Te Pou Oranga Kai O Aotearoa

Risk Management Programme (RMP) Template for Dairy Processors – Liquid Milk Domestic Supply

Issued under section 12(3A) of the Animal Products Act 1999

December 2008

Disclaimer

Considerable effort has been made to ensure that the information provided in the Risk Management Programme **(RMP)** Template for Dairy Processors – Liquid Milk, Domestic Supply is accurate, up to date, and otherwise adequate in all respects. Nevertheless, this RMP template is approved STRICTLY on the basis that the Crown, the New Zealand Food Safety Authority **(NZFSA)**, its statutory officers, employees, agents, and all other persons involved with the writing, editing, approval or publication of, or any other kind of work in connection with this template:

a. disclaim any and all responsibility for any inaccuracy, error, omission, or any other kind of inadequacy, deficiency, or flaw in, or in relation to, the RMP Template for Dairy Processors – Liquid Milk, Domestic Supply; and

b. without limiting (a) above, fully exclude any and all liability of any kind, on the part of any and all of them, to any person or entity that applies the RMP Template for Dairy Processors – Liquid Milk, Domestic Supply.

RMP Template for Dairy Processors – Liquid Milk, Domestic Supply

This RMP template applies to businesses that are involved in the manufacture of Liquid Milk and is an acceptable alternative to an individually tailored RMP. For an RMP template relating to farm dairy activities please see the RMP Template for Farm Dairies – Domestic Supply. www.nzfsa.govt.nz/dairy/publications/cop/index.htm

The Guidance for RMP Template for Dairy Processors – Liquid Milk, Domestic Supply should be referred to when completing this RMP template.

This RMP template is intended for small to medium sized operations which manufacture Liquid Milk for the domestic market (Australia and New Zealand only) in accordance with the permitted methods of processing as described in the Food (Milk and Milk Products Processing) Standard 2007. www.nzfsa.govt.nz/policy-law/legislation/food-standards/index.htm
An RMP based entirely on this template without modification, and for which this template is confirmed as appropriate, does not require independent evaluation and may be submitted directly to NZFSA with an application for registration.

An RMP based on this template may be registered with a condition that verification by a recognised person may have to occur within three months of registration.

The RMP template starts on the next page. This page is provided as a cover note and is not part of the RMP.

1. Operator and Day-to-day Manager Details	
1.1 Full legal name (Company, sole trader, or partnership):	
1.2 Trading name (if different from 1.1):	
1.3 Contact details: Phone No: Fax No: Email: [ ] I give consent to being provided electronic information.	Postal address (for communication): Physical address(es) of the business
1.4 Day to day manager of the RMP:	
1.5 Name of persons nominated to authorise a part of a document that makes up this RMP:	
1.6 Name of persons performing key tasks under the RMP including, corrective action, and operator verification activities:	
1.7 Key competencies needed by the day-to-day manager, the persons identified in section1.5, the persons identified in section 1.6, to enable the effective operation of this RMP:	
1.8 The procedures detailing how records (demonstrating that the competencies documented under section 1.7 have been achieved and maintained) are kept are specified in Appendix D section 2	

2. Scope of the RMP	
2.1 Description of the physical boundaries to which this RMP applies (a plan may be included to amplify the description):	
2.2 Business ID/unique location identifier:	
2.3 The RMP covers the following processes or activities, and considers the potential risk factors involved in them: [ ] Refrigerated Storage [ ] Separation [ ] Defined Heat Treatment [ ] Mixing / Blending [ ] Packing [ ] Labelling [ ] Other (describe): _____	
2.4 The relevant sources of potential risk factors that may affect the dairy material or dairy product operations within the physical boundaries of this RMP are specified in Table 4 of Appendix M.	
2.5 The following products or activities of the operator that occur within the physical boundaries of the RMP are excluded because they are covered under a different RMP or under the Food Act (if applicable): Product or activity: Covered under either: (please select) [ ] Another RMP No:_____; or [ ] Food Act:	
2.6 The interfaces between the products under this RMP and the products excluded from this RMP are managed in the following way (if applicable):	
2.7 In the event that a person other than the operator uses areas inside the physical boundaries of this RMP, for any activity not covered by the RMP, then the interface with the activity outside the physical boundaries will be managed in the following way to ensure that the effectiveness of this RMP is not compromised (if applicable):	
2.8 The authorities and responsibilities for resolving issues associated with the activity referred to in clause 2.7 (if applicable):	
2.9 Where a loss stream is identified e.g. animal feed, then this is handled in accordance with Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act).	

3. Animal Product Description	
3.1 Name or type of all animal materials or animal products entering the physical boundaries of the RMP:	Raw milk
3.2 Name of product leaving the physical boundary of the RMP (product description):	Liquid Milk (manufactured in accordance with a permitted method of processing, namely pasteurisation)
3.3 Intended consumer:	Humans (general public)
3.4 Intended use of product:	Chilled ready-to-eat (the product does not require further processing or additional preparation by the consumer)
4. Limits	
4.1 Regulatory limits in relation to risks from hazards to human health:	*Salmonella* spp.ND/25g *L. monocytogenes* ND/25g Coagulase Positive Staphylococci (*S.aureus*) 1000cfu/g *B. cereus* 1000cfu/g *E. coli* 100cfu/g
4.2 Regulatory limits in relation to wholesomeness are outlined in Appendix N	
4.3 Any Operator defined limits (in relation to hazards to human health, wholesomeness):	
4.4 Regulatory limits in relation to risks from false or misleading labelling or representation of liquid milk are addressed by compliance with the Food Standards Code	
4.5 If the regulatory limits are not met then the process outlined in Appendix I is carried out	
5. Description of Process	
5.1 Inputs:	Refer to Table 3 of Appendix M
5.2 Main Process Steps:	Refer to Table 3 of Appendix M
5.3 Outputs:	Refer to Table 3 of Appendix M
6. Uncontrolled Hazards	
There will be no likely uncontrolled hazards present in Liquid Milk because they are controlled in the processes set out in the appendices.	

