Ministry for Primary Industries
Manatū Ahu Matua

Animal Products Notice

Dairy Processing Specifications

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1 November 2018

Issued under the Animal Products Act 1999

New Zealand Government

TITLE

Animal Products Notice: DRAFT Dairy Processing Specifications

COMMENCEMENT

This Animal Products Notice comes into force on [Effective Date]

REVOCATION

(1) Predecessors to this Notice, which have been revoked on commencement of this Notice, include the following Notices and Approved Criteria issued under the Animal Products Act 1999

a) Animal Products (Dairy Processing Specifications) Notice 2011; and
b) Animal Products (Export Requirements – Dairy Products) Notice 2005; and
c) Animal Products (Raw Milk Products Specifications) Notice 2009; and
d) Animal Products (Exemptions from Labelling Standards for Dairy Product and Dairy Material Intended for Export) Notice 2006; and
e) DPC1: Animal Products (Dairy) Approved Criteria for General Dairy Processing; and
f) DPC2: Animal Products (Dairy) Approved Criteria for Farm Dairies; and
g) DPC3: Animal Products (Dairy) Approved Criteria for the Manufacturing of Dairy Material and Product; and
h) DPC4: Animal Products (Dairy) Approved Criteria for the Storage and Transportation of Dairy Material and Products.

ISSUING AUTHORITY

This Animal Products Notice is issued under section… of the Animal Products Act 1999,

Dated at Wellington, 1 November 2018

Paul Dansted
Director, Food Regulation
Ministry for Primary Industries
(acting under delegated authority of the Director-General)

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Introduction

This introduction is not part of the Animal Products Notice, but is intended to indicate its general effect.

Purpose

(1) This Notice sets specifications that are necessary to give effect to the Animal Products (Dairy) Regulations 2005 to ensure that dairy material and dairy products processed in New Zealand are fit for intended purpose. It specifies requirements relating to:

a) the processing of dairy material and dairy products; and
b) ensuring that dairy material and products remain free from contamination, adulteration and deterioration; and
c) composition of dairy products; and
d) requirements for dairy processors, risk management programme operators and other specified persons; and
e) requirements for the contents of a risk management programme.

(2) The requirements set out in this Notice complement the Animal Products (Risk Management Programme Specifications) Notice.

(3) This Notice sets out the technical criteria to be met in order to satisfy the Dairy Regulations and to confirm that dairy material and dairy product is fit for its intended purpose.

(4) For clarity, this Notice does not apply to activities covered under the Raw Milk for Sale to Consumers Regulations 2015.

Background

(1) This Notice consolidates and recasts existing requirements. In doing so references have been updated and in some cases language has been modified to reflect current preference.

(2) Any amendments to current requirements are considered to provide additional clarity and not impose additional cost of compliance on dairy processors or RMP operators. Requirements associated with milk cooling have been amended in accordance with previous public consultation.

(3) Predecessors to this Notice, which have been consolidated, include the following Notices and Approved Criteria issued under the Animal Products Act 1999

a) Animal Products (Dairy Processing Specifications) Notice 2011; and
b) Animal Products (Export Requirements – Dairy Products) Notice 2005; and
c) Animal Products (Raw Milk Products Specifications) Notice 2009; and
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g) DPC3: Animal Products (Dairy) Approved Criteria for the Manufacturing of Dairy Material and Product; and
h) DPC4: Animal Products (Dairy) Approved Criteria for the Storage and Transportation of Dairy Material and Products.

Who should read this Animal Products Notice?

(1) This Notice should be read by:

a) farm dairy operators; and
b) manufacturers of dairy material or dairy products; and
c) operators of risk management programmes that cover the processing of dairy material and dairy products; and

d) processors who store dairy material or dairy products; and
e) processors who transport milk or other dairy material or dairy products; and
f) evaluators and verifiers of dairy risk management programmes;
g) farm dairy assessors; and
h) MPI recognised laboratories that test dairy material or dairy product.

Why is this important?

This is a key document for anyone processing, storing and transporting dairy product in New Zealand.

Document history

Version Date	Section Changed	Change(s) Description
November 2018		New document

Other information

(1) Dairy material and dairy product is also required to comply with the standards of the Australia New Zealand Food Standards Code that apply to New Zealand. This includes requirements for the composition of specified dairy products, nutrient fortification, microbiological parameters, chemical contaminants and natural toxicants.

(2) The information contained within a border throughout this document is for guidance and is not part of the statutory requirements.

Part 1: Requirements

1.1 Application

(1) This Notice applies to:

a) the processing of dairy material and dairy products; and
b) risk management programmes that cover the processing of dairy material or dairy products; and
c) dairy processors, dairy risk management programme operators and exporters of dairy products; and
d) anyone who develops, validates, evaluates, verifies, assesses, approves or registers a dairy risk management programme, a component of a risk management programme or particular dairy processing activities; and
e) anyone responsible for determining the conformance of dairy material and dairy products against the required fitness for intended purpose outcomes.

(2) The requirements specified in this document are to be used by recognised agencies and persons when evaluating or verifying a risk management programme covering dairy processing activities.

1.2 Incorporation by reference

(1) Codex Standard 206-1999 General Standard for the use of Dairy Terms

1.3 Definitions

(1) In this Notice, unless the context otherwise requires:

Act means the Animal Products Act 1999

acceptance limit means the minimum or maximum value that is permissible in order for something to be considered conforming or acceptable for use, supply or sale

adequate means sufficient to accomplish the intended purpose

agricultural compound has the same meaning as given to it in the Agricultural Compounds and Veterinary Medicines Act 1997

APC means aerobic plate count incubated at 30°C for 72 hours

applicable recognised agency means the agency recognised by the Director-General for the purposes of verification of the risk management programme that covers the non-conforming dairy material or dairy product

approved means approved under the Act

aseptic packaging means the packaging of commercially sterile product into sterilised containers followed by hermetic sealing with a sterilised closure in a manner which prevents viable microbiological recontamination of the sterile product

assessment means systematic examination of an individual, organisation, plan, programme, or system against regulatory requirements

CIP means cleaning in place

clean means free of soil, food residue, dirt, grease, cleaning or sanitising agents or other objectionable matter

Codex means the Codex Alimentarius Commission Joint Food and Agriculture Organisation (FAO)/ World Health Organisation (WHO) Food Standards Programme

competent person means a person who can be shown to have sufficient experience, training and knowledge to perform the nominated function

commencement of milking means the time at which the first milk is drawn from an animal that is producing milk intended for supply at a discrete milking

completion of milking means the time at which the last cluster is removed from an animal that is producing milk intended for supply at a discrete milking, and without delaying the milking without just cause

compliance refers to all aspects of confirming that products, facilities, people, programmes, and systems meet regulatory requirements and, where applicable, export requirements issued under section 167(1) of the Act for the purposes of section 60

continuous milking means milking for six hours or longer from the time that milk first enters any bulk milk tank

corrective action means action taken to rectify, eliminate the causes of, and prevent recurrence of any problem, failure or non-compliance identified in a plan, procedure, process, product, programme, or system

critical control point (CCP) means a step in a process at which a control can be applied which is essential to prevent, eliminate, or reduce a food safety hazard to an acceptable level

critical hygiene area means any area within a dairy premises where ingredients, processing aids, dairy material or dairy product, will be or may be exposed to the processing environment, and is not intended to undergo a defined heat treatment

critical limit means a criterion which separates acceptability from unacceptability

critical measurement means any measurement (such as of weight, time, or temperature) identified in an RMP as critical for the purpose of ensuring the safety, integrity, and fitness for purpose of final product

critical non-compliance means an action, event or omission which will, or is reasonably likely to result in:

a) failure to follow the lawful direction of an Animal Products Officer; or
b) an alleged offence against the Animal Products Act 1999; or
c) a critical situation; or
d) failure of a critical control point within a risk management programme; or
e) failure to identify when dairy material or dairy product is non-conforming; or
f) failure to stop a non-compliance; or
g) failure to keep accurate and complete records; or
h) failure to provide accurate, complete, and timely reports; or
i) failure to dispose of non-conforming dairy material or dairy product in compliance with requirements under the Act; or
j) failure to prevent recurrence of a non-compliance; or
k) failure to rectify a non-compliance within the specified timeframe

critical situation means any situation which, in the professional judgement of an Animal Products Officer, places public health, animal health, market access, official assurances, national good, or the credibility of MPI or the Director-General at risk, or where an offence is suspected

dairy factory means a place engaged in the manufacture of dairy material and dairy products and includes a skimming station, a buying or receiving station, or any other premises ancillary to a dairy factory

dairy manufacturer means the operator of a dairy factory

date of manufacture means the date on which the product becomes the product as described

date of packaging means the date on which the product is placed in the outer container in which it is intended to be sold or exported

days unless specified otherwise, refers to calendar days

disease means any illness which has the potential to make the raw milk unfit for the manufacture of dairy products for human or animal consumption

diseased means the clinical or pathological manifestation of infection

DWSNZ means the latest edition of the Drinking Water Standard for New Zealand issued by the Ministry of Health

evaluation has the same meaning as that given to it in the Animal Products (Risk Management Programme Specifications) Notice 2008

export means transport of goods outside New Zealand

facilities includes water supply, steam supply, refrigeration, heating, ventilation, vacuum, air conditioning, treatment and filtration, supply of gases, lighting, effluent disposal, waste disposal and sanitary arrangements

farm dairy assessment means a systematic and independent review and examination of the design and operation of a farm dairy, and includes review of the farm dairy construction, facilities, equipment, services, activities, procedures and records to confirm that raw milk processing is in compliance with the registered RMP and requirements under the Act

farm dairy assessor means a person recognised under section 103 of the Act to assess farm dairy operations

follow-on formula means relevant product, whether packaged or not, in the form in which it is intended to leave the premises

food safety criteria means the criteria specified in Part 2 of this Notice that dairy material or dairy product must conform to

finished product means dairy material or product which has been packed, in the manner intended for sale, and is awaiting the decision concerning conformance with regulatory requirements

Food Standards Code means the Australia New Zealand Food Standards Code

foreign matter means any extraneous thing:

a) that is injurious to health or harmful; or
b) that is offensive; or
c) the presence of which would be unexpected or unreasonable in food of that description prepared or packed for sale in accordance with good trade practice

general PSLs means general product safety limits that apply to dairy products intended to be consumed by the general population

HACCP means the Hazard Analysis and Critical Control Point system adopted by the Codex Alimentarius Commission and set out in the Annex to Codex Alimentarius General Principles of Food Hygiene CAC/RCP 1-1969, Revised 2003, “Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application”

