

**New Zealand Food Safety Authority**  
**P O Box 2835, Wellington, New Zealand**

**NZFSA Dairy & Plants Standard**

**Circular number 77**  
*Dairy Industry Regulations 1990*

***D121.1 Dairy Heat Treatments***

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121.1	14 April 2003	Promulgated by Circular number 77	Director, NZFSA Dairy & Plants	

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## Issue of Circular and implementation

Regulation 59 of the *Dairy Industry Regulations 1990* allows the Director-General of the Ministry of Agriculture and Forestry (MAF) to issue Circulars setting out criteria for matters which must be approved by, or done to the satisfaction of, the Director-General, pursuant to the *Dairy Industry Regulations 1990*.

This Circular, no. 77, containing 'NZFSA Standard D121.1, "Dairy Heat Treatments,"' is issued in accordance with that regulation 59.

This Circular, no. 77, takes effect on 14 April 2003

This standard applies to all heat treatments where there is:

- a legal requirement for the produce to have received a defined heat treatment, i.e. thermisation, pasteurisation or UHT treatment; and/or
- a label claim for a defined heat treatment; and/or
- certification that the produce has received a defined heat treatment in accordance with standards enforced by NZFSA.

This Standard does not apply where dairy produce already heat treated in accordance with this Standard are used for the manufacture of dairy products, provided that any transport, storage and manufacture following the heat treatment is done in accordance with a NZFSA-approved PSP.

All heat treatments within the scope of this Standard will be validated, evaluated and verified in accordance with this Standard from the date of issue by Circular.

### **New and relocated heat treatment equipment and new Product Safety Programmes (PSPs)**

This Standard will apply to all new and relocated heat treatment equipment and new Product Safety Programmes (PSPs) from the date of issue by Circular.

### **Existing installed heat treatment equipment and Product Safety Programmes (PSP)**

Existing installed heat treatment equipment and Product Safety Programmes (PSP) approved under the previous regulatory requirements will need to comply with this Standard within 24 months of the date of issue, i.e. by 14 April 2005.

Between the date of issue and 14 April 2005, existing installed heat treatment equipment and approved Product Safety Programmes (PSP) must comply with either:

- the previous regulatory regime; i.e. the standards and codes that have a continued approval as listed in the next section; or
- NZFSA Standard D121.1 "Dairy Heat Treatments".

After 14 April 2005 existing, installed heat treatment equipment that fails to comply with this Standard may be used to treat liquid dairy produce used for the manufacture of dairy products providing the following conditions are satisfied:

1. The HACCP plan for the process is revised to include an interim control plan which specifically:
  - identifies the non-compliances; and
  - identifies the hazards resulting from the non-compliant equipment; and
  - identifies the control measures to reduce the hazards to an acceptable level such that the dairy product can be demonstrated to be safe; and
  - states the date that the non-compliance will be resolved; and
2. The HACCP plan is evaluated by NZFSA Compliance/Third Party Agency (TPA), and if they are satisfied the interim control plan will reduce the risk to an acceptable level, recommends that NZFSA:

- approve the interim control plan as part of the PSP; and
  - replace the existing premises registration with a registration with an expiry date and conditions permitting manufacture in accordance with the interim control plan until that expiry date.
3. NZFSA considers the recommendation and if satisfied, the Director:
- provides a letter approving the interim control plan as part of the PSP; and
  - registers the premises with an expiry date and conditions permitting manufacture in accordance with the interim control plan until that expiry date.
4. Produce manufactured in registered premises in accordance with an interim control plan:
- must not be labelled with the defined heat treatment, e.g. pasteurised, and
  - may have restricted access to importing countries and provision of export certification, refer Appendix Two.

After 14 April 2005, any produce manufactured from dairy produce treated by non-compliant heat treatment equipment, without a NZFSA-approved interim control plan as part of the PSP, is managed in accordance with MAF Standard D108 “Non-conforming Dairy Produce”.

### **Approved codes of practice and standards**

Approval for the following service categories and section is withdrawn from 14 April 2003

- Service categories Pv (validation of pasteurisation control and calibration services) and Pr (re-checking of pasteurisers between validations) and section 13 of MAF Standard MRD-Stan 1, Rev 4, “Standard for Inspection, Audit, Validation and Approval Services”.

Approval for the following MAF standards is withdrawn from 14 April 2005:

- MAF Standard MRD-Stan 3, Rev 2, “Standard for Pasteurisation Heat Treatments”
- MAF Standard MRD-Stan 4 “Standard for Checking the Operation of Pasteurisers”, except section 8 which is revoked from 14 April 2003.

Circular numbers 10, 15, 27 and 28, relating to pasteurisation, are revoked from 14 April 2005.

In Circular number 27, MAF withdrew approval for the following standards from 1 July 2001. These standards are not approved by NZFSA to deliver the outcomes of either MRD-Stan 3 and MRD-Stan-4 or NZFSA Standard D121.1 “Dairy Heat Treatments”.

- MQD 1B “Dairy Food Manufacturing Equipment”
- MQD 12 “Market Milk Code of Practice”, and

MAF had approved the following standard and codes to meet the requirements of MRD-Stan 3 and MRD-Stan 4. The standard and codes have been identified as being superseded or possibly not delivering the outcomes of NZFSA Standard D121.1 Dairy Heat Treatments. Therefore the standard and codes of practice cannot be used to comply with NZFSA Standard D121.1, “Dairy Heat Treatments”. As a consequence the approvals for the following codes of practice and standards are withdrawn from 14 April 2005:

- 3-A Accepted Practices 603-06, 1992. “Sanitary Construction, Installation, Testing and Operation of High-temperature Short-time and Higher-temperature Shorter-time Pasteuriser Systems”
- AS 3993.1, 1992. “Equipment for the Pasteurisation of Milk and Other Liquid Dairy Products; Part 1: Continuous-flow Systems”
- NZCP 7, Issue 1, 1996. “Pasteurisation Equipment and Instrumentation Code of Practice”.
- NZCP 7, Issue 2, 1996. “Pasteurisation Equipment and Instrumentation Code of Practice”.
- NZCP 7, Issue 3, 1999. “Pasteurisation Equipment and Instrumentation Code of Practice”.

Based on application, NZFSA will approve codes of practice or other standards where they deliver the outcomes of this NZFSA Standard D121.1, "Dairy Heat Treatments".

For the complete list of standards and codes approved by NZFSA to deliver the outcomes of this Standard contact NZFSA Dairy and Plant Products or check its website ([www.nzfsa.govt.nz/dairy/registers/app-stds.htm](http://www.nzfsa.govt.nz/dairy/registers/app-stds.htm))



Tim Knox  
**Director, Dairy and Plant Products**  
**New Zealand Food Safety Authority**

14 April 2003

*(Signed under authority delegated by the Director-General of MAF, pursuant to regulation 59 of the Dairy Industry Regulations 1990.)*

## Foreword

The functions of the MAF Food Assurance Authority have been transferred to the New Zealand Food Safety Authority (NZFSA), a semi-autonomous body reporting to the Minister of Food Safety. Decisions by NZFSA are under the authority delegated by the Director-General of MAF.

Existing MAF Standards are still valid and will be reissued as NZFSA documents. Until that time they are referred to as MAF Standards.

Where a PSP or code of practice has been previously approved by MAF, it is also approved by NZFSA and is referred to as "NZFSA-approved".

Under the *Dairy Industry Act 1952* and the *Dairy Industry Regulations 1990*, NZFSA is responsible for providing a framework that is adequate to provide assurances that dairy products manufactured in New Zealand are safe. Heat treatment of dairy produce is a key control step in achieving this objective.

NZFSA Standards are intended to assist the industry by interpreting the regulatory requirements, and indicating acceptable criteria for complying with the requirements and verifying compliance.

The existing MAF standards (MRD 3 and 4) for heat treatment and NZFSA-approved codes need to be updated to take account of developments since they were written and to provide clearer guidance. Therefore this revised NZFSA Standard for heat treatments is required to ensure that the heat treatments being used are effectively controlling pathogenic micro-organisms.

All product safety programmes (PSPs) for the manufacture of dairy products must include provision for the control of potentially pathogenic organisms. MAF Standard D110, "Dairy HACCP Plans", requires that PSPs for the manufacture of dairy product must include validated HACCP analyses/plans of the processes covered by the PSP. Where such HACCP analyses/plans include heat treatment as a critical control point for the control of pathogens, heat treatments operated in accordance with this standard are equivalent to a critical control point (CCP) developed in accordance with MAF Standard D110.

This Standard:

- defines the legal requirements for the defined heat treatments; and
- provides the basis for label claims for the defined heat treatments; and
- provides the basis for certification of the defined heat treatments to NZFSA Standards; and
- provides a common basis for validation, evaluation and verification.

Specifically, this Standard defines the heat treatment outcomes, and evaluation and verification requirements for:

- thermisation for cheese-making; and
- pasteurisation; and
- ultra high temperature (UHT) treatment

of all dairy produce used in the manufacture of dairy products.

