New Zealand Food Safety

Haumaru Kai Aotearoa

The DPC's have been withdrawn. For more information on these changes:

Approved criteria, codes of practice, and guidance for dairy

DPC 3: Animal Products (Dairy): Approved Criteria for the Manufacturing of Dairy Material and Product

Pursuant to clause 9 of the Animal Products (Dairy Processing Specifications) Notice 2006, I, Carol Barnao, Director (Standards) issue the "DPC 3: Animal Products (Dairy): Approved Criteria for the Manufacturing of Dairy Material and Product" for the purpose[s] of-

(1) Setting out additional criteria for the general dairy processing of dairy material or dairy products that are valid and appropriate requirements against which to assess such operations.

(2) The criteria in this document are to be used by recognised agencies and persons when evaluating or verifying a risk management programme covering dairy processing activities unless alternative criteria have been recognised as valid and appropriate, and approved.

Signed at Wellington this 26 / 01 /2010

[Signed]

Carol Barnao

Director (Standards)

New Zealand Food Safety Authority

(Acting under delegated authority)

Contents

Notice

1 Scope and Application

(1) This document sets out additional criteria for the general dairy processing of dairy material or dairy products that, in the view of the Director-General, are valid and appropriate requirements against which to assess such operations.

(2) These criteria are applicable to—
(a) Dairy processors
(b) Dairy risk management programme Operators (RMP Operators).

These criteria are to be read in conjunction with all other requirements and criteria applicable under the Animal Products Act 1999. Other related criteria can be found on the NZFSA website at http://www.nzfsa.govt.nz/dairy.

(3) This approved criteria applies from 1st February 2010.

2 Outcome

(1) This document sets out the approved criteria for the general dairy processing of dairy material and dairy products against which a risk management programme, risk management programme operator or dairy processor will be assessed and judged to meet the requirements of the Animal Products Act 1999 applicable to dairy processors.

(2) The criteria in this document are to be used by recognised agencies and persons when evaluating or verifying a risk management programme covering dairy processing activities unless alternative criteria have been recognised as valid and appropriate, and approved as set out under clause 3.

3 Approval of Alternative Criteria

Alternatives to the approved criteria in this document may be recognised as valid and appropriate by the Director-General and approved in writing. Any approved alternative must be kept with the programme and made available during evaluation or verification of the programme.

4 Interpretations

Unless the context otherwise requires, the interpretations used by this document are detailed in the NZFSA document "Glossary of Terms for Dairy" provided on the NZFSA website at http://www.nzfsa.govt.nz/dairy.

5 Dairy Export Requirements and Official Assurances

Processors, risk management programme operators and exporters of dairy material and dairy product intended for export must identify and ensure compliance with all relevant export requirements in accordance with Part 5 of the Animal Products Act 1999. The relevant export requirements can be obtained from the NZFSA website www.nzfsa.govt.nz.

6 Verification

(1) Verification of the approved criteria contained in this and related criteria, including NZFSA approved alternative criteria, will be performed by recognised agencies and persons when evaluating and verifying dairy risk management programmes.

(2) If all relevant specifications and approved criteria are complied with then the Recognised Agency or person provides a recommendation to NZFSA Approvals for risk management programme registration.

(3) If all approved criteria are not complied with by a dairy RMP operator then no recommendation should be provided.

(4) NZFSA Compliance and Investigation Group will also assess compliance with approved criteria outlined in this document as part of any allocated systems audits which are part of scheduled activities.

(5) If a critical non-compliance is identified by a Recognised Agency or person or as part of an NZFSA Compliance and Investigation Group audit then registration of a dairy risk management programme may be reviewed by NZFSA Approvals.

Requirements for Manufacturing

7 Storage of Dairy Material

(1) A risk management programme covering the storage of dairy material must provide the following:

- (a) In regard to premises, facilities and equipment, procedures that ensure that:
  - (i) all areas are kept clean and tidy at all times;
  - (ii) rubbish and wastes are disposed of;
  - (iii) facilities and equipment are maintained;
  - (iv) building integrity is maintained;
  - (v) regular assessments are made and deficiencies documented; and
  - (vi) appropriate corrective actions are completed to rectify any deficiencies.
- (b) A HACCP plan for ensuring the safety of products that is:
  - (i) developed in compliance with NZFSA "Animal Products (Dairy) Approved Criteria for General Dairy Processing"; and
  - (ii) validated and evaluated in compliance with NZFSA requirements;
  - (iii) adequately providing for materials and products to be kept clean, and stored in a manner that minimises:
    - (A) the risks of contamination and spoilage;
    - (B) the proliferation of pathogenic micro-organisms; and
    - (C) the development of toxins.

(c) Procedures for:
  (i) assessing incoming dairy material or product for potential contaminants and damage; and
  (ii) managing the disposal of dairy material or product that fails this assessment.

8 Transport of Dairy Material

Commentary:

Criteria pertaining to the transport of dairy material are now contained in the document: Animal Products (Dairy) Approved Criteria for Storage and Transportation of Dairy material and Products.

9 Manufacturing Premises Cleaning

(1) A risk management programme for the manufacturing of dairy material or dairy product must provide for cleaning procedures that cover the cleaning of the premises, facilities and equipment as well as maintenance, housekeeping and hygiene requirements to ensure that:
  (a) rubbish and wastes are disposed of;
  (b) facilities and equipment are maintained in a good state of repair;
  (c) facilities and equipment are maintained in a good state of hygiene;
  (d) building integrity is maintained;
  (e) regular assessments are made and deficiencies documented; and appropriate corrective actions are completed to rectify any deficiencies.

(2) The cleaning procedures must outline how equipment and product contact surfaces are cleaned and how the effectiveness of cleaning is monitored.

10 Product Safety and HACCP

(1) The HACCP plan for ensuring the safety of product must be developed in compliance with NZFSA "Animal Products (Dairy) Approved Criteria for General Dairy Processing" and validated and evaluated in compliance with NZFSA requirements.

