



Te Pou Oranga Kai O Aotearoa

DISCUSSION PAPER No. 3/02

Dairy Heat Treatments

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1. Executive Summary

NZFSA* Standards MRD-Stan 3, "Standard for Pasteurisation Heat Treatment" and MRD-Stan 4, "Standard for Checking the Operation of Pasteurisers" contain specific requirements for pasteurisation. These Standards are due for review and revision in the "D-series" standard format. New Zealand requirements need to be included and importing country requirements, such as those for the EU, need to be separated out. The two MRD standards also need to be aligned with the current standards for product safety programmes (D101.2) and HACCP plans (D110.1). A single New Zealand Food Safety Authority Dairy and Plant Products Group NZFSA Standard is needed to cover all defined heat treatments operated by dairy manufacturers to treat dairy produce for the manufacture of dairy products for human consumption.

Ministry of Agriculture and Forestry (MAF) Discussion Paper No. 35, "Dairy Heat Treatment" was published in September 2001 with draft Standard D121, "Dairy Heat Treatments", dated 21 September 2001, to consult with industry on the proposed requirements for dairy heat treatments. Feedback from this consultation highlighted strong industry concerns with the proposed requirements for dairy heat treatments. This resulted in the draft Standard being withdrawn from the group of standards being presented to the Dairy Product Safety Advisory Council's (DPSAC) December 2001 meeting for endorsement.

This discussion paper considers the background and concerns relating to the purpose, design, operation and assessment of dairy heat treatments that were raised by industry during consultation in late 2001 and outlines how these could be resolved.

This paper proposes the following:

- That a NZFSA Standard relating to dairy heat treatments be drafted and provided for industry consultation.
- That this Standard requires:
 - The three heat treatments (thermisation for cheese manufacture, pasteurisation and UHT treatment) defined in this Standard meet the outcomes for these heat treatments.
 - All dairy produce, used for the manufacture of dairy products be heat treated by one of the three defined heat treatments. An exception is when the manufacturer has a NZFSA-approved PSP which includes a validated HACCP plan covering either the heat treatment identified and operated as a critical control point, or other control measures which reduce biological hazards (pathogenic micro-organisms) to an acceptable level.
 - Heat treatment steps in other manufacturing processes, e.g. evaporation, have equivalent outcomes to pasteurisation.
 - Heat treatments that are new, relocated or have undergone a significant change must be evaluated before being used to treat dairy produce used in the manufacture of dairy products.
 - Heat treatments be verified as part of the PSP verification.
 - The intensity and frequency of heat treatment verification be dependent on the verification category and level of performance of the manufacturer, unless additional requirements are specified by the competent authority of an importing country.
- Assuming that the Standard is issued on or about 31 January 2003, that it comes into force 18 months later.

For consistency, "MAF" has been replaced by "NZFSA" throughout this paper when referring to current documents.

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".

Similarly, documents previously published by MAF such as MAF Standards are now referred to as "NZFSA* Standards". The asterisk denotes that the Standard was originally published as a MAF Standard.

2. Purpose

This discussion paper considers the background and concerns relating to the purpose, design, operation and assessment of dairy heat treatments that were raised by industry during consultation in late 2001 and outlines how these could be resolved.

3. Risk Assessment

An assessment of the hazards in raw milk and the associated risks for New Zealand has not yet been undertaken. It is anticipated that this assessment will be undertaken in 2002. The effectiveness of control of hazards by thermisation, pasteurisation and UHT treatment is well established by historical data, though there is no recent scientific validation.

4 Background

4.1 HISTORY

Heat treatment is almost universally used as the primary measure for the control of microbial hazards in the processing of dairy products. It has a long history as a public health measure in New Zealand, beginning with the pasteurisation of milk for cheese making in 1896 at the Waverley dairy factory. The *New Zealand Food Regulations 1984* specify the heat treatment requirements for dairy products sold in New Zealand. These regulations are due to be repealed in late 2002 when the *Australia New Zealand Food Standard Code* comes fully into force. The processing requirements (section 1.6.2) of the *Australia New Zealand Food Standards Code* do not apply in New Zealand. The requirements for heat treatment of dairy products sold in the New Zealand market are currently under review.

In 1996, the New Zealand-EU veterinary agreement was signed. The agreement includes standards for trade between New Zealand and the European Union. The agreement recognises the New Zealand regulatory system for pasteurised dairy products for human consumption, except colostrum and derivatives, as defined by the *Dairy Industry Act 1952*, the *Dairy Industry Regulations 1990* and the *Food Act 1981*, as being equivalent to the "European Community's Milk and Milk Products Hygiene Directive (92/46/EEC)".

NZFSA* Standards MRD-Stan 3 and 4, published in 1993, are due for review. These Standards are issued under the *Dairy Industry Act 1952* and cover pasteurised dairy products manufactured in New Zealand for sale or export.

The NZFSA-approved dairy industry code NZCP 7, "Pasteurisation Equipment and Instrumentation Code of Practice", published in 1996, upgraded the requirements for pasteurisation equipment for the Dairy Board-aligned sector of the dairy industry. It came into effect on 1 July 2001. Exemptions have been allowed in some cases.

In 1999, MAF commenced the issue of a series of "D-series" standards. At this time, it was noted that a standard was required to provide clarification on the independent evaluation of pasteurisers.

In 2001 an industry Working Group was formed to consider the background relating to heat treatment in the dairy industry, and recommend:

- if an NZFSA Standard was required and, if so, the content of the Standard's acceptable criteria;
- if any supporting materials were required, e.g. guidelines and codes of practice; and
- the strategy and timeline for implementation of the proposed Standard.

In September 2001, based on the Working Group's deliberations, MAF published Discussion Paper No 35, "Dairy Heat Treatment" and a draft Standard, D121.1 "Dairy Heat Treatments" for industry consideration and comment. Feedback from this consultation highlighted strong industry concerns with the proposed requirements for dairy heat treatments. This resulted in the draft Standard being withdrawn from the group of standards being presented to the Dairy Product Safety Advisory Council's (DPSAC) December 2001 meeting for endorsement.

In late 2001, MAF asked the Working Group to reconvene to consider the concerns and to determine how these could be resolved.

4.2 CURRENT STATUS

The defined heat treatments, thermisation for cheese manufacture, pasteurisation and UHT treatment, are used throughout the New Zealand dairy industry for the control or destruction of pathogenic micro-organisms in dairy produce for human consumption and also produce for animal feed.

Heat treatments are applied to dairy produce using a range of processing technology including plate, tube and spiral flow heat exchangers, batch heating and holding in vats and saucepans, as well as evaporators and cream treatment equipment such as Vacreators. Similarly heat treatments operate over a wide range; from large scale, highly automated, computer-controlled equipment to small scale manually operated facilities.

Heat treatments are used on milks from sheep, goats and cows and cream, skim milk, milk concentrates etc from these milks.

4.3 NEW ZEALAND'S LEGAL REQUIREMENTS

4.3.1 Dairy Industry Act 1952

4.3.1.1 Dairy Industry Regulations 1990

The *Dairy Industry Regulations 1990* require manufacturers to operate in accordance with an approved product safety programme (PSP). For approval of a PSP, the Director General must be satisfied that:

- "Dairy products manufactured sampled, examined, tested, stored and transported in accordance with the programme will be safe; and
- The programme provides for the keeping of such records; and the availability for inspection of those records in such a manner and to such an extent; and such inspection of those records as to enable it to be readily ascertained whether or not the programme has been and is being complied with."

Also the PSP must provide:

- "adequately for the control of potentially pathogenic organisms."

In addition all dairy manufacturing premises (factories) must be registered. For registration the:

"Equipment, facilities....are designed, constructed and maintained so as to avoid hygiene hazards, and to permit easy and thorough cleaning, disinfection and visual inspection"

"No equipment in the premises will permit the inadvertent intermixing of raw milk or cream, or any unsafe dairy product with any safe dairy product."

No changes are to be made to registered premises, or to equipment or facilities in the premises unless:

- “The change has been approved by the Director-General; and the change is carried out in a manner that in the opinion of the Director-General, will not result in or create a threat to the safety of dairy product manufactured or stored in the premises.”

4.3.1.2 NZFSA Standards

NZFSA Standards apply to all manufacturers of dairy products in New Zealand, with the exception of those covered by the harmonisation project in 4.3.2.4 below.

a. D101, “Product Safety Programmes”

Manufacturers must operate in accordance with an approved PSP that provides adequately for the control of potentially pathogenic organisms. To achieve this control acceptable criteria to have in place include procedures for the operation, monitoring and recording of all critical control points in the manufacturing process, such as pasteurisation. The procedures for the operation, validation and evaluation of pasteurisation equipment are in compliance with the requirements specified in:

- NZFSA* Standard MRD-Stan 3, “Standard for Pasteurisation Heat Treatments,” and
- NZFSA* Standard MRD-Stan 4, “Standard for Checking the Operation of Pasteurisers”, and
- NZFSA* Standard D403, “Evaluation of Heat Treatment Equipment Plans” (once promulgated).