This standard applies to all heat treatments where there is:

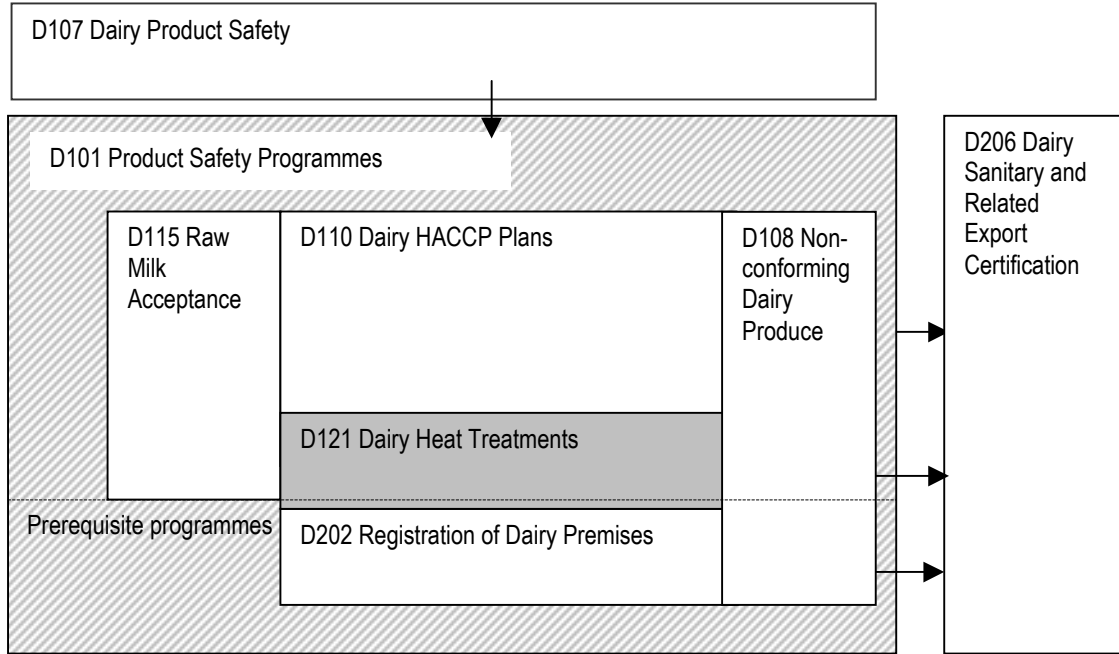
- a legal requirement for the produce to have received a defined heat treatment; and/or
- a label claim for a defined heat treatment; and/or
- certification that the produce has received a defined heat treatment in accordance with standards enforced by NZFSA.

This Standard does not apply where dairy produce already heat treated in accordance with this Standard are used for the manufacture of dairy products, provided that any transport, storage and manufacture following the heat treatment is done in accordance with a NZFSA-approved PSP.

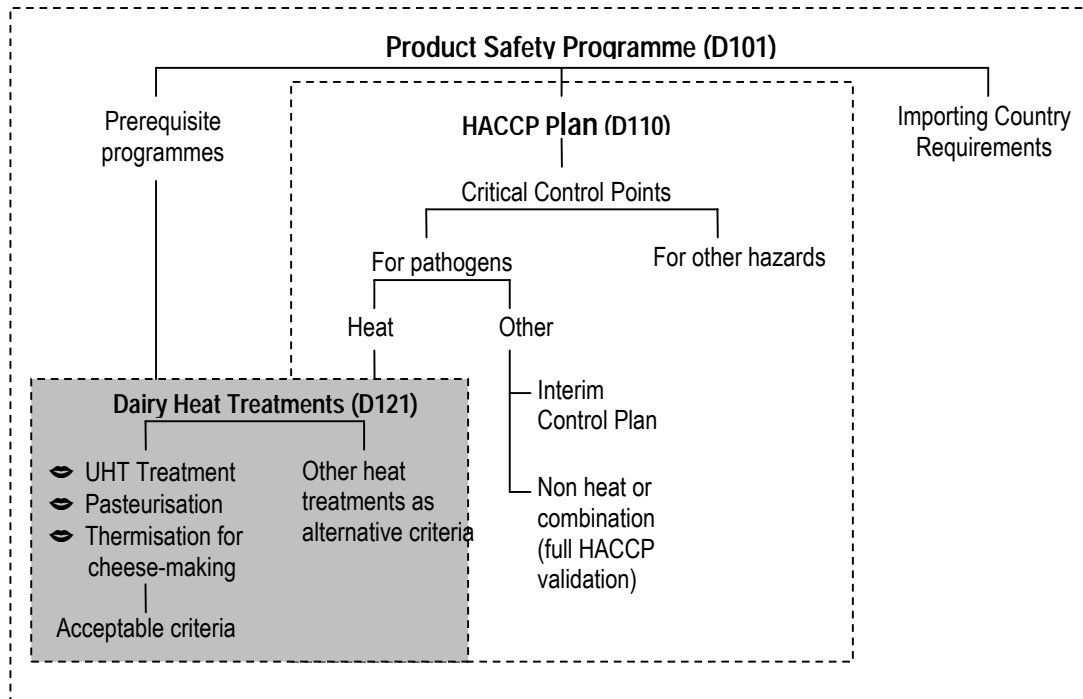
# Preface

## CONTEXT

This standard relates to other NZFSA standards as shown diagrammatically below.



The following diagram provides a more detailed overview of the relationship between this Standard (D121), HACCP Plans (D110) and PSPs (D101).



## RESOURCES

The following standards must be read in conjunction with this Standard:

- MAF Standard D101 “Product Safety Programmes”
- MAF Standard D107 “Dairy Product Safety”
- MAF Standard D108 “Non-conforming Dairy Produce”
- MAF Standard D109 “Dairy Product Conformance”
- MAF Standard D110 “Dairy HACCP Plans”
- MAF Standard D115 “Raw Milk Acceptance”
- MAF Standard D201 “Performance Measurement of Dairy Manufacturers”
- MAF Standard D202 “Registration of Dairy Premises”
- MAF Standard D206 “Dairy Sanitary and Related Export Certification”

A NZFSA Dairy operational guideline “Guideline: Dairy Heat Treatment” provides information to assist in meeting the outcomes required by this Standard. A copy of this guideline can be obtained from the NZFSA website ([www.nzfsa.govt.nz/dairy/publications/guidelines](http://www.nzfsa.govt.nz/dairy/publications/guidelines)).

## EFFECTIVE CHANGES<sup>1</sup>

This Standard will introduce the following changes to the previously existing situation:

1. This Standard defines the heat treatment outcomes, and evaluation and verification requirements for the following defined heat treatments:
  - thermisation for cheese-making, and
  - pasteurisation, and
  - ultra high temperature (UHT) treatment.
2. This standard applies where there is
  - a legal requirement for the produce to have received a defined heat treatment (thermisation, pasteurisation or UHT treatment); and/or
  - a label claim for a defined heat treatment; and/or
  - certification that the produce has received a defined heat treatment in accordance with standards enforced by NZFSA.
3. This Standard does not apply where dairy produce already heat treated in accordance with this Standard are used for the manufacture of dairy products, provided that any transport, storage and manufacture following the heat treatment is done in accordance with a NZFSA-approved PSP.
4. Outcomes for thermisation for cheese making are modified as follows:
  - Thermisation is only permitted for cheese with less than 39 percent moisture (by mass), pH less than 5.6 and with no increase in pH on ripening.
  - Thermisation for cheese making can only be used where the raw milk being treated contains low numbers of pathogenic micro-organisms.
  - The thermisation temperature and time, and cheese storage temperature have been altered to those that have a known effect on pathogens.
  - Thermisation steps are designed, installed, operated and maintained in a manner that ensures that no untreated or partially treated milk or dairy produce passes forward.

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<sup>1</sup> This section is provided to assist manufacturers to ascertain the extent of the changes that this Standard introduces. The information in this section is advisory and in all cases the Standard takes precedence.

5. The outcome for UHT treatment is modified to enable the use of time temperature combinations sufficient to ensure a commercially sterile product.
6. Heat treatment steps in other manufacturing processes, e.g. evaporation, must meet the outcomes for the defined heat treatment, e.g. pasteurisation, and be evaluated and verified in accordance with this Standard to be assessed as providing that defined heat treatment.
7. Heat treatments that are new, relocated or have undergone a significant change must be validated and evaluated before being used to treat dairy produce for the manufacture of dairy products.
8. Heat treatments are verified as part of the PSP verification.
9. The intensity and frequency of heat treatment verification depend on the verification category and level of performance of the manufacturer, unless additional requirements are specified by the competent authority of an importing country.
10. The roles and requirements of codes of practice are clarified.
11. Acceptable criteria are provided which outline:
  - criteria for heat treatments which include documentation and training, equipment, operation and reporting; and
  - criteria for validation of heat treatments by manufacturers; and
  - criteria for evaluation and external verification, including performance based verification and verification of manufacturers' regular reports; and
  - the competency requirements for heat treatment validators, evaluators and verifiers.
12. The requirement for heat treatments to comply with the importing country requirements as contained in official assurances is outlined.
13. The process performance of each of the defined heat treatments is provided to assist validation of alternative time temperature combinations for the manufacture of safe dairy products. These process performances are currently incomplete and are subject to revision.
14. A NZFSA operational guideline "Guideline: Dairy Heat Treatment" is also available which answers some frequently asked questions, provides useful references and some suggested solutions to the criteria in the Standard.

## **FUTURE INTENTIONS**

Work has commenced on amending the *Animal Products Act 1999* (APA) to include dairy operations in the scope of that legislation. This legislation places an increasing emphasis on HACCP as the means of managing hazards, such as pathogenic micro-organisms, in human food and animal feeds. The validated HACCP plan is the platform for an operator's Risk Management Programme (which is the APA version of a PSP)

The Dairy HACCP Working Group is currently redeveloping the MAF Standard D110, "Dairy HACCP Plans" to

- ensure consistent and uniform application of HACCP principles;
- ensure the integration of end product testing as part of the internal verification;
- provide for more effective use of information from existing supporting systems; and
- prepare the HACCP documentation required to support the development of Risk Management Programmes in the dairy industry.

It has been recognised that it is desirable to have more complete scientific information on the process performance (lethal effects) of the defined heat treatments. Although we have provided some information on the processes performance in Appendix Three, this information is incomplete. NZFSA Dairy is working with the NZFSA Programme Development Group to ensure that this information will be available to enable HACCP to be fully implemented in the New Zealand dairy industry.

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# NZFSA Standard D121.1, “Dairy Heat Treatments”

## 1. SCOPE

This Standard defines the heat treatment outcomes for:

- thermisation for cheese-making, and
- pasteurisation; and
- ultra high temperature (UHT) treatment

of dairy produce, used in the manufacture of dairy products.