(2) The programme for sampling and testing that is carried out to verify that dairy material and dairy product is safe must include the following:
  (a) procedures to demonstrate how it is ensured that samples are representative and sampling does not contaminate the dairy product; and
  (b) the sampling and testing plans for product safety parameters outlining the test methods, sampling frequency, product safety limits and action if limits are exceeded; and
  (c) procedures for ensuring all testing and analyses are undertaken using registered test methods; and
  (d) testing is conducted in a NZFSA registered laboratory accredited/recognised in the appropriate category for the required analysis.

11 Pathogen Management

(1) A risk management programme for the manufacturing of dairy material or dairy product must include an environmental pathogen management plan to monitor and control pathogens in the environment, in the manufacturing environment, in the manufacturing process and on equipment.

(2) The risk management programme must contain procedures for the validation of the environmental pathogen management plan and the evaluation of the environmental pathogen management plan in compliance to the requirements specified in NZFSA Animal Products (Dairy Recognised Agency and Recognised Persons Specifications) Notice 2005.

Commentary:

The pathogen management systems will be used to minimise the opportunities for pathogens to gain entry to the manufacturing premises. The system includes control of people, equipment and consumables. The system defines what materials may be introduced into critical hygiene areas and how each is handled safely. The introduction of wood into critical hygiene areas is avoided where possible. If wood is introduced, the risk management programme and HACCP plan must demonstrate how the associated risks are managed.

12 Pest Management

(1) The risk management programme operator will ensure that an effective pest management programme is in place to ensure that pests do not infest, spoil or contaminate dairy material or dairy products, and that the application of pesticides in the environment of dairy stores does not endanger product safety.

(2) The pest management programmes will be assessed as part of the Recognised Agency verification of the risk management programme.

13 Control of Foreign Matter

(1) A risk management programme for the manufacturing of dairy material or dairy product must include procedures to protect the manufacturing process from the entry of, or contamination from, foreign matter.

(2) These procedures must include the following:
- (a) the means to monitor and document all intrusive maintenance of product contact areas of equipment and to ensure that product safety is not compromised during these operations;
- (b) the means to clean and maintain all in-line product filters, including milk filters, strainers, sifters and magnets;
- (c) procedures to operate and check in-line metal detectors, to report and follow-up when metal is detected or the metal detector breaks down;
- (d) procedures to regularly check all equipment in critical hygiene areas for potential sources of foreign matter, to report and rectify any problems.

14 Raw Milk

Commentary:

The procedures for raw milk acceptance including the coverage of receipt, standards, sampling/testing and handling of non-compliant raw milk is in: DPC2 Animal Products (Dairy) Approved Criteria for Farm Dairies

15 Ingredient Control

(1) A risk management programme for the manufacturing of dairy material or dairy product must include procedures to ensure dairy raw materials, ingredients, additives, processing aids and cleaning chemicals are:
- (a) stored under appropriate conditions;
- (b) protected from potential contaminants, infestation and spoilage; and
- (c) handled under appropriate stock management systems.

(2) The risk management programme will include the procedures to prevent the contamination of edible materials from inedible materials and any associated matter.

16 Packaging

(1) A risk management programme for the manufacturing of dairy material or dairy product must include procedures for ensuring the use of clean, non-toxic, non-contaminating materials for product packaging.

(2) These procedures must include provisions for:
- (a) assuring the dairy materials' integrity, cleanliness, and freedom from contamination upon receipt;

(b) maintaining and assuring the materials' integrity, cleanliness and freedom from contamination during storage and prior to use;
(c) ensuring that the labelling of dairy material or dairy products is in compliance with NZFSA "Animal Products (Export Requirements – Dairy Products) Notice 2005".

17 Integrity and Labelling of Dairy Material or Dairy Product

(1) A risk management programme for the manufacturing of dairy material or dairy product must include:
(a) procedures to maintain the integrity of dairy material or dairy products throughout the manufacturing process, including provision for the segregation and identification of colostrum and colostrum-containing products until the manufacturer makes a conscious decision to mix colostrum with other dairy material or dairy products;
(b) procedures to ensure that labelling of dairy products is in compliance with NZFSA Animal Products (Export Requirements - Dairy Products) Notice 2005;
(c) procedures to ensure that sampling and testing is carried out to verify that dairy material or dairy product is truthfully labelled, including:
(i) requirements to demonstrate how it is ensured that samples are representative and sampling does not contaminate the produce; and
(ii) the sampling and testing plans for truth of labelling parameters that outline test methods, sampling frequency, truth of labelling limits and action if limits are exceeded.
(d) procedures to ensure all food safety and identity testing and analyses is undertaken using a NZFSA approved test method in a NZFSA laboratory accredited/recognised in the appropriate category for the required test.

Commentary:

Refer to NZFSA "Animal Products (Dairy) Approved Criteria for General Dairy Processing," which defines the specific requirements to be met.

18 Infrastructural Services

(1) A risk management programme for the manufacturing of dairy material or dairy product must include the procedures for monitoring performance and maintaining filtration systems for ventilation and product contact air.

(2) The risk management programme will include the procedures to ensure the provision of potable water, ice, and steam that are safe and suitable for their intended use at the point of use, and will not compromise the safety of the dairy material or dairy product being processed.

19 Water Quality Criteria

(1) Water that comes into direct or indirect contact with dairy material or dairy products must:
(a) be potable water; or
(b) The risk management programme operator may use an alternative water quality standard provided:
(i) the water quality standard is determined by an analysis of hazards; and
(ii) the hazard analysis includes all hazards to the point of use and considers the intended use of the water; and
(iii) the water will not compromise the safety of the dairy material or dairy product being manufactured.

Commentary:

The analysis of hazards is undertaken using HACCP. NZFSA "General Dairy Processing" provides, as Annex 4A, the Codex guideline "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application".

