Australia
New Zealand
Dairy Authorities'
Committee

ANZDAC

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Guidelines For Food Safety

Validation and Verification of Heat Treatment Equipment and Processes

FOREWORD

The development of this Guideline is an initiative of the Australia New Zealand Dairy Authorities' Committee (ANZDAC). Members of ANZDAC are:

Australian Quarantine and Inspection Service

Dairy Authority of South Australia

Dairy Food Safety Victoria

Department of Health Western Australia

New South Wales Food Authority

New Zealand Food Safety Authority

Safe Food Queensland

Tasmanian Dairy Industry Authority

This Guideline is not intended as a mandatory standard. The purpose of this Guideline is to assist industry and regulators with the implementation of food safety standards and the application of good food safety practice. Accordingly, this Guideline may require amendment from time to time in order to remain aligned with food safety standards.

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Introduction

With the emphasis on food safety within the dairy industry and the regulated implementation of HACCP based food safety programs there exists a need to ensure that heat treatment equipment such as pasteurisers are designed, installed, operated and verified in a manner that results in no untreated or partially treated milk or dairy products.

This document prepared by a working group under the direction of the Australia and New Zealand Dairy Authorities Committee (ANZDAC) was developed to provide guidance on equipment and processing parameters that are to be reviewed and assessed as part of validation and verification of heat treatment.

Systems for the validation and verification of heat treatment should be incorporated as an integral part of each dairy factory's food safety program, where critical heat treatment processes are conducted. For each heat treatment process and/or pasteuriser the dairy factory will be expected to have a program of checking and testing including procedures and recording of the results of such activities.

The requirements for the pasteurisation and heat treatment of milk and dairy products are contained in the Food Standards Code, the Export Control (Milk and Milk Products) Orders 2005 and the relevant State, Territory or Country legislation.

1 Scope

The conditions and procedures in this document apply to both continuous flow and batch heat treatment systems.

2 References

- AS 3993 - 2003 Equipment for the pasteurisation of milk and other liquid dairy products – continuous flow systems.
- D121.1, Dairy Heat Treatments – NZFSA, 2003.
- IDF Bulletin 200, 1986 Monograph on Pasteurised Milk
- Export Control (Milk and Milk Products) Orders 2005.
- Food Standards Code published by Food Standards Australia New Zealand.
- Relevant State dairy legislation

3 Definitions

Batch pasteurisation: A volume of milk or liquid dairy product heated and cooled uniformly to achieve pasteurisation

Continuous-flow system: A system in which the product passes in continuous flow through heating and cooling equipment in order to receive the required heat treatment. Such systems usually incorporate one or more regeneration sections in which there is transfer of heat between the hot pasteurised product and incoming raw product.

Headspace: The space between the surface of the milk or liquid dairy product and the lid of the heating vessel.

HTST: Hight Temperature Short Time Pasteurisation is used for continuous flow pasteurisation.

New pasteuriser for the purposes of this document is one purchased direct from the manufacturer or agent and which has not been previously used.

Note:
Any pasteuriser not conforming to this definition will be considered to be an existing pasteuriser.

4 Standards and Validation for Heat Treatment Equipment

Heat treatment processes are often designed to balance a sufficient heat treatment to achieve a safe outcome and minimal heating effect on the quality and flavour of product. This minimum treatment means that the process should be tightly controlled to ensure that the equipment design and operation are working effectively.

In some cases the intensity of controls can be reduced by increasing the heat treatment so that there is a wider safety margin. For example where milk or milk products are heated to greater than 85°C it may not be necessary to monitor holding time, dependent on fat content and particle size.

4.1 Heat Treatment Equipment

HTST pasteurisers

It is expected that all new HTST pasteurisers, not including vacreators, used for the pasteurisation of milk and the manufacture of dairy products should meet the AS 3993 - 2003 requirements.

Existing pasteurisers are expected to meet the retro-fit standard described in Appendix C as a minimum.