HACCP plan means a documented system, prepared in accordance with all the principles of HACCP, to ensure control of significant food safety hazards in a food handling process. A HACCP plan will always include one or more critical control points

hazard analysis means the process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan

hazard identification and analyses means a documented system prepared in accordance with the principles of HACCP but differing from a HACCP plan because CCPs are not identified

heat treatment means the use of heat as a critical control point for the control of pathogenic micro-organisms. The term "heat treatment" includes the heat treatment equipment, drawings, manuals, operating and maintenance plans or procedures, training and validation programmes, and records

herd owner means the owner or part owner of a milking herd

infant formula means an infant formula represented as a breast milk substitute for infants and which satisfies the nutritional requirements of infants aged up to 4 months to 6 months

infant formula product means a product based on milk or other edible food constituents of milk origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants, and includes infant formula and follow-on formula

infection means the entry and development, or multiplication, of an infectious agent in the body of humans or animals

label in relation to any dairy material or product, means any tag, brand, mark, or pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, or impressed on, attached to, or forming part of, the material's or product's container. Container includes crate, can, box, case, wrapper, tin, and every other receptacle or covering used for the packing of dairy material or product

lot means a quantity of dairy product manufactured during a discrete period of time, typically not exceeding 24 hours, in one continuous process

manufacture means all activities involved with converting dairy material into dairy product (with or without other substances or ingredients), and its preparation in a dairy factory for sale. This includes receipt or deposit of the dairy material from which it is manufactured and the packaging for final sale

milk harvester means a person involved in the milking of animals at a farm dairy

milking means the extraction of milk from a milking animal

milking animals means animals from which milk is intended to be harvested for the purposes of sale, trade or export, with or without further processing, during their milking-life from commencement of first lactation until they are withdrawn from the milking herd, and includes non-lactating periods

milking herd means the milking animals kept and milked for any purpose covered by the Act, including but not limited to, cows, sheep, goats, and buffalo

milking plant means equipment used at a farm dairy including:

a) equipment for the extraction, filtering, cooling, or storing of milk such as milking machine, milk pumping equipment, milk lines, plate heat exchanger and other milk cooling equipment, bulk milk tank and other milk storage equipment; and
b) equipment for the preparation of milk for transport; and
c) equipment for the cleaning, sanitising, or maintaining the farm dairy and items at or within the farm dairy; and
d) equipment for the treatment of farm dairy water or preparation of animals for milking; and
e) the consumable items required for the above such as rubberware, hoses and airlines; and
f) any other plant and equipment with which milk comes into contact in a farm dairy

monitor in the context of a HACCP plan, means the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a critical control point is under control

MPI means the Ministry for Primary Industries

NCCP means National Chemical Contaminants Programme enabled under the Dairy Industry (National Residue Monitoring Programme) Regulations 2002

national Tb eradication scheme means the National Operational Plan for the National Bovine Tuberculosis Pest Management Strategy (NBTPMS), prepared pursuant to section 100B of Biosecurity Act 1993, to give effect to the Biosecurity (National Bovine Tuberculosis Pest Management Plan) Order 1998, and any subsequent amendments or replacements

non-compliance means any failure to comply with requirements imposed by or under the Act, including requirements within the applicable RMP, and **non-compliant** has a similar meaning

non-conforming in relation to dairy material and dairy product, means any dairy material or dairy product that is known or suspected:

a) not to meet requirements imposed by or under the Act; or
b) not to have been processed in accordance with requirements imposed by or under the Act.

operator defined process measure or ODPM means a discrete process step or set of process steps applied during the manufacture of the raw milk product that:

a) contributes to achieving the food safety criteria; and
b) is documented in the operator's programme; and
c) includes, but is not limited to, cooking time and temperature, acidification and pH; and
d) reduction, maturation time and temperature, water activity and salt concentration

outer packaging means the packaging used to enclose the smallest packaged item intended for sale

owner includes:

a) any agent, manager, lessee, or bailee of an owner; and
b) in the case of a farm, a farm dairy, or any part of a farm or farm dairy, a sharemilker of an owner; and
c) where an owner is a body corporate, every person who is a manager, secretary, director or other principal officer (however described) of the body

pathogen means a human or animal disease-causing organism

pathogen elimination step means a processing step, or a combination of processing steps, that effect a 5-log reduction in the number of pathogens of human health significance in raw milk

pest means harmful or destructive organism which may affect the fitness for intended purpose of the dairy material or dairy product

point of use means the point at which the material, e.g. water, comes into contact with the dairy material or dairy product, or in a situation of indirect contact, comes into contact with the equipment, item or other material that comes into contact with the dairy material or dairy product

potable water means drinking-water which does not contain any determinands which exceed the Maximum Acceptable Values (MAVs) given in the DWSNZ

prerequisite programme means a documented programme covering good manufacturing practice (GMP)-based food hygiene activities that may interact at a number of process steps within and across various processes in a food premises, and that have the potential to influence the hygiene status of the product and/or control hazards. This is can also be good hygienic practice (GHP) or good operating practice (GOP)

procedure means documented in writing and followed by the operator

pure milk means the whole of the milk drawn at the time of milking from a healthy animal; but does not include milk mixed with any preservative or chemical or colouring matter of any kind

raw milk means milk that has not been subjected to any processing intended to alter the quality or compositional characteristics of the milk

raw milk product means a processed dairy product:

a) that has not received a pathogen elimination step; and

b) in which as a result of its nature and the manner in which it is processed, may allow the survival of pathogens, but in the case of pathogens specified in the food safety criteria, will not support their growth or allow their survival, to levels that exceed those specified in the food safety criteria; ands
c) that is not raw drinking milk; and
d) that is not made from colostrum

recognised evaluator means a person recognised by the Director-General under section 103 of the Act to perform evaluation functions and activities as set out in the Animal Products Notice: Dairy Recognised Agencies and Persons Specifications

registration means registration under the Act

regulations means the Animal Products (Dairy) Regulations 2005

RMP means a registered risk management programme

season means the period from the 1st of June to the 31st of May of the following calendar year unless the RMP specifies an alternative 12 month period

shelf life means the period nominated by the manufacturer during which the product maintains its fitness for the intended purpose at a specific storage temperature and at other specified conditions

significant change means any change made to key staff, environment, premises, equipment, facilities, process or product, which may affect the fitness for the intended purpose of the dairy material or dairy product

specific PSLs means specific product safety limits that apply to dairy 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 including infants and young children, the old, pregnant and immuno-compromised)

standard of identity means a standard that defines the meaning of a term or designation used to describe a product such a standard typically includes the name of the product, its definition, and essential composition and quality factors

starter culture means a preparation of micro-organisms that is free of pathogens, and prepared for the purpose of modifying the characteristics of the dairy material

store means premises (not being a dairy factory or farm dairy or a retail shop or store ancillary to a dairy factory or farm dairy) used for storing dairy material or dairy product prior to:

a) delivery of the material to the place of sale for consumption or for end use for purposes other than consumption; or
b) its export

supporting system means a system used to support the overall ongoing compliance of the Hazard Identification and Analyses or HACCP plan, but which does not necessarily influence the hygiene status of the product and/or control hazards

Tb means bovine tuberculosis

Tb clear means achieving and maintaining a rating of “C5” through to “C10” under the national Tb eradication scheme

validation means the process by which the operator ensures that the programme, plan or system is complete, and meets the requirements of the Act and any relevant animal product regulations and specifications; and when implemented, will consistently achieve the required outcomes of the programme, plan or system

veterinarian has the meaning given to it in the Veterinarians Act 2005 and veterinary has a corresponding meaning

veterinary medicine means any substance, mixture of substances, or biological compound used or intended for use in the direct management of an animal

visibly abnormal milk includes but is not limited to milk that is watery, discoloured, slimy, ropy, or has visible clots, flakes or gross alterations in appearance

withheld means excluded permanently from supply, delivery or sale, and withhold has the same meaning

working days means Monday to Friday inclusive, excluding statutory holidays

(2) Any term or expression defined in the Act or Regulations that is used, but not defined, in this Notice has the same meaning as in the Act or Regulations (as the case may be).

Part 2: General dairy processing requirements

2.1 Object of this Part

(1) This Part sets out the requirements that apply generally to dairy processors who intend to process dairy material and dairy products, and to RMPs and the operators of RMPs that cover the processing of dairy material and dairy products.

(2) It includes:

a) procedures or systems to be included in an RMP to ensure that non-conforming product will be managed in accordance with the Animal Products (Dairy) Regulations 2005; and
b) the application of HACCP Principles as described by Codex; and
c) procedures for reporting, notifications and the keeping of record; and
d) conformance criteria for dairy material and or dairy product, such as tolerance limits for chemical residues and contaminants, microbiological parameters and wholesomeness.

2.2 Application of this Part

(1) This Part applies to:

a) operators of RMPs that cover the processing of dairy material and dairy products; and
b) dairy processors; and
c) dairy material and dairy product.

2.3 RMP requirement

(1) The RMP must describe the procedures and systems that ensure the requirements and obligations in this Notice that apply to RMPs, RMP operators and dairy processors covered by the RMP will be met, and that dairy processors covered by the RMP are aware of the requirements that apply to them.

2.4 General requirement to keep records

(1) Dairy processors must have access to and implement documented procedures that provide for the keeping of adequate and auditable records to demonstrate that relevant requirements have been met.

(2) Records must be:

a) retained for a period of at least:

i) four years; or
ii) the shelf life of any associated dairy material or dairy product, if the shelf life is longer than four years; or
iii) such other period that specified in this Notice;

and;

b) legible and retrievable within two working days; and
c) accessible to the recognised verifier, the recognised verifying agency, animal product officers, the Director-General and any other person authorised by the Director-General.

2.5 Traceability

(1) Dairy processors must have procedures to ensure that traceability is maintained for all dairy material and dairy product, and for material added to dairy material and dairy product during processing, including other dairy material, ingredients, additives and processing aids.

(2) Tracing of material under clause 2.5(1) is required on the basis of one step forward and one step back, specifically:

a) the supplier and identity of all material that makes up the dairy material or dairy product, including the batch reference for each input; and
b) tracing through the process; and
c) the recipient and identity for all dairy material and dairy products leaving the dairy processor's control.

(3) Traceability must be maintained so that the RMP operator can readily trace back and forward to identify all product that may be affected when, for example, an ingredient used is subsequently identified as unsafe. Records must be sufficient to facilitate a recall of all affected dairy product when affected product is identified.

2.6 Reporting responsibilities

(1) Unless otherwise specified under the Act:

a) RMP operators must ensure that all reports required to be provided under this Notice to their recognised agency for verification or recognised RMP verifier are provided as required in a manner acceptable to the recognised agency for verification or recognised RMP verifier; and
b) the RMP operator or their delegate must sign or confirm the validity of all reports in a manner acceptable to MPI; and
c) the RMP operator must ensure that it has an agreement with its RMP verifier on the method of reporting and the format and content of reports.

2.6.1 Exception Events

(1) The following are exception events:

a) the discovery of non-conforming dairy material or dairy product; and
b) the discovery of a non-compliance suspected or known to have occurred, including any failure to comply with the RMP; and
c) the discovery of a critical non-compliance.

(2) Dairy processors must:

a) notify the RMP operator without delay once they become aware that an exception event has occurred; and
b) initiate an investigation to determine, as appropriate:

i) the root cause; and
ii) any processes, raw materials, dairy material or dairy product that may be or is affected;

and;

c) initiate corrective actions to ensure that control is restored.

2.6.2 Reporting exception events

(1) Upon becoming aware of any exception event under clauses 2.6.1 (1) an RMP operator must report the matter to their RMP verifier within 1 working day of discovering or being made aware of the exception event.

(2) In meeting clause 2.6.2(1) an initial verbal report to the RMP verifier is acceptable, but must be confirmed in writing within 3 working days.

(3) The RMP operator must obtain confirmation of receipt of the exception event report from their RMP verifier or the recognised agency responsible for their verification. The response may be by any means deemed suitable by the RMP verifier such as email, phone call or short message service (sms), but must be from a person and not an automated response.

Guidance

Information may come from a variety of sources indicating that dairy material or product is non-conforming, or is reasonably likely to be non-conforming, or that a critical non-compliance has occurred. Information sources include verification audits, operator monitoring and customer/importing country monitoring and/or findings. Where the non-conformance is also covered by an exporter non-conformance notification under section 51 of the APA, that notification may be reported to the RMP verifier to satisfy clause 2.6.2.