(2) Water that does not come into direct contact or indirect contact with dairy material or dairy products must meet the requirements of clauses 19(1) or 19(2), or meet an alternative non-contact water quality standard if appropriate.

(3) If an alternative non-contact water quality standard is used, the risk management programme operator must determine the appropriate standard by an analysis of hazards taking into consideration the intended use of the water.

Commentary:

A. Ice should be made from water that complies with clauses 19(1) or 19(2). Ice and steam should be produced, handled and stored to protect them from contamination. Steam used in direct contact with food or food contact surfaces should not constitute a threat to the safety and suitability of food.

B. When determining the use of water such as reused or recycled water, the water must meet the quality specified in clauses 19(1) or 19(2). For CIP, the final rinse water must comply with clauses 19(1) or 19(2) and the water used for other stages of CIP must be determined by the criteria for alternative water quality in clauses 19(1) or 19(2).

20 Water Management Plan

The risk management programme operator must implement a water management plan that includes:

(a) the water quality standard (including criteria) as determined through an analysis of hazards; and
(b) any treatment(s) required for the water to meet the appropriate water quality standard(s); and
(c) a water sampling and testing programme for compliance monitoring and process control monitoring; and
(d) requirements to keep relevant records as long as necessary for traceback purposes and verification; and
(e) an action plan in the event of non-compliance with the water management plan; and
(f) the procedures covering water reticulation; and
(g) procedures for ensuring that the supervisor of any water treatment plant has relevant water treatment training and/or qualifications;
(h) procedures for ensuring the operators of any water treatment plant have relevant water treatment training and experience.

Commentary:

Relevant training and qualifications which may be considered for water treatment plant supervisors:

- relevant degree, i.e. BE (Civil or Chemical), BSc or BTech; or

- demonstrated competence as a technical professional, i.e. Registered Engineer or equivalent; or

- relevant Water Treatment Certificate or an equivalent NZQA-registered qualification; and

- relevant water supply and treatment experience.

21 Water Reticulation

The risk management programme operator must implement procedures covering water reticulation that include:

(a) systems to ensure that water of the intended quality is delivered at the point of use; and
(b) systems to ensure that there is no unintentional mixing of water of different standards; and

(c) systems to ensure that the water treatment and reticulation system is not a source of contamination; and
(d) a corrective action plan with appropriate sanitation procedures to be implemented in the event of the reticulation system becoming contaminated.

22 Water Testing

(1) The water testing programme can be subdivided into two parts as follows:
(a) Compliance monitoring – testing the water for compliance with the criteria in clauses 19(1) or 19(2); and
(b) Process control monitoring – the regular monitoring of treated water to ensure that the treatment is effective, e.g. residual chlorine test.

(2) A competent and trained person samples the dairy factory water at sample points representative of the water being used following the sampling requirements specified in the "Drinking Water Standard for New Zealand 2005 (Revised 2008)".

(3) The water samples are tested by a laboratory accredited by an accreditation body to ISO Standard 17025 to test drinking water.

(4) The determinands tested include:
(a) the Priority One determinands specified in the DWSNZ 2005:
(b) Escherichia coli; and
(c) Protozoa (Giardia and Cryptosporidium) which are not tested directly, but an assessment of their presence in the water supply must be made; and
(d) the Priority Two determinands 2a-2c specified in the DWSNZ 2005:—
(i) 2a – Chemical and radiological determinands that could be introduced into the water supply by the treatment chemicals at levels potentially significant to health.
(ii) 2b – Chemical and radiological determinands of health significance that have been demonstrated to be in the water supply at levels potentially significant to health.
(iii) 2c – Micro-organisms of health significance that have been demonstrated to be present in the water supply significant to health.

Commentary:

A. The Priority 2 determinands depend on the characteristics of the water supply and water treatment process. Dairy factories sourcing water from different supplies and in different areas of the country may have different Priority 2 determinands.

B. Where the Priority One and Two determinands are not tested as specified in DWSNZ 2005, the manufacturer holds records that demonstrate, using hazard analysis or an alternate standard, that the compliance monitoring in their programme will adequately demonstrate compliance with the criteria in clause 19(1).

(5) The risk management programme operator determines the frequency of compliance testing taking the following into consideration:
(a) the variability of the source water; and
(b) the reliability of the water treatment process; and
(c) the severity of risk to product safety, which depends on the nature of the hazard.

(6) The hazard and risk analysis should determine whether compliance testing, any additional testing and corrective actions are required for any of the following circumstances:
(a) a new source of supply is to be used; or
(b) there is a problem with the water quality; or
(c) any changes are noticed to the taste, odour, colour or turbidity of the water; or
(d) when nearby industrial or farm activities could affect the source of the supply; or

(e) following damage to, or intrusive maintenance of, the water treatment system and/or reticulation system.

(7) The following records are kept for as long as is necessary for traceback purposes and inspection:
(a) the information used to determine the appropriate frequency of testing; and
(b) the information used to determine the Priority Two determinands to be tested; and
(c) the results of the compliance monitoring tests.

23 Process Control Monitoring of Water

(1) The water analysis carried out in process control monitoring will depend on the water treatment system and may include chlorine, pH and turbidity measurements.

(2) A suitably skilled person will monitor process control using documented test methodologies (including calibration procedures) and/or calibrated equipment.

(3) Process control monitoring of the treated water is conducted:
(a) at a frequency appropriate to the water treatment process and the intended use of the water;
(b) using methods appropriate to the water treatment method and intended use of the water.

(4) The following records are kept for as long as is necessary for traceback purposes and inspection:
(a) the information used to determine the appropriate frequency and method of monitoring; and
(b) the results of the monitoring.

24 Non-complying Water

(1) Where water is identified as non-complying, the appropriate corrective action(s) stipulated in the water management plan is to be carried out.