Note that the Standard does not require pasteurisation, only the management of critical control points, and, where pasteurisation is used, compliance with other NZFSA Standards.

b. D110, “Dairy HACCP Plans”

From 23 December 2000 all product safety programmes must include validated HACCP analyses/plans of the processes covered by the PSP. This includes a hazard analysis to identify potential hazards, and identification of critical control points.

c. D202, “Registration of Dairy Premises”

The requirements for heat treatment equipment in a registered premises are that:

- It is designed and constructed to ensure that it can be adequately cleaned, disinfected and maintained.
- It is made of materials with no toxic effect and it is durable and movable where necessary or capable of being disassembled.
- It is designed to achieve the required food temperature as rapidly as necessary
- The temperature can be monitored and controlled.
- Where necessary, such equipment has effective means of controlling and monitoring humidity, air-flow and any other characteristic likely to have a detrimental effect on the safety or suitability of the dairy produce.

These requirements are intended to ensure that:

- harmful or undesirable micro-organisms or their toxins are eliminated or reduced to safe levels, or their survival and growth are effectively controlled;
- where appropriate, critical limits established in HACCP plans can be monitored; and
- temperatures and other conditions necessary to ensure food safety and suitability can be rapidly achieved and maintained.

Depending on the nature of the food operations undertaken, adequate facilities are available for heating, cooling, cooking, refrigerating and freezing food, for storing

refrigerated or frozen foods, monitoring food temperatures, and when necessary, controlling ambient temperatures to ensure the safety and suitability of food.”

d. MRD-Stan 3, “Standard for Pasteurisation Heat Treatments”

This Standard defines heat treatment conditions for the pasteurisation of dairy products.

It specifies the heat treatment conditions for the batch holding method ("low temperature, long time"), the "high temperature, short time" (HTST) method, and the "higher heat, shorter time" (HHST) method. It does not include ultra pasteurisation or ultra high temperature (UHT) treatment.

The Standard specifies a range of alternative time/temperature combinations for HTST and HHST pasteurisation. For products with greater than 10% milkfat content, and sweetened and concentrated dairy products, there are listed time/temperature combinations to ensure a heat treatment equivalent to pasteurisation. It also allows for heat treatment as part of the manufacturing process, rather than as a separate pasteurisation step, provided the heat treatment and control procedures are equivalent to those required for pasteurisation.

The heat treatment conditions have been reviewed by the NZCP 7 Working Group and the NZFSA Heat Treatment Working Group, and amendments have been recommended.

The phosphatase test is used to detect unpasteurised cows' milk.

e. MRD-Stan 4, “Standard for Checking the Operation of Pasteurisers”

This Standard defines the checks that need to be carried out, and their frequency, to ensure that HTST and batch pasteurisers operate correctly and that no unpasteurised product goes forward for further processing. It requires an annual independent evaluation of the checking programme.

MRD-Stan 4:

- requires that pasteurisers be installed to comply with either MQD 1A, “Sanitary Design of Dairy Food Factories” or MQD 12, “Market Milk Code of Practice” both of which are no longer NZFSA-approved codes;
- refers to IDF Bulletin 200 (1986), “Monograph on Pasteurised Milk”, Chapter IX, and MQD 1B, “Dairy Food Manufacturing Equipment”, Section 5.2.5 for pasteuriser commissioning;
- requires that records be kept to demonstrate that no unpasteurised milk passes forward for further processing. Records of pasteuriser operation must be kept as required by MQD 1B, Section 5, and they must be available for inspection;
- describes the checks that must be carried out.

4.3.1.3 NZFSA-approved codes of practice and standards

a. NZCP 7, “Pasteurisation Equipment and Instrumentation Code of Practice”

Dairy industry code NZCP 7 was approved as a standard for pasteurisation equipment by Dairy Circulars 27 and 28.

NZCP 7 covers design and operation of equipment. This includes control and recording instrumentation, for pasteurisation temperatures from 69°C to 100°C of milk and other liquid dairy produce, for batch, HTST and HHST heat treatment. It contains significant additional requirements compared to the older standard MQD 1B (see below), in order to provide greater assurance of correct pasteurisation. The Standard also provides for computer control of pasteurisers. The new requirements add significantly to the cost of pasteurisation equipment.

NZCP 7 is also approved as a standard for the assessment of pasteurisers during validation.

It is stated, in Circulars 27 and 28 and NZCP 7, that “all dairy industry pasteurisers shall comply with NZCP 7 by 1 July 2001”. This statement has been misunderstood because, read in isolation, it appears to make NZCP 7 the sole mandatory code of practice. However it is clear from the approval statement for NZCP 7 that pasteurisers may comply with other NZFSA-approved standards. These include AS 3993.1 and 3-A Accepted Practice 603-06, which have been specifically approved. Therefore as far as NZFSA is concerned, the implementation deadline applies only to those companies that include NZCP 7 in their approved product safety programme.

The dairy industry parties who were involved in the development of NZCP 7 had agreement that this code should apply to all pasteurisers in the part of the industry they represented, i.e. the co-operative dairy companies and the Dairy Board. The industry is free to make such an agreement, but NZFSA cannot enforce it except in accordance with the law it administers. The *Dairy Industry Regulations 1990* do not specify a single standard for pasteurisation equipment, but instead specify the outcomes that such equipment must achieve to satisfy NZFSA, i.e. that it:

- is in all respects suitable for, and capable of, the manufacture of safe dairy products; and
- controls potentially pathogenic organisms.

Transition arrangements for those who are complying with NZCP 7 are given in Circulars 27 and 28 and NZCP 7. These specify that companies may continue to comply with the older standard MQD 1B until 1 July 2001, but the relevant parts, as follows, of NZCP 7 must be complied with:

- when major alterations are carried out;
- when new pasteurisation equipment is installed.

Computer control systems and electronic data recording for pasteurisers must comply immediately.

Two planned sections of NZCP 7 have not been completed. These are requirements for UHT treatment and requirements for other forms of heat treatments. The latter was intended to cover heat treatment in equipment such as evaporator pre-heaters.

b. AS 3993.1: 1992. “Equipment for the pasteurisation of milk and other liquid dairy products. Part 1: Continuous-flow systems”

This Standard sets out the requirements for the design and operation of equipment, including control and recording instrumentation, used for continuous-flow pasteurisation at temperatures between 60°C and 100°C of milk and other liquid dairy products. This Standard was approved as a standard for pasteurisation equipment by Dairy Circulars 27 and 28.

c. 3-A, “ Accepted Practices for the Sanitary Construction, Installation, Testing and Operation of High-temperature Short-time and Higher-heat Shorter-time Pasteuriser Systems, Revised, Number 603-06”

This document includes criteria for design, material, fabrication, installation, testing and operation of HTST and HHST pasteurisers. Dairy Circulars 27 and 28 approved this as a standard for pasteurisation equipment.

d. MQD 1: Code of Practice. “Part B, Dairy Food Manufacturing Equipment” (also known as DDM 1) and MQD 12: “Market Milk Code of Practice”

These codes contain sections on the design of heat treatment and pasteurisation equipment, and procedures for checking their operation and keeping records. They are no longer approved codes, but are sometimes referred to in product safety programmes.

4.3.2 Food Act 1981

4.3.2.1 Food Regulations 1984

Processing requirements for milk and milk products are regulated under the *Dairy Industry Act 1952* and the *Food Act 1981*. Foods sold in New Zealand must comply with the heat treatment provisions of the *Food Regulations 1984*. The heat treatment provisions of the *Food Regulations 1984* are provided in Annex A.

Under the Food Standards Treaty signed by Australia and New Zealand in 1995, the joint *Australia New Zealand Food Standards Code* will become in December 2002 the sole set of the food standards for composition, labelling and other matters included in the scope of the joint food standards system.

In late 2002, it is proposed that the *Food Regulations 1984* be revoked and where necessary, measures previously contained in the regulations be retained as a New Zealand Standard.

4.3.2.2 Australia New Zealand Food Standards Code

Under the provisions of the *Trans-Tasman Mutual Recognition Act 1997*, matters relating to health and safety of persons in New Zealand (such as heat treatment) may differ from those applying in Australia. The heat treatment provisions of the *Australian Food Standards Code* and the joint *Australia New Zealand Food Standards Code* do not apply in New Zealand.

The Ministry of Health has published a public discussion document proposing to revoke the *Food Regulations 1984*. Processing requirements and public health and safety issues falling outside the scope of the Treaty will be retained in New Zealand Food legislation.

4.3.2.3 New Zealand Milk and Milk Products Processing Standard 2002

The Ministry of Health discussion document proposes to revoke all milk and milk product regulations in the *New Zealand Food Regulations 1984* i.e. regulations 92-122, and including the processing requirements in the proposed "New Zealand Milk and Milk Products Processing Standard 2002". The proposed draft Standard is provided as Annex B to this discussion document.

The deadline for comments on this draft Standard was 31 May 2002. The New Zealand Food Safety Authority is currently considering the submissions received and will be making a recommendation to the Minister in August 2002.