7. Identification and Control of Hazards and Other Risk Factors

7.1 In order to identify, control, manage, eliminate, or minimise risk factors involved in processing and producing Liquid Milk, and to ensure that the Liquid Milk is fit for its intended purpose, the standards, processes, and procedures detailed in Appendix A – Appendix N will be used and adhered to.

7.2 The operator ensures that the following legislative requirements:

- Animal Products Act 1999
- Animal Products (Dairy) Regulations 2005
- Animal Products (Dairy Processing Specifications) Notice 2006
- Food Act 1981

- Australia New Zealand Food Standards Code (FSC), Chapter 1 – Chapter 2 General Food Standards
- FCS Standard 2.5.1 – including packaged cow's milk for retail sale: milkfat minimum 32 g/kg, protein (measured as crude protein) minimum 30 g/kg and skim milk: milkfat maximum 1.5 g/kg protein (measured as crude protein) minimum 30 g/kg
- FSC Part 1.2 – Labelling and Other Information Required

are met by:

- having knowledge of where to obtain an up-to-date version of them; and
- refering to them frequently and if there are any changes to any processes.

7.3 Critical control point/s (CCP):	Pasteurisation
7.4 Justification for the CCP's identification:	NZFSA determination, facilitated by application of Codex Alimentarious Decision Tree
7.5 Critical limits to be met and the justification for those limits:	Food (Milk and Milk Products Processing) Standard 2007 The term "pasteurisation" for milk or a milk product means treatment according to one of the following methods- (i) The holding method, by which the milk or milk product is rapidly heated to a temperature of not less than 63 degrees Celsius and not more than 66 degrees Celsius, retained at that temperature for not less than 30 minutes, and then- (A) immediately and rapidly reduced to 5 degrees Celsius or less in the case of milk or milk products other than cream, or to 7 degrees Celsius or less in the case of cream; and (B) maintained at or below that temperature until the milk or milk product is removed from the premises for delivery; (ii) The high-temperature short-time method, by which the milk or milk product is rapidly heated to a temperature of not less than 72 degrees Celsius, retained at that temperature for not less than 15 seconds, and then treated in accordance with subparagraphs (A) and (B) of the method in paragraph (i); (iii) Any other heat treatment method that is as effective in terms of bacterial reduction as methods (i) and (ii).

8. RMP Document List , Responsibilities For and Authorisation of RMP

The following is a list of all documents that comprise this RMP, with their date or version at the time of registration:

Document:	**Operator's own documents / records based on the template requirements**						
	Reference (location) and title:						
	Person Responsible for Implementation and Authorisation Prior to Use:	Name: Signature:					
Main part of RMP (this document):	Completed RMP Template						
GOP (Supporting Systems):	**Appendix**	**Completed Requirements**	**Required Records Attached**	**Operator's own documents / records for additional products / processes / procedures**	**Date**	**Name and Signature**	**Version No.**
Design and construction of buildings, facilities and equipment	A						
Potable Water	B						
Cleaning and sanitation	C						
Personnel competency, health and hygiene	D						
Pest control	E						

Packaging materials and ingredients (specifications, use, storage and handling)	F						
Document control and record keeping	G						
Traceability and inventory control	H						
Handling of non-conforming product and recall	I						
Reporting	J						
Operator Verification and other operational requirements	K						
Process control and other operational requirements	L						
HACCP Application - Liquid Milk	M						
Product Safety Limits	N						
Other documents:							
Site plan of physical boundaries							

Water management plan						
Heat treatment plan						

9. Notification Procedures

9.1 If there is any change to the name or position of the day-to-day manager of this RMP then the Director-General of NZFSA will be notified in writing, without unnecessary delay, by the day-to-day manger or the operator.

9.2 If any emerging, new, or exotic biological hazard, or new chemical hazard in relation to the RMP comes to the operator's notice the Director-General of NZFSA will be notified in writing, as soon as practical after its discovery.

9.3 The day-to-day manager or the operator will notify the RMP verifying agency in writing, of the following issues relating to the operation of this RMP, without unnecessary delay:

a. any significant concern about the fitness for intended purpose of animal material or animal product:

b. where the cumulative effect of minor amendments necessitates the registration of a significant amendment to the RMP as provided in section 25 of the Animal Products Act 1999:

c. where the RMP is no longer considered to be effective;

d. where the premises identified as being used by the RMP are not or no longer suitable for use:

e. where anything within the physical boundaries of the RMP is used for additional purposes or by other operators and the RMP has not adequately considered relevant hazards or other risk factors.

10. Recall of Liquid Milk

10.1 The criteria for deciding when a Liquid Milk recall will be initiated is set out in the "Recall Guidance Material" referred to in Appendix I. The criteria set out in the Recall Guidance Material will be adhered to.

10.2 The process for the retrieval and disposal of Liquid Milk will be managed in accordance with the processes set out in Appendix I.

10.3 The system for notifying the Director-General of NZFSA, and the RMP verifier or verifying agency, as soon as possible when Liquid Milk is recalled from trade, distribution, or from consumers because it is not or may not be fit for its intended purpose, is set out in the "Recall Guidance Material" referred to in Appendix I. The system set out in the Recall Guidance Material will be adhered to.

