CCP Management For Dairy Suppliers

February 2015

Overview

- Pasteurization definitions and types of heat treatment devices
- MDLZ International Heat treatment examples
- Background to CCP validation
- Verification

Continuous systems

- Verification and monitoring activities
- Temperature requirements
- Flow and holding time considerations
- Flow diversion device, balance tank, plates, cooling considerations
- Corrective actions

Batch systems

- Verification and monitoring activities
- Temperature and time requirements
- Batch considerations
- Corrective actions
- Operator requirements
- Examples of CCP issues

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Definitions

Continuous-flow pasteurisation: A system in which a product passes in a continuous flow through heating and cooling equipment in order to receive the required heat treatment, can incorporate regeneration sections in which there is transfer of heat between the hot pasteurised product and incoming raw product .

Batch pasteurisation: A volume of milk that is heated and cooled uniformly to achieve pasteurisation.

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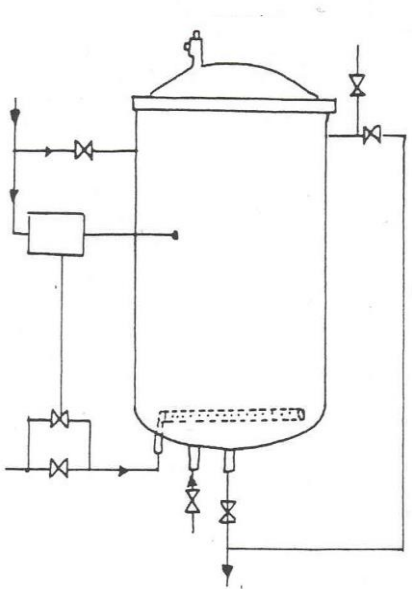
Types of Heating Devices



Batch system without hold tube

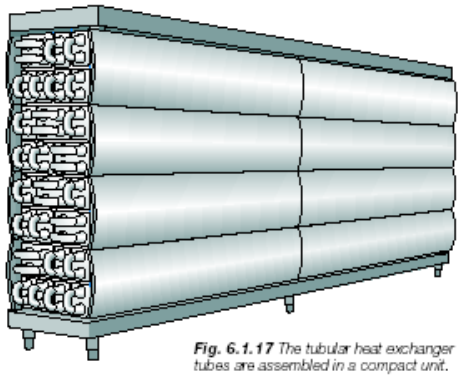


Fig. 6.1.17 The tubular heat exchanger tubes are assembled in a compact unit.

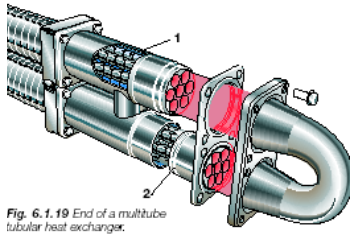
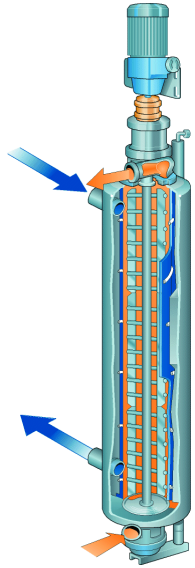


Fig. 6.1.19 End of a multitube tubular heat exchanger.

Tubular heat exchangers



Scraped heat exchanger

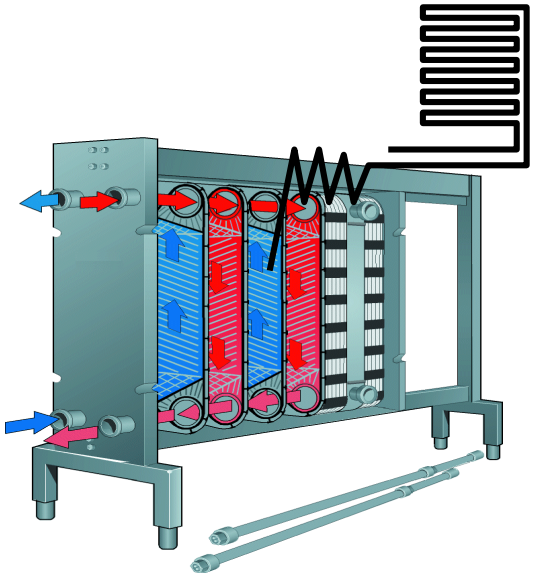


Plate heat exchanger with hold tube

1.1. Definition of milk pasteurization:

The terms "pasteurization", "pasteurized" and similar terms shall mean the process of heating every particle of milk or milk product, in properly designed and operated equipment, to a minimum specified temperature for a minimum pre-defined time.