4.3.2.4 NZFSA Harmonisation Project for Ice Cream Manufacturers and Specialist Cheese Manufacturers

As a general rule, manufacturers of dairy products must comply with the *Dairy Industry Act 1952* and the regulations and standards under that Act; and manufacturers of foods for sale on the domestic market must comply with the *Food Act 1981* and regulations and standards under that Act. To simplify the complications caused by these dual requirements, the NZFSA is moving towards harmonised food safety requirements. For this purpose, codes of practice for ice cream manufacture and specialist cheese manufacture have been developed that will be acceptable for both regulatory systems.

Manufacturers who supply only the New Zealand and Australian markets have been invited to join the development project. For these manufacturers, the status quo applies for the duration of the project.

The proposed requirements of these codes that are known at this stage are consistent with the proposed standard. The draft codes are currently being consulted on and should be issued in late 2002.

For manufacturers in this group who are registered and operating under the *Food Hygiene Regulations 1974* or who have an approved Food Safety Programme, the standards listed in 4.3.1.2 above do not apply. The longer term objective of harmonisation is that the requirements for food safety programmes, product safety programmes and risk management programmes (established under the *Animal Products Act 1999*) should be consistent and achieve the same objectives.

4.4 IMPORTING COUNTRY REQUIREMENTS

The requirements for importation of dairy produce into Australia, the European Union and the USA that relate to heat treatment are provided in Annex C.

A summary of attestations relating to heat treatment that are provided in official assurances, including export certificates, is provided on the NZFSA/Dairy website www.nzfsa.govt.nz/dairy. These attestations are currently being reviewed by NZFSA as part of the official assurances project.

5. Issues

The concerns raised by industry in submissions in response to MAF Discussion Paper No. 35, "Dairy Heat Treatment" published in September 2001 and draft Standard D121, "Dairy Heat Treatments", dated 21 September 2001 and the recommended means of resolving these are outlined below.

5.1 RELATIONSHIP OF THE STANDARD TO FOOD REGULATIONS

A number of submissions sought clarification of the relationship of the Standard to the requirements of the *New Zealand Food Regulations 1984*.

All food sold for consumption in New Zealand or Australia needs to comply with either the *Australia New Zealand Food Standards Code* or the *New Zealand Food Regulations 1984*. The *New Zealand Food Regulations 1984* will be replaced in December 2002 by the "New Zealand Milk and Milk Products Processing Standard 2002" (see section 4.3.2.3 above).

Dairy produce exported from New Zealand must comply with the *Dairy Industry Act 1952*, the piece of legislation under which the proposed standard for dairy heat treatment will be issued.

Although the proposed standard for dairy heat treatment and the proposed "New Zealand Milk and Milk Products Processing Standard 2002" do not need to be the same, it is appropriate that they be consistent to enable manufacturers to produce products for both domestic and export sale.

To enable this NZFSA Dairy and Plant Products has provided input into the drafting of the "New Zealand Milk and Milk Products Processing Standard 2002".

5.2 NEED FOR THE STANDARD

Some submissions asked whether a new standard was necessary and suggested that the existing NZFSA* Standards, MRD 3 and 4, were probably sufficient. NZFSA reconsidered why these existing standards needed replacing.

The proposed Standard is being developed to replace the existing standards for a number of reasons:

- Firstly, to clarify the requirements of other manufacturing processes considered to be equivalent to pasteurisation, such as evaporation in the manufacture of milk powder and vacreation in the manufacture of butter.
- As well, it was necessary to include in a standard the outcomes for thermisation for milk and cream used for cheese manufacture and UHT treatment of dairy produce.
- In addition, it was necessary to explain the relationship between the NZFSA Standard for dairy heat treatment and the heat treatments required as importing country requirements, as it was perceived by many that EU and US requirements may have become the standard for all heat treatments not just those treating dairy products for export to those countries.
- Previously it had been identified that a standard was required to provide the criteria for validation, evaluation and verification of heat treatments which were not contained in MRD 3 and 4. As well a set of criteria were required to replace the requirements for checking the operation of pasteurisers that was contained in MRD 4.

- Finally a framework is required for the development, assessment and approval of industry codes of practice.

Based on this assessment of the existing Standards it was agreed that a new standard was required.

5.3 RELATIONSHIP TO HACCP

In the September draft Standard, heat treatments defined as critical control points and control measures to control pathogenic micro-organisms were required to comply with the Standard. In addition the acceptable criteria attempted to define the elements of the HACCP plan related to those critical control points.

There were a number of submissions which suggested that the Standard only applied to critical control points. This meant that control measures such as casein hot washes and thermisation (except in cheese manufacture) were clearly excluded from the scope of the Standard. Other submissions were concerned that the validation described in the draft Standard was not consistent with validation associated with critical control points in a HACCP plan.

NZFSA and the Working Group recognised that although under the *Animal Products Act 1999* (APA), the defined heat treatments (UHT, pasteurisation and thermisation for cheese manufacture) would be operated as critical control points, this was not appropriate for the industry at this stage. Furthermore the HACCP Working Group was commencing work on the HACCP specification and guidelines for the APA and it was better to have the requirements for heat treatments as critical control points and control measures defined in that document.

In the past pasteurisation has been considered and operated as a prerequisite programme by the former MAF and dairy manufacturers. Prerequisite programmes are documented programmes covering Good Manufacturing Practice (GMP)-based food hygiene activities that may interact at a number of process steps within and across various processes in the food premises, and that have the potential to influence the hygiene status of the product. Prerequisite programmes are also known as supporting systems. Examples of prerequisite programmes in the dairy industry include CIP systems, ingredients acceptance, pest management and pathogen surveillance programmes.

As a consequence of these deliberations, it was agreed that there was a requirement for a standard covering the defined heat treatments where these were operated as prerequisite programmes. Furthermore, the Working Group agreed that where the heat treatment was operated within the context of a fully validated HACCP plan, the proposed Standard would not apply. In this way the proposed Standard would serve as a transitional arrangement for regulating the defined heat treatments until such time as the APA (and full HACCP) was fully implemented and in force in the dairy industry. When this happens the Standard for heat treatments, operated as prerequisite programmes, will become redundant.

5.4 SCOPE OF THE STANDARD

5.4.1 HACCP context

In the past, there has been a view that if milk is pasteurised, the product manufactured from that milk is assumed to be safe. To this end, a lot of attention focussed on the pasteuriser rather than the management of hazards and risks throughout the process. Related to this, some perceived that the boundaries of the Standard for heat treatment/pasteurisation were not clearly defined and could be applied over the whole process.

Since MRD 3 and 4 were issued, MAF (in 1999) made HACCP plans a mandatory component of PSPs. The use of HACCP plans means that hazards throughout the process are identified and the risks appropriately managed. Heat treatment, such as pasteurisation, is one of the measures used to control microbiological hazards. In many instances the heat treatment will be the critical control point. This means that the Standard for heat treatment now needs to be written in the context that all manufacturers will have an operational HACCP plan in place as part of their PSP.

5.4.2 Pathogens

Some submissions asked that the pathogens of concern be identified as part of the Standard. There were also others who considered that demonstration of control of food borne pathogens such as *Salmonella* should be sufficient. Generally there was limited understanding of heat treatment's role in destroying milk-borne micro-organisms such as *Mycobacterium tuberculosis* and *M. bovis* which cause tuberculosis and the difficulty of testing for such organisms in milk and dairy produce.

The Working Group did note that while some information on the lethal effects is provided in the draft Standard, this information is incomplete. For heat treatment such as pasteurisation to be used as a critical control point within a HACCP plan, it is necessary to have more complete scientific information on the performance (lethal effects) of the defined heat treatments. 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 when the *Animal Products Act 1999* comes into force in the dairy industry.

5.4.3 Use of prepasteurised produce

Manufacturers in their submissions asked that we consider whether the scope of the heat treatment Standard needed to cover all heat treatments, or whether the scope could be restricted to the heat treatment of raw dairy produce. This would enable those manufacturers who used prepasteurised dairy ingredients, such as pasteurised milk or cream, to use heat treatments that did not have to comply with the Standard. In this situation they would rely on HACCP analysis to identify and the HACCP plan to manage hazards. Consequently any heat treatments used would be validated as part of the validation of the HACCP plan.

This request was discussed thoroughly. In the past pasteurisation has existed in the absence of HACCP plans and has been relied on as the "cure-all" and insurance policy for all situations. It is speculated that the requirement for pasteurisation of ice cream mixes was a means to ensure that any contamination of prepasteurised ingredients through handling and the addition of ingredients, such as raw egg, would be reduced to a safe level.

The Working Group agreed that manufacturers were now operating in an environment where HACCP plans were required, and where hazards and sources were systematically identified and suitable control measures were in place to prevent or reduce the level of risk to a safe level. This means, that provided micro-organisms such as *Mycobacterium tuberculosis* and *M. bovis* were controlled through the use of prepasteurised dairy ingredients, the manufacturer could manage the hazards appropriately. Based on this, it was agreed that the Standard apply only to the heat treatment of raw dairy produce.

5.5 THERMISATION, MANUFACTURE AND STORAGE

Concern was expressed that the storage temperature (2°C or higher) permitted for thermised cheese in the previous draft of the heat treatment Standard, could be inappropriately used for soft and semi soft cheeses, where the pH and water activity of the cheese would be insufficient to destroy pathogenic micro-organisms. The Working Group recommended that the draft Standard be revised so thermisation was only permitted for cheeses with less than 39 percent moisture, less than pH 5.5 and where the pH of the cheese does not increase on ripening.