(4) Exception reports must include the following:

a) a detailed description of the exception event; and
b) if no dairy material or dairy product is affected, a statement confirming that no dairy material or dairy product is affected; and
c) if dairy material or dairy product is affected;

i) the identity and description, quantity and location of all dairy material or dairy product that is, or is suspected to be, non-conforming and whether the material or product is isolated; and
ii) if dairy material or dairy product is not isolated, the methods being used to secure it against use or trade; and
iii) the extent of all dairy material or dairy product is affected or suspected to be affected;

and;

d) In the case of clause 2.6.2(4)c)iii):

i) the date since the last acceptable measurement or satisfactory laboratory test result was obtained; and
ii) the processing lines or areas affected; and
iii) if tracing has not been completed, justification for the range of dairy material or dairy product suspected to be affected; and
iv) the name, title, and contact details of the person responsible for managing the exception; and
v) the date that any investigation or traceback to determine the cause is expected to be completed; and
vi) the corrective actions that are planned, in progress or completed and the schedule for commencement and completion.

(5) As much of the following information that is available at the time must be provided to the RMP verifier as part of the exception report, with the balance and any updates provided as the information becomes available:

a) an account of all the actions taken; and
b) the outcome of the traceback; and
c) the cause(s) of the exception; and
d) the evidence that all suspect dairy material or dairy product is identified and isolated; and
e) the corrective actions that have been completed and those still to be completed, with the date for completion; and
f) the evidence that the exception has been resolved; and
g) the identity of conforming and correctly labelled dairy material or dairy product held in isolation; and
h) the identity of non-conforming dairy material or dairy product.

(6) If the information reported to the RMP verifier is inadequate or incomplete, the RMP verifier or MPI will take the actions deemed necessary to either:

a) obtain all relevant information in order to verify that hazards and risk factors are adequately managed; or
b) protect public or animal health on the basis of the limited information available.

2.6.3 Reporting on Demand

(1) RMP operators must provide any additional information or data related to the dairy processing activities of dairy processors covered by the RMP when requested by the Director-General or their RMP verifier.

2.7 HACCP requirements

(1) The RMP operator must complete either a Hazard Identification and Analyses or HACCP plan for the dairy processing activities covered by the RMP.

(2) The Hazard Identification and Analyses or HACCP plan must:

a) be developed in a systematic manner following the Codex HACCP Principles as set out in the Codex Annex to the General Principles of Food Hygiene CAC/RCP 1-1969, Revised 2003, "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application"; and
b) be confirmed by a competent person or persons to be valid for the processing activities covered by the RMP.

(3) Where a HACCP plan includes heat treatment as a critical control point for the control of pathogens, the heat treatment must be operated in accordance with the relevant requirement for the dairy heat treatments in clause 5.15 of this Notice.

Guidance

The Hazard Identification and Analyses or HACCP plan development process will take one of two paths depending on whether critical control points (CCPs) are identified. The result will be either:
(a) a HACCP plan where CCPs are identified; or
(b) a Hazard Identification and Analyses where no CCPs are identified.

Documented and effective prerequisite programmes, and other supporting systems must also be developed prior to implementing HACCP.

Applying the Codex HACCP principles will enable RMP operators to satisfy sections 17(2) and (3) of the Act and clause 10 and 11 of the Animal Products (Risk Management Programme Specifications) Notice 2008 and any equivalent clauses in any Notice that amends or replaces it.

2.8 Management of non-conforming dairy material and dairy product

(1) The RMP must describe the procedures that ensure any non-conforming dairy material or dairy product is identified and detained until it is disposed of in accordance with the Animal Products Notice: Disposal of Non-conforming Dairy Material or Dairy Product.

(2) Dairy processors must notify the RMP operator of all non-conforming dairy material or dairy product and must follow the procedures referred to in clause 2.6.

(3) All non-conforming dairy material or dairy product must be reported to the RMP verifier by the RMP operator in accordance with clause 2.6.2 without delay, unless specified otherwise within this Notice or the Animal Products Notice: Disposal of Non-conforming Dairy Material or Dairy Product.

2.9 Conformance monitoring

(1) Dairy processors must have a sampling and testing plan when testing is required by this Notice or the RMP, or is determined to be necessary through the Hazard Identification and Analyses or HACCP plan including associated pre-requisite programmes.

(2) The sampling and testing plan must give consideration to the sampling and testing of dairy material, dairy product, processing environments, processing equipment, water and associated things that is necessary to monitor processing control measures and to confirm dairy product fitness for purpose and standard of identity.

(3) For clarity, the criteria in clauses 2.9(1) and 2.9(2) will typically mean that dairy processors who store or transport packaged dairy material or dairy product but do not handled exposed product will not be required to have a sampling and testing plan.

(4) The sampling and testing plan must specify:

a) what is to be sampled and how often; and
b) what it is that samples are to be tested for and test methods to be used; and
c) the acceptance limits for each sample type and test; and
d) the actions to be taken if limits are exceeded.

(5) The procedures in the sampling and testing plan must ensure that samples are representative and that sampling does not result in dairy material or dairy product becoming contaminated.

(6) Unless otherwise specified within this Notice, analysis of dairy material, dairy product, and samples from the manufacturing environment for any of the following purposes must be undertaken in a laboratory in accordance with clause 2.9(7) or 2.9(8):

a) food safety; and
b) product conformance and standard of identity; and
c) wholesomeness; and
d) RMP compliance, including testing under the environmental pathogen management plan.

(7) All testing under this clause must be completed:

a) in a MPI recognised laboratory that is accredited to ISO 17025 in an appropriate category for the required test; and
b) using a test method acceptable to MPI for the dairy material or dairy product under Part 3 of the Animal Products Notice: Specifications for Laboratories; and
c) where required, use any method specified under the Act.

(8) However, testing does not have to be done as required by clause 2.9(6) if the testing is not explicitly required under this Notice and:

a) the testing is not commercially available within New Zealand, provided the overseas laboratory uses test methods covered by its scope of accreditation under ISO 17025; or
b) the testing is for process or quality control purposes only and will not be used to justify reduced testing for food safety or fit for purpose.

(9) In developing sampling and testing plans for formulated products, dairy processors must have a clear understanding of the level of variability inherent in their processes for each parameter under consideration and must take into account the level of variability when determining the sampling frequency, timing and collection method.

(10) Sampling and testing plans may exclude routine testing of dairy material or dairy product for particular microbiological, chemical, physical, wholesomeness or standard of identity attribute where the Hazard Identification and Analyses or HACCP plan determines that testing is not required to confirm that product is fit for purpose.

(11) With regards to retesting after a final laboratory result has been issued:

a) results obtained from retesting a sample or submitting new samples of dairy product previously found to be non-conforming must not be used to reclassify non-conforming dairy material or dairy product as conforming; and
b) additional testing may be carried out on previously untested product to establish the extent of non-conformance within a product lot, for example to determine whether there is a clear separation of affected and unaffected dairy material or dairy product to support a product disposition application.

(12) Where a recognised laboratory has withdrawn a final laboratory result due to unequivocal evidence of a failure of its internal systems then retest results may be used in support of a product disposition application for the dairy material or dairy product originally deemed to be non-conforming.

2.10 Microbiological product safety limits

(1) All dairy products intended for human consumption must not contain pathogens or hygiene indicator organisms that:

a) in the case of dairy products intended for the general population, exceed the limits specified in the second column of Table 2.1 for the parameters identified in the first column; and
b) in the case of dairy products intended for specific populations, exceed the Specific Product Safety Limits (PSLs) specified in the third column of Table 2.1 for the parameters identified in the first column.

(2) All dairy products intended for animal consumption must not contain pathogens at levels that will be harmful to the intended species and age of animal. Dairy processors must determine the pathogens of relevance and the acceptance limits that are to apply for each pathogen of relevance.

(3) The applicable microbiological Product Safety Limits set out in Table 2.1 must not be exceeded at any time during the dairy product's shelf life when the product is handled and stored according to the manufacturer's advice or instruction.

(4) Where an RMP documents the requirement for routine pathogen testing, then either:

a) the testing must be initiated as soon as possible, and not later than seven days after the completion of product manufacture; or
b) all production lots processed since the last lot tested must be held under the dairy processors control until the required testing has been initiated.

(5) For clarification, the completion of manufacture for cheese means the end of maturation and subsequent preparation for transport including packaging and labelling.

(6) In the event that micro-organisms do exceed the limits in the applicable column of Table 2.1, the dairy product is deemed to be non-conforming and must be managed in accordance with clause 2.8.

Table 2.1: Microbiological product safety limits – Dairy Products for Human Consumption

Parameter	General Population	Specific Population	Explanatory Notes/Comments
Salmonella spp.	ND/25g	ND in 250g	The Specific PSL does not apply to infant formula product or foods for special medical purposes ND = not detected in the volume tested Composite of samples collected throughout the production run as defined by the manufacturer's RMP
		ND in 60 x 25g	The Specific PSL applies to infant formula product and foods for special medical purposes
L. monocytogenes	ND/25g	ND/25g	The general population PSL does not apply to ready to eat food in which growth of L. monocytogenes will not occur. This Specific Population PSL does not apply to infant formula products and foods for special medical purposes ND = not detected in the volume tested Composite of samples collected throughout the production run as defined by the manufacturer's RMP
	100 cfu/g	-	The general population PSL applies to ready to eat food in which growth of *L. monocytogenes* will not occur. Conditions under which growth will not occur are set out in standard 1.1.6-4 of the Food Standards Code. Ready to eat food is defined in standard 1.1.2-2 of the Food Standards Code.
	-	ND in 10 x 25g	This Specific Population PSL applies to infant formula products and foods for special medical purposes
Coagulase Positive Staphylococci (S. aureus)	1000 cfu/g	10 cfu/g (infant formula only) 100 cfu/g (other specific populations)	The limit of 10/g applies to infant formula products only. In all cases 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

Parameter	General Population	Specific Population	Explanatory Notes/Comments
			released enterotoxin is 'estimated' by the bacterial load
B. cereus	1000 cfu/g	100 cfu/g	The Specific PSL limit only applies to product designated as infant formula
E. coli	100 cfu/g	10 cfu/g	
Cronobacter spp. (formerly known as *E. sakazakii*)	Not Applicable	ND/300g	Applies to product designated as infant formula, human milk fortifiers or formula for special medical purposes intended for infants when intended as the sole source of nutrition. Samples are to comprise either: 30 x 10 g subsamples collected across a lot, or A composite of 30 or more subsamples collected throughout the production run for instance through a continuous inline sampling device.

Guidance

All dairy products manufactured for sale or sold in New Zealand and intended for human consumption must also comply with the microbiological limits specified in Schedule 27 of the Australia New Zealand Food Standards Code throughout the shelf life of the product.

For the purposes of clause 2.10, a pathogen detection is confirmed once the laboratory has issued the result in a final report. In some cases the laboratory may provide an early indication of the likely outcome. While dairy processors should take action immediately to investigate the root cause and apply corrective actions, the product becomes non-conforming once the dairy processor or RMP operator receives the final report indicating a result that exceeds a safety limit.

When a dairy processor or RMP operator requests a presumptive test only, or a more general test such as Listeria spp. rather than *Listeria monocytogenes*, the product is deemed non-conforming once the dairy processor or RMP operator receives the final report that indicates a positive finding for the presumptive test concerned. The dairy processor or RMP operator may elect to proceed with further confirmation, but the affected dairy material or dairy product must be managed as non-conforming as set out in clause 2.8.

2.11 Chemical contaminants and residues of agricultural compounds and veterinary medicines

(1) Dairy material and dairy products must not contain:

a) chemical residues exceeding the limits specified in the New Zealand (Maximum Residue Levels for Agricultural Compounds) Food Notice; and
b) chemical contaminants that exceed the limits specified for the dairy material or dairy product as listed in Table 2.2 – Limits for specified chemical contaminants.

Table 2.2: Limits for specified chemical compounds

	Nitrate (mg/kg)	Nitrite(mg/kg)
Infant formula products 0-12 months	50	5
General population (and dairy ingredients for infant formula products) – Milk Products	150	5
Buttermilk powder	150	15

(2) In giving consideration to chemical hazards when completing the HACCP Identification and Analyses or HACCP plan as required under clause 2.7 the RMP operator may defer to monitoring conducted under the MPI National Chemical Contaminants Programme for compounds shown to be managed effectively through national controls.