11. Operator Verification

11.1 The operator verification system for this RMP is specified in Appendix K.

12. Allowing Verifiers to Carry Out Verification (External Verification)

12.1 The name and contract details of the recognised verifying agency I have contacted to perform verification activities in respect of my compliance with the Animal Products Act 1999, other relevant legislation, and this RMP, are as follows:

Name and contact details of verifying agency:	

12.2 A letter from the verifying agency confirming they will verify the RMP at all sites covered by this RMP is attached.

12.3 I authorise my contracted verifier to have the freedom and access necessary to allow him/her to carry out verification functions and activities as specified in clause 17, Animal Products (Risk Management Programme Specifications) Notice 2008.

12.4 Any testing of products subject to this RMP will be conducted in a NZFSA recognised laboratory in the appropriate category for the required analysis.

13. Document Control

13.1 Significant and minor amendments to this RMP, which will be made to ensure that it is current and reflects the actual operations, will be identified and described in writing by the operator.

13.2 All amended parts of this RMP will be removed from use and replaced with the current versions at all locations to which it has been distributed without unnecessary delay after authorisation and, where necessary, after registration in accordance with section 25 of the Animal Products Act 1999

13.3 The operator acknowledges that any significant amendment to this RMP will require either:

a. the amendment to be submitted to a NZFSA recognised evaluator and then submitted along with the evaluators report to NZFSA for registration; or

b. a new RMP template completed and registered by NZFSA.

13.4 The remaining document control procedures for this RMP are set out in Appendix G.

14. Requirements for Records

14.1 The record keeping procedures for this RMP are set out in Appendix G.

15. Confirmation

- I, the operator of this RMP, confirm that all of the documents listed in section 8 of this template apply to my operation.
- I, the operator of this RMP, confirm that all equipment necessary to implement the RMP are available and ready to operate.
- I, the operator of this RMP, confirm that the RMP, including all Good Operating Practice (GOP) programmes (Appendices A – N), have been authorised by me.
- I, the operator of this RMP, confirm that this RMP will be implemented as written, including all GOP requirements and procedures given in the appendices.

Signature of Operator or Day-to-day Manager of RMP: _____

Date: / /

Appendix A: Design, Construction and Maintenance of Buildings, Facilities and Equipment

1. Fitness for Purpose Outcomes:

1.1 All premises, buildings, facilities, and equipment used to process, or in the process of, any dairy material or dairy products are:

a) designed, constructed, installed and operated in a manner that prevents or minimises contamination or deterioration of dairy material, dairy products, packaging, equipment, or the processing environment;

b) suitable for the processing of dairy material and dairy products of the class or description specified;

c) located so as to minimise the risk of flooding, objectionable smells, smoke, dust and other contaminants;

d) clean, hygienic and tidy and free from pests;

e) designed and constructed so that they are hygienic and easy to keep clean;

f) suitable and maintained to ensure the manufacture or storage of dairy products that are fit for the purpose of the class or description; and

g) designed, constructed, and maintained so as to avoid hygiene hazards and to permit easy and thorough cleaning, disinfection, and visual inspection.

1.2 Vehicle access and parking areas within the premises where dairy material or dairy products are processed is designed and constructed to prevent the contamination of manufacturing areas.

1.3 Suitable amenities are provided at all premises used to process any dairy material or dairy products for the personal hygiene of staff and visitors.

1.4 The design and use of equipment used to process any dairy material or dairy products does not permit either of the following:

a) the inadvertent mixing of raw milk or dairy material with any treated dairy material or product; or

b) the inadvertent mixing of any non-conforming dairy material or product with any conforming dairy material or product.

2. Records:

Records are kept detailing:

a) repairs and maintenance;

b) any equipment specifications and manufacturer’s instructions;

c) any building reports;

d) corrective action reports; and

e) internal audit reports.

and are kept up to date.

Appendix B: Potable Water

1. Fitness for Purpose Outcomes:

1.1 Water that comes into direct or indirect contact with dairy material or dairy products is potable water (i.e. complies with the New Zealand Drinking Water Standards).

1.2 An alternative water quality standard may be used provided that the water quality standard is determined by an analysis of hazards and other risk factors; the water is safe for its intended used at the point of use and the water will not compromise the safety of the dairy material or dairy product being manufactured.

1.3 An adequate supply of potable water or acceptable alternative in terms of paragraph 1.2 is available for hygienic operations so as to minimise contamination and maintain the fitness for intended purpose of dairy material and dairy product.

1.4 Water (and ice and steam) used in the processing of dairy material and dairy products complies with paragraphs 1.1 or 1.2.

1.5 Non-potable water is permitted in exceptional cases for steam production, fire control, refrigeration equipment and other similar purposes, provided that the pipes installed for this purpose preclude the use of this water for other purposes and present no direct or indirect risk of contamination of dairy material or dairy product.

1.6 Lines containing water that is not potable water are clearly labelled as such and are not connected to lines or tanks containing potable water.

1.7 Dairy material and dairy product coming into contact with non-complying water is managed in accordance with Appendix I.

2. Records:

2.1 Network-supplied (e.g. municipal supply)

A Water Management Plan (WMP) is written and implemented that includes:

a) the water quality standard; and

b) the procedures covering water reticulation and corrective actions.

Where water is identified as non-complying, the appropriate corrective action(s) stipulated in the WMP are carried out.

2.2 Own water supply (i.e not network-supplied)

A Water Management Plan **(WMP)** is written and implemented that includes:

a) the water quality standard (including criteria) as determined through an analysis of hazards;

b) any treatment(s) required for the water to meet the appropriate water quality standard(s);

c) a water sampling and testing programme for compliance monitoring and process control monitoring;

d) requirements to keep relevant records as long as necessary for traceback purposes and verification;

e) an action plan in the event of non-compliance with the WMP; and

f) the procedures covering water reticulation; and any corrective actions.