Other Continuous Flow Heat Treatment Systems

Continuous flow heat treatment systems which are not HTST, such as UHT and vacreators, should ensure the following:

- The equipment should include:
  - an indicating thermometer, so that the temperature can be monitored during processing,
  - a continuous recording device for time and temperature.
- Equipment needs to ensure that raw or partially treated product cannot contaminate the pasteurised product
- Equipment needs to ensure that services, such as cleaning systems, cannot contaminate the product.

Batch pasteurisation

Design of batch pasteurisers should take into consideration the following:

- Vessels should be enclosed during operation to ensure both product and headspace temperatures meet the temperature specified in the approved food safety plan, and to protect product from contamination with condensate or extraneous matter.
- Vat agitation should be sufficient to ensure that the temperature throughout the vat is constant and uniform.
- Outlets and fittings should be designed to ensure that there are no dead spots where product may not be effectively heat treated.
- The equipment should include:
  - an indicating thermometer, so that the temperature can be monitored during processing,
  - a continuous recording device for time and temperature (such as a data logger), and
  - a head space thermometer.

- Equipment needs to ensure that raw or partially treated product can not contaminate the pasteurised product (this is included to ensure that raw milk from the feed line can not drip into the vessel during or after pasteurisation).
- Filters to control particle size may need to be installed where ingredients which have not been pre-treated and with variable particle size are added such as addition of fresh fruit.
- Equipment needs to ensure that services, such as cleaning systems, cannot contaminate the product.

All heat treatment equipment shall comply with Food Standards Code Chapter 3 Food Safety Standards 3.2.3, clause 12.

All dairy factories should provide documented evidence to verify that the heat treatment equipment complies with these standards.

4.2 Validation of Heat Treatment

Information should be available to describe how the heat treatment system has been designed to ensure that it is effective; this is the validation. The following information should be available for all heat treatment processes, including HTST, UHT and batch:

4.2.1 Provide information on design of equipment, generally through a schematic diagram but simple processes maybe described. This should include (where applicable):

- Description of heating process *such as plate heat exchanger; steam jacketed vessel; stove top.*
- Position of temperature probes;
- Type of agitation;
- Product flow and line connections identifying that raw and pasteurised product is separated; and
- Evidence of assessment of potential processing risks *such as dead spots where heat treatment may not be effective.*

4.2.2 Provide heat treatment critical limit specifications showing assessment of critical inputs relating to products and source of validation information. This information should identify:

- Time and temperature of heat treatment *such as minimum 72°C for 15 seconds or 63°C for 30 minutes, for whole milk.*
- Description of product(s) being heat treated, there may be different critical limits for each product *eg milk and cream should have different heat treatments.*
- including fat content and particle size for each product type. Refer to Appendix B.

The process must show compliance to the Food Standards Code Standard 1.6.2, an extract is provided in Appendix A.

Information on heat treatments equivalent to pasteurisation for common types of dairy produce is provided in Appendix B.

4.2.3 Document corrective action and controls to be implemented when the system is found to be non-compliant. This information will generally be contained within the food safety program.

4.3 Verification of Heat Treatment

To verify the effectiveness of heat treatments operational monitoring and testing procedures should be followed. This provides evidence that the specifications set through validation continue to be met during processing. Evidence of competency of personnel conducting verification should be available in accordance with food safety program requirements. Alternative verification systems may be applied, and are expected to achieve an equivalent outcome. These proposals may be assessed and approved by your Regulatory Authority.

4.3.1 Provide evidence of Certification of compliance of HTST pasteurisation equipment to AS3993-2003 conducted by competent technical personnel, such as a qualified engineer.