(2) Dairy material and dairy product coming into contact with non-complying water (refer to clauses 19(1) or 19(2)) must be managed in accordance with NZFSA "Animal Products (Dairy) Approved Criteria for General Dairy Processing".

25 Dairy Heat Treatments

The risk management programme operator must implement dairy heat treatment procedures and processes as provided in Appendix One of this Approved Criteria.

Commentary:

This criteria is currently under review. Upon completion of this review the technical requirements relating to heat treatment will be included in the contents of this criteria document.

26 Independent Verification Programme

Dairy manufacturing premises intending to manufacture dairy products eligible for export must participate in the NZFSA dairy independent verification programme and furnish past and forecast production information to NZFSA or the recognised agency on request.

27 Non-operating Registered Manufacturing Premises

(1) Where a company ceases to use a premises for the manufacture of dairy material or dairy products covered by a registered risk management programme, the company has these options:
(a) maintain registration so as to be able to quickly resume manufacturing or storage operations; or
(b) surrender the risk management programme, and if restarting, apply for a new risk management programme.

(2) To maintain registration of a non operating factory, the company will:
- (a) either maintain the factory in a fully operational state with a current registered and audited risk management programme; or
- (b) prepare a specific "non operational" risk management programme which includes any special arrangements made for mothballing, and submit it to NZFSA for registration; and
- (c) maintain the registered risk management programme, and review it annually.

(3) The risk management programme of a non operating registered manufacturing premises will include:
- (a) resolving any pathogen tracebacks so that the factory is clear before mothballing;
- (b) a pest control programme (rodents, birds, insects) using traps, baits or fumigation;
- (c) appropriate pathogen surveillance (reduced);
- (d) entry controls and security;
- (e) periodic in house inspections and corrective actions;
- (f) annual inspection by a NZFSA recognised inspection service to ensure that minimum requirements for registration are maintained, with completion of corrective actions;
- (g) details of arrangements for ventilation, drainage sanitation, internal sanitation, plant readiness and maintenance (valves, instruments, motors, etc.), CIP and water treatment;
- (h) keeping records of all the activities above;
- (i) sending exception reports during the month they occur, and in particular any:
  - (i) alteration to the pasteuriser or its controls;
  - (ii) alteration to or alternative use of the premises;
  - (iii) alteration to or removal of manufacturing plant and equipment;—
- (j) sending status reports to NZFSA at least every 6 months.

(4) NZFSA will register a non operational RMP covering the mothballing arrangements and review this RMP annually.

(5) While it is non operational, the areas of the factory used for handling dairy material or dairy products will not be used for any activities likely to prejudice product safety if the premises is to be recommissioned including storage of non dairy goods that may pose a risk to product safety and storage of surplus equipment.

28 Starting a Non-operating Registered Manufacturing Premises

(1) Before processing dairy material or dairy products through a non-operating manufacturing premises, the operator will:
- (a) notify NZFSA immediately of the intention to restart, the proposed date and the likely duration of use;
- (b) conduct a pre start inspection using NZFSA recognised inspectors and complete corrective actions;
- (c) confirm the pasteuriser has not been altered since the previous validation and, if necessary, revalidate the pasteuriser;
- (d) ensure pathogen monitoring samples for the critical hygiene area are negative immediately before start up and confirm with NZFSA and if necessary resolve any pathogen tracebacks so that the factory is clear before processing commences;
- (e) reactivate the original risk management programme or have a risk management programme registered before any production commences;
- (f) send NZFSA immediate reports of these actions.

(2) NZFSA will as soon as possible after notification:
- (a) review the original RMP if it has not been reviewed within the preceding 12 months;

(b) programme a visit to the site where it is intended that it will be in use for more than 1 month.

29 Performance Measurement of Dairy Manufacture

(1) Each manufacturer operating under the Regulatory Model (RM) regulatory system is assigned to one of the following performance assessment categories based on their demonstrated compliance with regulatory requirements:
(a) Reduced Assessment category,
(b) Standard/Entry Assessment category, or
(c) Increased Assessment category.

Reduced Assessment Category

(2) Manufacturers in the reduced assessment category demonstrate that:
(a) there is at least a two year history of compliance with regulatory requirements;
(b) there is timely, accurate and complete communication with the contracted recognised agency (RA);
(c) critical non-compliances are managed appropriately, with risk analysis and actions taken to eliminate the risk of potential non-compliances; and
(d) all non-conforming produce is disposed of in accordance with regulatory requirements.

Standard/Entry Assessment Category

(3) Manufacturers in the standard/entry assessment category demonstrate that:
(a) there is compliance with regulatory requirements;
(b) there is timely, accurate and complete reporting to the contracted RA;
(c) critical non-compliances are identified and managed in accordance with regulatory requirements; and
(d) all non-conforming produce is disposed of in accordance with regulatory requirements.

Increased Assessment Category

(4) Any dairy manufacturer who:
(a) consistently fails to meet regulatory requirements,
(b) provides inadequate or late reports, and/or
(c) does not have sufficient control mechanisms in place to give confidence that product is being produced in a consistently safe manner:—

is assigned to the Increased Frequency category.

Entry Classification

(5) When a manufacturer is accepted into the Regulatory Model system, the Recognised Agency reviews the manufacturer's demonstrated compliance. Where the manufacturer demonstrates an appropriate level of compliance, they are assigned to the Standard/Entry Assessment category. If the manufacturer fails to demonstrate compliance in any one or more areas, they are assigned to Increased Assessment category.

(6) The Recognised Agency advises the responsible person of the category to which they have been assigned the frequency of assessments and the date of effect.

30 Demonstration of Compliance

(1) The manufacturer demonstrates continuous compliance at the level appropriate to the category to which they are assigned. Refer to Table A9.1 below for the criteria used to determine compliance. Failure in any area to comply at the level appropriate to the category or the inability to demonstrate appropriate compliance results in reclassification to a category with higher levels of assessment.