Appendix C: Cleaning and Sanitation

1. Fitness for Purpose Outcomes:

1.1 Effective cleaning and sanitation of the premises, facilities and equipment is carried out to minimise the contamination of dairy material or dairy product.

1.2 Effective procedures are established and carried out to ensure:

a) appropriate and adequate maintenance, cleaning, and sanitation of processing premises, facilities, essential services, and equipment (including conveyances);

b) management of waste;

c) control of pests;

d) control pathogenic micro-organisms; and

e) documentation of a cleaning and sanitation procedure.

1.3 Measures are in place to ensure the fitness for purpose of treated dairy material and dairy product is not compromised by contamination from services (including coolants, heating media and/or cleaning solutions).

1.4 Measures are in place to ensure that the maintenance compounds and their intended use will not adversely affect the suitability for processing of dairy material, or fitness for intended purpose of the dairy product.

2. Records:

2.1 Cleaning records are kept showing:

a) when the cleaning was performed;

b) what was cleaned;

c) who performed the cleaning; and

d) how the cleaning was performed, whether in accordance with documented procedure.

Appendix D: Personnel Competency, Health and Hygiene

1. Fitness for Purpose Outcomes:

1.1 All personnel are at all times competent and medically fit to perform their duties, and behave hygienically. Personnel include all workers, contractors providing services, and visitors.

1.2 All persons, including visitors, whose presence or actions, at any premises or place where dairy material or product is processed, may result in contamination of dairy material or product, are required to:

a) wear appropriate protective clothing;

b) follow an appropriate personal hygiene routine: and

c) behave in such a manner as may be necessary or desirable to minimise contamination to dairy material, dairy product and associated things.

1.3 All persons, including visitors, who are known to be, or suspected of being, infected by or a carrier of a disease or illness of public health concern (including a notifiable infections disease listed in section A of Part 1 of the Health Act 1956) that is likely to be transmitted through dairy material, dairy product, or associated things are precluded from:

a) working in areas where dairy material or dairy product is processed, if that may result in contamination of dairy product; or

b) handling dairy material, dairy product, or associated things that may result in contamination of dairy product.

2. Records:

2.1 The following records are kept:

a) induction/training records for staff and contractors; and

b) records of compliance of staff, contractors and visitors hygienic practices (problems observed, and any corrective action taken (including restoration of control, product disposition and prevention of recurrence)).

Appendix E: Pest Control

1. Fitness for Purpose Outcomes:

1.1 Pests are controlled so as to minimise the contamination of dairy material and dairy product, packaging, other inputs, equipment, and the cheese processing environment. Pests include rodents, birds, insects, dogs and cats.

1.2 Effective procedures are established and carried out to ensure:

a) management of waste;

b) control of pests; and

c) control of pathogenic micro-organisms.

1.3 A procedure is effective if it reduces to an acceptable level the exposure of dairy material and dairy product and associated things to risk factors associated with waste, pathogenic micro-organisms, pests and inappropriate or inadequate maintenance, cleaning and sanitation.

1.4 Measures are in place to ensure that pests do not spoil or contaminate dairy material or products, and that the application of pesticides in the manufacturing environment of dairy factories or stores does not adversely affect the fitness for the intended purpose of the dairy material or product.

2. Records:

2.1 Records containing the following information are kept:

a) observations from monitoring, including any evidence of pests;

b) location of bait stations;

c) name, amount and point of use of any pesticides used; and

any corrective action taken (including restoration of control, product disposition and prevention of recurrence).

Appendix F: Packaging Materials and Ingredients (Specifications, Use, Storage and Handling)

1. Fitness for Purpose Outcomes:

1.1 Safe and suitable ingredients and packaging materials (i.e clean, non-toxic, non-contaminating materials) are used for containing dairy material and dairy products.

1.2 Any packaging materials (including reusable packaging and inner and outer packaging of any kind) used for dairy material, dairy product, and associated things are designed, made, stored, and used in a manner that –

a) maintains the status of the dairy material as suitable for use in processing;

b) maintains the status of the dairy product as fit for its intended purpose; and

c) minimises contamination of the dairy material or dairy product.

2. Records:

2.1 The following records are kept:

a) Any letters of guarantee from suppliers, specifications, compliance statements such as certificates of conformance;

b) confirmations of acceptance and records of any external cross-checking test results; and

c) records of any problems detected and any corrective action taken (including restoration of control, product disposition and prevention of recurrence).

Appendix G: Document Control and Record Keeping

1. Fitness for Purpose Outcomes:

1.1 All documents and any parts of a document that form part of this RMP—

(a) are legible; and

(b) are dated or marked to identify its version; and

(c) clearly indicate any changes made to the RMP; and

(d) are identified as comprising part of the RMP; and

(e) are signed, either directly or within the document control system, by the operator or day- to- day manager; and

(f) are made available when required to any person with responsibilities under the programme.

1.2 This RMP and all reference material relating to it are readily accessible, or can be retrieved and made available to recognised persons, animal product officers and the Director-General or persons authorised by the Director-General, within two working days of any request.

1.3 One copy of all obsolete documents from a registered RMP are retained for 4 years and made available to recognised persons, animal product officers and the Director-General and persons authorised by the Director-General, as required.

1.4 All records necessary to demonstrate compliance with the RMP are:

a) legible;

b) are stored for four years, or for the shelf life of the product to which the records relate (whichever is longer) in a manner which protects the records from damage, deterioration or loss;

c) can be retrieved and made available to recognised persons, animal product officers and the Director-General or persons authorised by the Director-General, within two working days of any request.