Product	Time/Temperature Combination*	Z value (°C)	Min effective temperature (°C)	Reference
Milk (Batch process)	63°C, 30mins	6.3	63	Mondelēz model CCP2 (Pasteurisation Batch dairy expectations)
Milk (Continuous process)	Various: 72°C, 15.0 seconds	6.3	72 (temperature may be driven by equipment limitations such as the length of the holding tube)	Mondelēz model CCP1 (Pasteurisation HTST/HHST)

*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).

*If the receiving material is “pasteurized or unpasteurized concentrate”, please refer to table 5.1 from Dairy processing expectations for applicable time/temperature requirements.

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Table 5.1 Example of MDLZ International Heat treatment time and temperature requirements for concentrated products.

[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°)
[11,24] Pre-pasteurised concentrate after transport from another location(whey or skim milk >24%, or whole milk > 30%)	Target organism: Salmonella Senftenberg 775W	Follow CCP1 using 72°C/ 82 sec (z=8C°)

Note: All Dairy material received by a plant, whether pre-pasteurised or raw must undergo a heat treatment.

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General background to Validation of CCP Heat Treatment

- 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.
- Description of heating process such as plate heat exchanger, steam jacketed vessel
- Position of probes and valves
- Type of agitation (batch)
- 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.
- System validate under worse case scenario: e.g. max flow rate, product flow type.

Verification of Heat Treatment

- To verify the effectiveness of the heat treatment operational monitoring and testing procedures must be followed.

Why?

- Provides evidence that the specifications set through validation continue to be met during processing.

- Competency of personnel conducting the verification should be available in accordance with food safety program requirements.

Section1: Continuous Heat Systems

Verification activities and calibration requirements around CCP equipment –Continuous heat exchangers

Verification checks	Frequency and Reason	Monitoring	Equipment Calibration/Verification	Frequency
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	CCP Temperature probes, *consider the tolerance of the probes to set up the critical limits.	Yearly
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 Continuously monitored	Verification of FDD (valve change at critical limit) and chart recorder time ,reaction time for FDD, and alarms	Yearly
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	Verification of the holding time by direct measurement e.g. salt test	Yearly
Pressure difference	Daily, to verify that pressure is 1PSI higher on pasteurized side compared to raw, ensuring no cross contamination occurs over the production.	Continuous is preferred.	Pressure probes, and crack test of plates in heat exchangers	Yearly
Pasteurization records	Daily to verify that pasteurization was not compromised.	N/A		

Continuous= <1sec

Note: Calibration frequency should be aligned to local regulation if stricter than MDLZ International requirements.

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Types of Heating Equipment and Daily Checks required.

Types of heating systems	Temperature	Pressure	Cut in Cut out	Flow rate	Records
Plate heat exchangers	yes	yes	yes	yes	yes
Tube heat exchangers	yes	N/A	yes	yes	yes
Scraped heat exchangers	yes	N/A	yes	yes	yes
Batch systems- without hold tube	Yes	N/A	N/A	N/A	yes

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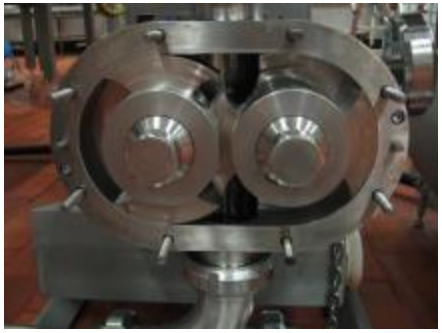
Time /Flow Requirements

Flow meter: Flow rate must be continuously monitored and recorded.

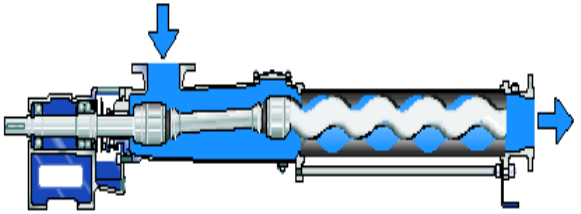
Timing pump: Record flow once per shift, after speed changes or check seal daily if required by authority.

- Residence time needs to be calculated at the maximum flow rate and ensure this is not exceeded during production.
- Flow must be verified regularly (min once per year, or more frequently if required)
- Risk of extraneous matter/ lubricants needs to be assessed /wear and tear depending on the pump type may affect the max speed of flow.