(3) Dairy material or dairy product is deemed to be non-conforming when a chemical contaminant or residue is present in the dairy material or dairy product at a level that exceeds an applicable limit specified in one of the instruments referred to in clause 2.11(1) or, if applicable, clause 8.4.

2.12 Radiological standards

(1) Dairy processors must raise an exception report if they become aware that dairy material or dairy product has been exposed to radionuclides at a level that would result in contamination, such as exposure through imported ingredients.

Guidance

Radionuclide levels in dairy product are monitored under a regulated control scheme which establishes the national status of radionuclides. Where individual product levels are needed, for assurances relating to certification, separate testing will be required.

2.13 Wholesomeness and foreign matter

(1) Dairy processors must ensure that dairy products are wholesome and do not contain any objectionable or offensive matter, or any physical hazard that constitutes a risk of injury to the intended consumer.

(2) RMP operators covering dairy manufacture must define acceptance criteria for wholesomeness and physical hazards in the dairy material and dairy products they manufacture.

Guidance

All dairy products manufactured in New Zealand, must comply with composition and nutrient fortification limits specified in the Australia New Zealand Food Standards Code unless the product is for export and an exemption has been issued under section 60B of the Act and that exemption applies to the dairy product and the intended market(s).

2.14 RMP evaluation and performance based verification

(1) The RMP operator must ensure verification of compliance with the requirements set out in this Notice as part of the RMP verification undertaken by an agency that is recognised under the Act for the purpose, and at the frequency determined by the Director-General under regulation 28(1) of the Regulations.

(2) In the case of dairy processors that are under an RMP that does not provide for export of dairy products with an official assurance, the frequency and intensity of RMP verification is determined by:

a) the ongoing performance of RMP operator; and
b) the performance of all dairy processors covered by the RMP; and
c) the nature of dairy processing undertaken under the RMP scope; and
d) the RMP verification category previously assigned and recent verification outcomes.

(3) In the case of dairy processors that are under an RMP that provides for the export of dairy products with an official assurance the verification requirements and frequencies set out in the Animal Products Notice: Export Verification Requirements apply.

Part 3: Farm dairies

3.1 Background

(1) This Part sets out additional requirements in relation to the harvesting, cooling and storage of raw milk in farm dairies and associated activities that support the harvesting and supply of raw milk that is fit for its intended purpose.

3.2 Application

(1) This Part applies to:

a) operators of RMPs that cover the processing of raw milk at farm dairies; and
b) farm dairy operators, farm dairy owners and milk harvesters; and
c) dairy material and dairy product.

3.3 General Requirements

(1) Raw milk presented for supply must be processed in accordance with the requirements set out in this Part and must meet the minimum criteria specified in clauses 4.3, 4.4 and 4.5 of this Notice.

(2) Raw milk that does not conform to the minimum criteria specified in Part 4, or that has not been processed in accordance with this Part, the RMP or any applicable export notices issued under section 60 of the Act must either be withheld or managed as non-conforming dairy material in accordance with clause 2.8.

(3) An RMP covering farm dairy activities must describe the systems, procedures and manner in which the requirements in this Part will be met by all farm dairy operators covered by the RMP, for example by:

a) incorporating by reference MPI Operational Codes within the RMP; or
b) issuing instructions; or
c) formalising requirements within contractual arrangement or on-farm quality programmes.

(4) Milk held in a bulk milk tank at the farm dairy is deemed to be presented for supply unless collection has been disabled, for example by using a lock on the outlet, and the bulk milk tank is clearly labelled at the outlet to indicate that the contents are not for supply or collection.

3.4 Farm dairy operators and personnel

(1) Farm dairy operators must:

a) have a sound understanding of the operation and maintenance of their milking equipment; and
b) be familiar with, and comply with, the requirements within the RMP that apply to them; and
c) be competent to undertake dairy processing activities at the farm dairy; and
d) ensure that all milking personnel, including relief milkers, are suitably trained for the activities that they undertake, and be familiar with the procedures that they are required to follow.

3.5 Farm dairy location, design, and facilities

(1) The RMP operator must ensure that:

a) farm dairies must be located to minimise the impact of hazards and risk factors such as flooding, objectionable smells, smoke, dust, and other contaminants; and
b) only suitable materials are used for the construction of the farm dairy; and

c) that the minimum standards for the design, construction, and maintenance of milking plants, and for materials and substances coming into contact with, or impacting on, milk for supply are documented in the RMP; and
d) farm dairy operators are made aware of the requirements under this clause.

(2) Milking areas must be located, designed, and constructed so that:

a) floors and, where required, walls are easily cleaned and maintained; and
b) drainage is effective; and
c) lighting and working space is sufficient to:

i) allow for proper milking; and
ii) enable milking animal health to be observed including the stripping and observation of foremilk when needed; and
iii) minimise the risk of contamination of milk during milking.

(3) Milking areas and milk storage areas must be located, designed, and constructed so as to:

a) protect milk against risk factors such as manure, dust, foreign matter, objectionable smells, pests including birds, rodents, insects, and other contaminants; and
b) be easy to wash, clean and inspect; and
c) provide adequate shelter to protect milk and milking activities from adverse weather and the environment; and
d) have proper and adequate facilities for filtering, cooling and storing milk in accordance with clause 3.9.

(4) The milking plant must be designed, constructed and maintained to a standard that will ensure that:

a) milk will be protected from contamination, taints and spoilage at all times; and
b) all materials and substances coming into contact with milk, either directly or indirectly, will not contaminate the milk, cause it to deteriorate or otherwise cause it to be unfit for its intended purpose; and
c) it can be easily and properly cleaned, sanitised and maintained.

3.6 Farm dairy environment

(1) The farm dairy and its surroundings must be kept clean and tidy, and free from harbourage for birds, rodents, insects and other pests.

3.7 Farm dairy water

(1) Farm dairies must have enough water of suitable quality to:

a) rinse, clean, sanitise and rinse surfaces that may come into contact with milk; and
b) clean the farm dairy after each milking, including the yard; and
c) clean teats and udders; and
d) enable milk harvesters to maintain clean hands and forearms; and
e) maintain a clean environment in all milk handling areas; and
f) if necessary, cool milk.

(2) All water that may come into direct or indirect contact with milk intended for supply must:

a) be of suitable quality so that the raw milk is protected from microbiological, chemical and physical contamination and remains fit for its intended purpose; and
b) meet the following criteria or comply with clause 3.7(3):

i) *E. coli* – absent in 100ml; and either:

1) Turbidity – maximum 5 NTU (Nephelometric Turbidity Units); or

2) Clarity maximum of 5 NTU equivalent where the method and device used to measure clarity is correlated to the results obtained using an American Public Health Association (APHA) reference method for turbidity as specified in the DWSNZ, with records of the correlation held and made available for inspection;

and;

ii) have no water supply or reticulation system hazards identified;

and;

c) the sampling for the criteria in 3.7(2)b) must be carried out by a farm dairy assessor or an independent person competent in water sampling; and
d) the testing for clause 3.7(2)b) must be carried out by a farm dairy assessor or an independent person competent in the relevant testing; and
e) the testing to for clause 3.7(2)b) must be carried out by a laboratory accredited for water testing and with the test concerned under its scope of accreditation.

(3) If the farm dairy water criteria in clause 3.7(2)b) are not met the farm dairy operator must develop and follow a water management plan that:

a) describes the procedures to be followed to ensure that milk is protected from any possible microbiological, chemical or physical contamination from the water used; and
b) identifies any hazards or deficiencies and the steps to be followed to protect milk and milk contact surfaces; and
c) is accepted by the farm dairy assessor on behalf of the RMP operator.

(4) Water that does not meet the criteria in clause 3.7(2) or (3) is non-conforming and if used in the farm dairy for any purpose described under clause 3.7(1) the milk must be withheld from supply.

Guidance

Indirect contact with milk includes water used for:
- Rinsing and washing the milking equipment including the bulk milk tank(s)
- Washing and rinsing the hands and forearms milk harvesters involved in cupping

Water used for teat cleaning and milk cooling must be visually clean and to minimise udder infections it should meet the farm dairy water standard. However it is not considered to be water that may come into indirect contact with milk.

3.8 Milk harvesting

(1) Milking, milk receiving and milk storage areas must only be used for milking, breeding, veterinary treatment, and animal husbandry activities.

(2) Milking equipment in farm dairies must only be used for the handling of milk.

(3) Milking animals must have clean teats when milked.

(4) Milking procedures must be documented and followed to prevent contamination of milk during milking, including sources of contamination such as soiled teats and udders, milk harvester contact, adverse weather and the milking environment.

(5) Milk must be protected from taints and spoilage.

(6) Abnormal milk must be withheld from supply.

3.9 Milk filtering, cooling and storage

(1) Farm dairies must have adequate milk filtration equipment and milk cooling facilities to enable milk to be filtered and cooled in accordance with this clause.

(2) During, or immediately following milking, raw milk must:

a) be filtered through a clean, hygienic filter of a design that will ensure that:

i) sediment and foreign matter is removed without removal of constituents naturally present in the milk from healthy animals; and
ii) without causing contamination of the milk;

and;

b) be immediately cooled to ambient temperature; and
c) be cooled to 10°C or below within four hours of the commencement of milking; and
d) be cooled to 6°C or below within six hours from the commencement of milking or within two hours from the completion of milking, whichever occurs first; and
e) be held at or below 6°C, without freezing, until collection or the next milking; and
f) not exceed 10°C during subsequent milkings.

(3) In situations of where there is continuous or extended milking, such as automated milking systems, the milk must enter the bulk milk tank at 6°C or below and be stored in accordance with clause 3.9(2)e) and (f).

(4) Clause 3.9(2)b) to f) does not apply when manufacture starts within two hours of the completion of milking, provided that manufacture occurs at the same place and the storage conditions applied protect the milk from deterioration.

(5) In satisfying the milk cooling requirements of clause 3.9(2) or (4), farm dairy operators must not delay the milking of any animals in order to delay the time that milking is completed.

(6) RMP operators must ensure that periodic checks are made to verify that the milk cooling requirements are being met.

(7) Farm dairy operators must periodically monitor and record milk cooling performance to confirm that milk cooling requirements in this clause can and are being met.

(8) The farm dairy operator may have a suitably qualified person undertake the monitoring set out in clause 3.9(7).

(9) Temperature measurements and recording of milk temperature can be accomplished using any reliable method provided that:

a) there is no risk to the milk, for example ensuring that glass thermometers are not used; and
b) the method is recorded; and
c) the accuracy of the temperature measurement device is known.

(10) Farm dairy operators must withhold from supply milk that has not been cooled in accordance with this clause unless the milk has been assessed and confirmed as fit for intended purpose through suitable means such as:

a) sensory evaluation; or
b) microbiological testing; or
c) titratable acidity; or
d) a predictive risk assessment model that has been validated and evaluated.

(11) If farm dairy operators become aware that milk filtering or cooling performance is inadequate they must:

a) notify the RMP operator of any affected milk being held at the farm dairy; and
b) take corrective action; and

c) in the case of inadequate milk cooling performance, repeat the checks described in clause 3.9(7) until the milk cooling requirements in this clause are met.

(12) Raw milk that is not cooled and processed in accordance with this clause and is not confirmed as suitable under the provisions specified in clause 3.9(10) is non-conforming and must be managed as withheld milk on farm or non-conforming dairy material in accordance with clause 2.8.