1.5 Records relating to the RMP's monitoring, corrective action and operator verification for the RMP, include:

a) the date and where appropriate, the time of activity;

b) a description of the results of the activity;

c) means to identify the person or persons who performed the activity.

1.6 All records are readily accessible, or can be retrieved and made available to recognised persons, animal product officers and the Director-General or persons authorised by the Director-General, within two working days of any request.

2. Records:

2.1 Records are kept including:

a) Compliance records (cleaning and sanitation programme records, maintenance programme records, internal audit reports, supplier agreements/specifications etc);

b) processing records (data logger printout for heat treatment if applicable);

c) inventories; and

d) records on dairy material supplier for the RMP operations (farm dairy), including:

- the name (if any) or unique location identifier (N.B. the requirement for a NZFSA registered RMP for farm dairy operators) of every farm dairy from which raw milk is supplied for the manufacture of dairy products;
- the name and either location or address of each farm dairy operator;
- the name and either location or address of each farm dairy owner, if the operator is not the owner;
- the location of each farm dairy (on request);
- the amounts of milk received on each day from each farm dairy; and
- sufficient detail to allow the identification of dairy products containing or made from milk from each farm dairy.

Appendix H: Traceability and Inventory Control

1. Fitness for Purpose Outcomes:

1.1 An effective system for recalling products that are not fit for intended purpose, from distribution or sale, has been developed and is implemented.

1.2 A tracking system has been implemented that:

a) allows for the identification of dairy material, dairy product and ingredients added to dairy material or dairy product; and

b) enables the movement of the dairy material, dairy product, or ingredients to be traced throughout the dairy processing, either forwards or backwards.

2. Records:

2.1 Records containing the following information are kept:

a) Traceability and inventory records (including any records of reworked product);

b) records of receipt and dispatch of products; and

c) observations from monitoring and any corrective action taken (including restoration of control, product disposition and prevention of recurrence).

Appendix I: Handling of Non-conforming Product and Recall

1. Fitness for Purpose Outcomes:

1.1 "Non-conforming" in relation to dairy material and dairy product, means any dairy material or dairy product that is suspected or known not to meet regulatory requirements or not to have been processed in accordance with regulatory requirements, including this RMP.

1.2 All non-conforming products are handled in a manner that facilitates their identification and traceability, and prevents contamination and deterioration of other products, and a system is in place for the recall of products that are not fit for intended purpose from distribution or sale.

1.3 A procedure is in place that ensures any dairy material or dairy product that is nonconforming is identified and detained.

1.4 All non-conforming dairy material or dairy product is reported to the recognised agency responsible for verification by the day-to day manager without delay.

1.5 All testing of non-conforming dairy material and dairy product is carried out by a recognised dairy laboratory that is recognised in the appropriate category for the required test, using the test methods as specified in the Animal Products (Dairy Recognised Agency and Recognised Persons Specifications) Notice 2005.

1.6 For recall procedures, refer to "Recall Guidance Material" available from the http://www.nzfsa.govt.nz/processed-food-retail-sale/recalls/guidance/index.htm

2. Records:

2.1 The following records are kept:

a) identification of the affected products;

b) the nature and extent of the problem;

c) the location of the affected products in the distribution chain; and

d) document all events and associated information in the case that you need to refer to this at a later date. This could include keeping a log of events, contacts, telephone calls, mailing lists, letters sent, etc.

Appendix J: Reporting

1. Fitness for Purpose Outcomes:

1.1 A reporting system is in place for exception reporting to ensure all dairy product is fit for intended purpose.

Exception reporting includes the reporting of the following:

(a) identification of non-conforming dairy material or dairy product; and

(b) occurrence of a critical non-compliance (ie failure to comply with regulatory requirements)

Non-conforming in relation to dairy material and dairy product, means any dairy material or dairy product that is suspected or known not to meet regulatory requirements or not to have been processed in accordance with regulatory requirements.

A critical non-compliance is an action, event or omission which may result in —
(i) failure to follow the lawful direction of an Animal Products Officer;
(ii) an alleged offence against the Animal Products Act 1999;
(iii) a critical situation;
(iv) failure of a critical control point within a risk management programme or approved plan;
(v) failure to identify when dairy material or dairy product is non-conforming;
(vi) failure to stop a non-compliance;
(vii) failure to keep accurate and complete records;
(viii) failure to provide accurate, complete, and timely reports;
(ix) failure to dispose of non-conforming dairy material or dairy product in compliance with regulatory requirements;
(x) failure to prevent recurrence of a non-compliance; or
(xi) failure to rectify a non-compliance within the specified timeframe.

1.2 Reporting Requirements – Responsibilities

- The RMP operator reports to the recognised agency.
- The RMP operator or their delegate will sign all reports.
- The RMP operator and the recognised agency will agree on the method of reporting and the format and content of the report.

1.3 A system is in place to ensure that any of the following exceptions are reported to the recognised agency as soon as practicable, but no later than 24 hours, after the occurrence of the exception or the result is known by the testing laboratory. Initial notification in writing (including via e-mail or fax) to the recognised agency of an exception is followed by a telephone conversation with a person (not an answering service) to confirm receipt. Initial verbal will be undertaken, but the following will be confirmed in writing within 72 hours:

a) identification of non-conforming dairy material or dairy product, and

b) occurrence of a critical non-compliance.

2. Records:

2.1 Exception reports include the following:

a) a detailed description of the exception;

b) the extent of any contamination or potential contamination, e.g. date since last acceptable result, the product lines affected etc; and

description, quantity and location of all non-conforming dairy material or dairy product and whether it is isolated.