Centrifugal pump



Positive displacement pump



Screw/ mono pump

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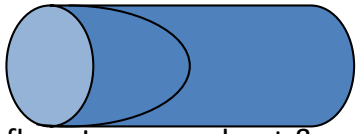
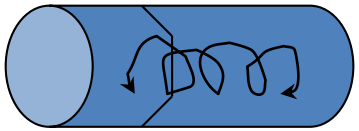
Residence time considerations: Why is the type of Flow important to consider when establishing residence time for critical limit?

→ **Laminar flow (worst case scenario) :** Velocities are maximum at center of tube. Maximum speed is 2X the average speed. Gives wide distribution of residence time. We divided the calculated holding time by 2 when we considerer a laminar flow



Streamline Flow
Re= <2100

→**Turbulent flow:** Irregular flow. Increases heat & mass transfer efficiency and flatter velocity gradient profile. We divided the calculated holding time by 1.2 when we considerer a turbulent flow



Turbulent Flow
Re= >4000

e.g. milk/skim milk will have a flow like water (turbulent), increase viscosity of products changes flow from turbulent to laminar e.g. concentrated products, cream, ice-cream.

Note: If flow type is not determined then laminar flow must be used as worst case scenario.

How to calculate the residence time/length of holding tube

When determining the type of flow in the system the actual characteristics/ properties of the product instead of water must be taken into consideration.

Examples of the determination of the Flow Type using properties of Water	
Re<4000 Laminar	**Re>4000 Turbulent**
V= Q/ A A- area in m^2 (hold tube) Q- flow in m^3/ s V- velocity in m/s	**V= Q/ A** A- area in m^2 (hold tube) Q- flow in m^3/ s V- velocity in m/s
V= (4xQ)/(ΠxD²) D- diameter of the tube in m	**V= (4xQ)/(ΠxD²)** D- diameter of the tube in m
Re= (VxD)/v v- kinematic viscosity (m^2/s)= μ /ρ	**Re= (VxD)/v** v- kinematic viscosity (m^2/s)= μ /ρ
μ in kg/(ms)- water at 75C=0.000378Kg/(ms) ρ in kg/m^3- water at 75C=974.68kg/m^3	μ in kg/(ms)- water at 75C=0.000378Kg/(ms) ρ in kg/m^3- water at 75C=974.68kg/m^3
Ex 1: Q= 10l/min= 0.01 m^3/hr= 0.000167m^3/ s or 0.08505247 m/s length= 1.5m d= 50mm= 0.05m A= ΠxD²/4 μ in kg/(ms)- solution at 75C=0.00282Kg/(ms) ρ in kg/m^3- solution at 75C=958kg/m^3	**Ex 2:** Q= 40l/min= 0.04 m^3/hr= 0.000667m^3/ s or 0.3397006 m/s length= 1.5m d= 50mm= 0.05m A= ΠxD²/4 μ in kg/(ms)- water at 75C=0.000378Kg/(ms) ρ in kg/m^3- solution at 75C=958kg/m^3
v=2.9436E-06 m^2/s V=0.08509554 m/s	v=3.8782E-07 m^2/s V=0.33987261 m/s
Re= 1445 (Laminar flow)	**Re=43818 (Turbulent Flow)**
Efficiency factor (η) = 0.5 standard when flow is laminar.	**Efficiency factor (η) = 0.83 standard when flow is turbulent.**

How to calculate the residence time/length of holding tube

Once the type of flow has been established it is then possible to determine either the length of the holding tube or the residence/holding time from the calculation below.

1. $V = \frac{Q \times HT}{3600 \times \eta}$ dm³ 2. $L = \frac{V \times 4}{(\Pi \times D^2)}$ dm	Q = flow rate of pasteurization, L/hour HT = holding time, seconds L = Length of holding tube, dm D = inner diameter of holding tube, dm V = volume of milk, dm or L η = efficiency factor

Note: The correlation flow rate/holding time for the fastest particle must be documented and filed with the HACCP plan based on minimum temperature and maximum flow rate. Correlation of time to flow rate can be expressed as Litres per hour.