Table A9.1: Criteria for the Demonstration of a Level of Compliance Appropriate to each Performance Assessment Category

Category	Reduced Assessment	Standard/Entry Assessment	Increased Assessment
Risk Management Programme.	The risk management programme is registered by NZFSA, is current and validated.	The risk management programme is registered by NZFSA, is current and validated.	The RMP is deficient, or the RMP is not fully implemented, or the RMP is not current, or the RMP requires evaluation or registering, or the RMP is in the process of evaluation or registering.
RMP components: e.g. Pasteuriser, Pathogen Management Plan, Pest Management Plan.	All components validated by manufacturer and evaluated, and No critical non-compliances identified during evaluation.	All components validated and evaluated, and no critical non-compliances identified during evaluation.	One or more component evaluations required, or one or more critical non-compliances identified during evaluation.
RMP HACCP plan.	Internally validated, and Evaluated and operational as part of risk management programme.	Internally or externally validated, and evaluated but non-compliance pending action, or plan under development.	No evaluated RMP HACCP plan in place.
Verification of compliance with RMP.	Compliance with risk management programme demonstrated for two seasons.	Isolated non-compliance with RMP, corrected as required by Recognised Agency.	Regular or persistent non-compliances with RMP, or failure to complete corrective action required by Recognised Agency.
Reporting.	exception reports complete, accurate and on time for at least two seasons, and Proactively advises the Recognised Agency of any non-compliances identified & corrected.	exception reports complete, accurate and on time for at least one season, or exception reports are complete accurate and on time.	exception reports contain incomplete information or factual errors or are persistently late; or exceptions are not reported.

Category	Reduced Assessment	Standard/Entry Assessment	Increased Assessment
Management of critical non-compliances.	Critical non-compliances identified, and full traceback completed to identify root causes, and corrective actions completed in a timely manner, and full analysis of the risk to the operation from this type of non-compliance completed, and actions taken to eliminate the risk of potential non-compliances or monitoring systems implemented to identify potential non-compliance in the operation.	Critical non-compliances identified and managed in accordance with NZFSA requirements.	Critical non-compliances not identified, or Critical non-compliances are identified and inadequately managed.
Disposition of non-conforming dairy material or product.	All non-conforming dairy material or product disposed of in accordance with NZFSA requirements.	All non-conforming dairy material or product disposed of in accordance with NZFSA requirements.	Non-conforming dairy material or product not disposed of in accordance with NZFSA requirements.

31 Assessment Requirements

(1) The risk management programme operator ensures that the assessments required for the performance assessment category to which they have been assigned are undertaken as specified.

(2) The assessment requirements for each performance assessment category are specified in Table A9.2 below.

Table A9.2 Assessment Requirements for each Performance Assessment Category

Assessment	Performance Assessment Category		
	Reduced Assessment Category:	Standard/Entry Assessment Category	Increased Frequency Category
RMP verification.	Full verification of the risk management programme is required every two years; A surveillance verification of the risk management programme is required in the alternate year.	Full verification of the risk management programme is required on an annual basis.	Full verification of the RMP is required at least every six months. The frequency is defined by the Recognised Agency and is dependent on the degree of non-compliance and risk. The Recognised Agency may increase the frequency of Recognised Agency assessment at its own discretion. In addition, the recognised agency may also directly monitor the manufacturer and charge for these activities.

Assessment	Performance Assessment Category		
	Reduced Assessment Category:	Standard/Entry Assessment Category	Increased Frequency Category
Risk management programmes HACCP plans.	Dairy manufacturers with risk management programme HACCP plans must have them verified at the same frequency as the risk management programme .	Dairy manufacturers with risk management programme HACCP plans must have them verified at the same frequency as the risk management programme .	Dairy manufacturers with risk management programme HACCP plans must have them verified at the same frequency as the risk management programme.
Regular reporting .	Quarterly.	Monthly.	Monthly or more frequently as specified .

32 Reclassification

(1) The Recognised Agency initiates a review of the category to which a manufacturer is assigned on receipt of any of the following.

(a) When, as a result of verifications, the Recognised Agency is satisfied that the manufacturer demonstrates compliance appropriate to the recommended reclassification category;

(b) Reclassification to a category with increased or reduced assessment;

(c) Reclassification occurs when:

(i) as a result of an assessment, the Recognised Agency 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

(ii) the manufacturer demands, requests, suggests, or pressures the Recognised Agency to censor or falsify an assessment report.

Report of a Critical Non-compliance

(2) A report of a critical non-compliance by a manufacturer provided by the Recognised Agency in accordance with the reporting requirements specified in NZFSA Animal Products (Dairy) Approved Criteria for General Dairy Processing and NZFSA Animal Products (Dairy) Approved Criteria for Recognition of Agencies and Persons.

Request for Review by the Dairy Manufacturer

(3) 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 Recognised Agency.

Request for Review by another Party

(4) 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 Recognised Agency.

Review

(5) The Recognised Agency reviews the category to which a manufacturer is assigned and, where appropriate, assigns a new category.

(6) This review considers all the available information including any case that has been provided in writing. The Recognised Agency may, for the purposes of the review, undertake or commission an assessment of the manufacturer's risk management programme. This assessment may be at the manufacturer's expense where the manufacturer has requested the review.

Outcome

The Recognised Agency advises NZFSA and the responsible person of the outcome, either:

(a) advising the category to which they have been assigned, the frequency of assessments, and the date of effect; or

(b) confirming the existing category if there is no change of classification.

Appendix One: Dairy Heat Treatments

1 Criteria for Heat Treatments

(1) Where one or more of the heat treatments (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 risk management programme. The risk management programme demonstrates delivery of the outcomes of this document and meets the following criteria for heat treatments. These requirements relate only to operations where the heat treatment step has been defined as a critical control point as part of a Hazard Analysis of Critical Control Points (HACCP) analysis or where attestations relating to heat treatment are required for export certification. The risk management programme may reference all or part of NZFSA-registered codes of practice and standards for dairy heat treatments to deliver some or all the following criteria.