Appendix K: Operator Verification and Other Operational Requirements

1. Fitness for Purpose Outcomes:

1.1 To verify compliance to documented procedures and to confirm the effectiveness of the RMP verification is undertaken, including internal audits, at the required frequencies.

1.2 A system is documented that covers all the components of operator verification including:

a) the operator verification activities to be undertaken, and their frequency;

b) any actions to be undertaken when corrective actions are not effective;

c) any actions to be undertaken when all or part of the RMP is not effective; and

d) any recording and reporting requirements.

1.3 All operator verification activities are transparent and traceable, and undertaken by suitably skilled person nominated by the operator or day-to-day manager. Persons carrying out operator verification activities are independent of the process or operation monitoring and corrective action activities being verified and familiar with the contents of the RMP, including its expected outcomes.

1.4 Internal audits are undertaken by the person responsible at an appropriate frequency for a small to medium sized business to ensure compliance with the documented RMP, including GOP and process control procedures, and to identify and correct any problems.

1.5 A review of the RMP is undertaken at least annually and when significant changes in the product, process or premises are made; or the RMP is not working effectively.

1.6 Observations made during the internal audit and corrective actions taken are recorded.

1.7 Internal audits consist of a review of records, reality checks, and confirmation that deficiencies or non-compliances identified from the last audit have been rectified.

1.8 All records under this RMP are reviewed for:

a) completeness and accuracy of required information;

b) documentation of corrective actions;

c) any trends, new hazards, recurring problems; and

d) compliance with documented control procedures.

1.9 Reality checks include observation of;

a) workers' performance and compliance with documented hygienic procedures and operating procedures;

b) compliance with process parameters such as processing times and temperatures;

c) hygienic status of the premises internal and external environment, facilities; and

d) equipment.

1.10 All deficiencies found at previous audits are followed up.

1.11 When ongoing or recurring non-compliances occur, the following actions are taken:

a) investigate to determine possible causes of non-compliance;

b) take appropriate corrective actions to regain control and prevent recurrence of the problem;

c) increase surveillance of the system; and

d) review the RMP or the relevant GOP programme and make necessary changes.

2. Records:

2.1 The following records are kept:

a) Internal audit reports;

b) other information or evidence relating to operator verification activities (test results);

c) information relating to monitoring of activities (this includes the name of the observer/monitoring person, the date and time of the observation and the subject and description of the observation);

d) copies of any communication sent to the NZFSA or the recognised RMP verifying agency; and

e) any corrective action taken (including restoration of control, product disposition and prevention of recurrence).

Appendix L: Process Control and Other Operational Requirements

1. Fitness for Purpose Outcomes:

1.1 Dairy heat treatment procedures and processes are implemented.

1.2 Heat treatment (pasteurisation) is designed, installed, operated and maintained in accordance with this RMP.

1.3 This RMP references sufficient documentation, including design drawings, plating diagrams, computer/PLC programs, operating procedures, training programmes and records, to ensure that staff and contractors (as appropriate):

a) have the knowledge and skills necessary to understand the hazards managed by the heat treatment;

b) understand the heat treatment and how it operates;

c) operate, check and maintain the heat treatment including monitoring, taking timely and appropriate corrective action(s) when there is “loss of control”;

d) and record keeping; and

e) the heat treatment is able to be readily validated by the RMP operator; and

f) the heat treatment is readily evaluated and verified by the Recognised Agency.

1.4 For pasteurised products released for sale before results of microbiological tests are available, phosphatase testing is undertaken of the dairy material immediately after heat treatment using an NZFSA-registered test method to demonstrate that the dairy material has been correctly pasteurised and not re-contaminated.

1.5 The heat treatments used (pasteurisation and liquid milk treatment) have the following process parameters.

2. Pasteurisation

2.1 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. Pasteurization 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, pasteurization is designed to achieve at least a 5 log reduction of C. burnettii in whole milk (4% milkfat).

2.2 The term “pasteurisation” for milk or a milk product means treatment according to one of the following methods-

(i) The holding method, by which the milk or milk product is rapidly heated to a temperature of not less than 63 degrees Celsius and not more than 66 degrees Celsius, retained at that temperature for not less than 30 minutes, and then-
(A) immediately and rapidly reduced to 5 degrees Celsius or less in the case of milk or milk products other than cream, or to 7 degrees Celsius or less in the case of cream; and
(B) maintained at or below that temperature until the milk or milk product is removed from the premises for delivery;
(ii) The high-temperature short-time method, by which the milk or milk product is rapidly heated to a temperature of not less than 72 degrees Celsius, retained at that temperature for not less than 15 seconds, and
then treated in accordance with subparagraphs (A) and (B) of the method in paragraph (i);
(iii) Any other heat treatment method that is as effective in terms of bacterial reduction as methods (i) and (ii).

3. Records:

3.1 The following records are kept:
a) Heat treatment plan

Appendix M: HACCP Application – Liquid Milk

Scope:

Hazard Analysis and Critical Control Point (HACCP) is a management tool to assess food safety hazards (either microbiological, chemical or physical hazards) and identify "Critical Control Points" (CCPs), as defined in the Animal Products (Dairy Processing Specifications) Notice 2006, to eliminate or control the hazards to an acceptable level.