This standard applies to all heat treatments where there is:

- a legal requirement for the produce to have received a defined heat treatment; and/or
- a label claim for a defined heat treatment; and/or
- certification that the produce has received a defined heat treatment in accordance with standards enforced by NZFSA.

This Standard does not apply where dairy produce already heat treated in accordance with this Standard are used for the manufacture of dairy products, provided that any transport, storage and manufacture following the heat treatment is done in accordance with a NZFSA-approved PSP.

Importing country and export certification requirements may place additional requirements on the heat treatments used in the manufacture of dairy products and dairy produce. Further information is provided in Appendix Two.

## 2. DEFINITIONS

NZFSA Dairy & Plant Products Group definitions of terms can be found in their “Glossary of Terms,” available on the Dairy & Plants website ([www.nzfsa.govt.nz/dairy](http://www.nzfsa.govt.nz/dairy)).

These definitions must be read in conjunction with the interpretations in the *Dairy Industry Act 1952* and the *Dairy Industry Regulations 1990*.

**Acid food** – A food that has a natural pH of 4.6 or below.

**Acidified low-acid food** – A food which has been treated so as to attain an equilibrium pH of 4.6 or lower after heat processing.

**Aseptic processing and packaging** – is the processing and packaging of commercially sterile product into sterilised containers followed by hermetic sealing with a sterilised closure in a manner which prevents viable microbiological recontamination of the sterile product.

**Clean** – Free of soil, food residue, dirt, grease, cleaning or sanitising agents or other objectionable matter.

**Code of Practice** – Document developed and owned by industry, which sets out means of meeting regulatory requirements. Codes of Practice may be approved by NZFSA as the basis for satisfying all or part of the dairy industry regulatory requirements.

**Critical Control Point (CCP)** – A step (in a process) at which a control can be applied and is essential to prevent, eliminate, or reduce a food safety hazard to an acceptable level.

**Critical non-compliance** – An action, event or omission which may result in:

- Failure of dairy produce to comply with regulatory requirements;
- Failure to follow the lawful direction of an Inspector;
- An alleged offence against the *Dairy Industry Act 1952* or *Dairy Industry Regulations 1990*;
- A critical situation;
- Failure of a critical control point within a NZFSA-approved programme or plan;
- Failure to identify when dairy produce is non-conforming;
- Failure to stop a non-compliance;
- Failure to keep accurate and complete records;
- Failure to provide accurate, complete, and timely reports;
- Failure to dispose of non-conforming dairy produce in compliance with regulatory requirements;
- Failure to prevent recurrence of a non-compliance; and/or
- Failure to rectify a non-compliance within the specified timeframe.

**Commercial sterility** – The absence of micro-organisms capable of growing in the food at normal non-refrigerated conditions at which the food is likely to be held during manufacture, distribution and storage.

**Dairy produce** – Milk, cream, butter, cheese, and any other product of milk or cream.

**Dairy product** – Dairy produce intended for sale in, or export from, New Zealand for human consumption; and

- a. includes raw milk or cream intended for sale in New Zealand for human consumption as raw milk or cream<sup>2</sup>; but
- b. does not include raw milk or cream intended to be processed before sale in New Zealand for human consumption.

**Dairy manufacturer** – Operator of a manufacturing unit processing dairy produce (dairy factory). Where the term “manufacturer” is used, this means dairy manufacturer in accordance with this definition.

**Designated Person** – An employee of the organisation covered by a NZFSA-approved programme (e.g. PSP, QCP), who is authorised by the accountable person to:

- evaluate HACCP monitoring data and take corrective action where necessary; and
- sign summaries of records and copies of records and test reports on the accountable person’s behalf.

**Evaluation** – Assessment of an individual, plan, programme, or system to determine compliance with regulatory requirements. This will involve review of documentation and, in some cases, review of operations or observation of practice. It is undertaken by a competent individual contracted to an impartial agency (e.g. TPA or Assessor, NZFSA Compliance).

**HACCP** – Hazard Analysis and Critical Control Point system adopted by the Codex Alimentarius Commission. HACCP is a systematic identification of hazards and the measures for their control to ensure the safety of food. It focuses on prevention rather than end-product testing.

**HACCP Plan** – A documented system, prepared in accordance with the principles of HACCP, to ensure control of significant food safety hazards in a food handling process.

**HAZOP** – Hazard Analysis and Operability Review. A systematic identification of possible hazards and operational difficulties in relation to plant and equipment design.

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<sup>2</sup> Under section 11A of the Food Act 1981 a milk producer may sell raw milk to any person if:

- (a) It is sold—
  - (i) At the producer’s dairy premises; and
  - (ii) In a quantity not exceeding 5 litres at any one time; and
- (b) The person intends the milk for consumption by the person or the person’s family;— and the person may buy it accordingly.

**Heat treatment** – the use of heat as a critical control point for the control of pathogenic micro-organisms. The term “heat treatment” includes the heat treatment equipment, drawings, manuals, operating and maintenance plans/procedures, training and validation programmes, and records.

**Heat treatment equipment** – all equipment, including control systems/automation, used for heat treatment.

**Low acid food**– Low-acid food means any food, other than alcoholic beverages, where any component has a pH value greater than 4.6 and a water activity greater than 0.85.

**NZFSA Compliance** - The Compliance and Investigation Group of NZFSA, reporting to the Director, Compliance and Investigation.

**Non-compliance** – Any failure to comply with regulatory requirements.

**Safe** – In relation to any dairy product, ‘safe’ means satisfactory, fit for human consumption, and not having in it or on it any pathogenic organisms

- (a) That are present in an amount that makes the product harmful or injurious to the health of the people who may eat or drink it; or
- (b) That
  - (i) Are not present in an amount that makes the product harmful or injurious to the health of the people who may eat or drink it; but
  - (ii) By virtue of their ability to reproduce, to produce toxins, or both, make the product potentially harmful or injurious to the health of the people who may eat or drink it.

In relation to any dairy produce that is not a dairy product, ‘safe’ means satisfactory, and fit for the manufacture of dairy products.

**Sanitary** – The number of micro-organisms in the environment is at a level that does not compromise product safety or wholesomeness.

**Significant change** – Any change made to key staff, environment, premises, equipment, control systems/automation, facilities, process or product that may affect food safety.

#### *Commentary*

*The NZFSA Dairy operational guideline “Guideline: Dairy Heat Treatment” provides some examples of significant changes related to heat treatments.*

**Stove-top heat treatment** – a non-automated heat treatment undertaken in a vessel without fittings for pipe-work, e.g. a saucepan.

**Third Party Agency (TPA)** – Organisation approved by NZFSA to carry out evaluation and/or verification services.

**Wholesome** – Dairy produce that is free of any characteristic that renders it offensive or unpalatable to the consumer, including anything that is decomposed, dirty, rotten, spoiled or diseased, or affected by any disease, objectionable taint or smell or containing any foreign matter.

**Validation** – Obtaining evidence that the elements of the HACCP plan are effective.

**Verification (external)** – Application of methods, procedures, tests and other checks, in addition to monitoring, to determine compliance with NZFSA-approved plans, programmes and systems, and to confirm the ongoing applicability of those.

### 3. OUTCOMES

The heat treatment reduces the number of pathogenic micro-organisms to an acceptable level, that together with other measures, results in a safe dairy product in accordance with a Product Safety Programme approved under regulations 3, 4, 6(2), 9(b, d, e, f, g, j, k, l, and m) and registered premises that meet the criteria in regulations 17(f, g, and i) of the *Dairy Industry Regulations 1990*.

#### 3.1 Heat treatment requirements

Dairy produce used for the manufacture of dairy products is demonstrated to have received a defined treatment when it has been heat treated using properly designed, installed, operated, and maintained heat treatments in accordance with

- the following:
  - defined heat treatments and associated requirements; and
  - limits on produce contamination; and
  - requirements for further processing and cooling; and
- the procedures and records for the heat treatment contained in the PSP.

Heating and holding steps in some manufacturing processes may provide adequate heat treatment to ensure product safety. These manufacturing processes are considered to provide the defined heat treatment when:

- the defined heat treatments and associated requirements provided in section 3.1.1 for the defined heat treatment are demonstrated to be met during the manufacturing process, and
- all other requirements for the defined heat treatments (refer sections 3.1.2, 3.1.3, 4 and 5) are met.

##### *Commentary*

*Examples of heating and holding steps, which may provide heat treatment with the same process performance as pasteurisation, include evaporation in the production of milk powder, cream treatment (Vacreator and Flavourtech) in butter making and deodorisation in AMF manufacture.*

#### 3.1.1 Defined heat treatments

The defined heat treatments (thermisation for cheese-making, pasteurisation and UHT treatment) and associated requirements are outlined below. Appendix Three provides these heat treatments' process performance.

##### **A. Thermisation for cheese-making**

Thermisation for cheese-making (also known as thermalisation) is only permitted for the manufacture of cheeses with moisture content less than 39 percent moisture (by mass), pH less than 5.6 and where the pH of the cheese does not increase on ripening.

Thermisation for cheese-making is:

- rapidly heating liquid dairy produce containing low numbers of pathogenic micro-organisms to a temperature of no less than 64.5°C, and retaining it at that temperature for no less than 16 seconds; and
- labelling the cheese with the date of commencement of manufacture; and
- prior to sale:
  - storing the cheese at a temperature of not less than 7°C for a period of not less than 90 days from the date of commencement of manufacture; and
  - demonstrating that pathogens are at a safe level in the cheese.

