally or by an external company, and taking into consideration the product being produced

8. **What equipment required to perform crack test? Pasteurizer, spray dryer? At what frequency?**

   A: Crack test is required for pasteurizer (heat plate exchanger) must be carried out on a yearly basis and for spray dryer every two years.

QUESTIONS & ANSWERS

9. **Will the SQE document be updated (Peter mentioned to add the ice cream mixes)?**

   A: The SQE manual will be updated in 2020. The part related to ice cream will be included in the dairy material expectations manual which will be also updated.

10. **Ice cream to follow which PEM plan? Plan I?**

    A: Plan A, but would need to add salmonella to zones 2/3

11. **When dairy processing expectation will be available? What is implementation timing for the updates?**

    A: The plan is to implement the new revision of the dairy processing expectations manual later this year (2020)

12. **Maybe it is also good to inform a bit about the product approval it selves? (supervised / pre-shipment samples)**

    A: MDLZ R&D & procurement will share more details when setting the project

13. **How is the frequency of audits for Tier 2 suppliers? The same as for Tier 1 all 2 years?**

    A: Tier 2 suppliers are audited when new, once they are approved, a GFSI certification and the report are needed every 2 year to grant the re-approval.

QUESTIONS & ANSWERS

14. **Crack test for the spray drying Equipment. the frequency is each 2 years no matter the type of Equipment (insulated...)?**

    A: Crack test of the spray drying equipment (each type) must be carried out at a frequency of every two years. The test shall be performed with a 100% inspection of the spray drier.

15. **What is the time frame for establishing the amended documents? Please mark the updates in the documents.**

    A: The plan is to implement the new revision of the dairy processing expectations manual later this year (2020)

16. **What is meat by : position of DV continuously monitored?**

    A: This means that the position of divert valve device must be all the time monitored and recorded to ensure it is closed during the pasteurization/production and prevent any contamination of the pasteurized material by the non-pasteurized material

QUESTIONS & ANSWERS

17. **Are you aware of the research of Ellen Wemmenhoven which proofs Listeria does not grow in Gouda like cheeses? and therefore is not as high a risk as RTE meat? would you re-consider the Tier 1, if you have this proof?**

    A: We are aware of the publications from Ellen but have not reviewed the specific study looking at Gouda-like cheeses. If there is good evidence from peer-reviewed publications to show that a pathogen is not a concern in a particular raw material, we would re-consider that risk rating that this material has been given if we believe it is not appropriate and better fits with another rating.

18. **Could you please tell us more about that salt test? Can that salt test be performed by external company? how often should it be performed?**

    A: The salt test is used as a direct measure of the flow rate of the material going through the pasteurizer. It is performed by filling the equipment with water and sodium chloride (NaCl) solution, the conductivity of the material is then measured at the exit (end) of the pasteurizer. This measurement gives a good estimation on how quickly the material goes through the equipment and allows direct correlation with the flow rate. The salt test can be performed by an external company.

    The salt test is not mandatory as per MDLZ SQE. Indeed the focus is currently on the theoretical calculations. However, if the holding time is defined based on the salt test results, then the test should be part of the validation or re-validation of the kill step and performed at least every 2 years or when a major change occurs (equipment/process or installation).

THANK YOU

More questions?:

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