Principle 1 Conduct a hazard analysis – NZFSA has completed this step
Principle 2 Determine the CCPs – NZFSA has completed this step
Principle 3 Establish Critical Limits – NZFSA has completed this step (see Appendix L: Process Control and other operational requirements)
Principle 4 Establish a system to monitor control of the CCP – RMP requirement
Principle 5 Establish the corrective action to be taken when monitoring - RMP requirement
Principle 6 Establish procedures for verification to confirm that the HACCP system is working effectively – RMP requirement
Principle 7 Establish documentation concerning all procedures and records appropriate to these principles and their application – RMP requirement

Table 1

Components	Description / Details
Material being processed	Raw Milk
Products	Liquid Milk
Process	From receipt of raw milk to dispatch from the premises Key processing operations: - Receipt of raw milk - Homogenisation - Pasteurisation/cooling - Storage

Table 2
Product Description:

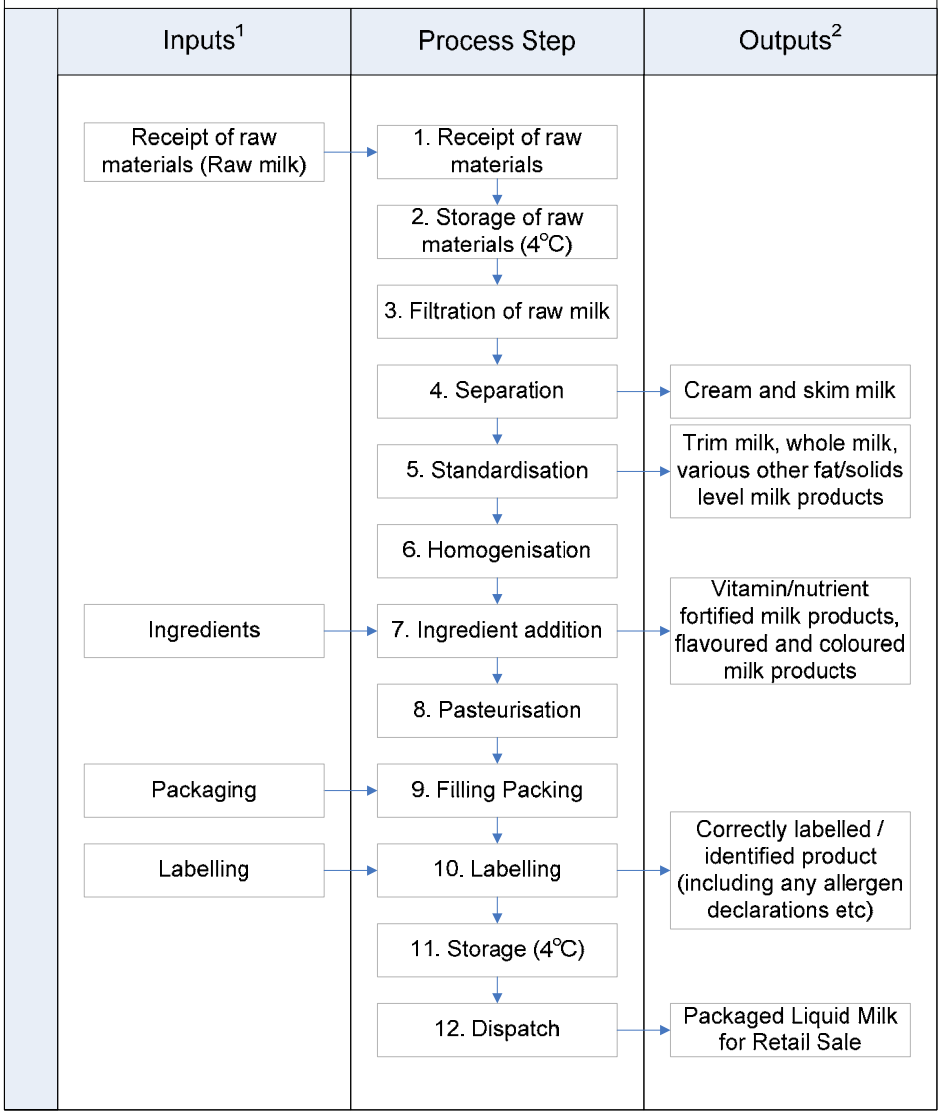
Product	Liquid Milk
Intended consumer	Humans (general public)
Intended use of product that leaves RMP	Chilled ready-to-eat Ingredient for preparation of other foods
Regulatory limits	As outlined in Appendix N: Product Safety Limits
Other regulatory limits	Food Standards Code (Parts 1 and 2) New Zealand (Milk and Milk Products Processing) Food Standards 2002

Process Description

The process flow diagrams show the key steps based on a generic process. Process steps and their sequence may differ for each premises. The generic process described below is adapted to fit the operator subject to this RMP.

Table 3

Process Flow Diagram for the Processing of Liquid Milk



[1] An input is any material, additive, processing aid, ingredient, or packaging that is added or used for the production or processing of a food product.
[2] An output is any material or product resulting from any operation under an RMP.

Table 4: Principle 1 - 3 - Conduct a hazard analysis, Determine the CCPs, Establish Critical Limits

Process Step	Potential impact of step on hazards	Control measure	Is the control measure a CCP?
Receipt of raw materials	Bacterial pathogens e.g. *Salmonella* spp., *E coli, Listeria monocytogenes.* Foreign matter, e.g. glass, metal	Document control and record keeping (supplier agreements/specifications)	No
Storage of raw materials	Bacterial pathogens	Design, construction and maintenance of buildings, facilities and equipment Traceability and inventory control Cleaning and sanitation Pest control	No
Filtration	Foreign matter	Design, construction and maintenance of buildings, facilities and equipment Cleaning and sanitation	No
Pasteurisation	Bacterial pathogens	Performance requirements Animal Products (Dairy Manufacturing) Approved Criteria	Yes

Outcome of CCP determination

The following CCP's were identified for the processing of Liquid Milk for retail sale:

- Heat treatment (Pasteurisation)

CCP Limits

When the critical limits for a critical control point have been met (see above Principle 1 – 3 Hazard analysis and CCP determination, critical limit determination), the process and/or product is deemed to be safe at that point in the process because the product outcomes have been met. Consequently, where critical limits are exceeded, then the process or product may be deemed to be unsafe.