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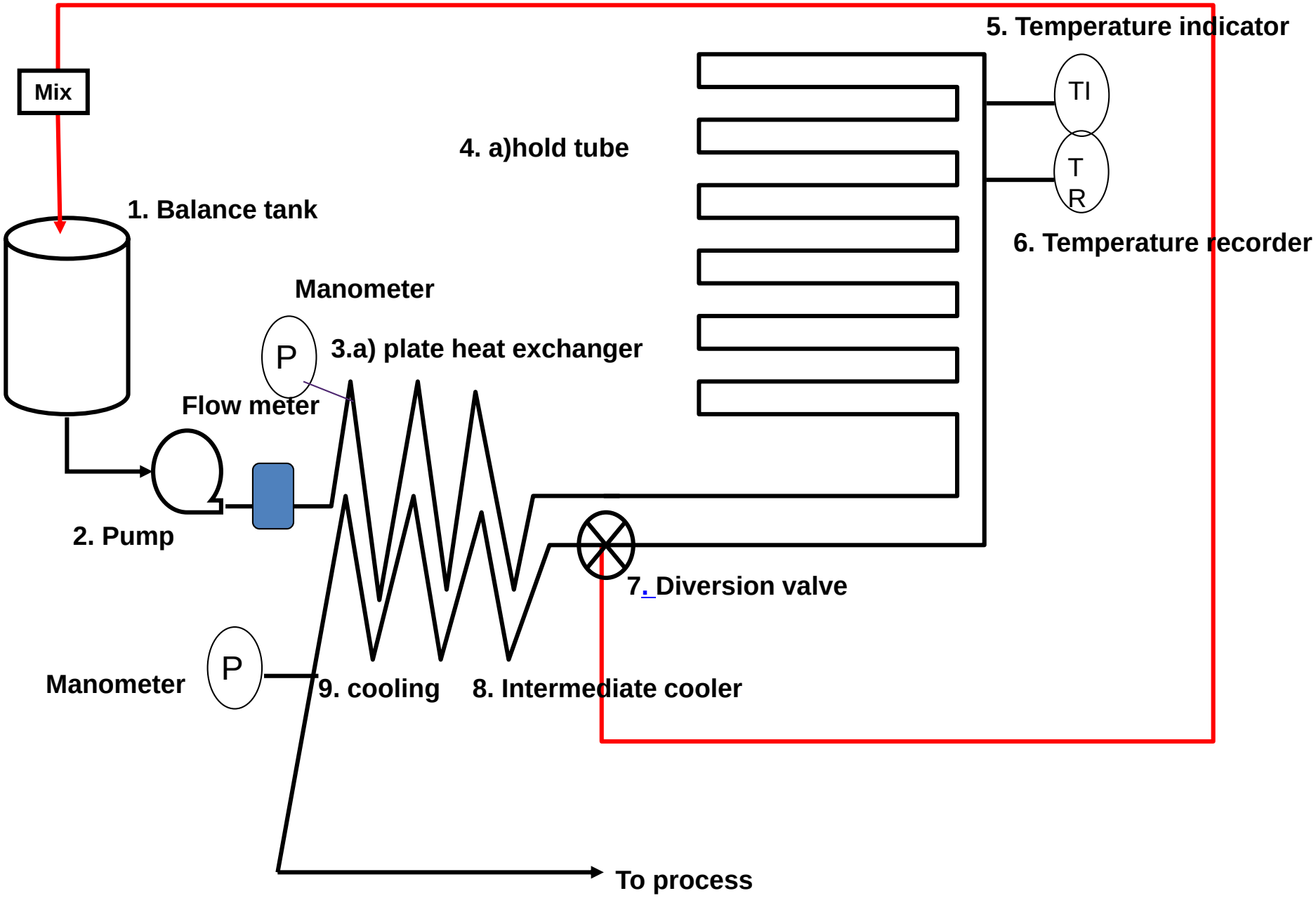
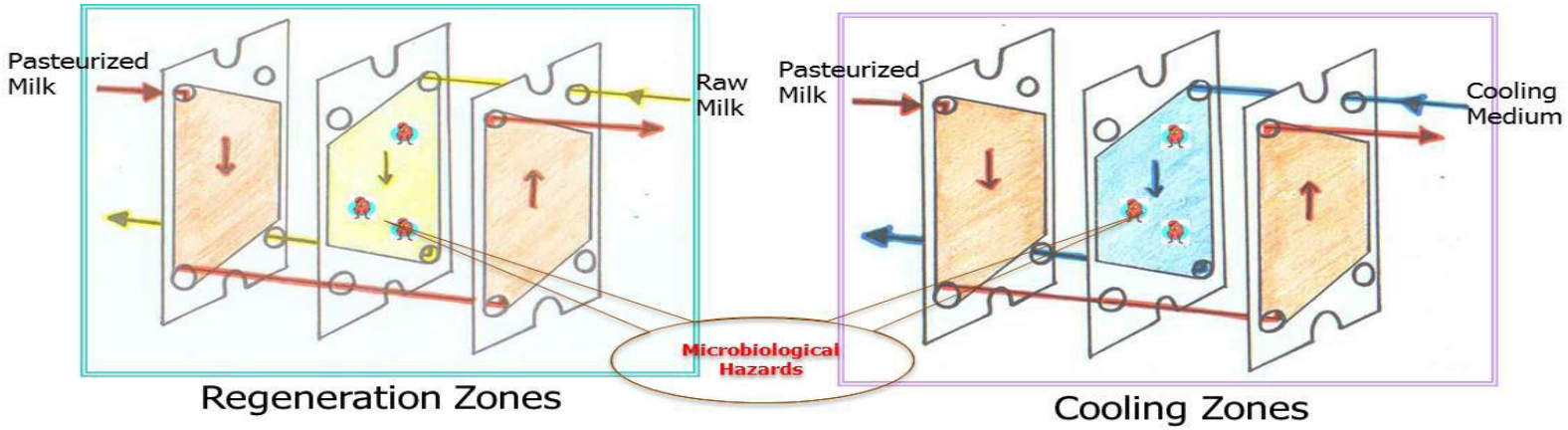
Basic pasteurization process:



Key Equipment considerations: Plates of heat exchangers

- Micro leaks in plates/gasket leaks- when using for heat regeneration product to product **Must** maintain positive pressure differential on treated product side 1PSI , even in start-up/shut down or divert- continuous monitoring preferred.
- Maintenance: Integrity testing of plates
- Fouling of plates, increasing limiting factor to heat transfer efficiency (Cleaning in Place)
- Pressure drops (due to changing viscosity of product)
- Water used as the heat regeneration medium (temperature control and water quality checks)



Note: Alternative systems such as duo safety plates can be used and then pressure does not have to be monitored.

Key Considerations: Cooling Section

- Chemicals used can be a source of chemical contamination of the product
- Cold water used must be in water testing program
- Cooling section maintenance

Key Flow considerations: Holding tube

A tube of sufficient length to guarantee the minimum residence time of the product to achieve the desired lethality.

- Must be designed to achieve maximum flow and minimum temperature.
- Divert valve distance from hold tube must be sufficient to react to drop in temperature.
- Recommended to be made of non-removable sections, sloped to avoid air entrapment and give uniform flow.

Note: If multiple tubes are available for different recipes then the correct length must be verified before start of production.

Temperature Requirements

- Temperature must be monitored at the coldest point in your system.
- Product temperature must be continuously monitored and recorded.

Temperature Indicator	Temperature Recorder
Accuracy needs to be checked minimum once per year • Most accurate temperature device • Probe should be in product and not in the heating medium. • Annual Calibration/verification of thermometer accuracy must be carried out over correct temperature range. • Indicating probe must be at the end of the holding tube, coldest spot.	**Accuracy needs to be checked minimum once per year** • Difference shall not be >0.5°C compared to the indicator thermometer • Annual Calibration/verification of thermometer accuracy must be carried out over correct temperature range. • Has to be in close proximity to the indicator to avoid temperature deviations. • Must be able to activate the diversion valve.

Note: The frequency of calibration shall be as often as is necessary to maintain the accuracy within the limits described.

Key Considerations: Flow diversion device

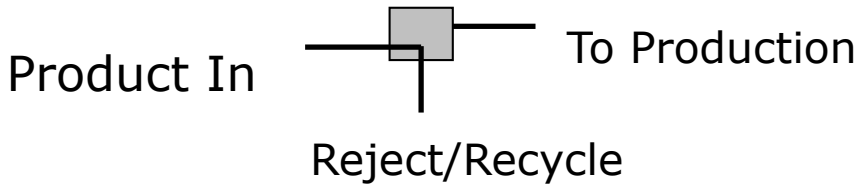
Flow diversion device is designed to change the direction of product flow when either temperature is lower than minimum (and flow higher than maximum when flow meter is available).

- Can be located after the holding tube or after the cooling section. Function must be automatically triggered (usually by compressed air).