3.10 Maintenance, housekeeping and hygiene

(1) Farm dairy operators must ensure that:

a) rubbish and wastes are disposed of appropriately and do not attract or harbour pests; and
b) facilities and equipment are maintained in a good state of hygiene and repair; and
c) building integrity is maintained; and
d) regular assessments are made of the farm dairy, structures, storage facilities, milking equipment including rubberware, facilities and services, with deficiencies documented; and
e) appropriate corrective action is taken in the event of deficiencies or non-compliance.

3.11 Cleaning

(1) Farm dairy operators must have and follow written procedures that ensure:

a) the milking plant in farm dairies is:

i) maintained in an appropriately hygienic state and will not cause milk to deteriorate or become contaminated; and
ii) cleaned only with maintenance compounds approved by the Director-General under the Regulations, including detergents and sanitisers, and in compliance with the label instructions; and
iii) cleaned, sanitised and maintained in a manner that minimises the risk of milk being contaminated from the environment or by the maintenance compounds used, for example by rinsing with suitable farm dairy water; and
iv) protected from contamination following cleaning;

and;

b) yards and milking areas are clean following each milking; and
c) all other areas in the farm dairy including milk storage areas are kept clean; and
d) cleaning circuits and cleaning equipment are maintained appropriately.

(2) The procedures required under this clause must include, at a minimum:

a) the frequency of cleaning; and
b) the maintenance compounds used; and
c) the working strength and temperature of the cleaning solutions used; and
d) any special requirements to ensure that the cleaning and sanitising is effective.

3.12 Colostrum and other specialty milks

(1) The farm dairy operator must have written procedures for the handling of specialty milks including colostrum to ensure:

a) segregation so they are not unintentionally mixed with or collected with other milks; and
b) that bulk milk tanks used to store specialty milks are clearly identified so that the milks are not unintentionally mixed with or collected with other milks throughout harvesting and storage; and
c) that they are withheld from supply for human consumption except when there is a written supply agreement with a dairy processor for supply of the colostrum or other specialty milk.

3.13 Parturition records

(1) Farm dairy operators intending to milk animals for the supply of colostrum for human consumption must record the date they gave birth.

3.14 Milking animal health

(1) Farm dairy operators and RMP operators must only present for supply raw milk for human or animal consumption that has been obtained from healthy milking animals and is in all respects fit for the intended purpose.

(2) Farm dairy operators must have and follow written procedures that ensure:

a) milk presented for supply is from milking animals that are outwardly healthy and show no clinical signs or other evidence of diseases capable of contaminating milk with pathogenic microorganisms or toxic substances; and
b) that animals showing clinical signs of, or diagnosed with, infectious diseases communicable to humans through milk are:

i) identified; and
ii) isolated from the herd if instructed to do so by a veterinarian; and
iii) have their milk withheld until the clinical signs have been resolved;

and;

c) farm dairy operators obtain veterinary supervision or advice when problems with milking animal health are suspected; and
d) records are kept to show compliance with this clause.

(3) For the purposes of clause 3.14(2), "diagnosed" means the confirmed diagnosis of a veterinarian, and infectious diseases communicable to humans include:

a) tuberculosis; and
b) listeriosis; and
c) brucellosis; and
d) salmonellosis; and
e) yersiniosis; and
f) leptospirosis.

(4) Milking animals shown to have tested positive for bovine Tb are considered to be diagnosed with an infectious disease communicable to humans through milk immediately the animal is confirmed to be a bovine Tb reactor or when directed to slaughter by a veterinarian.

(5) Any milking animal to which clause 3.14(6) applies, or when a veterinarian has given an equivalent instruction, must be segregated and not milked for human or animal consumption.

(6) Milk from an animal that is bovine Tb first test positive but has not been confirmed to be a reactor and has not been directed to slaughter by a veterinarian must either;

a) be directed to a use where it will be given a heat treatment at least equivalent to pasteurisation; or
b) directed to waste, and not fed to animals.

(7) In addition to the requirements of clause 3.14 (3), animals suffering from the following conditions must be identified and isolated from the herd, and their milk must not be presented for supply to processors of dairy material until the clinical signs of discomfort and disease have been resolved:

a) severe diarrhoea with depression and dehydration; and
b) severe weight loss, and emaciation of non-nutritional origin; and
c) severe injury of, or abscess on, any body part; and
d) non-metabolic nervous disease; and

e) fever, including those associated with retained foetal membranes and parturition difficulty; and
f) severe infection of the genital tract with discharge that may reasonably contaminate the udder; and
g) clinical signs of a systemic illness or disease.

(8) If the animal's mammary gland is inflamed or injured, the affected glands must be identified and the milk from them must not be presented for supply to processors of dairy material until healed or any clinical signs have resolved.

(9) Dairy goats suffering from caprine arthritis encephalitis must be culled.

(10) Unless otherwise required in this clause or instructed by a veterinarian, animals which are sick or diseased must be treated to ensure resolution of the condition and to alleviate unnecessary pain and distress.

3.15 Animal treatments

(1) Where milking animals receive any form of treatment:

a) the treatment and its use must be appropriate and efficacious, and recognised as appropriate for the condition being treated in milking animals; and
b) any veterinary medicine used must be either registered or exempt from the requirement for registration under the ACVM Act; and
c) the farm dairy operator must accurately follow the instructions on the label of any veterinary medicine used, or the written instructions provided by a veterinarian; and
d) the farm dairy operator must use veterinary medicines in accordance with the product label or veterinary instructions, in conjunction with appropriate milking procedures, to ensure that maximum acceptable residue limits are not exceeded; and
e) veterinary medicines must not be used immediately prior to milking unless instructed to do so by a veterinarian.

(2) The milk from animals which have been treated must be withheld from supply for the time specified on the label or as provided for in clause 3.18(1)b).

(3) When animals are treated for mastitis in any gland, the milk from all glands must be withheld.

(4) If treatment fails to resolve the clinical signs of infection, then:

a) the animal(s) must be identified and, if necessary, kept isolated from the milking herd;
b) further veterinary advice sought; and
c) records kept.

3.16 Animal health and treatment records

(1) Farm dairy operators must keep records of sick, diseased and treated animals, using a unique animal identifier, which show:

a) the date that sick or diseased animals were identified and, where necessary, isolated from the herd;
b) the type of disease, suspected disease or condition;
c) details of any treatment given to provide sufficient information for traceback purposes, including:

i) the trade name of the product used; and
ii) the dose(s) administered, by whom and when;

and;

d) the date and milking that milk was first withheld;
e) the date and milking when the animal was returned to the milking herd or was permanently removed from the herd; and

f) the name of the veterinarian consulted, if one was consulted.

(2) The records required in this clause must be kept for at least 4 years for traceback purposes.

3.17 Veterinary inspections

(1) Farm dairy operators must ensure that the health and condition of the milking herd, including animals under treatment, is subject to observation by a veterinarian at least once per dairy season.

(2) A record of the veterinarian's observation under clause 3.17(1) must be retained along with any observations or recommendations provided by the veterinarian.

3.18 Milk withholding

(1) Farm dairy operators must withhold that:

a) is tainted, impure, adulterated or otherwise not fit for its intended purpose; or
b) is required to be withheld in accordance with agricultural compound and veterinary medicine label instructions, unless:

i) the variation is given under the written instruction of a veterinarian; or
ii) the Director-General is satisfied that, in a particular case, associated risks are being effectively managed as described in a significant amendment to the RMP;

and;

c) is colostrum unless there is a written supply agreement and the milk is identified in accordance with clause 3.12.

3.19 Management of withheld milk

(1) Milk that is required to be withheld must be harvested and stored in such a way that there is no risk of mixing it, or cross-contaminating it, with milk intended for human consumption.

(2) Milk from diseased animals that is withheld under clauses 3.14(2)b), (3), (7), (8) or (9):

a) must not be used for the manufacture of dairy products for human or animal consumption; and
b) must not be fed to milking animals.

(3) Milk containing chemical residues that is withheld under clause 3.15(2) or 3.15(3):

a) must not be used for the manufacture of dairy products for human or animal consumption; and
b) may be fed to calves or other food producing animals, provided that the milk will not result in residues in those animals and is in compliance with the Agricultural Compounds and Veterinary Medicines Act 1997.

(4) Milk withheld due to milk cooling failure may be fed to calves while it remains fit for that purpose.

(5) Raw milk that is withheld from supply and managed in accordance with the provisions of this clause is not considered to be non-conforming and as such is not required to be managed as non-conforming dairy material under clause 2.8.

(6) Farm dairy operators must have procedures in place for the disposal of milk should the need arise.

3.20 Management of chemical substances

(1) Farm dairy operators must minimise the risk of contaminating milk with agricultural compounds including veterinary medicines, maintenance compounds, hazardous substances or other chemical substances by:

a) preventing the storage in farm dairies of pesticides, agricultural compounds and other chemical substances other than veterinary medicines and maintenance compounds required to maintain the milking plant and farm dairy facilities; and
b) managing the use of agricultural compounds, pesticides, hazardous substances, fuels, and other chemical substances in or near farm dairies:

i) in accordance with their label instructions and precautions except as provided for under clause 3.18 (1)b) for veterinary medicines; and
ii) in a manner that minimises exposure of milking animals, their water and feed;

c) recording all use of agricultural compounds, pesticides and hazardous substances on the farm and in or around the farm dairy.

(2) Farm dairy operators must not present any milk for supply that:

a) may be contaminated with veterinary medicines, extraneous substances, hazardous substances, milk-tainting substances, agricultural compounds or any other substance, capable of rendering raw milk unfit for intended purpose; or
b) that exceeds any applicable allowable residue or contaminant limit.

3.21 Records and reporting

(1) Where records are required, they must be retained by farm dairy operators or RMP operator as specified within this Notice.

(2) RMP operators must hold the details of every farm dairy that is covered by the RMP, including:

a) the physical location and unique identification assigned to the farm dairy whether a name, supply number or other form of identification; and
b) the name and location or address of the farm dairy operator; and
c) the name and location or address of the farm dairy owner, if the farm dairy operator is not the owner.

(3) The RMP operator must ensure farm dairy operators are advised of the following in a sufficiently timely manner to allow corrective action to be taken when required:

a) the temperature of the milk at the time of collection, if the milk is collected or rejected at the farm dairy; and
b) test results for all required parameters in Tables 4.2, 4.3 and 4.4 other than inhibitory substances; and
c) test results for all inhibitory substance tests that give a positive result.

(4) Operators of RMPs covering farm dairies must provide the following information to the RMP verifier in a manner and frequency, not to exceed every three months, that is agreed with the RMP verifier:

a) The unique farm dairy identifier for each farm dairy operator given notice to rectify hygiene deficiencies including:

i) elevated aerobic plate counts; or
ii) elevated somatic cell counts; or
iii) elevated total coliform counts;

and;

b) The unique farm dairy identifier for each farm dairy supply failing to meet any acceptable limits for:

i) chemical residues or contaminants, including inhibitory substances, along with the compound if identified and the estimated concentration;
ii) two month geometric aerobic plate count average; or
iii) three month geometric somatic cell count average;

and;

c) the unique farm dairy identifier for any farm dairy supply suspended or discontinued due to unresolved milk quality failures or a failure to meet RMP requirements; and
d) the number of:

i) farm assessments completed in the last period;
ii) the number of unacceptable assessment outcomes and the number remaining unresolved; and
iii) the number of farm dairy assessments yet to be completed in the current season (excluding farm dairies that require revisits);

and;

e) summarised performance trends over time for the overall farm dairy milk supply covered by the RMP, including:

i) raw milk quality conformance and non-conformance; and
ii) somatic cell count averages; and
iii) foreign matter; and
iv) chemical residues and contaminants, including inhibitory substances, exceeding acceptable limits; and
v) other information that may give the RMP verifier a more complete picture of conformance.

(5) Operators of RMPs covering farm dairies must advise their RMP verifier of any non-compliance against the RMP or non-conforming dairy material, in accordance with clause 2.8.