Note: The temperature time combination for thermisation is based on the following papers:

- D'Aoust J-Y, Emmons D B, McKellar R, Timbers G E, Todd E C D, Sewell A M & Warburton D W (1987) J Food Protection 50: 494-501. Thermal inactivation of Salmonella species in fluid milk.
- D'Aoust J-Y, Park C E, Szabo R A & Todd E C (1988) J Dairy Science 71: 3230-3236. Thermal inactivation of Campylobacter species, Yersinia enterocolitica and Escherichia coli O157:H7
- Farber J M, Sanders G W, Speirs J I, D'Aoust J-Y, Emmons D B and McKellar R (1988) International J Food Microbiology 7: 277-286. Thermal resistance of Listeria monocytogenes in inoculated and naturally contaminated raw milk.

#### *Commentary*

*MAF Standard D107 "Dairy Product Safety" Table A1.1 provides the limits for pathogenic micro-organism in cheese.*

### **B. Pasteurisation**

Pasteurisation is:

- rapidly heating milk to a temperature of no less than 72° C and retaining it at that temperature for no less than 15 seconds; or
- rapidly heating milk to a temperature of no less than 63° C and retaining it at that temperature for no less than 30 minutes.

Dairy produce may be rapidly heated and held using a temperature and holding time combination with the same process performance as pasteurisation for the produce concerned.

#### *Commentary*

*Table A1.3 in Appendix One of this Standard provides temperature and holding time combinations with the same process performance as pasteurisation for a range of liquid dairy produce including milk, milk with added sweeteners, concentrated dairy produce and ice-cream.*

### **C. Ultra high temperature (UHT) treatment**

UHT treatment of liquid dairy produce is:

- the application of heat to continuously flowing liquid dairy produce using such temperatures for such time that renders the produce commercially sterile at the time of processing; then
- aseptic packaging resulting in commercially sterile product.

#### **3.1.2 Produce contamination**

Thermisation for cheese-making, pasteurisation and UHT treatment must be undertaken using heat treatments that are designed, installed, operated and maintained in a manner that ensures that no untreated or partially treated dairy produce passes forward or is mixed with treated produce.

The safety and wholesomeness of treated produce must not be compromised by contamination from services (coolants, heating media and/or cleaning solutions).

#### **3.1.3 Further processing and cooling**

At the end of the heat treatment and prior to further processing or storage, the dairy produce must be immediately heated or cooled to a temperature that maintains the produce in a wholesome condition either until further processing or for the duration of its shelf life.

## **4. EVALUATION**

External evaluation of all heat treatments covered by this Standard that are

- new,
- relocated or

- have undergone a significant change,

for:

- compliance with the outcomes described in section 3 of this Standard, and
- confirmation that those means of complying with this Standard that are either specified or referenced in the PSP can be or are being followed;

must be undertaken by NZFSA or a NZFSA-approved TPA as part of a PSP evaluation prior to the processing of dairy produce for the manufacture of dairy products.

Finished produce manufactured from dairy produce heat treated during commissioning of a heat treatment, prior to the evaluation of the heat treatment and the resolution of any critical non-compliances, must be isolated, appropriately labelled and secured against use, sale or export and managed as non-conforming produce (refer MAF Standard D108).

## 4.1 Compliance

Heat treatments that comply with:

- the outcomes described in section 3 in this Standard; and
- those means of complying with this Standard that are either specified or referenced in the PSP

are used to treat dairy produce used for the manufacture of dairy products.

## 4.2 Non-compliance

Heat treatments that fail to comply with the criteria in section 4.1 must not be used to treat produce used for the manufacture of dairy products. All critical non-compliances must be resolved prior to heat treating any produce used for the manufacture of dairy products.

Any produce manufactured from produce treated by critically non-compliant heat treatments must be managed in accordance with MAF Standard D108 “Non-conforming Dairy Produce”.

### *Commentary*

*Where a critical non-compliance is identified, all produce treated by the heat treatment since the last recorded demonstration of compliance by that heat treatment must be managed as non-conforming produce.*

## 5. VERIFICATION (EXTERNAL)

External verification of compliance with the outcomes described in section 3 of this Standard is undertaken by NZFSA or a NZFSA-approved TPA as part of a PSP assessment. The frequency and intensity of the external verification is defined by NZFSA, based on the verification category to which the heat treatment is assigned and the manufacturer’s performance.

### *Commentary*

*Some importing countries may require specific minimum verification requirements of heat treatment including the frequency of verification and the type of verifier to be used. Where product is being manufactured for export to these countries and the specific verification requirements are more frequent or require a specialist verifier in excess of that specified by performance based verification category to which the manufacturer is assigned then these importing country verification requirements take precedence.*

## 5.1 Compliance

The manufacturer is compliant with the outcomes described in section 3 of this Standard if:

- the means to deliver the outcomes described in section 3 of this Standard are documented (either specified or referenced) in NZFSA-approved PSPs; and
- they operate in accordance with that NZFSA-approved PSP, and
- the heat treatment has a current evaluation, i.e. the heat treatment is not new, has not had any significant changes or been relocated; and
- they demonstrate compliance appropriate to the performance-based verification category to which they have been assigned.

Manufacturers operating in compliance with the outcomes described in section 3 of this Standard and a NZFSA-approved PSP are entitled to:

- produce milk or cream intended for the manufacture of dairy products,
- transport or store dairy produce,
- manufacture, transport, or store dairy products for sale and/or export.

Manufacturers demonstrating compliance appropriate to a verification category that is better than their current verification category are entitled to a review of the verification category to which they have been assigned.

## 5.2 Non-compliance

The dairy manufacturer is non-compliant if one or more of the criteria in section 5.1 for verifying compliance are not met.

All critical non-compliances are resolved prior to heat treating any produce for the manufacture of dairy products. Any produce manufactured from produce treated by critically non-compliant heat treatments is managed in accordance with MAF Standard D108 "Non-conforming Dairy Produce".

### *Commentary*

*Where a critical non-compliance is identified, all produce treated by the heat treatment since the last recorded demonstration of compliance by that heat treatment, is managed as non-conforming produce.*

Non-compliance with the outcomes described in section 3 of this Standard (including selling or exporting dairy products not manufactured in accordance with an approved PSP) constitutes an offence under regulation 49 of the *Dairy Industry Regulations 1990*.

If a dairy manufacturer does not operate in accordance with the outcomes in this Standard:

- a Notice may be issued by a NZFSA Inspector to remedy any defects;
- export certification and/or use of any NZFSA marks may be suspended;
- approval of the PSP may be withdrawn; and/or
- prosecution for this and other offences may occur.

# Appendix One: Acceptable Criteria

NZFSA Dairy and Plants recognises that a manufacturer can meet the outcomes in section 3 of the Standard in a number of different ways.

Following are criteria by which a dairy manufacturer may be judged to satisfactorily achieve the outcomes described in section 3 of this Standard. A Product Safety Programme (PSP) that includes procedures for ensuring that each of these criteria is satisfied and meets all other relevant PSP requirements will be approved by NZFSA.

Manufacturers may provide proposals for alternative criteria, which are other ways of delivering the outcomes in this Standard. NZFSA will approve these proposals provided it can be demonstrated to NZFSA's satisfaction that the required outcomes will be achieved. A guide to the information required in these proposals and the procedures used by NZFSA to assess proposals can be obtained from NZFSA Dairy and Plants.

Similarly industry sectors may develop codes of practice that contain means of satisfying these criteria, and/or alternative means of achieving the outcomes described in section 3 of the Standard. NZFSA will approve these industry codes of practice for use by the sector concerned provided it can be demonstrated to NZFSA's satisfaction that the required outcomes will be achieved.

## 1. CRITERIA FOR HEAT TREATMENTS

Where one or more of the heat treatments defined in section 3 of this Standard (thermisation for cheese-making, pasteurisation, or UHT treatment) is used, the heat treatment is designed, installed, operated and maintained in accordance with the manufacturer's PSP. The PSP demonstrates delivery of the outcomes of this Standard and meets the following criteria for heat treatments. The PSP may reference all or part of NZFSA-approved codes of practice and standards for dairy heat treatments to deliver some or all the following criteria.

The PSP provides a list/matrix (also known as the heat treatment plan) of the documents necessary to meet this Standard. This list/matrix includes the document names, references and the locations where they are held.

### 1.1 Criteria for documentation and training

The PSP contains sufficient documentation, including design and "as-built" drawings, plating diagrams, computer/PLC programs, operating procedures, training programmes and records, to ensure that:

- staff and contractors have the knowledge and skills necessary to:
  - understand the hazards managed by the heat treatment;
  - understand the heat treatment and how it operates;
  - operate, check and maintain the heat treatment including monitoring, taking timely and appropriate corrective action(s) when there is "loss of control", and record keeping; and
- the heat treatment is readily validated by the manufacturer; and
- the heat treatment is readily evaluated and verified by NZFSA Compliance/TPA.

#### *Commentary*

*Operator knowledge and skills are essential for the effective operation of the heat treatment. This knowledge and skill is required for relief and backup staff operating the heat treatment. There should be no production if a trained operator is not available.*

## 1.2 Heat treatment equipment

The heat treatment equipment meets the criteria in Table A1.1.

## 1.3 Heat treatment operation

In addition to the criteria in the following sections, heat treatments are operated, checked and maintained in accordance with the criteria provided in Table A1.2.

### 1.3.1 Operational considerations

#### A Holding time calculation

In calculating the holding time for produce in the holding section, the flow conditions existing in the holding section are taken into account by calculating the Reynolds Number of the product in the holding section at the heat treatment temperature.

$$\text{Reynolds Number, } Re = \rho v D / \mu$$

where:

$\rho$  = density, kg/m<sup>3</sup>

$v$  = velocity of flow, m/s

$D$  = diameter, m

$\mu$  = viscosity of produce at the heat treatment temperature, Pa s

Laminar flow is assumed when the Reynolds number is less than 4000. For laminar flow, the holding time is calculated by assuming that the maximum velocity is twice the average velocity based on the maximum flow rate.