4.3.2 Monitoring of pasteurisation and verification of equipment should be conducted as follows:

- **HTST** as documented in appendix A of AS 3993-2003. The following is a summary of these checks which are described in detail in the AS 3993-2003:
  - Comparing indicating and recording thermometer readings;
  - Operation of diversion and alarms;
  - Operation of recording systems;
  - Thermometer and pressure gauge calibration;
  - Verification of integrity of heat transfer surfaces;
  - Heat exchanger gaskets;
  - Verification of holding time by direct measurement;
  - Diversion response time;
  - Leak paths (if appropriate);
  - Operation of pressure differential diversion (if appropriate);
  - Pressure differential control systems (if appropriate);
  - Secure medium integrity (if appropriate).
- **Other Continuous flow systems**

  Daily - These checks are to be completed and recorded each time the heat treatment equipment is used:
  - Product temperature monitoring recorded continuously during heat treatment.
  - Compare indicating thermometer (product temperature) reading to recording thermometer reading. If the difference is more than 0.5°C corrective action should be taken (as per food safety program).

  Six Monthly
  - Calibration of thermometers and recording devices including accuracy of time recording (as per food safety program). Thermometer accuracy should be within 0.5°C.

- **Batch pasteurisation**

  Daily - These checks are to be completed and recorded each time the pasteuriser is used:

  – Product temperature monitoring recorded continuously during heat treatment.

  – Headspace temperature monitoring and recording to occur at the beginning and end of the critical temperature cycle.

  – Compare indicating thermometer (product temperature) reading to recording thermometer reading. If the difference is more than 0.5°C corrective action should be taken (as per food safety program).

  Six Monthly

  – Calibration of thermometers and recording devices including accuracy of time recording (as per food safety program). Thermometer accuracy should be within 0.5°C.

4.3.3 This verification should be conducted by suitably qualified/trained staff.

4.3.4 Records of verification activities should be retained and available for audit purposes as part of the businesses food safety program.

5 Heat Treatment Commissioning and Modification

The program of checking and testing at commissioning (verification of equipment prior to use) and following subsequent modifications ensures that heat treatment equipment is always operated for the specified product in a manner that complies with the appropriate standards. The results of the checks should be evaluated by competent technical personnel, such as an appropriately qualified engineer.

When deficiencies occur, the frequency of checking should be increased until the problem has been proven to be remedied. Any non-conforming product resulting from these deficiencies should be handled in accordance with the businesses food safety plan.

Any change that could affect any performance characteristic of the heat treatment equipment for the specified product, and the reasons for it, should be documented.

New and modified heat treatment equipment should be commissioned before they are put into normal use and then frequently checked until a record of proven calibration and reliability has been established. For continuous flow pasteurisers this should be in accordance with the AS3993-2003. For batch pasteurisers these should be the 6 monthly checks described in Section 4.3. Other maintenance operations and checks may also be conducted as is necessary to confirm the reliability of the equipment to meet the standards.

All checks should also be carried out and documented where any modifications that may affect operating conditions are made to existing heat treatment equipment.

6 Pasteuriser Operators

Pasteuriser/heat treatment equipment operation is a critical process in the production of safe dairy products. It is essential that operators of this equipment are suitably trained to monitor, interpret records and take corrective and preventative actions when necessary.

Clause 3 of Standard 3.2.2 in the Food Standards Code (Food handling - skills and knowledge) requires that a food business should ensure that persons undertaking or supervising food handling operations have:

(a) skills in food safety and food hygiene matters; and

(b) knowledge of food safety and food hygiene matters, commensurate with their work activities.

Dairy factories should be able to demonstrate that operators of HTST pasteurisers have completed suitable training and been assessed as competent. Training in heat treatment under the VET food processing certificate program is an option for demonstrating compliance to this requirement.

APPENDIX A

FOOD STANDARDS CODE – STANDARD 1.6.2 PROCESSING REQUIREMENTS

Clauses

1 Processing of milk and liquid milk products

(1) Milk must be pasteurised by –

(a) heating to a temperature of no less than 72°C and retaining at such temperature for no less than 15 seconds and immediately shock cooling to a temperature of 4.5°C; or

(b) heating using any other time and temperature combination of equal or greater lethal effect on bacteria;

unless an applicable law of a State or Territory otherwise expressly provides.