(6) Operators of RMPs covering more than one farm dairy must provide the Director-General with details of the farm dairy operators, farm dairy locations, and the unique identification assigned to each farm dairy when there are significant changes or upon request.

Guidance

Operators of RMPs covering farm dairies are to provide MPI with details of the farm dairy operators, locations, unique identifier or supply number and species of milking animals.

3.22 Operator non-compliance and non-conforming dairy material

(1) Milk that has not been processed in compliance with clause 3.22(2) is non-conforming and must be identified and managed as such.

(2) Raw milk is non-conforming when:

a) it has not been harvested, filtered, cooled and stored in accordance with relevant regulatory requirements and the RMP; and
b) it fails to meet food safety criteria as set out in Part 4; and
c) it does not meet any applicable, notified export requirements issued under the Act.

(3) Farm dairy operators must:

a) advise the RMP operator of any non-compliance or non-conforming dairy material;
b) advise any person receiving non-conforming raw milk of the non-conformance without delay;

c) withdraw from supply any non-conforming milk that is still under the farm dairy operator's control; and
d) take all reasonable steps to ensure that inadvertent collection of non-conforming milk will not occur. When withdrawing milk from supply, and either:

i) remove non-conforming milk from the bulk milk tank without delay; or
ii) if for any reason the milk cannot be removed immediately, apply clear signage near the outlet of the bulk milk tank and disable raw milk collection, for example by way of a vat lock.

(4) On becoming aware of non-conforming milk RMP operators must:

a) advise any person that they have supplied non-conforming raw milk to of the nature of the non-conformance without delay; and
b) comply with the applicable requirements under clause 4.9 and 4.10.

(5) Non-conforming milk must be managed in accordance with clause 2.8 unless withdrawn from supply at the farm dairy.

(6) Appropriate corrective actions that are specified in the RMP must be undertaken following the identification of non-conforming milk to ensure future compliance.

3.23 Chemical contaminants, compliance monitoring and surveillance

(1) Farm dairy RMP operators must ensure that all farm dairy operators covered by their programme, are aware that sampling of their milk may occur at any time under the NCCP.

(2) If an RMP covers more than one farm dairy the RMP operator must ensure that MPI has details of all farm dairies covered by their programme, including a unique farm identifier such as supplier number, location of the farm dairy, the farm dairy operator and their primary contact details.

(3) RMP operators must manage any non-conformance or potential non-conformance that is identified through the NCCP, and notified by either MPI or the RMP verifier, in accordance with the requirements of their RMP, and clause 4.8. In addition, if a non-conformance is confirmed, manage that non-conformance in accordance with clause 2.8.

3.24 Farm dairy assessment

(1) The RMP must provide or incorporate by reference an appropriate, documented farm dairy assessment system that:

a) ensures that each farm dairy covered by the RMP will be assessed by a recognised farm dairy assessor at a frequency and intensity determined by the performance of the farm dairy, with a minimum of one full assessment or surveillance assessment each dairy season; and
b) all farm dairies and farm dairy operators covered by the RMP conform to regulatory requirements and the RMP, and that all raw milk presented for supply is fit for purpose; and
c) includes procedures for:

i) recording who performs each assessment; and
ii) how assessments will be conducted; and
iii) the recording and reporting of assessment findings; and
iv) follow-up and escalation of assessment findings as necessary; and
v) ensuring that corrective action is taken in the event of non-compliance.

(2) The RMP may incorporate by reference an appropriate MPI Operational Code as a means of satisfying 3.24(1).

(3) Farm dairy assessors must have:

a) suitable equipment to enable them to fulfil the farm dairy assessment function and to collect and test or dispatch water samples; and
b) knowledge of the RMP and the farm dairy assessment system applied under the RMP.

(4) A recognised farm dairy RMP verifier may assesses a farm dairy provided that:

a) all obligations applicable to a farm dairy assessor and the farm dairy assessment under the RMP are met; and
b) for farm dairies that process raw milk intended to be eligible for export, the same person cannot assess and verify the same farm dairy within the dairy season.

Part 4: Raw milk acceptance

4.1 Object of this Part

(1) This Part sets out the requirements relating to the process for accepting raw milk intended for further processing into dairy products, whether at collection from a farm dairy or receipt at a storage facility, transfer facility or manufacturing premises.

4.2 Application

(1) This Part applies to:

a) operators of RMPs that cover the processing or receipt of raw milk; and
b) farm dairy operators; and
c) dairy processors who transport or store dairy material and dairy product; and
d) dairy processors who receive raw milk and manufacture dairy material and dairy product; and
e) any other person presenting raw milk for supply or sale, or receiving raw milk; and
f) MPI recognised laboratories that test raw milk to confirm conformance to this Notice; and
g) exporters of dairy products.

4.3 Use, sale, supply or export of tainted, impure or adulterated milk

(1) Farm dairy operators must not present for supply, and dairy processors must not accept, milk for human consumption that is tainted, impure, adulterated or otherwise not fit for its intended purpose, unless the milk concerned is to be managed as non-conforming dairy material under clause 2.8.

(2) Dairy processors must not supply, sell, offer or expose for sale, export or attempt to export, milk:

a) to which any substance (whether or not a natural constituent of milk) has been added; or
b) from which any natural constituent has been removed; or
c) that is colostrum or contains more immunoglobulin than is normally found in milk given by a healthy milking animal after 4 days and 8 milkings from giving birth;

unless, the addition, removal, or level of immunoglobulin is clearly communicated to the person to whom the milk is sold or suppled.

4.4 Raw milk to be fit for the intended purpose

(1) Raw milk, used for the manufacture of dairy products for human or animal consumption must be wholesome and must not contain or be affected by:

a) anything that is, decomposed, dirty, rotten, spoiled or affected by disease; and
b) any objectionable taint or smell that indicates the milk is not wholesome or that will not be reduced to an acceptable level by an approved process; and
c) objectionable or harmful material or foreign matter; and
d) any chemical substance in an amount that exceeds an applicable maximum limit under clause 4.4(3) or that otherwise makes it harmful or injurious to the health of any person or animal who may consume it or any dairy products made from it.

(2) Raw milk and other raw dairy material used for the manufacture of any dairy product must not:

a) be subject to a notice of direction issued under section 81 of the Act that prohibits use of the raw milk or dairy material; or
b) have been condemned under section 90 of the Act.

(3) Raw milk must be fit for its intended purpose and when intended for the manufacture of dairy products for human or animal consumption:

a) must be produced by healthy milking animals; and
b) must not contain microbiological contaminants at a level that may result in the dairy product not being fit for its intended purpose; and
c) must not contain:

i) residues of agricultural compounds and veterinary medicines exceeding the limits specified in the current Food Notice: Maximum Residue Levels for Agricultural Compounds; or
ii) inhibitory substance residues that exceed 0.006 i.u./ml penicillin equivalent; or
iii) incidental contaminants in excess of the limits specified in Standard 1.4.1 of the Australia New Zealand Food Standards Code; or
iv) residues of chemical substances that are not permitted to be used on milking animals or in approved maintenance compounds;

and;

d) must not contain milk that exceeded the limits specified in Table 4.1 unless the milk will be managed as non-conforming dairy material under clause 2.8. For clarity, milk cannot be intentionally consolidated or diluted as a means of appearing complaint with this clause; and
e) the maximum limits specified in of Table 4.1.

Table 4.1: Additional Maximum Permissible Limits for Chemical Substance in Raw Milk

Chemical Substance	Maximum Permissible Limit	Comments
Penicillin	4 µg/kg	Applies at the point of receipt at a dairy manufacturing premises

4.5 Raw milk intended for dairy products that may be exported

(1) Raw milk intended to be eligible for the manufacture of dairy products for export, other than to Australia, must not contain residues of pesticides and other agricultural compounds, veterinary medicines or extraneous contaminants that exceed:

a) the maximum limits specified by the current version of the FAO/WHO Codex Alimentarius Commission as follows:

i) Codex Alimentarius List of Codex Pesticide residues in Food: Extraneous Maximum Residue Limits; and
ii) Codex Alimentarius List of Codex Maximum Residue Limits for Veterinary Drug Residues in Food.

4.6 Farm dairy operators notification of suspect milk

(1) Farm dairy operators must advise the RMP operator, if that is another person, as soon as they become aware or suspect that milk they have produced:

a) may not be fit for its intended purpose; or
b) is not to be presented for supply based on the criteria in clauses 4.3, 4.4 and 4.5; or
c) does not meet the food safety or milk supply requirements of the applicable RMP.

(2) The RMP must describe how the advice in clause 4.6(1) is to be provided and the farm dairy operators covered by the RMP must be aware of this.

4.7 Refusal to accept suspect milk

(1) Dairy processors must refuse to collect, transport, deliver or receive raw milk if it is suspected not to be fit for its intended purpose unless:

a) the collection, transport or delivery is to facilitate disposal in accordance with the Animal Products Notice: Disposal of Non-conforming Dairy Material or Dairy Product; and
b) all transport units and equipment coming into contact with suspect milk are cleaned and sanitised before they are used to transport conforming raw milk.

(2) Clause 4.7(1) applies regardless of any obligations under a contract or under the articles of association of the company for whom the milk is being collected.

a) where a dairy processor refuses to accept, transport, deliver or receive raw milk under clause 4.7(1),any affected RMP operators and dairy processors must be notified of the refusal; and
b) the RMP verifier must be informed by the operator of the RMP as part of the routine reporting requirements under clause 3.21(4); and
c) details of the refusal must be recorded and made available at the RMP verifier's request.

(3) Farm dairy operators must ensure that milk under their control that has been refused collection, delivery or receipt is withheld and not presented for supply, with a record kept outlining the reason for refusal and what happened to the milk.

4.8 Determination of the suitability of suspect milk

(1) On receipt of notification of suspect milk, the RMP operator must:

a) determine the location of the suspect milk and, if possible at the time, arrange for the milk to be withheld from supply by the farm dairy operator; and
b) prevent collection or further consolidation and processing of that milk if it is possible to do so; and
c) either reject or sample and test the milk or any dairy material containing the milk to determine if it is fit for its intended purpose, or do both.

(2) Raw milk shown to be conforming and fit for its intended purpose may be used for the manufacture of dairy products.

(3) Raw milk shown to be non-conforming and must be managed as non-conforming dairy material in accordance with clause 2.8 and must not be intentionally consolidated or diluted in an attempt to reduce the level of contamination in the milk or dairy material.

(4) Where the milk has been consolidated with other milk, it is the responsibility of the RMP operator under which the milk is being processed to ensure that the affected milk, and any dairy material or dairy product containing any of the affected milk, is managed as non-conforming dairy material in accordance with clause 2.8 of this Notice.

4.9 Non-conforming raw milk

(1) Dairy processors, including farm dairy operators, must ensure that milk known or suspected to be non-conforming is managed as non-conforming dairy material or dairy product in accordance with clause 2.8 and reported in accordance with clause 3.21, along with any dairy material or product that has been manufactured from that milk.

(2) Milk that is known or suspected not to be fit for its intended purpose may continue to be processed into dairy products provided that:

a) the affected milk is processed in a manner that minimises contamination of personnel and processing environments; and

b) conforming milk, dairy material, dairy products and ingredients are not exposed to non-conforming milk, dairy material, dairy products directly or indirectly; and
c) all dairy material or finished product that contains or may contain any part of the affected milk is managed in accordance with the requirements under with clause 2.8.

4.10 Disposal of Raw Milk not fit for purpose

(1) Where the milk in a farm bulk milk tank fails to meet the criteria in clause 4.3, 4.4 or 4.5:

a) the RMP operator must ensure that the farm dairy operator is aware that the milk will not be collected for processing; and
b) the farm dairy operator must ensure that the RMP operator is aware that the milk will be withheld from supply in accordance with clause 4.6.