The critical limits must be measurable, achievable and appropriate to the CCP and hazard(s) being controlled and wherever possible, there should be a scientific basis for the control process and the limits set for each CCP.

Principle 4 - **Establish a system to monitor control of the CCP**

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures are able to detect loss of control at the CCP. Further, monitoring will provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Data derived from monitoring is evaluated by a person nominated by the operator/day- to-day manager with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring is sufficient to guarantee the CCP is in control. Most monitoring procedures for CCPs will be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing.

Principle 5 - Establish the corrective action to be taken when monitoring

Where the critical limits for a CCP have been exceeded, the following corrective actions are taken:

- Bring the defective process back under control.

- Determine and control any affected product. All product processed back to the point where the CCP was known to be within limits is considered “affected” and is to be treated in accordance with “Non-conforming Dairy Material and Dairy Product” and “Reporting Requirements”.
- Take action to ensure the non-conformance does not recur. In this regard the investigation should determine the root cause of the problem, take action to prevent recurrence and follow up with monitoring and reassessment to ensure the corrective action is effective. This step may involve reassessment of the control measures and/or modification of the HACCP Plan.

Principle 6 – Establish procedures for verification to confirm that the HACCP system is working effectively

Procedures are established for verification. The frequency of verification is sufficient to confirm that the HACCP system is working effectively, Verification activities include:

- review of the HACCP system and its records
- review of deviations and product dispositions; and
- confirmation that the CCPs are under control.

Principle 7 - Establish documentation concerning all procedures and records appropriate to these principles and their application

All records and documents associated with monitoring CCPs are signed by the person(s) doing the monitoring.

Documented monitoring procedures will provide information on:

- who will undertake the monitoring (this person must be trained and have appropriate responsibility to initiate corrective action)
- frequency of the monitoring including statistically valid sampling regimes;
- what will be monitored;
- where monitoring will occur; and
- how critical limits will be monitored.

Appendix N: Product Safety Limits

1. Fitness for Purpose Outcomes:

1.1 All dairy products are wholesome and do not contain any foreign matter that constitutes a food safety hazard.

1.2 The levels of toxic trace metals in dairy product do not exceed the limits specified in the FSC (refer to Volume Two Standard 1.4.1 Contaminants and Natural Toxicants (refer to http://www.foodstandards.govt.nz/). Maximum residue limits (MRLs) and extraneous residue limits (ERLs) published by Codex and the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2002 can be found on the NZFSA website.

1.3 Product safety limits (PSLs) for Pathogenic Bacteria (Human Consumption)

Pathogen	General PSLs (1, 3)	Specific PSLs (2, 3)	Explanatory Notes / Comments
Salmonella spp.	ND/25g	ND/250g	ND = not detected in the volume tested Composite of samples collected throughout the production run as defined by the manufacturer's RMP
L.monocytogenes	ND/25g(4)	ND/25g	ND = not detected in the volume tested Composite of samples collected throughout the production run as defined by the manufacturer's RMP
Coagulase Positive Staphylococci (*S. aureus*)	1000/g	100/g	It is critical that sampling and testing are performed in a way that correctly estimates the maximum number of S. aureus reached in a product. This is important because the risk posed by released enterotoxin is 'estimated' by the bacterial load
B.cereus	1000/g	100/g (5)	
E.coli	100/g	10/g	

(1) General PSLs: For product to be consumed by the general population.

(2) Specific PSLs: For products that are specifically designated for, and are likely to form, a substantial part of the dietary intake of more susceptible members of the population (i.e. infants and young children, the old, pregnant and immuno-compromised).

(3)Sampling Rates: If testing is required, the rate of sampling for each organism/product combination should be decided as part of a HACCP analysis performed on the manufacturing process

(4)Listeria monocytogenes: A figure of 100/g has been proposed by the Joint FAO/WHO Food Standards Programme, Codex Committee on Food Hygiene in the "Draft Guidelines for the Control of Listeria monocytogenes in Foods" and is obtaining increasingly wide acceptance. In the future, it may be appropriate to adopt a PSL of 100/g in circumstances where it can be shown that growth is extremely unlikely to occur during the life of the product. However, before this occurs, NZFSA and the dairy industry will need to be convinced that the 100/g figure has become accepted by reputable food safety authorities worldwide.

(5)Bacillus cereus: This limit only applies to product designated as infant formula.

1.4 All dairy products subject to this RMP which are manufactured, for sale in New Zealand or Australia comply with microbiological limits specified in the Australia New Zealand Food Standards Code (FSC).

1.5 The limits described are not exceeded at any time during the product's shelf life (assuming the product is handled and stored according to the manufacturer's guidelines).

1.6 In the event that pathogenic micro-organisms do exceed the limits the product is deemed to be non-conforming.

1.7 Results from retesting of product previously found to contain pathogens in excess of limits contained in this section will not be used. However additional testing may be carried out on previously untested product to establish limits of non-conformance in a product lot (e.g. where determination of cut-off points is required).

1.8 Where the laboratory has unequivocal evidence that the 'suspect' result arises from a failure of its internal systems (NB this requires clear documentation) then retest results may be used to establish the limit.

2. Records:

2.1 The programme for sampling and testing that is carried out to verify that dairy material and dairy product meets the product safety limits and includes the following:

a) procedures to demonstrate how it is ensured that samples are representative and sampling does not contaminate the dairy product;

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.