Turbulent flow is assumed where the Reynolds number exceeds 4000. For turbulent flow, the holding time is calculated from the actual measured fastest particle velocity based on the maximum flow rate. As the ratio of maximum velocity varies with Reynolds number it is recommended that the design is reviewed by a heat treatment validator or evaluator. As an initial guide for turbulent flow, the maximum velocity may be assumed to be 1.33 times the average velocity for Reynolds number=4000, and 1.25 times the average velocity when the Reynolds number exceeds 20000.

#### B. Steam condensate

Where steam is introduced into produce to assist in a temperature change, the volume of the condensed steam is included when calculating the volume of produce present in the holding section.

#### C. Single phase flow

For continuous heat treatments the heat exchanger and holding tube contain only liquid and no vapour, entrained air or air pockets that might affect the holding time.

### 1.3.2 Thermisation for cheese-making

The liquid dairy produce being thermised for cheese-making is within the action limits defined in MAF Standard D115, "Raw Milk Acceptance" for microbiological contamination.

The heat treatment is operated to deliver the outcomes for thermisation for cheese-making contained in sections 3.1.1, 3.1.2 and 3.1.3 of the Standard. In addition, where the liquid dairy produce contains particles of diameter:

- of less than 200  $\mu\text{m}$  it is considered to be thermised when it is rapidly heated to a temperature of no less than 64.5°C and holding it at that temperature for no less than 16 seconds; and

- of 200 µm or more and less than 500 µm it is considered to be thermised when it is rapidly heated to a temperature of no less than 64.5°C and holding it at that temperature for no less than 17 seconds; and
- of 500 µm or more and less than 1000 µm it is considered to be thermised when it is rapidly heated to a temperature of no less than 64.5°C and holding it at that temperature for no less than 19 seconds;

Note: Thermisation of particles in milk based on calculations by Dr Ken R Morison at Canterbury University

The cheese is manufactured and stored to ensure that:

- acid production during cheese-making is within the range specified in the PSP; and
- prior to sale, pH, salt and moisture in the cheese are within the range specified in the PSP for the cheese.

### **1.3.3 Pasteurisation**

The heat treatment is operated to deliver the outcomes for pasteurisation contained in sections 3.1.1, 3.1.2 and 3.1.3 of the Standard.

To receive a heat treatment equivalent to pasteurisation, dairy produce is heated to at least the minimum temperature and held for at least the minimum holding time combinations specified for the composition of the dairy produce concerned in sections A, B and C below. In cases where the composition or particle size of the dairy produce is outside the limits specified below, alternative criteria will need to be validated to demonstrate the effectiveness of the time temperature combination in controlling the hazard(s) and approved by NZFSA.

#### **A Milks with less than 10 percent fat and no added sweeteners**

Milks with no added sweeteners and with less than 10 percent fat and particles of diameter less than 200, 500 or 1000 µm is considered to be pasteurised when it has been heated to and held at the minimum temperature for the minimum holding times specified in Table A1.3 (A1, A2, and A3).

#### **B Dairy produce with greater than 10% fat content and/or containing added sweeteners and concentrated dairy produce.**

The following dairy produce is considered to be pasteurised when it has been heated to and held at the minimum temperature for the minimum holding times specified in Table A1.3 (B1, B2 and B3):

- dairy produce (including cream) with a fat content of 10% or greater; and/or
- dairy produce with added carbohydrate sweeteners; and/or
- concentrated dairy produce with total solids to greater than 15%.

#### **C Ice cream mixes**

Ice cream mixes containing particles of diameter less than or equal to 1000 µm are considered to be pasteurised when they have been heated to and held at the minimum temperature for the minimum holding times specified in Table A1.3 (C).

#### **D Other dairy produce**

In cases where the composition or particle size of dairy produce is outside the limits specified above, alternative criteria require HACCP validation, to demonstrate the effectiveness of the time temperature combination in controlling the hazard(s), and NZFSA-approval.

### **1.3.4 UHT treatment**

The heat treatment is operated to deliver the outcomes for UHT treatment contained in sections 3.1.1, 3.1.2 and 3.1.3 of the Standard.

UHT treatment is normally in the range of 135 to 150°C in combination with appropriate holding times necessary to achieve commercial sterility. The HACCP analysis identifies hazards and the HACCP plan, including the temperature and holding time, is validated in accordance with NZFSA Standard D110, "Dairy HACCP Plans".

The products subjected to commercial sterilisation are microbiologically stable at room temperature, either measured after storage until end of shelf life or incubated at 55°C for 7 days or at 30°C for 15 days in accordance with appropriate standards such as [IDF Standard 48:1969 (under review)].

*Commentary*

- A. *A HACCP-based approach can be used to identify and control non-pathogenic spoilage organisms such as Bacillus stearothermophilus.*
- B. *Additional heating or holding time is required for to achieve commercial sterility where:*
- *large numbers of highly heat resistant spores of thermophilic or thermoduric micro-organisms such as bacilli are present; and/or*
  - *ingredients such as cocoa are used; and/or*
  - *the produce contains discrete particles.*
- C. *IDF Standard 48:1969 has been withdrawn by the International Dairy Federation (IDF) and not been replaced. In the continued absence of a suitable Codex Alimentarius or IDF standard for assessment of commercial sterility, manufacturers may consider using this withdrawn standard.*

## **1.4 Reporting to NZFSA Compliance/TPA**

The accountable person or their delegate (refer MAF Standard D102 "Product Safety Programme Reporting Requirements" section 1) includes in their regular report to NZFSA Compliance/TPA (refer MAF Standard D102 "Product Safety Programme Reporting Requirements" section 3) the following information for each heat treatment:

In the "Status - PSP components" section:

- Number of validations completed in the last period. For each validation, the number of non-compliances identified and the number of non-compliances remaining unresolved; and
- Number of evaluations completed in the last period. For each evaluation, the number of non-compliances identified and the number of non-compliances remaining unresolved; and
- The date of the last (external) verification, the number of non-compliances identified and the number of non-compliances remaining unresolved; and
- The anniversary of the last (external) verification.

In the "Trends" section:

- The results of microbiological/phosphatase/other testing used to demonstrate the effectiveness of the heat treatment and the protection of the heat-treated produce from contamination.

In the "Proposed Changes" section:

- Any significant changes to the heat treatment during the last period; and
- Any planned or proposed significant changes and the date of the change.

**Table A1.1: Criteria for heat treatment equipment:**

	Criteria for heat treatment equipment
Equipment sanitation	1. The facilities ensure that product contact surfaces are clean and sanitary before produce is treated.
Particle size	2. The facilities ensure that particle size is controlled to ensure complete heat treatment of all particles.
Heating temperature and holding time	3. It can be demonstrated that the minimum heat treatment temperature is achieved. 4. The constant and uniform achievement of the minimum holding time is demonstrated.
Protection from contamination	5. It can be demonstrated that the safety of the heat treated produce is not compromised by contamination from untreated or partially treated produce or services in the event of: <ul style="list-style-type: none"> <li>▪ normal operation, or</li> <li>▪ failure to meet the minimum time and temperature requirements, or</li> <li>▪ for automated plants, a systems, service or equipment failure. (For manually operated plants, operating, maintenance and control procedures must be designed to prevent contamination in the event of a systems, service or equipment failure, refer Table A1.2.)</li> </ul>
Maintaining wholesomeness	6. It can be demonstrated that after heat treatment, the produce is immediately heated or cooled to the temperature specified in the PSP.
Ease of access	7. The heat treatment equipment is designed, constructed and installed in a way that allows the heat treatment to be readily validated, evaluated and verified.

**Table A1.2: Criteria for the operation of dairy heat treatments**

	Operating/Maintenance Criteria	Monitoring criteria	Criteria for Corrective Actions	Criteria for Documentation and Records
Equipment sanitation	<ol style="list-style-type: none"> <li>1. The equipment is clean and sanitary before produce is treated.</li> <li>2. Deposits on equipment surfaces do not jeopardise the safety of the produce being treated.</li> </ol>	<ol style="list-style-type: none"> <li>3. The means are in place to demonstrate equipment cleanliness and sanitation.</li> <li>4. The means are in place to demonstrate that equipment surfaces do not bear deposits that jeopardise the safety of the produce being treated.</li> </ol>	<ol style="list-style-type: none"> <li>5. Where the operating, maintenance and/or monitoring criteria are not met, produce is stopped from feeding forward.</li> <li>6. When the operation, maintenance and/or monitoring criteria are not met the means are in place to ensure:                             <ul style="list-style-type: none"> <li>▪ The appropriate action is taken to restore control; and</li> <li>▪ Where necessary to prevent recurrence of the event that led to the loss of control, the equipment and/or its operation are upgraded; and</li> <li>▪ Any liquid produce stopped from feeding forward is either retreated by the heat treatment or disposed of in accordance with MAF Standard D108 Non-conforming Dairy Produce; and</li> <li>▪ Any dairy product manufactured from produce treated by non-compliant heat treatments is managed in accordance with MAF Standard D108 Non-conforming Dairy Produce.</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>7. Documented procedures and records are maintained:                             <ul style="list-style-type: none"> <li>▪ To demonstrate that no untreated or partially treated product passes forward; and</li> <li>▪ To demonstrate appropriate and complete corrective action is taken when there is loss of control; and</li> <li>▪ To provide full traceability of lots made from the heat treated produce; and</li> <li>▪ For the checking and maintenance of the heat treatment equipment, systems and operation.</li> </ul> </li> </ol>
Particle size	<ol style="list-style-type: none"> <li>8. The size of particles in the produce does not exceed the limit specified for the time temperature combination in use.</li> </ol>	<ol style="list-style-type: none"> <li>9. The means are in place to demonstrate the control of the size of particles in the produce.</li> </ol>	Criteria 5 and 6 apply	Criteria 7 applies

	Operating/Maintenance Criteria	Monitoring criteria	Criteria for Corrective Actions	Criteria for Documentation and Records
Heating temperature and holding time	<p>10. The heat treatment is operated to ensure the following</p> <ul style="list-style-type: none"> <li>▪ For continuous processes, all produce including the fastest particle achieves the minimum heat treatment temperature for the minimum holding time specified; or</li> <li>▪ For batch processes, all the produce and headspace achieves the minimum heat treatment temperature for the minimum holding time specified.</li> </ul>	<p>11. The means are in place (see Note 1 below) to accurately and reliably:</p> <ul style="list-style-type: none"> <li>▪ Demonstrate all produce has been heated and held to at least the minimum temperature ; e.g. for continuous processes monitoring and recording of the produce temperature are continuous and automatic; and</li> <li>▪ Demonstrate all the produce has been held for at least the minimum holding time; e.g. for continuous processes with automatic flow control, monitoring and recording of the flowrate are automatic and continuous; and</li> <li>▪ For batch processes, demonstrate that the headspace was at the minimum heat treatment temperature for the minimum holding time specified.</li> </ul> <p>12. The means are in place to ensure following checks are completed on a regular basis and the findings recorded:</p> <ul style="list-style-type: none"> <li>▪ The accuracy of temperature monitoring; and</li> <li>▪ The accuracy of the holding time; and</li> <li>▪ The correct operation of the system to prevent untreated or partially treated produce passing forward.</li> </ul>	Criteria 5 and 6 apply.	Criteria 7 applies.