5.6 PHOSPHATASE TESTING

The role of phosphatase testing for verification of pasteurisation was considered by the Working Group. There is a long and accepted history of testing for the presence of alkaline phosphatase to rapidly confirm whether pasteurisation has been successful. The enzyme is destroyed by pasteurisation times and temperatures. Recent developments in the methodology in the early 1990s have resulted in the fluorometric detection of phosphatase. This methodology has higher sensitivity than the traditional phosphatase tests, provides quantitative results and the reading is not subject to interference by product colour.

The Working Group agreed that phosphatase testing does have an important role to play in demonstrating that the heat treated produce is pasteurised. The Group also considered that the presence of pathogen micro-organisms in the finished product may also be an indicator of unsuccessful pasteurisation or post pasteurisation contamination. The Working Group recommended that phosphatase testing be used for testing pasteurised dairy produce used for manufacturing those products that leave a manufacturer's control before the results of microbiological testing are available e.g. fresh milk.

5.7 PRESCRIPTIVE CRITERIA

A number of submissions noted that the criteria provided in the draft Standard for heat treatment equipment and its operation were prescriptive and suggested that the criteria be outcome-based. This would enable manufacturers to consider the outcomes that need to be delivered in the context of the nature of their operation and provide solutions that may not already be contained in codes such as NZCP 7. This was particularly relevant for small manufacturers without automated control systems.

Views contrary to this were also received. Some commented that manufacturers required solutions to enable equipment suppliers to readily quote and that outcome-based criteria made it difficult to comply easily. There was also the view that solutions developed by each manufacturer to meet the outcome could lead to number of different solutions which would be difficult to assess for compliance. At the ultimate extreme, there was the opinion that outcomes could lead to inconsistent standards for heat treatment across the industry, and that food safety could be compromised thereby jeopardising New Zealand's reputation as a supplier of dairy products.

As a consequence of consultation with the Ministry of Health and various sector groups it was agreed that the criteria in the Standard be outcome-based. To assist manufacturers find suitable solutions NZMP, a subsidiary of Fonterra Co-operative Group Ltd, agreed that it would be revising NZCP 7 to comply with the Standard and seeking reapproval soon after the issue of the heat treatment Standard. It was also agreed to provide some suggested solutions for smaller manufacturers as part of a guideline document prepared by the Heat Treatment Working Group and published by the NZFSA. It is acknowledged that a manufacturer may choose to use all or part of the NZCP 7 or the suggested solutions or be free to develop other means of complying with the outcomes of the Standard and the acceptable criteria.

In addition to this it was agreed that manufacturers would need to be able to demonstrate to the heat treatment assessor how the heat treatment plan delivered the required outcomes. Furthermore it was noted that the assessors required training to enable them to be able to assess whether the solution provided by the manufacturer delivered the outcome, as there was a widespread view amongst manufacturers that assessors were reluctant to accept anything other than what was prescribed in a NZFSA-approved code or standard.

5.8 CODES OF PRACTICE AND APPROVED STANDARDS

Manufacturers have the option of following other NZFSA-approved codes of practice and standards as the means of complying with NZFSA Standards. A large number of submissions related to codes of practice such as NZCP 7, and approved standards.

5.8.1 NZCP 7

There were a large number of submissions made regarding NZCP 7. NZFSA does not own NZCP 7 nor does it have responsibility for it. The following information is provided to update the dairy industry on the developments relating to NZCP 7 as we understand them.

5.8.1.1 Ownership and availability

NZCP 7 is owned and controlled by NZMP. NZMP staff have also indicated that, although NZMP owns the intellectual property, the revised version of NZCP 7 will be made available to other dairy manufacturers in New Zealand.

5.8.1.2 Process for review and reapproval of NZCP 7

NZMP is currently reviewing NZCP 7 to ensure it is aligned with the draft Standard and to include the additional material required for evaporators to comply with the Standard. They anticipate that the new version will be evaluated and ready for approval by NZFSA soon after the issue of the proposed Standard in January 2003. In this way NZCP 7 will be available early in the 18 month transition period.

5.8.1.3 Is NZCP 7 compulsory?

NZCP 7, when approved by NZFSA, will provide a set of solutions that comply with the new Standard. NZMP has advised that it anticipates that NZCP 7 will become the standard for the defined heat treatments operated by that company. However NZCP 7 is only one way of meeting the proposed Standard. Other dairy manufacturers may reference other approved codes and standards or develop their own means of complying with the proposed Standard.

5.8.1.4 NZCP 7 and importing country requirements

NZCP 7, when approved by NZFSA, will provide a set of solutions that satisfy importing country requirements in those cases where New Zealand's official systems are accepted as equivalent to those of the importing country, viz. products under the NZ/EU Veterinary Agreement and the FDA Memorandum of Understanding. Its equivalence to other importing country requirements, such as the US Grade "A" Pasteurised Milk Ordinance, has not been established.

5.8.1.5 NZCP 7 transition arrangements

NZFSA-approved PSPs that currently reference versions 1,2 or 3 of NZCP 7, will need to be revised to ensure the heat treatment complies with the requirements of the Standard and the new version of NZCP 7 where this is referenced in the PSP.

5.8.2 Other codes and standards for heat treatment

As with the revision to NZCP 7, standards such as the US 3A , "Accepted Practices for the Sanitary Construction, Installation, Testing and Operation of High-Temperature Short-time and Higher-heat Shorter-time Pasteuriser Systems, Revised, Number 603-06) and the Australian Standard AS39931.1, "Equipment for the pasteurisation of milk and other liquid dairy products. Part 1: Continuous flow systems", will require evaluation to determine if they deliver the outcomes of the proposed Standard, before they are approved by NZFSA. To date, NZFSA has not received any requests for these to be evaluated for approval.

5.8.3 Ice cream and cheese manufacturers' codes of practice.

These two codes of practice are due to be published and approved by the NZFSA in 2002. These codes outline the requirements of food safety programmes for the manufacture of ice cream and cheese to be sold in New Zealand and Australia. To export dairy products from New Zealand to countries other than Australia, the manufacturers require an approved product safety programme. These codes can form the basis of a PSP provided requirements related to reporting, the operation of an independent verification programme and the assessment of the defined heat treatments meet the requirements of existing NZFSA Standards.

5.9 VALIDATION, EVALUATION AND VERIFICATION

A number of submissions highlighted that there is considerable confusion about the differences between validation, evaluation and verification and responsibility for them. This has been compounded by uncertainty (described in NZFSA Discussion Paper 1, "The Optimal Regulatory Model in The New Zealand Dairy Industry" published January 1999) over the existing pasteuriser validators' roles.

5.9.1 What is validation?

5.9.1.1 Existing NZFSA Dairy Standards

MRD-Stan 4 requires an independent evaluation of a pasteuriser by a competent person who is recognised by NZFSA for validation of pasteurisation control and calibration services (service category Pv) in terms of MRD-Stan 1. Evaluation is not defined in either MRD-Stan 1 or 4. MRD-Stan 1 defines validation as:

- “The confirmation, by a competent, impartial agency, that a procedure is complete and will deliver the expected food safety outcomes and is being implemented as documented.”

Since 1999 and the introduction of the D-series standards, MAF Food: Dairy defined validation as:

- “The assessment of a plan, programme or system to ascertain that it is complete, is being implemented as documented, and is delivering the expected outcomes. The owner of the plan, programme or system is responsible for ensuring validation is completed.”

This definition carries with it an understanding that the manufacturer is responsible for checking that all the requirements (plans, programmes and systems), as specified by legislation and clarified by NZFSA Standards, are in place.

5.9.1.2 HACCP

A key step in the development and application of a HACCP plan is the validation step. The Codex HACCP Guideline defines validation as:

- “Obtaining evidence that the elements of the HACCP plan are effective.”

Critical limits must be specified and validated if possible for each Critical Control Point. Where possible, validation activities should include actions to confirm the efficacy of all elements of the HACCP plan.

It is generally accepted that the manufacturer is responsible for HACCP validation.

5.9.1.3 Draft Codex Validation Guideline

A guideline on the validation of food hygiene control measures has been drafted and is at Step 3 in the Codex process. This draft defines validation as:

- “The obtaining of evidence that the food hygiene control measures selected to control a specific hazard(s) in a specific food(s) are capable of consistently controlling the hazard to the level specified.”

New Zealand suggested to the Drafting Group that the definition should read:

- “The obtaining of evidence that the food hygiene control measures selected to control a specific hazard(s) in a specific food(s) are capable of, and can be demonstrated as being effective in controlling the hazard to the level specified.”

5.9.1.4 Animal Products Act 1999

The *Animal Products Act 1999* (APA) requires operators to have a risk management plan (RMP); a key component of which is the HACCP plan. Specifications pursuant to the APA require operators to validate their RMPs when they are first developed and after amendment. The validation and re-validation activities must demonstrate:

- the documentation is complete and complies with the requirements of the APA and any relevant animal product regulations and specifications; and
- the risk management programme is capable of achieving its outcomes; and

- that, in the case where an amended risk management programme is implemented, it will consistently deliver the documented outcomes.