(2) The risk management programme must contain a heat treatment plan which may be a list or matrix of referenced documents that make up the heat treatment plan. This list/matrix includes the document names, references and the locations where they are held.

(3) The heat treatment plan would be expected to contain or reference documents that cover:

Equipment identification

Equipment performance criteria

Products and critical limits

Management of changes (that relate to heat treatment)

Operator training

Drawings of the equipment

Computer control system (where applicable)

Operator procedures

Calibrations

Operating records.

2 Criteria for Documentation and Training

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

(a) staff and contractors (as appropriate)
  (i) have the knowledge and skills necessary to understand the hazards managed by the heat treatment;
  (ii) understand the heat treatment and how it operates;
  (iii) operate, check and maintain the heat treatment including monitoring, taking timely and appropriate corrective action(s) when there is "loss of control";
  (iv) and record keeping; and
(b) the heat treatment is readily validated by the RMP operator; and
(c) the heat treatment is readily evaluated and verified by the Recognised Agency.

Commentary:

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

3 Heat Treatment Equipment

The heat treatment equipment meets the criteria in Table A4.1.

4 Heat Treatment Operation

In addition to the criteria in the following clauses, heat treatments are operated, checked and maintained in accordance with the criteria provided in Table A4.2.

5 Operational Considerations

A Holding Time Calculation

In calculating the holding time for dairy material 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.

Reynolds Number, $Re = \rho vD/\mu$

where:

ρ = density, kg/m3

v = velocity of flow, m/s

D = diameter, m

μ = viscosity of dairy material 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 dairy material to assist in a temperature change, the volume of the condensed steam is included when calculating the volume of dairy material 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.

6 Thermisation for Cheese-making

(1) The liquid dairy material being thermised for cheese-making is within the action limits defined in NZFSA Animal Products (Dairy) Approved Criteria for Farm Dairies for microbiological contamination.

(2) The heat treatment is operated to deliver the outcomes for thermisation for cheese-making contained in the Animal Products (Dairy Processing Specification) Notice 2006. In addition, where the liquid dairy material contains particles of diameter:

(a) of less than 200 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 16 seconds; and

(b) 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

(c) 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 —

(d) the cheese is manufactured and stored to ensure that:

(i) acid production during cheese-making is within the range specified in the risk management programme; and

(ii) prior to sale, pH, salt and moisture in the cheese are within the range specified in the risk management programme for the cheese.

Commentary:

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

7 Pasteurisation

(1) The heat treatment is operated to deliver the outcomes for pasteurisation contained in the Animal Products (Dairy Processing Specifications) Notice 2006.

(2) To receive a heat treatment equivalent to pasteurisation, dairy material 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 material concerned in clauses A, B and C below.

(3) In cases where the composition or particle size of the dairy material 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 registered by NZFSA.

A Milk 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 A4.3 (A1, A2, and A3).

B Dairy Material with Greater than 10 Percent Fat Content and / or Containing Added Sweeteners and Concentrated Dairy Material.

The following dairy material 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 A4.3 (B1, B2 and B3):

(a) dairy material (including cream) with a fat content of 10% or greater; and/or
(b) dairy material with added carbohydrate sweeteners; and/or
(c) concentrated dairy material 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 A4.3 (C).

D Other Dairy Material

In cases where the composition or particle size of dairy material 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).

8 Ultra High Temperature (UHT) Treatment

(1) The heat treatment is operated to deliver the outcomes for UHT treatment contained in the Animal Products (Dairy Processing Specifications) Notice 2006.

(2) 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 Animal Products (Dairy) Approved Criteria for General Dairy Processing.

(3) The products subjected to commercial sterilization 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.

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:
    (i) large numbers of highly heat resistant spores of thermophilic or thermoduric micro-organisms such as bacilli are present; and/or
    (ii) ingredients such as cocoa are used; and/or
    (iii) the dairy material 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.

Table A4.1: 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 dairy material 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 dairy material is not compromised by contamination from untreated or partially treated dairy material or services in the event of: normal operation, or failure to meet the minimum time and temperature requirements, or 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 A4.2.)
Maintaining wholesomeness	6. It can be demonstrated that after heat treatment, the dairy material is immediately heated or cooled to the temperature specified in the RMP.
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 A4.2: Criteria for the Operation of Dairy Heat Treatments

	Operating, Maintenance Criteria	Monitoring Criteria	Criteria for Corrective Actions	Criteria for Documentation and Records
Equipment sanitation	The equipment is clean and sanitary before dairy material is treated. Deposits on equipment surfaces do not jeopardise the safety of the dairy material being treated.	The means are in place to demonstrate equipment cleanliness and sanitation. The means are in place to demonstrate that equipment surfaces do not bear deposits that jeopardise the safety of the dairy material being treated.	Where the operating, maintenance and/or monitoring criteria are not met, dairy material is stopped from feeding forward. When the operation, maintenance and/or monitoring criteria are not met the means are in place to ensure: The appropriate action is taken to restore control; and Where necessary to prevent recurrence of the event that led to the loss of control, the equipment and/or its operation are upgraded; and Any liquid dairy material stopped from feeding forward is either retreated by the heat treatment or disposed of in accordance with with NZFSA Animal Products (Dairy)Approved Criteria for General Dairy Processing; and Any dairy material or dairy product manufactured from dairy material treated by non-compliant heat treatments is managed in accordance with	Documented procedures and records are maintained: To demonstrate that no untreated or partially treated product passes forward; and To demonstrate appropriate and complete corrective action is taken when there is loss of control; and To provide full traceability of lots made from the heat treated dairy material and For the checking and maintenance of the heat treatment equipment, systems and operation.