(2) Liquid milk products must be heated using a combination of time and temperature of equal or greater lethal effect on the bacteria in liquid milk that would be achieved by pasteurisation or otherwise produced and processed in accordance with any applicable law of a State or Territory.

Editorial note:
For the purposes of clause 1 of this Standard, milk and liquid milk products includes milk and liquid milk products used in the production of any cream and cream products, fermented milks, yoghurt, dried, condensed and evaporated milks, butter and ice cream.

APPENDIX B

HEAT TREATMENT EQUIVALENT TO PASTEURISATION FOR COMMON TYPES OF DAIRY PRODUCE

	All dairy produce (excluding ice cream) with						Ice Cream mixes with particles <1000 µm
	Milks with <10% fat and no added sweeteners and particles			Dairy produce with ≥ 10% fat and/or added sweeteners and concentrated dairy produce with > 15% total solids and particles			
Particle Diameter	<200 µm Ø	200 to <500 µm Ø	500 to <1000 µm Ø	<200 µm Ø	200 to <500 µm Ø	500 to <1000 µm Ø	
Minimum holding time (seconds)	Minimum Temperature (°C)						
1.0	81.6	-	-	84.4	-	-	-
2.0	79.0	81.6	-	81.8	84.4	-	-
3.0	77.6	79.0	-	80.4	81.8	-	-
4.0	76.5	77.6	81.6	79.3	80.4	84.4	-
5.0	75.7	76.5	79.0	78.5	79.3	81.8	-
6.0	75.1	75.7	77.6	77.9	78.5	80.4	-
7.0	74.6	75.1	76.5	77.4	77.9	79.3	-
8.0	74.1	74.6	75.7	76.9	77.4	78.5	-
9.0	73.7	74.1	75.1	76.5	76.9	77.9	-
10.0	73.3	73.7	74.6	76.1	76.5	77.4	85.5
11.0	73.0	73.3	74.1	75.8	76.1	76.9	-
12.0	72.7	73.0	73.7	75.5	75.8	76.5	-
13.0	72.4	72.7	73.3	75.2	75.5	76.1	-
14.0	72.1	72.4	73.0	74.9	75.2	75.8	-
15.0	72.0	72.1	72.7	74.8	74.9	75.5	79.5
30.0	70.7	70.8	70.9	73.5	73.6	73.7	-
60.0	69.4	69.4	69.5	72.2	72.2	72.3	-
Minimum holding time (minutes)	Minimum Temperature (°C)						
1	69.4	69.4	69.5	72.2	72.2	72.3	-
2	68.1	68.1	68.1	70.9	70.9	70.9	-
5	66.4	66.4	66.4	69.2	69.2	69.2	-
10	65.1	65.1	65.1	67.9	67.9	67.9	74.0
15	64.3	64.3	64.3	67.1	67.1	67.1	-
20	63.8	64.8	64.8	66.6	66.6	66.6	69.0
25	63.3	63.3	63.3	66.1	66.1	66.1	-
30	63.0	63.0	63.0	65.8	65.8	65.8	-

Notes:

1. Ø signifies particle diameter
2. Minimum holding time
   The minimum holding time is set at 1 second to give an adequate safety margin. Shorter holding times will require validation to demonstrate the effectiveness of the time temperature combination in controlling the hazard(s).
3. Lowest allowable temperature
   The pasteurising temperature given for a 30 minute holding time is the lowest allowable temperature for pasteurising the specified product types.

The information contained within this table is taken from the NZFSA, D121.1. Dairy Treatments Standard 2003. This document references original data sources.