Guidelines for developing and implementing RMPs and HACCP plans for the meat and seafood industry have been published by the NZFSA. These Guidelines include information on validation.

It has been agreed that, in 2003, the APA be amended to encompass dairy processing. In preparation for this change, NZFSA Dairy has formed the HACCP Working Group to develop material for the development of HACCP plans under the APA and to replace the existing NZFSA Standard D110, "Dairy HACCP Plans". This material will include more information on validation of dairy HACCP plans in the context of an RMP.

5.9.1.5 NZFSA and harmonisation

NZFSA is developing a definition for validation that is consistent and appropriate across all NZFSA documentation. NZFSA has decided to present this standard in the interim without these definitions, as the intent of the standard is still clear and the temporary omission of the definitions does not warrant the further delay to consultation on this standard.

This definition will be used in the proposed standard for dairy heat treatments. To assist in the understanding of the steps involved in validation of heat treatments, it is proposed that additional commentary will be added to the draft standard.

5.9.2 What is evaluation?

Evaluation is the 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).

Evaluation is the means by which NZFSA determines whether the individual, plan, programme, or system should be approved, e.g. approval of a PSP. New plans, programmes, or systems require evaluation prior to approval and then are required to be re-evaluated after any significant change. Evaluation is undertaken after validation is completed.

The Working Group considered the evaluation process and determined that evaluation of the heat treatment plan is a key part of the evaluation of a PSP and is required to be undertaken by a specialist evaluator. The extent of the heat treatment evaluation would be dependent primarily on the quality of the validation exercise. Where the validation of the heat treatment plan has been undertaken by a competent person and is thorough and well documented then less effort would be required for evaluation.

5.9.3 What is verification?

Verification is the 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.

Verification by audit is the means by which the NZFSA determines whether the operation is being operated in accordance with the PSP previously approved for that operation. The Working Group recognised that for heat treatments that have undergone no significant changes, a regular audit of the heat treatment is required to confirm that it continues to be operated in accordance with the heat treatment plan that was approved as part of the PSP. The verification of the heat treatment would be undertaken as part of the regular PSP verification audit. The Working Group also recognised that specialist skills were required for a thorough verification of the heat treatment. However where a manufacturer had an excellent performance history, a full specialist verification could be replaced by an audit by a PSP verifier who would call in a heat treatment specialist if problems were identified.

5.9.4 Performance based verification

There has been a widespread demand for performance-based verification of the defined heat treatments. The current annual system does not recognise manufacturer's competence and ability to operate heat treatments that comply with requirements. Furthermore the existing system does not identify where there is an increased risk to public safety through inappropriate management and operation of heat treatments and respond accordingly. The Working Group agreed that performance-based verification of heat treatment be drafted into the proposed standard for consideration by industry. Furthermore, the Working Group suggested that a manufacturer's performance could be assessed on factors such as non-compliances, maintenance, significant changes, validations, checks, documentation and records and internal audits of the PSP

5.9.5 Assessment of heat treatment plans and PSPs

NZFSA Dairy and Plant Products reviewed how to manage the assessments (validation, evaluation and verification) of the heat treatment plan in the context of the overall PSP assessment. It was agreed that the assessment of the heat treatment plan was part of the PSP assessment rather than a separate assessment. Using the APA experience with the canning of low acid foods, it was recognised that in order for the PSP to be completely assessed a specialist heat treatment assessor may be required to be part of the PSP assessment team, if the other members of the assessment team did not have the necessary knowledge and skills.

Validation of the heat treatment is the responsibility of the manufacturer and could be undertaken by either by an employee of the manufacturer or by a contractor. Evaluation and verification of the heat treatment would be undertaken either by a TPA approved individual or by a NZFSA assessor, depending on whether the manufacturer is operating under the Optimal Regulatory Model (ORM) or not.

5.9.6 Future of Recognised Service Providers in the Service Category Pv

In line with the consultation paper on recognised service providers published in February 2002, the Working Group identified that the service category Pv (validation of pasteurisation control and calibration services) would disappear and that alternative systems would be required to maintain the specialist skills necessary for the assessment of heat treatment plans.

As a consequence the Working Group recommended that the competency requirements for specialist heat treatment validators, evaluators and verifiers be defined in the draft Standard based on the current D-series standards for Third Party Agencies (TPAs) (D501, D502 and D503). The Working Group also suggested that the Standard also define the additional knowledge and skill required by PSP evaluators and verifiers to enable them to assess heat treatments in future.

5.10 VERIFICATION FOR CERTIFICATION

With the development of the e-certification system, NZFSA has been investigating the most effective way of verifying the heat treatment assurances it provides in export certificates. This certification is the means by which the NZFSA determines that the assurance given in the export certificate is actually true. A number of options were considered including the current system of relying on the annual evaluation by the pasteuriser validators which require test reports and also declarations provided in the summaries of records.

The Working Group considered the options and agreed that the current system of relying on the annual pasteuriser validation was a good starting point but inadequate as it did not provide a means to assess the compliance of the heat treatment between assessments. The Working Group agreed that the regular verification should continue as a basis for certification and this is supported by PSP verifiers' reviews of manufacturers' regular reports. This would then require that a business process be developed to enable the PSP verifiers to easily communicate the outcome of their assessment of the manufacturer's regular report to the NZFSA. Based on this the Working Group also suggested that the proposed Standard also outline the information relating to the defined heat treatments to be provided by the manufacturers in their regular reports.

5.11 TRANSITION PERIOD AND ARRANGEMENTS

In the submissions there was concern expressed about the proposed transition arrangements.

The draft Standard had proposed an 18 month transition period of the date of issue. Recognising that there were a number of heat treatments, primarily evaporators, that would not be able to be upgraded in time to meet the requirements of the Standard, provision was made for interim control plans to be approved by NZFSA as part of the PSP. These interim control plans would identify the hazards and risks associated with the non-conforming heat treatment and outline how these would be controlled. Where the heat treatment and interim control plan did not comply with the requirements of an importing country, then that premises would be removed from the list for that country and NZFSA could not provide certification for export to that country.

This restriction on export was of concern to a number of manufacturers, who were unclear about the importing country requirements for the countries they export to. NZFSA prepared a list of all the heat treatment attestation it provides and published it on its website early in 2002. Further work is currently being undertaken by NZFSA to clarify the countries to which each attestation relates.

The Working Group reconsidered the concept of the interim control plan and agreed that it was appropriate that this facility be provided in the redrafted Standard to enable the managed upgrade of the heat treatment equipment.

5.12 IMPORTING COUNTRY REQUIREMENTS

5.12.1 United States

There was a query about whether the heat treatment had to comply with the exact requirements of the 3 A Standard when exporting to the USA. Dairy products exported from New Zealand to the US have to comply with different requirements depending on the type of product (refer Annex C.3). There is no specific requirement to comply with the 3A Standard, although this is one way of meeting the requirements.

6. Implementation

6.1 MECHANISM FOR IMPLEMENTING

The changes proposed above would be implemented by preparing a NZFSA D-series Standard for the three defined dairy heat treatments: UHT, pasteurisation and thermisation for cheese manufacture.

The Standard would outline the outcomes for these heat treatments and provide acceptable criteria by which a dairy manufacturer could deliver these outcomes.

6.2 CHANGES REQUIRED FOR IMPLEMENTATION

6.2.1 By NZFSA Dairy and Plant Products

- development with the NZQA of the qualifications for heat treatment validators, evaluators and verifiers;
- development of business system for management of performance based verification of dairy heat treatments;
- development of the verification database to enable PSP verifiers to communicate their assessment of manufacturer's regular reports to NZFSA;
- publication of a guideline to support manufacturers and assessors in understanding and complying with the proposed Standard.

6.2.2 By manufacturers

- review and where necessary upgrade/revise the existing heat treatment plan (heat treatment equipment, operation, procedures, documentation) as part of the PSP to ensure it is delivering the outcomes of the Standard;
- validation and evaluation of the heat treatment plan and approval of the revised PSP; and
- verification of PSP, including the heat treatment, in the normal cycle;
- upgrade regular reports to include additional information on the heat treatments.

6.2.3 By Third Party Agencies

- development of systems for managing heat treatment assessors.

6.2.4 By NZFSA Compliance and Investigation and Third Party Agencies

- training of current PSP evaluators and verifiers to assess heat treatments;
- training of current PSP evaluators and verifiers to review manufacturers' regular reports and provide appropriate communication with NZFSA;
- revision of evaluation and verification criteria to include requirements of the new Standard; and
- evaluation of revisions to PSPs.

6.2.5 By Recognised Service Providers in the Service Category Pv

- decision whether to become a contract heat treatments validator or evaluator/verifier managed as part of a TPA.

6.3 PROPOSED IMPLEMENTATION PERIOD

A 12-month implementation period is usually used for NZFSA D-series Standards unless there is some specific reason otherwise. In this instance an 18 month implementation period is proposed to provide two off-seasons to enable the upgrade of heat treatment equipment to comply with the proposed standard.

Assuming that the Standard is issued on or about 31 January 2003, then the Standard will come into force on 31 July 2004.