	Operating, Maintenance Criteria	Monitoring Criteria	Criteria for Corrective Actions	Criteria for Documentation and Records
			NZFSA Animal Products (Dairy) Approved Criteria for General Dairy Processing.	
Particle size	The size of particles in the dairy material does not exceed the limit specified for the time temperature combination in use.	The means are in place to demonstrate the control of the size of particles in the dairy material.	Criteria 5 and 6 apply	Criteria 7 applies
Heating temperature and holding time	The heat treatment is operated to ensure the following For continuous processes, all dairy material including the fastest particle achieves the minimum heat treatment temperature for the minimum holding time specified; or For batch processes, all the dairy material and headspace achieves the minimum heat treatment temperature for the minimum holding time specified.	The means are in place (see Note below) to accurately and reliably: Demonstrate all dairy material has been heated and held to at least the minimum temperature ; e.g. for continuous processes monitoring and recording of the dairy material temperature are continuous and automatic; and Demonstrate all the dairy material 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 For batch processes, demonstrate that the headspace was at the minimum heat treatment temperature for the minimum holding time specified. The means are in place to ensure following checks are completed on a regular basis and the findings recorded: The accuracy of	Criteria 5 and 6 apply.	Criteria 7 applies.

	Operating, Maintenance Criteria	Monitoring Criteria	Criteria for Corrective Actions	Criteria for Documentation and Records
		temperature monitoring; and The accuracy of the holding time; and The correct operation of the system to prevent untreated or partially treated dairy material passing forward.		
Protection from contamination	The heat treatment is operated to ensure: No untreated or partially treated dairy material passes forward; and Treated dairy material is not contaminated by untreated or partially treated dairy material; and The safety and wholesomeness of treated dairy material is not compromised by contamination from services, e.g. coolants, heating media and/or cleaning solutions.	The means are in place to: Continuously monitor and record the operation of the heat treatment to prevent contamination; or Periodically monitor/check the heat treatment equipment to ensure no contamination occurs and record this; and For pasteurised products released for sale before results of microbiological tests are available, undertake phosphatase testing of the heat treated dairy material immediately after heat treatment using a NZFSA-registered test method to demonstrate the dairy material has been correctly pasteurised and not recontaminated. The means are in place to ensure following check is completed on a regular basis and the findings recorded: The correct operation of the system to prevent potentially contaminated dairy material passing forward.	Criteria 5 and 6 apply.	Criteria 7 applies.

	Operating, Maintenance Criteria	Monitoring Criteria	Criteria for Corrective Actions	Criteria for Documentation and Records
Maintaining wholesomeness	The dairy material is immediately heated or cooled to the temperature appropriate for further processing, specified in the RMP.	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 dairy material.	Criteria 5 and 6 apply.	Criteria 7 applies.

Notes:

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

Table A4.3: Heat Treatments Equivalent to Pasteurisation for Common Types of Dairy Material

	A1	A2	A3	B1	B2	B3	C
	All dairy material (excluding ice cream) with						Ice cream mixes with particles <1000µm Ø
	Milks with <10% fat and no added sweeteners and particles			Dairy material with ≥10% fat and/or added sweeteners and concentrated dairy material with >15% total solids and particles			
Particle diameter	<200 µm Ø	200 to <500 µm Ø	500 to<1000 µm Ø	<200 µm Ø	200 to 500 µm Ø	500 to <1000 µm Ø	
Minimum holding time (seconds)	Minimum temperature (◦C)						
1.0	81.6	-	-	84.4	-	-	
2.0	79.0	81.6	-	81.8	84.4	-	
3.0	77.6	79.0	-	80.4	81.8	-	
4.0	76.5	77.6	81.6	79.3	80.4	84.4	
5.0	75.7	76.5	79.0	78.5	79.3	81.8	
6.0	75.1	75.7	77.6	77.9	78.5	80.4	
7.0	74.6	75.1	76.5	77.4	77.9	79.3	
8.0	74.1	74.6	75.7	76.9	77.4	78.5	
9.0	73.7	74.1	75.1	76.5	76.9	77.9	
10.0	73.3	73.7	74.6	76.1	76.5	77.4	85.5
11.0	73.0	73.3	74.1	75.8	76.1	76.9	
12.0	72.7	73.0	73.7	75.5	75.8	76.5	
13.0	72.4	72.7	73.3	75.2	75.5	76.1	
14.0	72.1	72.4	73.0	74.9	75.2	75.8	
15.0	72.0	72.1	72.7	74.8 (refer note 6)	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	63.8	63.8	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. ∅ 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 ≥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 material or dairy product or whey is 10 percent or more, or if it contains added sweeteners, or is condensed milk or condensed dairy material or 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 material. 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 material. 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. Note that a maximum of 20% total solids, with a particle size <200 µm is permitted for the temperature/time combination of 72°C/15 seconds during turbulent flow situations only for concentrated milks. Acceptability has been determined from a study under these specific conditions.

7. Columns A1, A2 and A3 include all raw milk that is less than 10% fat.

8. 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.

9 Process Performance of the Defined Heat Treatments

(1) 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 material or 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.

A Thermisation

(2) 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.

B Pasteurisation

(3) Pasteurisation is a microbiocidal heat treatment aimed at reducing the number of any harmful microorganisms 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).

(4) Codex Code of Hygienic Practice for Milk and Milk Products CAC/RCP 57-2004.

C UHT Treatment

(5) Thermal processes necessary to obtain commercially sterile products are designed to result in the absence of viable microorganisms 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.

(6) Codex Code of Hygienic Practice for Milk and Milk Products CAC/RCP 57-2004
Codex Code of Hygienic Practice for Aceptically Processed and packaged Low-Acid Foods CAC/RCP 40-1993.
Codex Recommended International Code of Hygienic Practice for Low and Acidified Low Acid Canned Foods CAC/RCP 23-1979, Rev. 2 (1993).

10 Reporting to the Recognised Agency

(1) The responsible person or their delegate must notify the recognised agency of any significant changes related to the heat treatment or any planned or proposed significant changes, including the date of the change.