	Operating/Maintenance Criteria	Monitoring criteria	Criteria for Corrective Actions	Criteria for Documentation and Records
Protection from contamination	<p>13. The heat treatment is operated to ensure:</p> <ul style="list-style-type: none"> <li>▪ No untreated or partially treated dairy produce passes forward; and</li> <li>▪ Treated dairy produce is not contaminated by untreated or partially treated produce; and</li> <li>▪ The safety and wholesomeness of treated produce is not compromised by contamination from services, e.g. coolants, heating media and/or cleaning solutions.</li> </ul>	<p>14. The means are in place to:</p> <ul style="list-style-type: none"> <li>▪ Continuously monitor and record the operation of the heat treatment to prevent contamination; or</li> <li>▪ Periodically monitor/check the heat treatment equipment to ensure no contamination occurs and record this; and</li> <li>▪ For pasteurised products released for sale before results of microbiological tests are available, undertake phosphatase testing of the heat treated produce immediately after heat treatment using a NZFSA-approved test method to demonstrate the produce has been correctly pasteurised and not recontaminated.</li> </ul> <p>15. The means are in place to ensure following check is completed on a regular basis and the findings recorded:</p> <ul style="list-style-type: none"> <li>▪ The correct operation of the system to prevent potentially contaminated produce passing forward.</li> </ul>	Criteria 5 and 6 apply.	Criteria 7 applies.
Maintaining wholesomeness	<p>16. The produce is immediately heated or cooled to the temperature appropriate for further processing, specified in the PSP.</p>	<p>17. Where there is the opportunity for microbiological growth, the means are in place to accurately and reliably monitor and record the temperature of the heated/cooled produce.</p>	Criteria 5 and 6 apply.	Criteria 7 applies.

Notes:

1. The closer the heat treatment is operated to the minimum temperature and/or holding time, the greater the level of monitoring required.

**Table A1.3: Heat treatments equivalent to pasteurisation for common types of dairy produce**

	A1	A2	A3	B1	B2	B3	C
Particle diameter	All dairy produce (excluding ice cream) with						Ice cream mixes with particles <1000 µm Ø
	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			
	<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. Minimum temperatures

The values in **column A1** for times  $t < 15$  seconds are calculated from the following pasteurisation effect equations based on equations in IDF Bulletin 200, which are derived from experimental data.

$$T = 14885/(\log_{10} t + 41.97) - 273.1$$

where  $T$  = minimum temperature in °C.  
 $t$  = minimum holding time in seconds

The values in column A1 for times  $t \geq 15$  seconds are calculated from the equation:

$$\log_{10} t = -0.23102T + 16.03139$$

which is based on a log-time plot of the time temperature combinations 63°C/30 min and 72°C/15 s,

where  $t$  = minimum holding time in minutes  
 $T$  = minimum temperature in °C.

The values in **column B1** are based on the US FDA requirement that if the fat content of the dairy product or whey is 10 percent or more, or if it contains added sweeteners, or is condensed milk or condensed dairy product, the specified temperature is increased by 2.8°C (5°F). The values in column B1 have been obtained by adding this 2.8°C increase to values in column A1.

The values in **column C** are excerpted from the New Zealand Food Regulations 1984.

### 4. Lowest allowable temperature

The pasteurising temperature given for a 30 minute holding time is the lowest allowable temperature for pasteurising the specified product types, i.e. a lower temperature for a holding time longer than 30 minutes is not acceptable.

### 5. Particle sizes

The values in **column A2 and B2** are based on calculations by Dr Ken R. Morison at Canterbury University that:

- where the minimum temperature is 72°C or greater an adequate heat treatment for particles of 500 microns diameter can be estimated by applying a 0.7 second increase in minimum holding time at any specified temperature to the values for liquid dairy produce. This 0.7 second increase with adjustment for rounding of holding time to the next whole second has been applied to values in Columns A1 and B1.
- where the minimum temperature is less than 72°C, the additional holding time for particles of 500 microns diameter becomes relatively less significant compared to the total holding time. For a 30 second holding time an additional 0.1°C to the minimum specified temperature is required. For holding times of 60 seconds or longer no additional heating is required.

The values in **column A3 and B3** are based on calculations by Dr Ken R. Morison at Canterbury University that

- where the minimum temperature is 74.8°C or greater an adequate heat treatment for particles of 1000 microns diameter can be estimated by applying a 3.0 second increase in minimum holding time at any specified temperature to the values for liquid dairy produce. This 3.0 second increase has been applied to values in Columns A1 and B1.
- where the minimum temperature is less than 74.8°C, the additional holding time for particles of 1000 microns diameter becomes relatively less significant compared to the total holding time. For a 30 second holding time an additional 0.2°C to the minimum specified temperature is required. For a 60 second (1 minute) holding time an additional 0.1°C to the minimum specified temperature is required. For holding times of 2 minutes or longer no additional heating is required.

### 6. Holding times

The holding times specified in this section are minimum holding times and are based on all the liquid being held at or above the minimum stated holding temperature.

## 2. CRITERIA FOR VALIDATION OF HEAT TREATMENTS

As part of the PSP validation (refer MAF Standard D101 “Product Safety Programmes” Appendix One, section 2.2.3), the accountable person is responsible for ensuring that the heat treatment is validated.

Validation of a HACCP plan, otherwise known as HACCP validation, is the process of obtaining evidence that the elements of the HACCP plan are effective. In the context of controlling hazards using heat treatments, the validation of heat treatments includes the assessment:

- of the effectiveness of the time temperature combination in controlling the hazard(s); and
- that, in a specific manufacturing process, this time temperature combination is then consistently applied, there is no contamination of the heat treated produce and it is maintained in a wholesome condition.

Because the time temperature combinations for the heat treatments defined in this standard are historically known to be effective, the only validation required is that, in each manufacturing process:

- the time temperature combination is consistently applied; and
- there is no contamination of the heat treated produce; and
- the produce is sufficiently heated or cooled to maintain it in a wholesome condition.

These are assessed using the criteria from Tables A1.1 and A1.2 for each of the following categories:

- equipment sanitation; and
- particle size; and
- heating temperature and holding time; and
- protection from contamination; and
- maintaining wholesomeness; and
- ease of access.

Validation is completed on the development of a new heat treatment, on relocation, after each significant change and as part of the PSP review cycle.

The competency requirements for validators are provided in Annex A of this Standard.

Validation should include consideration of equipment performance and reliability, environmental conditions and potential for recontamination, variations to processes or product formulations that could affect the efficacy of the heat treatment, and monitoring or verification failures.

## 3. CRITERIA FOR EVALUATION OF HEAT TREATMENTS

The heat treatment is evaluated to deliver the evaluation requirements in section 4 of the Standard.

### 3.1 Heat treatments excluding stove-top heat treatments

A heat treatment evaluator evaluates all heat treatments, excluding stove-top heat treatments.

This evaluation is in two parts:

- the plans and specifications for the heat treatment equipment are evaluated as part of the approval of plans and specifications in the construction of dairy premises. (Refer MAF Standard D202, “Registration of Dairy Premises”, Appendix One, section 2.1.1 and Annex B section 2.2); and

- the heat treatment equipment and its operation are evaluated after the heat treatment has been commissioned (Refer MAF Standard D202 “Registration of Dairy Premises”, section 2.1.1 and Annex B section 2.4).

The competency requirements for evaluators are provided in Annex A of this Standard.

The evaluator develops and uses checklists based on the scope above. These checklists may also be developed using HACCP and HAZOP principles.

### **3.2 Stove-top heat treatments**

A PSP evaluator evaluates stove-top heat treatments.

The heat treatment is evaluated after the heat treatment has been commissioned (Refer MAF Standard D202 “Registration of Dairy Premises”, section 2.1.1 and Annex B section 2.4).

The competency requirements for evaluators are provided in Annex A of this Standard.

The evaluator develops and uses checklists based on the scope above using HACCP principles.

## **4. CRITERIA FOR (EXTERNAL) VERIFICATION**

The heat treatment is verified to deliver the verification requirements in section 5 of the Standard.

### **4.1 Performance-based (external) verification**

The heat treatment performance verification category applies to the premises registration.

Tables A1.4 and A1.5 provide the frequency and intensity of the external verification of heat treatments for:

- each verification category and
- the requirements to be eligible for reclassification to the next category of lower levels of verification (refer section 4.1.1 below).

A verifier, appropriate to the verification category in which the heat treatment is assigned, undertakes the verification. The competency requirements for verifiers are provided in Annex A of this Standard.

Table A1.6 provides the criteria used to demonstrate compliance at each verification category. Failure to meet any of the requirements results in reclassification to a performance verification category with higher levels of verification (refer section 4.1.1 below).