7. Proposal

With regards to dairy heat treatments, the following are proposed:

- That a standard relating to dairy heat treatments (D121.1) be drafted and provided for industry consideration.
- That this Standard requires:
 - The three heat treatments (thermisation for cheese manufacture, pasteurisation and UHT treatment) defined in this Standard meet the outcomes for these heat treatments.
 - All dairy produce, used for the manufacture of dairy products be heat-treated by one of the three defined heat treatments. An exception is when the manufacturer has a NZFSA-approved PSP which includes a validated HACCP plan covering either the heat treatment identified and operated as a critical control point, or other control

- measures which reduce biological hazards (pathogenic micro-organisms) to an acceptable level.
- Heat treatment steps in other manufacturing processes, e.g. evaporation, have equivalent outcomes to pasteurisation.
- Heat treatments that are new, relocated or have undergone a significant change must be evaluated before being used to treat dairy produce used in the manufacture of dairy products.
- Heat treatments be verified as part of the PSP verification
- The intensity and frequency of heat treatment verification be dependent on the verification category and level of performance of the manufacturer, unless additional requirements are specified by the competent authority of an importing country.
- Assuming that the Standard is issued on or about 31 January 2003, that it comes into force 18 months later.

8. Draft Standard

Draft NZFSA Standard D121.1, "Dairy Heat treatments", has been drafted based on the findings and recommendations of this discussion document. Copies of the draft Standard can be obtained from NSFSA's website (www.nzfsa.govt.nz/Dairy) or by contacting NZFSA: Dairy and Plant Products.

9. Consultation

The draft Standard is of concern to all manufacturers operating under a PSP in the New Zealand dairy industry and third party agencies. Internal and external consultation will be conducted according to the NZFSA: Dairy & Plants Consultation Policy. The deadline for submissions is **11 October 2002**. Instructions for making submissions are provided with the draft Standard.

10. References

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- *Australia New Zealand Food Standards Code*.
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- Dairy Circular No 28, "Implementation of NZCP 7: Pasteurisation Equipment and Instrumentation Code of Practice" MAF Regulatory Authority, March 1996.
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- “Draft proposed guidelines for the validation of food hygiene control measures” Codex Committee on Food Hygiene, Codex Alimentarius, CX/FH 03/X April 2002.
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- Draft NZFSA Standard D121 “Dairy Heat Treatments”, NZFSA: Dairy and Plant Products, August 2002.
- *Food Act 1981*.
- *Food Hygiene Regulations 1974*.
- *Food Regulations 1984*.
- “Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application”, Codex Alimentarius, Supplement to Volume 1B. Annex to CAC/RCP 1-1969, Rev 3 (1997).
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- NZFSA* Standard D110, “Dairy HACCP Plans”. MAF Food: Dairy and Plant Products.
- NZFSA* Standard D202, “Registration of Dairy Premises”. MAF Food: Dairy and Plant Products.
- NZFSA* Standard D501, “Technical Competency of Third Party Agency Individuals MAF Food: Dairy and Plant Products.
- NZFSA* Standard D502, “Accreditation and Approval of Third Party Agencies”. MAF Food: Dairy and Plant Products.
- NZFSA* Standard D503, “Third Party Agencies’ Responsibilities”. MAF Food: Dairy and Plant Products.
- NZFSA* Standard MRD-Stan 1, “Standard for Inspection, Audit, Validation and Approval Services”. Regulatory Authority, New Zealand Ministry of Agriculture and Forestry, 1998.
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- NZFSA* Standard MRD-Stan 4, “Standard for Checking the Operation of Pasteurisers”. Regulatory Authority, New Zealand Ministry of Agriculture and Forestry, 1993.
- MQD 1: Code of Practice. “Part B, Dairy Food Manufacturing Equipment” (also known as DDM 1). MAF Quality Management.
- MQD 12, “Market Milk Code of Practice” MAF Quality Management.
- NZCP 7, “Pasteurisation Equipment and Instrumentation Code of Practice”. NZ Dairy Board, Quality Section, 1996, revised 1999.
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<http://www.moh.govt.nz/moh.nsf/49ba80c00757b8804c256673001d47d0/0a26fac571b82ccacc256ba000117930?OpenDocument>, Ministry of Health, April 2002

Annex A: New Zealand Food Regulations 1984

Pasteurised Milk and Pasteurised Milk Products

Regulation 93:

- (1) In these regulations "pasteurised", in relation to milk, [standardised] milk, recombined milk, flavoured milk, skim milk or non-fat milk, [or reduced-fat milk,] cream, whipping cream or whipped cream, reduced cream or pouring cream, sour cream, light cream, and recombined cream, and any other milk product for which no standard is prescribed in regulations 92 to 122 of these regulations, means milk or a milk product that has been efficiently heat-treated by one of the following methods:
 - (a) The holding method, by which the temperature of the milk or milk product is raised to not less than 63° C and not more than 66° C, retained at not less than 63° C and not more than 66° C for at least 30 minutes, and then-
 - (i) Immediately and rapidly reduced to 5° C or less in the case of milk or milk products other than cream, or to 7° C or less in the case of cream; and
 - (ii) Maintained at or below that temperature until the milk or milk product is removed from the premises for delivery:
 - (b) The high-temperature short-time method, by which the temperature of the milk or milk product is raised to not less than 72° C, retained at that temperature for at least 15 seconds, and then treated in accordance with subparagraphs (i) and (ii) of paragraph (a) of this subclause:
 - (c) Any other method by which the milk or milk product is raised to any temperature and retained at that temperature for such period as is as effective as the temperature and time combination specified in paragraph (a) or paragraph (b) of this subclause, and then treated in accordance with subparagraphs (i) and (ii) of that paragraph (a).

[(2A) Subparagraphs (i) and (ii) of subclause (1)(a) of this regulation shall not apply to a milk or milk product that is to be used immediately for further processing (for example, in cheese making).]

- (3) No cows' milk, [standardised] cows' milk, recombined cows' milk, flavoured cows' milk, or skim cows' milk or non-fat cows' milk [or reduced-fat cows' milk] shall be deemed to be efficiently heat-treated for the purposes of subclause (1) of this regulation if, when it is subjected to the phosphatase test described in the Third Schedule to these regulations, it gives a reading exceeding 10 on the Lovibond Comparator APTW or APTW/7 discs.
 - (a) The sample shall have a standard plate count not exceeding 50 000 colonies per ml of pasteurised product.
 - (b) 3 out of 5 replicate portions of 0.1 ml shall not give evidence of acid formation and gas formation as described.

UHT (Ultra Heat Treated) Milk and UHT (Ultra Heat Treated) Milk Products-

Regulation 94:

- (1) In these regulations "ultra heat treated", in relation to milk, [standardised] milk, recombined milk, flavoured milk, skim milk or non-fat milk, cream, whipping cream or whipped cream, reduced cream or pouring cream, sour cream, light cream, and recombined cream, and any other milk product for which no standard is prescribed in regulations 92 to 122 of these regulations, means milk or a milk product that has been flow sterilised in properly operating equipment by a single uninterrupted continuous heating process to a temperature of not less than 133° C, either by direct heating with steam or indirect heating, to ensure preservation, treated in a manner to minimise loss of vitamins, and aseptically packed in containers that are hermetically sealed immediately thereafter.

- (2) UHT milk, UHT [standardised] milk, UHT recombined milk, UHT flavoured milk, UHT skim milk or UHT non-fat milk, UHT cream, UHT whipping cream or UHT whipped cream, UHT reduced cream or UHT pouring cream, UHT sour cream, UHT light cream, and UHT recombined cream, and any other UHT milk product for which no standard is prescribed in regulations 92 to 122 of these regulations, shall, when tested by the Sterility Test for UHT milk products described in these regulations, be reported as sterile.

Flavoured Milk

Regulation 97:

- (3) Flavoured milk shall be made from pasteurised milk, pasteurised [standardised] milk, pasteurised reduced-fat milk, pasteurised recombined milk, pasteurised recombined reduced-fat milk, pasteurised recombined non-fat milk, pasteurised skim milk, or pasteurised non-fat milk, or shall be pasteurised or shall be subjected to a method of heat treatment that is at least as effective as the process of pasteurisation.

Skim Milk or Non-Fat Milk

Regulation 98:

- (2) Skim milk or non-fat milk-
(b) Shall have been either pasteurised or ultra heat treated.

Reduced-Fat Milk

Regulation 98A:

- (2) Reduced-fat milk-
(c) Shall have been either pasteurised or ultra heat treated.

Cream or Raw Cream

Regulation 99:

- (4) Every reference in these regulations to "cream" as an ingredient that shall or may be included in a compounded food shall be deemed to include a reference to "pasteurised cream".

Whipping Cream or Whipped Cream

Regulation 100:

- (4) Whipping cream or whipped cream shall be pasteurised, ultra heat treated, or canned, or manufactured from pasteurised milk products.

Light Cream and Light Sour Cream

Regulation 101:

- (4) It shall be pasteurised, ultra heat treated, or canned, or manufactured from pasteurised milk products.