11 Summary of Requirements Relating to Validation, Evaluation and Verification of Heat Treatment Equipment and Systems (included in Heat Treatment Plans)

	Scope of Work	Who does it?	When and How often?
Validation	The person undertaking the validation ensures that heat treatment meets NZFSA requirements a desk top and on-site assessment. This includes such things as: Responsibilities Training Records Documented procedures Equipment Calibration Maintenance Monitoring (checks and tests).	A competent individual employed or contracted by the RMP holder (may be part of a team). Refer to clause 15 for requirements. Names of heat treatment validators should be named in or referenced from the risk management programme.	Validation is required when: New Heat treatment or significantly changed heat treatment. New or significantly changed risk management programme in relation to heat treatment.
Evaluation	Evaluates compliance with NZFSA requirements through such measures as: The examination of the validation report Competency of the person undertaking the validation Desk top and on-site evaluation of the heat treatment.	The person undertaking the evaluation must be: Recognised by NZFSA as a dairy heat treatment evaluator.	Evaluation is required when: New heat treatment or significantly changed heat treatment New or significantly changed risk management programme in relation to heat treatment NOTE Evaluation relates to change only.
Verification	The person undertaking the verification ensures that: The heat treatment complies with the risk management programme The heat treatment and the risk management programme comply with NZFSA requirements NOTE If a critical non-compliance is identified a heat treatment evaluator may be called in.	The person undertaking the verification must be: Recognised by NZFSA as a risk management programme verifier. Refer to NZFSA requirements for recognised persons.	Annually.

NOTE Operator verification includes checks that the operator is responsible for performing (monitoring and calibration as per the Heat Treatment Plan).

12 Validation of Heat Treatment

(1) As part of the risk management programme validation, refer NZFSA Animal Products (Dairy Risk Management Programme Specifications) Notice 2005, the responsible person is responsible for ensuring that the heat treatment is validated.

(2) Validation (in the context of heat treatment) is the process of obtaining evidence that the elements of the Heat treatment Plan are effective in controlling hazards.

(3) The validation of heat treatments includes the assessment:
- (a) of the effectiveness of the time temperature combination in controlling the hazard(s). Note that the time/temperature combinations for the heat treatments defined in this document are historically known to be effective and these therefore do not require validation on an individual risk management programme basis. If the time/temperature combinations are not included within this document then individual validation of these will be required; and
- (b) that, in a specific manufacturing process, this time/temperature combination is then consistently applied, there is no contamination of the heat treated dairy material and that the dairy material is sufficiently heated or cooled to maintain it in a wholesome condition

(4) These are assessed using the criteria from Tables A4.1 and A4.2 for each of the following categories:
- (a) equipment sanitation; and
- (b) particle size; and
- (c) heating temperature and holding time; and
- (d) protection from contamination; and
- (e) maintaining wholesomeness; and
- (f) ease of access.

(5) The validator is to report all non-compliances to the responsible person for resolution and reporting to the Recognised Agency.

(6) Validation is completed on the development of a new heat treatment, on relocation of an existing heat treatment, after each significant change.

(7) The competency requirements for validators are provided in clause 15 of this document.

(8) Validation must 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.

NOTE Validation may be performed against a code of practice or a suitable alternative.

13 Evaluation of Heat Treatments Excluding Stove-top Heat Treatments

The validation and evaluation processes may occur concurrently but must be carried out by different individuals. The evaluator must ensure that there is appropriate independence between the risk management programme operator and the validator. The operator is responsible for managing any potential conflicts of interest including the requirement for separation of design and development from validation.

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

(2) The evaluation consists of the assessment of:
- (a) the competency of the person undertaking the validation (refer to clause 15).
- (b) the validation report, with emphasis on areas where the validation report does not include sufficient information or where there are outstanding non-compliances. Where the evaluator finds that the validation and/or the report are inadequate they may reject the validation report.
- (c) the heat treatment and relevant documentation with attention to the areas which have been highlighted from examination of the validation report are evaluated for compliance with NZFSA requirements.

(d) the heat treatment equipment and its operation are evaluated between commissioning and first dairy material or dairy product through the heat treatment system.

(e) Desk-top and/or on-site scrutiny of any relevant drawings, specifications, software, equipment, the new or revised heat treatment plan, documented procedures, records and personnel.

(3) The competency requirements for heat treatment evaluators are provided in clause 16 of this document.

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

14 Evaluation of Stove-top Heat Treatments

(1) A risk management programme evaluator evaluates stove-top heat treatments.

(2) The risk management programme evaluator develops and uses checklists based on the scope above using HACCP principles.

NOTE A stove top heat treatment is defined as a non-automated heat treatment undertaken in a vessel without fittings for pipe-work eg a saucepan.

15 Competency Requirements for Validators

The validation of heat treatments must be undertaken by a person (or a team of people) who have:

(1) a relevant tertiary qualification or demonstrated competence as a technical professional in food processing engineering; and

(2) relevant and current knowledge of dairy heat treatment equipment or processes; and

(3) adequate knowledge of food safety; and

(4) successfully completed a NZQA-registered course in HACCP and been assessed as competent; and

(5) knowledge of NZFSA heat treatment requirements; and

(6) knowledge of software and experience in calibration.

16 Verification of Heat Treatment

A risk management programme verifier verifies all heat treatments as part of the RMP verification.

Verification of heat treatment includes:

Review of documentation and procedures to ensure currency

Review of heat treatment system and records to identify any significant changes made

Checks on resolution of any non-compliances identified (including exceptions reported)

Checks on preventative maintenance systems

Scrutiny of internal audit reports

Review of heat treatment records to ensure all checks and calibrations have been done as per the heat treatment plan

Review of staff training records.

NOTE Where there is doubt about whether a change is significant, changes not being managed in the correct way by the risk management programme operator or identification of serious problems with the operation of the heat treatment system a

Heat Treatment Evaluator may be called in by the risk management programme verifier.