All manufacturers’ heat treatments commence in the Standard/Entry Verification category. If at the first verification the heat treatment fails to demonstrate compliance in any one or more areas the TPA/NZFSA Compliance recommends to NZFSA that the heat treatment be assigned to the Increased Verification category.

**Table A1.4: External verification requirements of all heat treatments except stove-top heat treatments**

	Reduced verification	Standard/Entry Verification	Increased Verification
Verification intensity and verifier	<p>Year 1: PSP verifier*</p> <p>Year 2: Heat treatment verifier</p> <p>Year 3: PSP verifier*</p> <p>Year 4: PSP verifier*</p> <p>Year 5: PSP verifier*</p> <p>Year 6: Heat treatment verifier</p> <p>Year 7: PSP verifier*</p> <p>Year 8: PSP verifier*</p> <p>Year 9: PSP verifier*</p> <p>Year 10: Heat treatment verifier</p> <p>Subsequent years repeat starting at year 4.</p> <p>*Where this verification indicates there are problems or significant changes, then that verification is completed by a heat treatment verifier.</p>	<p>Year 1: Heat treatment verifier</p> <p>Year 2: Heat treatment verifier</p> <p>Year 3: PSP verifier*</p> <p>Year 4: Heat treatment verifier</p> <p>Subsequent years repeat starting at year 3.</p> <p>*Where this verification indicates there are problems or significant changes, then that verification is completed by a heat treatment verifier.</p>	<p>6 months: Heat treatment verifier</p> <p>12 months: Heat treatment verifier</p> <p>18 months: PSP verifier*</p> <p>24 months Heat treatment verifier</p> <p>Subsequent 6-month periods repeat starting at 18 months.</p> <p>*Where this verification indicates there are problems or significant changes, then that verification is completed by a heat treatment verifier.</p>
Eligibility for reclassification to next category		After 3 assessments by a heat treatment verifier and manufacturer demonstrates compliance appropriate to the reduced verification category.	After 2 years of satisfactory performance and manufacturer demonstrates compliance appropriate to the standard/entry verification category.

**Table A1.5: External verification requirements of stove-top heat treatments**

	Reduced Verification	Standard/Entry Verification	Increased Verification
Verification intensity and verifier	Not applicable	Annually by PSP verifier	6 monthly by PSP verifier
Eligibility for reclassification to next category		Not applicable	After 2 years of satisfactory performance and manufacturer demonstrates compliance appropriate to the standard/entry verification category.

**Table A1.6: Criteria for the demonstration of compliance appropriate to each performance verification category.**

Area	Reduced Verification	Standard/Entry Verification	Increased Verification
Non-compliances	<ul style="list-style-type: none"> <li>▪ No critical non-compliances.</li> </ul>	<ul style="list-style-type: none"> <li>▪ intermittent critical non-compliances; and</li> <li>▪ appropriate responses.</li> </ul>	<ul style="list-style-type: none"> <li>▪ one or more critical non-compliances and</li> <li>▪ inadequate responses.</li> </ul>
Maintenance	<ul style="list-style-type: none"> <li>▪ Preventative maintenance programme operating; and</li> <li>▪ Following all maintenance checks are completed to determine if any significant changes have been made.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Effective breakdown maintenance</li> <li>▪ Following all maintenance checks are completed to determine if any significant changes have been made.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Inadequate maintenance</li> <li>▪ Following all maintenance no checks are completed and/or significant changes are overlooked.</li> </ul>
Significant changes	<ul style="list-style-type: none"> <li>▪ Notified</li> </ul>	<ul style="list-style-type: none"> <li>▪ Notified</li> </ul>	<ul style="list-style-type: none"> <li>▪ Not notified</li> </ul>
Validations	<ul style="list-style-type: none"> <li>▪ Completed as required; and</li> <li>▪ Adequate and effective</li> </ul>	<ul style="list-style-type: none"> <li>▪ Completed as required; and</li> <li>▪ Inadequate</li> </ul>	<ul style="list-style-type: none"> <li>▪ No validations</li> </ul>
Checks	<ul style="list-style-type: none"> <li>▪ Completed as scheduled</li> </ul>	<ul style="list-style-type: none"> <li>▪ Completed as scheduled</li> </ul>	<ul style="list-style-type: none"> <li>▪ Not completed as scheduled; or</li> <li>▪ Not done at all</li> </ul>
Documentation and records	<ul style="list-style-type: none"> <li>▪ Comprehensive and complete; and</li> <li>▪ Records signed by operator and the designated person.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Sufficient; and</li> <li>▪ Records signed by operator and the designated person.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Inadequate</li> <li>▪ Records signed/not signed by operator and the designated person.</li> </ul>
Internal audit of PSP	<ul style="list-style-type: none"> <li>▪ completed &amp; adequate</li> </ul>	<ul style="list-style-type: none"> <li>▪ completed &amp; adequate</li> </ul>	<ul style="list-style-type: none"> <li>▪ none or</li> <li>▪ inadequate</li> </ul>

#### **4.1.1 Reclassification of verification category**

Reclassification of the verification category to which a manufacturer is assigned is undertaken in accordance with the latest version of MAF Standard D201, "Performance Measurement of Dairy Manufacturers", Appendix One section 5.

##### *Commentary*

*To assist you, the reclassification criteria from MAF Standard D201, "Performance Measurement of Dairy Manufacturers" that were current at the time of issuing this Standard are provided below. This may not be the most recent version of this material and it is recommended that anyone intending to use this material should contact NZFSA Dairy and Plants or check its website ([www.nzfsa.govt.nz/dairy](http://www.nzfsa.govt.nz/dairy)) to confirm that this is the current version*

#### **[5.0 Reclassification**

##### **5.1 Initiation of a review**

*NZFSA initiates a review of the category to which a manufacturer is assigned on receipt of any of the following communications.*

**5.1.1 TPA recommendation for reclassification to a category with decreased levels of assessment**

*When, as a result of verifications, the TPA is satisfied that the manufacturer demonstrates compliance appropriate to the recommended reclassification category, they must submit a recommendation to NZFSA for reclassification. TPA recommendations for reclassification are made using the form provided in Appendix Two.*

**5.1.2 TPA recommendation for reclassification to a category with increased levels of assessment**

*The TPA submits a recommendation to NZFSA to reclassify the manufacturer when:*

- *as a result of an assessment, the TPA identifies that the manufacturer fails to demonstrate compliance with any one or more of the criteria for the category to which they are assigned; or*
- *the manufacturer demands, requests, suggests, or pressures the TPA to censor; or*
- *falsify an assessment report.*

*TPA recommendations for reclassification are made using the form provided in Appendix Two.*

**5.1.3 Report of a critical non-compliance**

*A report of a critical non-compliance by a manufacturer provided by the TPA in accordance with the reporting requirements specified in MAF Standards D102, "PSP Reporting Requirements" and D503, "TPAs' Responsibilities".*

**5.1.4 Reapproval of PSPs**

*A PSP for reapproval in accordance with MAF Standard D101, "Product Safety Programmes".*

**5.1.5 Request for review by the dairy manufacturer**

*A request by a dairy manufacturer for NZFSA to review the category to which they are assigned. A manufacturer may request a review by notifying NZFSA in writing, setting out reasons for seeking the review. A copy of the request is sent by the manufacturer to the manufacturer's contracted TPA.*

**5.1.6 Request for review by another party**

*A request by any party for NZFSA to review the category to which a dairy manufacturer has been assigned. Any party may request a review by notifying NZFSA in writing, setting out reasons for seeking the review. Copies of the request must be sent by the party to the manufacturer and the manufacturer's contracted TPA.*

**5.2 Review**

*NZFSA reviews the category to which a manufacturer is assigned and, where appropriate, assigns a new category.*

*This review considers all the available information including any case that has been provided in writing. NZFSA may, for the purposes of the review, undertake or commission an independent assessment of the manufacturer's PSP. This assessment may be at the manufacturer's expense where the manufacturer has requested the review.*

**5.3 Outcome**

*NZFSA advises the accountable person of the outcome, either:*

- *advising the category to which they have been assigned, the frequency of assessments, and the date of effect; or*
- *confirming the existing category if there is no change of classification.]*

## **4.2 Verification of regular reports**

Within 14 days of month end (refer MAF Standard D503 “Third Party Agencies’ Responsibilities”) the PSP verifier responsible for the premises, reviews the heat treatment component of the regular report and verifies that the heat treatment in the previous period was adequate and provides this information to NZFSA.

Where there is inadequate or insufficient information provided to complete this verification, the PSP verifier obtains the necessary information from the manufacturer or the heat treatment verifier. This information is obtained either through provision of further reports, records or visit.

Where the PSP verifier identifies that the heat treatment may not have been adequate or was inadequate, the manufacturer and NZFSA are advised within 24 hours.

## **ANNEX A: COMPETENCY REQUIREMENTS**

### **1. Validators**

The validation of heat treatments is undertaken by a person who has:

- a relevant tertiary qualification or demonstrated competence as a technical professional in food processing engineering, e.g. registered engineer or equivalent; and
- relevant process knowledge or experience; and
- adequate knowledge of food safety; and
- successfully completed a NZQA-registered course in HACCP and been assessed as competent; and
- practical experience developing and implementing HACCP plans that include heat treatment critical control points; and
- successfully completed a NZQA-registered course for validation/evaluation/verification of dairy heat treatments and been assessed as competent by a NZQA-qualified assessor.