Note:

- If after the hold tube and before cooling, distance must be sufficient to allow activation of the valve before under processed product reaches it
- If after the cooling any deviation must lead to CIP
- Position must be continuously monitored and recorded and temperature activated.
- Maintenance of the seals of valves are crucial to avoid cross contamination risk by the under processed product.
- Daily cut in cut out to verify valve functionality is required.

Fail safe design valves: when valve fails flow would be rejected/ diverted



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Balance tank considerations

Balance tank regulates flow of product into the pasteurizer holding the supply of untreated product.

- Holds raw product overflow during operation (e.g. during divert)

Risks

- Siphon untreated product back along divert valve pipe e.g. when the return pipe is in contact with the raw product.
- Extraneous matter (metal/metal contact) or chemical contamination from cooling fluid (e.g. glycol in jacketed tank)/ check tank design

Corrective actions CCP Management
Continuous systems

- Under processed product shall be automatically diverted and reheated or discarded.
- Under pasteurised product found by documentation review = Category 1 hold.

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

- Hold and release required and corrective actions to be documented

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

Section 2: Batch Systems Requirements

Verification activities and calibration requirements around CCP equipment –Batch systems

Verification checks	Frequency and Reason	Monitoring	Equipment Calibration/Verification	Frequency
Temperature of heat treatment	Daily to verify correct heat treatment was applied	Continuous or manual recording.	Coldest spot study	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	Thermometer and recording devices	Yearly
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	Holding time accuracy	Yearly

*Continuous= <1sec

Note: The frequency of calibration shall be as often as is necessary to maintain accuracy within the limits described. Calibration frequency should be aligned to local authority requirements if more stringent than MDLZ International requirements.

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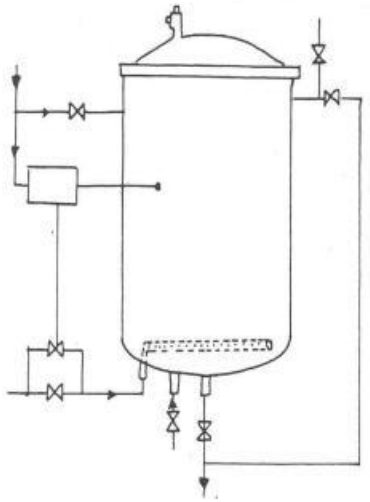
Time and Temperature requirements-Batch

- **Time:** Monitor that the right time for a specific recipe has been used.
- Coldest point or measured in a location representative for the entire batch.
- Product temperature can be monitored either continuously or manually.
- Airspace thermometer is required in batch systems (continuous monitoring, and air temperature 3˚ C above product temperature.

Note: Documentation of cold spot must be part of the plant HACCP plan.

Reminder

- Inlet piping must be disconnected after batch pumping is complete.
- Half-batches: Difficult to maintain uniform high temperature, particularly if lid is not insulated.



Corrective actions CCP Management

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.

- Under pasteurised product found by documentation review = Category 1 hold.

- Hold/Release documentation is required.
- Corrective actions must be documented.

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

Operators of any CCP heat treatment

- Heat treatment equipment operation, is a critical process in the production of safe Dairy products.

- Operators must be suitably trained to monitor, interpret records and take corrective actions and preventative actions when necessary.

- Must be able to demonstrate that the operators of HTST pasteurisers and other heating equipment have completed suitable training

“Plant must be able to show that operators have been assessed as competent.”

CCP Management Issues

Temperature issues

CCP Thermometers located at start of the holding tube, therefore not in the coldest spot.

Monitoring cracks

Pressure differences not monitored on the system

Annual crack tests not performed

Records

Daily verification activities of pasteurization records not carried out.

Cross contamination issues

CIP not performed when divert was located at end of cooling section

Divert Valve Issues

Divert not always checked daily as required or not continuously monitored.

Divert valve being triggered by a thermometer located before the holding tube.

Actual position of the valve not continuously monitored

Flow/time issues

Production Flow exceeding the maximum as per documented in the theoretical calculation

Theoretical calculation missing from the HACCP

Type of flow not considered in the theoretical calculation.

Remember

CCP Heat treatment –Eliminates pathogen from the product.

Recontamination risk needs be considered and controlled.

- PEM and Zoning
- Environmental Air Filtration
- Pest Control
- Water
- Plant and Equipment Structure
- Sanitation
- Others

MDLZ Documents

- Dairy Processing Expectations
- Supplier Quality Expectations
- Supplier HACCP Manual

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.aspx

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Thank You for Listening

Questions?