Reduced Cream, Pouring Cream, and Sour Cream

Regulation 102:

- (4) Reduced cream and pouring cream shall be pasteurised, ultra heat treated, or canned, or manufactured from pasteurised milk products.

Recombined Cream

Regulation 104:

- (1) Recombined cream shall be the product prepared from butter or milk fat, with drinking water and milk solids, which product has been either pasteurised or ultra heat treated.

Butter

Regulation 111:

- (1) Butter shall be a product in the form of a plastic emulsion, that is of the type water-in-oil, prepared from any one or more of the following:
 - (a) Pasteurised cream:
 - (b) Pasteurised milk:
 - (c) Butter oil, anhydrous butter oil, anhydrous milk fat:
 - (d) Whey.

Cheese

Regulation 113:

- (2) The milk or cream or mixture of milk and cream that is used in the manufacture of cheese-
 - (a) Shall be subjected to pasteurisation or an equivalent heat treatment; or
 - (b) Shall be subjected to heat treatment at a temperature of not less than 62° C for a period of not less than 15 seconds; and
 - (i) The cheese shall be labelled with the date of commencement of manufacture; and
 - (ii) The cheese shall be stored prior to sale at a temperature of not less than 2° C for a period of not less than 90 days from the date of commencement of manufacture; and
 - (iii) The cheese shall contain not more than:
 - (aa) 100 *Esherichia coli* per gram; and
 - (bb) 100 *Staphylococcus aureus* (coagulase producing) per gram; and
 - (iv) A 50 g sample of the cheese shall be free from *Salmonella*.

Processed Cheese (Regulation 115), Spreadable Processed Cheese (Regulation 116), Processed Cheese Food or Processed Cheese Spread (Regulation 117)

Heating to a temperature of at least 70° C for 30 seconds, or any other equivalent time and temperature combination.

General Standard for Cultured Milks and Fermented Milks

Regulation 118A

- (2) The milk products used in the manufacture of cultured milks and fermented milks shall be pasteurised in accordance with regulation 93 of these regulations, or shall be subjected to a method of heat treatment that is at least as effective as the process of pasteurisation.

Cultured Buttermilk

Regulation 118B

- (3) The milk products used in the manufacture of cultured buttermilk shall be pasteurised, or shall be subjected to a method of heat treatment that is at least as effective as the process of pasteurisation.

Yoghurt

Regulation 119

- (1) Yoghurt shall be a coagulated milk product obtained by fermenting pasteurised milk products, with or without dried milk products, with cultures of *Lactobacillus bulgaricus* and *Streptococcus thermophilus*, [or with other cultures] of suitable lactic acid producing bacteria, and shall have a pH value of not greater than 4.5.

Ice Cream

Regulation 121

- (4) The ice cream mix shall be efficiently heat-treated, either by being kept at a temperature of not less than 69° C for at least 20 minutes, or not less than 74° C for at least 10 minutes, or not less than 79.5° C for at least 15 seconds, or not less than 85.5° C for at least 10 seconds, or by an equivalent heat treatment, and then frozen.
- (5) After the ice cream mix has been subjected to heat treatment, no substance shall be added to it, except fruit, fruit syrup, fruit juice, or any other foodstuff that is pasteurised and is stored in a sealed, sterilised container.
- (6) Notwithstanding subclause (4) of this regulation, heat treatment shall not be required in respect of ice cream that is made from dry ingredients of the nature described in subclauses (1) and (2) of this regulation and drinking water, and that is sold only on the premises where it is manufactured.

Annex B: Draft New Zealand Milk And Milk Products Processing Standard 2002

The Minister of Health, under section 11C of the Food Act 1981, issues the following food standard.

FOOD STANDARD

1. Title

This food standard is the New Zealand Milk and Milk Products Processing Standard 2002.

2. Commencement

This food standard comes into force on 1 December 2002.

3. Interpretation

(1) In this food standard,

Code means the Australia New Zealand Food Standards Code.

ice cream treatment means heat treatment of an ice cream mix to be used in ice cream by keeping the ice cream mix-

- (a) at a temperature of either not less than 69°C for at least 20 minutes; or
- (b) at a temperature of either not less than 74°C for at least 10 minutes; or
- (c) at a temperature of either not less than 79.5°C for at least 15 seconds; or
- (d) at a temperature of either not less than 85.5°C for at least 10 seconds; or
- (e) at another temperature for a time which achieves an equivalent result to the results in paragraphs (a) to (d) above,

and then freezing the ice cream mix

pasteurisation for milk or a milk product means treatment according to one of the following methods-

- (a) The holding method, by which the temperature of the milk or milk product is raised to not less than 63°C and not more than 66°C, retained at not less than 63°C and not more than 66°C for at least 30 minutes, and then—
 - (i) Immediately and rapidly reduced to 5°C or less in the case of milk or milk products other than cream, or to 7°C or less in the case of cream; and
 - (ii) Maintained at or below that temperature until the milk or milk product is removed from the premises for delivery;
- (b) The high-temperature short-time method, by which the temperature of the milk or milk product is raised to not less than 72°C, retained at that temperature for at least 15 seconds, and then treated in accordance with subparagraphs (i) and (ii) of paragraph (a) of this definition;
- (c) Any other method that is as effective in terms of bacterial reduction as options (a) and (b)

cheese treatment means-

- (a) the subjection of milk or a milk product to be used in the manufacture of cheese to heat treatment at a temperature of not less than 64.5°C for a period of not less than 16 seconds; and
- (b) storing the resulting cheese product prior to sale 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

(2) Terms used in this food standard which are defined in the Code have the meanings given to them by the Code.

4. Alternative standards for processing of milk or milk products

(1) Subject to section 11A of the Food Act 1981 (which relates to the sale of small quantities of raw milk at farm premises) all milk and milk products manufactured for sale, used as ingredients in the manufacture of any food for sale, or sold by retail must-

- (a) be processed in accordance with clause 5 and clause 6 of this food standard, or
- (b) be processed in accordance with a product safety programme approved under the Dairy Industry Regulations 1990; or
- (c) be processed on premises in respect of which an exemption from the Food Hygiene Regulations 1974 has been granted by the Director-General of Health under section 8F of the Food Act, and be processed in accordance with the terms of that exemption.

(2) Subclause (1) does not apply to raw milk which is sold only by wholesale and which will be processed to the requirements of clause 4(1) before being sold for retail or used as an ingredient in products which are sold for retail.

5. Method for processing milk or milk products

A product listed in the left hand column of the Table to this clause complies with clause 4(1)(a) of this food standard if the milk or milk products from which it is made are processed according to a treatment listed for that product in the adjoining column of the Table and complies with clause 6.

TABLE 1

Product	Permitted methods of processing
Milk (of any type)	Pasteurisation
Cream (of any type)	Pasteurisation
Fermented milk products, including yoghurt	Pasteurisation
Cheese	Pasteurisation
Cheese with a moisture content < 39% moisture and a pH level < 5.6	Pasteurisation Cheese treatment
Emmental, Gruyere or Sbrinz Cheese	Pasteurisation Cheese treatment The method set out in the <i>Ordinance on Quality Assurance in the Dairy Industry</i> of the Swiss Federal Council of 18 October 1995
Butter	Pasteurisation
Ice cream	Ice cream treatment
Dried, evaporated and condensed milk	Pasteurisation

6. Further provisions in relation to milk and milk products

After any milk or milk product has been processed according to the treatment described in Table 1 to clause 5, any substance added must meet appropriate food safety standards in order to maintain the overall safety of the milk or milk product.

7. Relationship between this food standard and the Code

Where a manufacturer or retailer of a dairy product complies with clause 4(1)(a) or (b) of this food standard when manufacturing or selling that product, such compliance is sufficient to meet, as appropriate for that product, the requirements of clause 4(3) of Standard 2.5.1 of the Code, clause 3 of Standard 2.5.2 of the Code, clause 3 of Standard 2.5.3 of the Code, clause 4 of Standard 2.5.4 of the Code, clause 3 of Standard 2.5.5 of the Code, clause 3 of Standard 2.5.6 of the Code, and clause 4 of Standard 2.5.7 of the Code.

Annex C: Importing Country Requirements

C.1 AUSTRALIA

Food sold in Australia must either:

- comply with the *Australian Food Standards Code* or the joint *Australia New Zealand Food Standards Code*, or
- be produced in New Zealand or imported into New Zealand and meet New Zealand's legal requirements. This applies under the provisions of the *Trans-Tasman Mutual Recognition Act 1997* (TTMRA).

The heat treatment provisions of the *Australian Food Standards Code* and the joint *Australia New Zealand Food Standards Code* do not apply in New Zealand. Therefore foods sold in New Zealand must comply with the heat treatment provisions of the *New Zealand Food Regulations 1984* (see section 4.3.2 above)

The heat treatment requirements under the joint code, that apply in Australia, are:

4.4.1.1 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.

Editorial note for New Zealand:

For New Zealand purposes, processing requirements for milk and milk products are regulated under the *Dairy Industry Act 1952* and the *Food Act 1981*.