APPENDIX C

PASTEURISER RETRO-FIT STANDARD

The minimum requirements for an existing HTST pasteuriser installation under this program are:

(i) the holding tube shall meet the requirements of clause 12 of AS 3993.2003;

(ii) where a holding section is utilised in lieu of a holding tube then the minimum temperature/time conditions (72°C/15 seconds or equivalent) are to be certified by an appropriately qualified engineer of the company supplying the unit;

(iii) the data to be recorded must include the following:

a) the time and duration of any diversion of the dairy product; and

b) the temperature of the dairy product as it leaves both the holding section and the cooling section of the pasteuriser; and

c) the length of time of each process and the hour of the day when these processes are carried out; and

d) the date and type of product being manufactured or processed; and

e) the time during which the flow diversion device is in the forward flow position; and

f) the reasons for any diversion or abnormal function of the equipment.

(iv) double diversion valves to be fitted;

(v) fittings to be provided for salt conductivity tests;

(vi) a flow rate controller is to be installed where a timing pump or homogeniser of fixed speed is NOT used;

(vii) valving is to be arranged to drop pressure in the raw side of the regeneration section to zero if the plant goes into the divert phase;

(viii) the installation of pressure gauges and throttling valves to control the discharge pressure of pasteurised product by maintaining a positive pressure against the raw side pressure to eliminate the risk of cross contamination through the regeneration section.

(ix) differential pressures are not required and do not need to be monitored in systems that have been engineered to guarantee that at all times (including equipment failure and fatigue), pasteurised milk cannot become contaminated with raw milk or non-potable water supplies. This result can be achieved, for example, by using double skinned plates, which have leak escape passages separating pasteurised milk from raw milk and non-potable water in the heat exchanger. Where this option is employed, leak escape channels shall open to the atmosphere and shall be able to be readily and routinely checked for signs of leakage. Where leakage is detected, the affected plates shall be replaced. The sterile loop system is another system which maybe applied.

Where a pasteuriser using double skinned plates or the sterile loop system is installed items (vii) and (viii) would not apply.

APPENDIX D

EXPLANATORY NOTES

These notes are designed to provide assistance and background information for the assessment of compliance to this ANZDAC document.

Section 4.1 – Heat Treatment Equipment

Batch pasteurisation – "the equipment should include a headspace thermometer."

The USFDA PMO item 16p (A) Batch Pasteurisation provides a public health reason that addresses this issue.

> "Tests have shown that when foam is present on milk or milk product in vats or pockets during pasteurization, the temperature of the foam may be well below the pasteurization temperature. In such cases, pathogenic organisms that may be in the foam will not be killed. Experience indicates that some foam is present at some time in all vats, particularly at certain seasons. Furthermore, in filling vats, milk or milk product frequently is splashed on the surfaces and fixtures above the milk or milk product level, as well as on the underside of the vat cover. Droplets of this splash may drop back into the body of the milk or milk product, and since they may not have been at pasteurization temperature for the required time, they may contain pathogenic organisms."

The auditor should also take into consideration the nature of the product/ ingredients being heat treated. In circumstances where all milk products added to the batch have already received a lethal treatment eg pasteurised milk or cream or powdered milk and no other ingredients that are assessed as high risk, such as raw eggs, are added then the auditor may consider that this is not a lethal heat treatment and therefore monitoring of headspace temperatures may not be a critical control measure.

The factory may provide evidence of validation of alternative monitoring of heat treatment to verify that the process is effective without headspace monitoring. This may include adopting an increased level of heat treatment eg higher temperature and/or longer time with a study of headspace temperatures over a period of time with continuous recording during processing. This information should be available to the auditor as a validation of the process.

Competency of Personnel – Sections 4.3, 5 and 6

Where heat treatment is a critical process designed to ensure that the product is safe for human consumption it is essential that personnel conducting verification and validation of the equipment and processes are competent.

The factory's food safety program should address personnel competency. When contractors provide certification of equipment such as compliance to the AS3993 – 2003 the factory should be provided with some evidence, from the contractor, that they have the required knowledge to perform the assessment through qualifications and/or experience.

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