(2) Unless non-conforming milk is withheld by the farm dairy operator prior to collection as provided for under clause 3.18, the RMP operator must ensure that non-conforming milk is either:

a) rejected at the farm dairy and not collected, or rejected prior to delivery. In either case the RMP operator covering the farm dairy must report the details of the rejection in the regular performance report to the RMP verifier in accordance with clause 3.21(4); or
b) directed to disposal in accordance with clause 4.7(1); or
c) isolated and managed as non-conforming dairy material in accordance with the requirements under clause 2.8.

(3) Farm dairy operators must ensure that provision is made so that non-conforming milk, or milk that cannot be collected for any reason can be withdrawn and disposed of in accordance with local authority requirements.

(4) To prevent the spread of infectious disease, the Director-General or animal products officer may direct that the affected milk must be collected and processed in a manner suitable to destroy the infectious agent. In this situation, the affected milk and resulting produce must be isolated and disposed of in accordance with the instructions of the Director-General or animal products officer.

4.11 Sampling and testing of raw milk

(1) The RMP must describe a sampling and testing plan to monitor raw milk conformance.

(2) The sampling and testing plan is to be based on the outcome of the HACCP Identification and Analysis and any applicable prerequisite programmes, and must include the routine sampling and testing required under clause 4.12.

(3) Representative samples of raw milk must be collected and handled in accordance with the sampling and testing programme, and the portion of the sample that is tested must also be representative of the milk collected.

(4) Samples must be taken, handled and prepared in a manner that ensures they remain fit for their intended purpose.

(5) Samples must be kept under secure conditions and carry sufficient information to enable the specific farm dairy and collection consignment details to be determined.

(6) All milk testing must be undertaken in a laboratory that is recognised, under section 101 of the Act, for the appropriate category for the required test. All milk testing for the purposes of determining whether milk is fit for its intended purpose is to be undertaken using a MPI-accepted test method for the attribute concerned.

4.12 Minimum raw milk monitoring and action limits

(1) RMP operators must ensure that all farm dairy raw milk supplies are monitored at the minimum sampling and testing frequency specified in Tables 4.2, 4.3 and 4.4 unless the Director-General has determined that an alternative sampling and testing frequency is appropriate and achieves an equivalent level of confidence.

(2) Samples must be taken either on a random basis or when results are expected to be at their highest levels within the specified sampling period.

(3) Each test result obtained for raw milk is to be assessed against the action limits identified in the fifth column of Tables 4.2, 4.3 and 4.4 for conformance.

Table 4.2: Sampling and Testing of Raw Milk Hygiene – Cow's milk

Category/ Attribute	Minimum Frequency	Location of Sampling	Test	Raw Milk Hygiene Action Limit
Animal health	Three tests per month per farm. See clause 4.12.1(1).	Bulk milk tank of each farm dairy at the time of collection or receipt	Somatic cell count.	400 000 cells/ml.
Animal health	One test per month See clause 4.12.1(4)	Bulk milk tank of each farm dairy at the time of collection or receipt	Somatic cell count.	400 000 cells/ml.
Microbiological hygiene	Three tests per month per farm. See clause 4.12.1(1).	Bulk milk tank of each farm dairy at the time of collection or receipt	Aerobic plate count at 30 °C or Bactoscan®.	100 000 cfu/ml. See clause 4.12.1(2).
Microbiological hygiene	One test per month See clause 4.12.1(4).	Bulk milk tank of each farm dairy at the time of collection or receipt	Aerobic plate count at 30 °C or Bactoscan®.	100 000 cfu/ml. See clause 4.12.1(2).
Chemical residues	Three tests per month per farm. See clause 4.12.1(1).	Bulk milk tank of each farm dairy at the time of collection or receipt	Inhibitory substances.	0.003 IU penicillin or equivalent/ml.
Chemical residues	One test per month See clause 4.12.1(4).	Bulk milk tank of each farm dairy at the time of collection or receipt	Inhibitory substances.	0.003 IU penicillin or equivalent/ml.
Wholesomeness.	Monitor according to the conditions. See clause 4.12.1(3).	Bulk milk tank of each farm dairy at the time of collection and tankers.	Sensory evaluation	No presence of spoilage, visible foreign matter, discolouration, odours or taints.
Foreign matter	Monitor according to the conditions. See clause 4.12.1(3).	Bulk milk tank of each farm dairy at the time of collection and tankers.	Sediment	foreign matter grade B, and no objectionable material
Extraneous water	Monitor according to the conditions. See clause 4.12.1(3).	Bulk milk tank of each farm dairy at the time of collection and tankers.	Freezing Point Depression	-0.513 °C

Table 4.3: Sampling and Testing of Raw Milk Hygiene – milk from other species

Category/ Attribute	Minimum Frequency	Location of Sampling	Test	Raw Milk Hygiene Action Limit
Animal health	Three tests per month per farm. See clause 4.12.1(1).	Bulk milk tank of each farm dairy at the time of collection or receipt	Somatic cell count.	Goats - 1,500 000 cells/ml Other species 750,000 cells/ml
Animal health	One test per month See clause 4.12.1(4).	Bulk milk tank of each farm dairy at the time of collection or receipt	Somatic cell count.	Goats - 1,500 000 cells/ml Other species 750,000 cells/ml
Microbiological contamination.	Three tests per month per farm. See clause 4.12.1(1).	Bulk milk tank of each farm dairy at the time of collection or receipt	Aerobic plate count at 30 °C or Bactoscan®	100 000 cfu/ml. See clause 4.12.1(2).
Microbiological contamination.	One test per month See clause 4.12.1(4).	Bulk milk tank of each farm dairy at the time of collection or receipt	Aerobic plate count at 30 °C or Bactoscan®	100 000 cfu/ml. See clause 4.12.1(2).
Chemical contamination.	Three tests per month per farm. See clause 4.12.1(1).	Bulk milk tank of each farm dairy at the time of collection or receipt	Inhibitory substances	0.003 IU penicillin or equivalent/ml.
Chemical contamination.	One test per month See clause 4.12.1(4).	Bulk milk tank of each farm dairy at the time of collection or receipt	Inhibitory substances	0.003 IU penicillin or equivalent/ml.
Wholesomeness.	Monitor according to the conditions. See clause 4.12.1(3).	Bulk milk tank of each farm dairy at the time of collection or receipt	Sensory evaluation	Presence of spoilage, foreign matter, discolouration, odours and/or taints.
Foreign matter	Monitor according to the conditions. See clause 4.12.1(3).	Bulk milk tank of each farm dairy at the time of collection or receipt	Sediment	foreign matter grade B, and no objectionable material

Table 4.4: Sampling and Testing of Raw Milk Hygiene – Cow's colostrum (see clause 4.12.1(5))

Category/ Attribute	Minimum Frequency	Location of Sampling	Test	Raw Milk Hygiene Action Limit
Microbiological contamination.	Three tests per month per farm. See clause 4.12.1(1).	Bulk milk tank of each farm dairy at the time of collection or receipt	Aerobic plate count at 30 °C or Bactoscan®.	500 000 cfu/ml. See clause 4.12.1(2).
Chemical contamination.	Each consignment.	Bulk milk tank of each farm dairy at the time of collection or receipt	Inhibitory substances.	0.003 IU penicillin or equivalent/ml.

Category/ Attribute	Minimum Frequency	Location of Sampling	Test	Raw Milk Hygiene Action Limit
Wholesomeness.	Monitor according to the conditions. See clause 4.12.1(3).	Bulk milk tank of each farm dairy at the time of collection or receipt	Sensory evaluation	Presence of spoilage, foreign matter, discolouration, odours and/or taints.
Foreign matter	Monitor according to the conditions. See clause 4.12.1(3).	Bulk milk tank of each farm dairy at the time of collection or receipt	Sediment	foreign matter grade B, and no objectionable material

4.12.1 Notes to Tables 4.1-4.3

(1) The criteria applies to raw milk intended to be eligible for use in dairy products for export and raw milk not for use in dairy products for export that have exceeded the raw milk hygiene action limit within the previous four months.
Three tests per month means one random sample in the first 10 days of each calendar month, one in the second 10 days of the month, and one in the balance of the month. If no milk is tested within a 10 day period then a sample is to be taken and tested at the next opportunity, with a further random sample to be taken within the same period.
Where a farm dairy operator supplies milk under more than one RMP in a ten day period, only one test is required in that 10-day period provided there is no form of segregation at either a herd level or bulk milk tank level, and the farm dairy operator makes all results available to each RMP operator.

(2) When milk is tested for the aerobic plate count (APC), recognised laboratories must use 10^{-3} as the principal dilution. Where the Bactoscan® is used, the recognised laboratory must determine and document the correlation between Bactoscan® impulses the APC in raw milk at an appropriate frequency.

(3) The frequency of monitoring is determined by the likelihood of any of the following occurring in the milk: decomposition, dirt, rot, spoilage, clots, blood, disease, objectionable taints and odours, extraneous water, objectionable material or foreign matter. The RMP operator must hold records that demonstrate how the frequency of monitoring has been determined.

(4) The testing frequency applies to milk that is not for use in dairy products for export provided that the raw milk hygiene action limit has not been exceeded within the previous four months.

(5) For other species the RMP operator must establish the appropriate hygiene action limits.

4.13 Failing to meet raw milk hygiene action limits

(1) Where raw milk exceeds a hygiene action limit identified in Table 4.2, the RMP operator must establish that the raw milk used for the manufacture of dairy products is fit for purpose.

(2) Compliance may be established by:

a) sampling milk at a point prior to the commencement of manufacture, and testing for compliance with the minimum criteria; or
b) predictive modelling based on known parameters to determine the status of the milk at the start of manufacture; or
c) planned and discrete management of milk so that affected product can be clearly differentiated from unaffected product.

(3) Where raw milk is conforming but exceeds one or more hygiene action limits in Table 4.2 the RMP operator must:

a) notify the farm dairy operator of the result as soon as possible; and
b) provide information and advice as needed to enable the farm dairy operator to remedy the situation; and
c) undertake repeat sampling and testing of all further milk consignments for the attribute concerned until the raw milk is shown to consistently meet the action limit; and
d) in the case of repeated non-compliance with action limits, investigate the cause of the failure in order to remedy the situation by:

    i) applying alternative test methods to help identify the root cause; or
    ii) assessing the farm dairy, facilities, services, milking plant or milking animals as appropriate; or
    iii) reviewing farm dairy operator procedures; or
    iv) taking any further action that may be deemed appropriate.

(4) Farm dairy operators must take appropriate corrective actions when notified that raw milk they have presented for supply fails to meet any hygiene action limit.

(5) RMP operators must take action when farm dairy operators covered by the RMP fail to take appropriate corrective action.

Guidance

It is recommended that the supply contract contain provisions that allow the RMP operator to impose financial penalties or other sanctions on the raw milk supplier and/or initiate further actions. This should also include provision to refuse to accept supply after an appropriate notice period where a supplier persistently provides milk that does not meet milk hygiene criteria, or without notice in the case of a failure to meet food safety criteria.

4.14 Records of milk supply

(1) RMP operators must ensure a record is kept of:

a) each raw milk collection or delivery from a farm dairy for milk covered by the RMP; and
b) the amount of milk collected or delivered for each consignment from each farm dairy; and
c) with sufficient detail to allow the identification of dairy products containing or made from milk from each farm dairy; and
d) the temperature of the milk at the time of collection or delivery;
e) the tests undertaken and the results of those tests; and
f) in the case of milk that is shown to be non-conforming based on test results:

    i) the tracing forward undertaken to identify the dairy material or dairy product affected; and
    ii) the corrective actions taken; and
    iii) the follow-up monitoring undertaken and the results of that monitoring.