4.4.1.2 Processing of cheese and cheese products

Milk and milk products used to manufacture cheese or cheese products must -

- (a) be heat treated by being held at a temperature of no less than 72° C for a period of no less than 15 seconds, or by using a time and temperature combination providing an equivalent level of bacteria reduction; or
- (b) be heat treated by being held at a temperature of no less than 62° C, for a period of no less than 15 seconds, and the final product stored at a temperature of no less than 2° C for a period of 90 days from the date of manufacture of the cheese or cheese product.

Editorial note:

Processing requirements for milk and milk products used in the production of raw Swiss cheeses are contained in Standard 2.5.4.

Editorial note for New Zealand:

For New Zealand purposes, processing requirements for cheese and cheese products, other than raw Swiss cheese, are regulated under the *Dairy Industry Act 1952* and the *Food Act 1981*.

C.2 EUROPEAN UNION

C2.1 Pasteurised dairy products for human consumption except colostrum and derivatives

The European Community/New Zealand Veterinary Agreement on sanitary measures applicable to trade in live animals and animal products. Refer Directive 97/131/EC, Official Journal L 057, 26/02/1997, p. 0005 - 0059 (the EC/NZ Veterinary Agreement).

The EC/NZ Veterinary Agreement recognises the New Zealand regulatory system, as covered by the *Dairy Industry Act 1952*, the *Dairy Industry Regulations 1990* and the *Food Act 1981*, for pasteurised dairy products for human consumption, except colostrum and derivatives, as being equivalent to Council Directive 92/46/EEC (OJ No L268, 14.9.92,p.1) of 16 June 1992 laying down the health rules for the production and placing on the market of raw, heat-treated milk and milk based products (http://europa.eu.int/eur-lex/en/lif/dat/1992/en_392L0046.html) and its amendment (http://europa.eu.int/eur-lex/en/lif/dat/1995/en_395D0165.html)

The heat treatment requirements under this Directive that apply in the EC are:

Annex B

CHAPTER V Special requirements for the approval of treatment establishments and processing establishments

In addition to the general requirements laid down in Chapter I, treatment establishments and processing establishments must have at least:

- (e) if appropriate, centrifuges or any other suitable means for physically purifying milk;
- (f) 1. in the case of treatment establishments, heat-treatment equipment approved or authorized by the competent authority, fitted with:
 - an automatic temperature control;
 - a recording thermometer;
 - an automatic safety device preventing insufficient heating;
 - an adequate safety system preventing the mixture of pasteurized or sterilized milk with incompletely heated milk; and
 - an automatic recording device for the safety system referred to in the preceding indent or a procedure for monitoring the system's effectiveness.However when approving establishments, the competent authorities may authorize different equipment with equivalent performance guarantees and equal assurances with regard to hygiene.
- 2. in the case of processing establishments, in so far as such operations are carried out there, equipment and methods for heating, thermisation or heat treatment meeting the hygiene requirements.

Annex C

CHAPTER I Requirements for the manufacture of heat-treated milk and milk-based products

- 4. (a) Pasteurized milk must:
 - (i) have been obtained by means of a treatment involving a high temperature for a short time (at least 71.7°C for 15 seconds or any equivalent combination) or a pasteurization process using different time and temperature combinations to obtain an equivalent effect;
 - (ii) show a negative reaction to the phosphatase test and a positive reaction to the peroxidase test. However, the production of pasteurized milk which shows a negative reaction to the peroxidase test is authorized, provided that the milk is labelled as 'high-temperature pasteurized';
 - (iii) immediately after pasteurization, have been cooled to a temperature not exceeding 6° C as soon as possible.
- (b) UHT milk must:
 - have been obtained by applying to the raw milk a continuous flow of heat entailing the application of a high temperature for a short time (not less than +135° C for not less

- than a second) - the aim being to destroy all residual spoilage micro-organisms and their spores - using aseptic opaque containers, or containers made opaque by the packaging, but so that the chemical, physical and organoleptic changes are minimal,
- be of preservability such that no deterioration can be observed by means of random sampling checks after it has spent 15 days in a closed container at a temperature of +30° C; where necessary, provision can also be made for a period of seven days in a closed container at a temperature of +55° C.

Where the 'ultra high temperature' milk treatment process is employed by direct contact of milk and steam, the steam must be obtained from potable water and must not leave deposits of foreign matter in the milk or affect it adversely. Moreover, the use of this process must not cause any change in the water content of the treated milk.

- (c) Sterilized milk must:
 - have been heated and sterilized in hermetically sealed wrappings or containers, the seal of which must remain intact,
 - in the event of random sampling, be of preservability such that no deterioration can be observed after it has spent 15 days in a closed container at a temperature of +30° C; where necessary, provision can also be made for a period of seven days in a closed container at a temperature of +55° C.
 - (d) Pasteurized milk which has been subjected to high-temperature pasteurization, UHT milk and sterilized milk may be produced from raw milk which has undergone thermization or an initial heat treatment in another establishment. In this case the time-temperature set must be lower than or equivalent to pasteurization and the milk must show a positive reaction to the peroxidase test before the second treatment. Recourse to this practice must be brought to the attention of the competent authority. Mention of the first treatment must be made on the document provided for in Article 5 (8) of this Directive.
 - (e) Heating processes, the temperatures and duration of heating in respect of pasteurized, UHT and sterilized milk, the types of heating equipment, the flow-diversion valve and the types of temperature controlling and recording devices shall be approved or authorized by the competent authority of the Member States in accordance with Community or international standards.
 - (f) The data produced by recording thermometers must be dated and kept for two years so that they can be shown upon request to the officials appointed by the competent authority to inspect the establishment, save in the case of microbiologically perishable products, for which this period may be reduced to two months after the use-by or minimum durability date.
5. Heat-treated drinking milk must:
- (a) meet the microbiological standards laid down in Chapter II;
 - (b) not contain pharmacologically active substances in quantities higher than the limits laid down in Annexes I and III to Regulation (EEC) No 2377/90; the combined total of residues of all antibiotic residues may not exceed a value to be fixed in accordance with the procedure laid down in Regulation (EEC) No 2377/90.

C.3 USA

C3.1 Dry Milk Products

Memorandum of Understanding (MoU) between the Ministry of Agriculture and Fisheries and the Food and Drug Administration relative to Exporting Dry Milk Products to the United States (Federal Register, 3 October 1974. 39 FR 35697).

- The MoU between MAF and the FDA accepts the New Zealand regulatory system for dry milk products as being equivalent to, and meeting USA importing country requirements.
- All dry milk products (including nonfat dry milk, whole milk powder, dried whey, buttermilk powder, casein and caseinates) must be phosphatase negative, defined as "No indication of

under-pasteurisation or contamination with raw milk when tested by one of the methods in AOAC methods, 12th edition, section 16.101, et al".

Letter, Smucker, Acting Chief, Milk Safety Branch, CFSAN, to Haslam, Veterinary Counsellor, Australian Embassy, 13 September 1995:

- The Fluorophos and Charm II tests have been adopted for regulatory purposes as alternatives to the Scharer Rapid Method for the purpose of verifying proper pasteurisation of milk and dairy products. The pass fail standards are 500 milliunits/L.

C3.2 Milks, creams (up to 40% milkfat) and cultured milks

There is no agreement between New Zealand and the US covering these products. It is understood that exports must comply with the requirements of the "Grade "A" Pasteurised Milk Ordinance" (PMO). Similar requirements appear in US Military Standards, and in 21CFR131.3, with some simplification. (CFR is the Code of Federal Regulations, available on-line at www.access.gpo.gov/nara/cfr/cfr-table-search.html.)

C3.3 Frozen cream

Frozen cream (over 40% milkfat) is exported to the US under the provisions of the Federal Milk Import Act 1927 (<http://www.fda.gov/opacom/laws/fimilkat.htm>).

The Federal Milk Import Regulations define pasteurisation as the process of heating every particle of milk or cream to at least 143° F (62° C), and holding it at such temperature continuously for at least 30 minutes, or to at least 161° F (72° C), and holding it at such temperature continuously for at least 15 seconds.

A maximum bacterial count is specified for pasteurised milk.

Pasteurisation; equipment and methods. Adequate pasteurisation machinery that is easily cleaned and of sanitary construction capable of holding every portion of milk or cream at the required temperature for the required time.

The machinery is to be properly equipped with accurate time and temperature recording devices, always kept in good working order. The temperature at the time of heating and holding must invariably be recorded on thermograph charts, initialled, numbered, and dated by the official having jurisdiction over such farms and plants. All thermograph charts shall be held for a period of 2 years unless within that period they have been examined and released by such authorised agents.

C3.4 Cheese

The US requirements for heat treatment of dairy ingredients used in cheese making are in [21CFR 133](#). Examples are:

Hard cheeses (e.g. Cheddar, Gouda, Edam) and soft ripened cheeses

The milk may be pasteurised or clarified or both. Milk is deemed to be pasteurised if it has been held at 62° C for at least 30 minutes or an equivalent time and temperature, and 0.25 g of the cheese shows a phenol equivalent of not more than 3 µg using the AOAC phosphatase method.

If the milk is not pasteurised the cheese must be held at not less than 2° C for not less than 60 days.

Mozzarella

The dairy ingredients must be pasteurised.

C3.5 Butter and AMF

There are no specific requirements for heat treatment of milk or cream used for making butter or AMF.