### **2. Evaluators**

#### **2.1 PSP evaluators**

The general PSP evaluation of heat treatments is undertaken by an individual who has:

- successfully completed a NZQA-registered course for validation/evaluation/verification of dairy heat treatments and been assessed as competent by a NZQA-qualified assessor; and
- been approved for:
  - Product Safety Programme Evaluation;
  - Product Safety Programme Verification; or
  - HACCP Plan Evaluationin the appropriate product group in accordance with MAF Standard D501 “Technical Competency of Third Party Agency Individuals”; and
- employment or a contractual relationship with an accredited and approved TPA in accordance with MAF Standards:
  - D501 “Technical Competency of Third Party Agency Individuals”, and
  - D502 “Accreditation and Approval of Third Party Agencies”; and
  - D503 “Third Parties Agencies’ Responsibilities”; and
- in the previous 12 months, successfully demonstrated their competence to evaluate PSP’s to the accreditation body and NZFSA (refer MAF Standard D501 “Technical Competency of Third Party Agency Individuals”).

#### **2.2 Heat treatment evaluators**

The evaluation of heat treatments is undertaken by a person who has:

- a relevant tertiary qualification or demonstrated competence as a technical professional in food processing engineering, e.g. registered engineer or equivalent; and
- relevant process knowledge or experience; and
- adequate knowledge of food safety; and

- successfully completed a NZQA-registered course in HACCP and been assessed as competent; and
- practical experience developing and implementing HACCP plans that include heat treatment critical control points; and
- successfully completed a NZQA-registered course for validation/evaluation/verification of dairy heat treatments and been assessed as competent by a NZQA-qualified assessor ; and
- been approved for:
  - Heat Treatment (Pasteuriser) Evaluation,
 in the appropriate product group in accordance with MAF Standard D501 “Technical Competency of Third Party Agency Individuals”; and
- employment or a contractual relationship with an accredited and approved TPA in accordance with MAF Standards:
  - D501 “Technical Competency of Third Party Agency Individuals”, and
  - D502 “Accreditation and Approval of Third Party Agencies”; and
  - D503 “Third Parties Agencies’ Responsibilities”; and
- in the previous 12 months, successfully demonstrated the their competence to evaluate heat treatments to the accreditation body and NZFSA.

### **3. Verifiers**

#### **3.1 PSP verifiers**

The verification of heat treatments is undertaken by a person who meets the requirements of PSP evaluators (see section 2 above).

#### **3.2 Heat treatment verifiers**

The verification of heat treatments is undertaken by a person who meets the requirements of heat treatment evaluators (see section 2 above).

## Appendix Two: Importing Country Requirements

Some importing countries require official assurances (such as contained in memoranda of understanding/agreements/etc and export certificates) which:

- specify the heat treatment required, e.g. 72 °C for 15 seconds; or
- specify the heat treatment required or permit the demonstration of equivalence to the heat treatment; and/or
- require the demonstration of pasteurisation through phosphatase testing.

These importing country requirements are in addition to the requirements of NZFSA Standard D121, "Dairy Heat Treatments". This means that a manufacturer may meet the requirements of this Standard and yet not comply with the requirements of the importing country. If an importing country requires a specified heat treatment, the heat treatment is required to be evaluated and verified in accordance with this Standard.

Where NZFSA maintains a list of premises approved for exporting to a country and where a heat treatment does not meet the conditions for export to that country (including a heat treatment operating under an interim control plan) then NZFSA will remove that premise from the premises list.

It is the responsibility of exporters to identify and comply with all importing country requirements; non-compliance is at their commercial risk. The requirements for some importing countries, which have been officially confirmed, can be obtained from the Dairy and Plant Product Group of NZFSA or its website ([www.nzfsa.govt.nz/dairy](http://www.nzfsa.govt.nz/dairy)).

Where NZFSA provides official assurances to competent authorities of importing countries, the statements to which NZFSA attests must be verifiable. Relevant requirements are described in MAF Standard D206 "Dairy Sanitary and Related Export Certification". Manufacturers with heat treatments operating under an interim control plan will need to ensure the information provided under the interim control plan provides evidence of the heat treatment as attested to in the export certificate.

## Appendix Three: Process Performance of the Defined Heat Treatments

The defined heat treatments have the following process performances. This information is provided to assist validation of alternative time temperature combinations for the manufacture of safe dairy products. Further information on the process performance of the defined heat treatments is being consolidated, and when this information becomes available, will supersede this Appendix.

### 1. Thermisation

Thermisation aims at reducing the number of micro-organisms by a factor of  $10^3$  or  $10^4$  (log 3 or log 4). Micro-organisms surviving will be heat-stressed and become more vulnerable to subsequent microbiological control measures. Thermisation, in combination with normal cheese-making of cheeses with a moisture content of less than 39 percent (by mass) and pH less than 5.6, followed by storage at a temperature of not less than 7°C for a period of not less than 90 days from the date of commencement of manufacture, is intended to achieve a similar level of public health protection as pasteurisation.

- Codex Alimentarius (2003) Report of the Thirty-Fourth Session of the Codex Committee On Food Hygiene, Orlando, Florida, United States of America, 27 January - 1 February 2003, Appendix III. Proposed draft of Code of Hygienic Practice for Milk and Milk Products.

### 2. Pasteurisation

Pasteurisation is a microbiocidal heat treatment aimed at reducing the number of any harmful micro-organisms in milk and liquid milk products, if present, to a level at which they do not constitute a significant health hazard. Pasteurisation conditions are designed to effectively destroy the organisms *Mycobacterium tuberculosis* and *Coxiella burnettii*. As *C. burnettii* is the most heat-resistant non-sporulating pathogen likely to be present in milk, pasteurisation is designed to achieve at least a 5 log reduction of *C. burnettii* in whole milk (4% milkfat).

- Codex Alimentarius (2003) Report of the Thirty-Fourth Session of the Codex Committee On Food Hygiene, Orlando, Florida, United States of America, 27 January - 1 February 2003, Appendix III. Proposed draft of Code of Hygienic Practice for Milk and Milk Products.

### 3. UHT treatment

Thermal processes necessary to obtain commercially sterile products are designed to result in [12 log reductions of *Clostridium botulinum* and in] the absence of viable micro-organisms and their spores capable of growing in the treated product when kept in a closed container at normal non-refrigerated conditions at which the food is likely to be held during manufacture, distribution and storage.

- Codex Alimentarius (2003) Report of the Thirty-Fourth Session of the Codex Committee On Food Hygiene, Orlando, Florida, United States of America, 27 January - 1 February 2003, Appendix III. Proposed draft of Code of Hygienic Practice for Milk and Milk Products.

#### Commentary

*The Codex Committee on Food Hygiene is currently considering whether there is a scientific base for retaining the 12 log reduction of Cl. botulinum for UHT milk.*

# Appendix Four: Recommendation for Reclassification

## RECOMMENDATION FOR RECLASSIFICATION OF A HEAT TREATMENT FOR MANUFACTURERS OPERATING UNDER THE *DAIRY INDUSTRY REGULATIONS 1990*

Dairy manufacturer:

Accountable person:

NZFSA registration number:

PSP approval number:

Street address:

Postal address:

Telephone number:

Fax number:

Email address:

Identity of the heat treatment:

Produce treated by that heat treatment:

Identity, description and specification of the heat treatment equipment:

Countries exporting products to:

Current category: (Please circle current category)

Reduced  
Verification

Standard/Entry  
Verification

Increased  
Verification

Date assigned to current category:

Recommended category: (Please circle recommended category)

Reduced  
Verification

Standard/Entry  
Verification

Increased  
Verification

Recommended date for reclassification:

**Describe current performance by ticking the appropriate boxes below:**

Area	Reduced Verification	Standard/Entry Verification	Increased Verification
Non-compliances	<ul style="list-style-type: none"> <li>▪ No critical non-compliances.</li> </ul>	<ul style="list-style-type: none"> <li>▪ intermittent critical non-compliances; and</li> <li>▪ appropriate responses.</li> </ul>	<ul style="list-style-type: none"> <li>▪ one or more critical non-compliances and</li> <li>▪ inadequate responses.</li> </ul>
Maintenance	<ul style="list-style-type: none"> <li>▪ Preventative maintenance programme operating; and</li> <li>▪ Following all maintenance checks are completed to determine if any significant changes have been made.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Effective breakdown maintenance</li> <li>▪ Following all maintenance checks are completed to determine if any significant changes have been made.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Inadequate maintenance</li> <li>▪ Following all maintenance no checks are completed and/or significant changes are overlooked.</li> </ul>
Significant changes	<ul style="list-style-type: none"> <li>▪ Notified</li> </ul>	<ul style="list-style-type: none"> <li>▪ Notified</li> </ul>	<ul style="list-style-type: none"> <li>▪ Not notified</li> </ul>
Validations	<ul style="list-style-type: none"> <li>▪ Completed as required; and</li> <li>▪ Adequate and effective</li> </ul>	<ul style="list-style-type: none"> <li>▪ completed as required; and</li> <li>▪ Inadequate</li> </ul>	<ul style="list-style-type: none"> <li>▪ No validations</li> </ul>
Checks	<ul style="list-style-type: none"> <li>▪ Completed as scheduled</li> </ul>	<ul style="list-style-type: none"> <li>▪ Completed as scheduled</li> </ul>	<ul style="list-style-type: none"> <li>▪ Not completed as scheduled; or</li> <li>▪ Not done at all</li> </ul>
Documentation and records	<ul style="list-style-type: none"> <li>▪ Comprehensive and complete; and</li> <li>▪ Records signed by operator and the designated person.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Sufficient; and</li> <li>▪ Records signed by operator and the designated person.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Inadequate</li> <li>▪ Records signed/not signed by operator and the designated person.</li> </ul>
Internal audit of PSP	<ul style="list-style-type: none"> <li>▪ completed &amp; adequate</li> </ul>	<ul style="list-style-type: none"> <li>▪ completed &amp; adequate</li> </ul>	<ul style="list-style-type: none"> <li>▪ none or</li> <li>▪ inadequate</li> </ul>

**Information to be considered by NZFSA in the review:** (Please attach evaluation/verification reports or any other relevant information)

**TPA/NZFSA Compliance:**

**Contact person:**

**Signed:**

**Date:**

**Send to:** The Director  
 NZFSA Dairy and Plants  
 PO Box 2835  
 Wellington