Part 5: Dairy manufacture and storage

5.1 Object of this Part

(1) This Part sets out requirements for the manufacture or storage of dairy material or dairy product. The purpose of these requirements is to ensure that:

a) the location, design and construction of dairy premises and equipment is appropriate for the nature of processing undertaken; and
b) the facilities, services and equipment are appropriate and maintained to a level that will ensure dairy material and dairy products will be and will remain fit for their intended purpose; and
c) dairy processors have documented procedures and plans that ensure dairy material and dairy products will be and will remain fit for their intended purpose; and
d) that where required the processing activities are covered by an RMP that outlines the processes, procedures and systems that will ensure dairy material and dairy products will be and will remain fit for their intended purpose.

5.2 Definition

(1) In this Part dairy premises means premises that manufacture or store dairy material or dairy product.

5.3 Application

(1) This Part applies to:

a) RMPs and operators of RMPs that cover the manufacture or storage of dairy material or dairy products; and
b) dairy processors who manufacture or store dairy material or dairy product; and
c) dairy material and dairy product.

5.4 General requirements for dairy premises

(1) Dairy material and dairy products processed under an RMP must be manufactured and stored only in premises:

a) specified for the purpose within the RMP for the nature of processing and the type of dairy material or dairy product; and
b) that have been assigned a unique location identifier by MPI.

Guidance

Unique location identifiers (ULI) are assigned under clause 5(3) of the Animal Products (Risk Management Programme Specifications) Notice 2008.

5.5 Location, design and suitability of dairy premises

(1) Dairy premises must be located so as to minimise any potential adverse impact due to environmental factors including pest infestation, flooding, strong or objectionable odours, smoke, dust, fumes or other contamination.

(2) Dairy premises, equipment, facilities, and the manufacturing environment must be designed, constructed, and maintained so that:

a) they are hygienic; and
b) they are easily cleaned, disinfected and inspected; and
c) all wastes will be removed effectively without adversely affecting processing activities; and
d) dairy material, dairy product and raw materials are protected from contamination and deterioration during processing.

(3) The internal design and layout of dairy premises must permit good food hygiene practices, including protection against cross-contamination of dairy material or dairy product between and during operations.

(4) The dairy premises buildings, facilities and equipment must be easily maintained.

(5) Suitable amenities must be provided in dairy premises for the personal hygiene of staff and visitors.

(6) Vehicle access and parking areas in dairy premises must be designed and constructed to prevent the contamination of manufacturing areas.

(7) There must be provision for ensuring that manufacturing areas and dairy material and dairy product storage areas in dairy premises:

a) protect dairy material or dairy product against raw water, water that has not been adequately treated, effluent and other waste products including steam, fumes and dust, and other potential contaminants, strong or objectionable odours, animals and pests such as birds, rodents, and insects; and
b) have proper and adequate facilities for cooling raw milk or other dairy material, if such cooling is necessary in order to minimise deterioration or maintain suitability.

(8) Dairy premises must be designed to provide for the segregation and clear identification of specialty milk, including colostrum, and milk not intended for human consumption from other milk and dairy material and the design must not permit:

a) contact between any raw milk or untreated dairy material with any treated dairy material or dairy product; or
b) contact between any non-conforming dairy material or product with any conforming dairy material or dairy product; or
c) the contamination of dairy material with fluids used to heat, cool, or temper the dairy material.

(9) Dairy premises including any facilities and equipment must be, in all respects, suitable for the intended class or type of dairy material and dairy product specified and the nature of processing.

(10) Internal structures and fittings must be soundly built using durable materials that are easy to maintain, clean and, where appropriate, can be disinfected. In particular, the following specific conditions must be satisfied, where appropriate, to protect the safety and suitability of dairy material and dairy product:

a) the surfaces of walls, partitions and floors must be made of impervious materials with no toxic effect when in use; and
b) walls and partitions must have a smooth surface up to a height appropriate to the operation; and
c) floors must be constructed to allow for cleaning and, in wet areas, adequate drainage; and
d) ceilings and overhead fixtures must be constructed and finished to minimise the build-up of dirt and condensation, and the shedding of particles; and
e) doors must have smooth, non-absorbent surfaces, that are easy to clean and, where necessary, able to be disinfected; and
f) windows must be:

i) easy to clean; and
ii) constructed in a manner that minimises the build-up of dirt; and
iii) where necessary, fitted with removable and cleanable insect-proof screens; and
iv) where necessary permanently fixed.

(11) Storage facilities for raw material, dairy material or dairy product must be designed and constructed to:

a) permit adequate maintenance and cleaning; and

b) avoid pest access and harbourage; and
c) enable raw material, dairy material and dairy products to be:

i) effectively protected from contamination during storage; and
ii) stored in an environment that minimises deterioration, for example by appropriate temperature and humidity control.

(12) Facilities and equipment used to cool, store, freeze or temper raw material, dairy material or dairy product must be designed:

a) to achieve the required temperature of the material as rapidly as necessary to ensure that food safety and suitability are not compromised; and
b) maintain the required temperature effectively; and
c) allow temperatures to be monitored and controlled; and
d) have an effective means of controlling and monitoring relative humidity, air quality, airflow and any other characteristic if control of those characteristic is required to ensure that stored items remain fit for purpose.

5.6 Air quality and ventilation of dairy premises

(1) Adequate natural or mechanical ventilation must be provided to:

a) minimise air-borne contamination of food and food contact surfaces, for example from aerosols and condensation droplets; and
b) maintain air temperature at a level that ensures that:

i) raw materials, dairy material and dairy products are not adversely affected; and
ii) personnel required to work in the area are not affected in a way that could adversely affect the product;

and;

c) control odours which might affect the suitability of dairy material and products; and
d) control relative humidity, where necessary, to ensure the safety and suitability of dairy material and dairy products; and
e) ensure that air pressure differential between areas is maintained when positive pressure is determined through HACCP to be required within a processing area.

(2) Filtration systems used for ventilation and product contact air must be maintained and monitored to ensure adequate ongoing performance of the system.

5.7 Lighting of dairy premises

(1) Adequate natural or artificial lighting must be provided to enable hygienic operation, and where necessary, facilitate inspection. The light intensity must be appropriate for the nature of the activities undertaken.

(2) Lighting must be of a sufficient intensity and quality for the type of work being done, for example distinguishing between colours when this is necessary.

(3) Lighting fixtures must be sufficiently protected so that raw materials, essential services, dairy material and dairy products will not be contaminated by breakages.

5.8 Water used in dairy premises

(1) Water, ice and steam used in a dairy premises must:

a) be suitable at the point of use; and

b) not compromise the fitness for intended purpose of the dairy material or dairy product being manufactured or stored.

(2) Water, recovered or recycled water, ice and steam that does not comply with clause 5.8.1 must be clearly labelled as non-potable, or similar, and must not be mixed with water, steam or ice that does comply with clause 5.8.1.

(3) Recovered or recycled water may be used for cleaning in place if it meets the criteria specified in clause 5.8.1(2) or has been treated and purified to a potable water standard.

5.8.1 Water coming into contact with dairy product or material

(1) Water (including ice and steam) that comes into direct contact or indirect contact with dairy material or dairy product must be potable water at the point of use or meet the requirements set out in clause 5.8.1(2).

(2) A dairy processor may use an alternative water quality standard that is determined by the RMP operator to meet an adequate sanitary standard, provided that:

a) the water quality standard is determined by an analysis of hazards and other risk factors; and
b) the hazard analysis follows HACCP principles and considers all hazards through to the point of use as well as the intended use of the water; and
c) the water will not compromise the safety of the dairy material or dairy product being manufactured; and
d) use of the water will be adequately controlled so that it will only be used for the intended purpose.

5.8.2 Water not coming into contact with dairy material or dairy product

(1) Water that does not come into direct contact or indirect contact with dairy material or dairy product must meet the requirements of clause 5.8.1 or, if appropriate, meet an alternative non-contact water quality standard.

(2) If an alternative non-contact water quality standard is used, the appropriate standard must be determined by the RMP operator following the steps described in clause 5.8.1(2)a) to c):

5.8.3 Water reticulation

(1) Dairy manufacturers must document and implement procedures for water reticulation that include:

a) systems to ensure that the water of the intended quality is delivered at the point of use; and
b) systems to ensure that the water reticulation system and any treatment process is not adversely affected and that there is no unintentional mixing of water of different standards; and
c) a corrective action plan with appropriate sanitation procedures to be implemented in the event of the reticulation system becoming contaminated.

5.8.4 Requirement for water management plan

(1) Dairy manufacturers must document and implement a water management plan that includes:

a) the water quality standard (including criteria) as determined through an analysis of hazards and other risk factors; 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) an action plan in the event of non-compliance with the water management plan; and
e) the procedures covering water reticulation described in clause 5.8.3; and
f) procedures for ensuring anyone operating water treatment processes has relevant water treatment training and experience and are competent persons; and
g) keep relevant records.

5.8.5 Water analysis

(1) The water testing programme required under clause 5.8.4(1)c) must set out the criteria for compliance monitoring and process control monitoring of water.

(2) The dairy processor must ensure that water samplers are adequately trained and are competent persons for the purpose of sampling and handling water samples.

(3) Water testing for compliance monitoring purposes under clause 5.8.4 must be undertaken in a laboratory that is accredited to ISO 17025 and has the required test methods for drinking water under its scope of accreditation.

(4) For clarity, clause 5.8.5(3) does not apply to process control monitoring under clause 5.8.6.

(5) For compliance monitoring the RMP operator must determine and document:

a) where samples are to obtained to ensure they are representative of the water being used; and
b) the frequency of compliance testing taking the following into consideration:

i) the variability of the source water; and
ii) the reliability of the water treatment process; and
iii) the severity of risk to product safety, which depends on the nature of the hazard;

and;

c) the determinands to be tested, which must include:

i) *Escherichia coli;* and
ii) Priority One determinands specified in the DWSNZ, unless the hazard analysis determines that testing for a particular determinand is not relevant; and
iii) the Priority Two determinands 2a to 2c specified in the DWSNZ that could be in the source water supply, or introduced into the water supply, at levels potentially significant to health;

and;

d) an assessment for the presence of protozoa; and
e) any additional testing for relevant determinands and the corrective actions that may be required when:

i) a new source of supply is to be used; or
ii) there is a problem with the water quality; or
iii) any changes are noticed to the taste, odour, colour and turbidity of the water; or
iv) nearby industrial or farm activities could affect the source of the supply; or
v) there has been damage to, or intrusive maintenance of, the water treatment system or reticulation system; or
vi) any other event has occurred which could affect the suitability of the water for its intended purpose.

(6) Records must be kept for:

a) the results of the monitoring; and
b) the information used to determine the appropriate testing frequencies, the determinands not tested for under clause 5.8.5(5)c)ii) and iii), and the corrective actions that may be required.

5.8.6 Process Control Monitoring of Water

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

(2) Process control monitoring of the treated water must be conducted:

a) at a frequency appropriate to the water treatment process and the intended use of the water; and
b) using documented test methodologies appropriate to the water treatment method and intended use of the water including, as appropriate, calibration procedures and reference standards; and

c) by a suitably trained and competent person.

(3) Records must be kept for:

a) the results of the monitoring; and
b) the information used to determine the appropriate testing frequencies and methodologies, and the means by which process control is monitored.

5.8.7 Non-complying water

(1) Dairy material or dairy product coming into contact with non-complying water must be managed as non-conforming dairy material or non-conforming dairy product.

(2) Where water is identified as non-complying, any corrective action stipulated in the water management plan or elsewhere within the RMP must be carried out.

Guidance

Dairy processors with access to potable water should consider developing a contingency plan for situations where water is identified as not potable, for example natural disasters or boiled water notices.

5.9 Storage, separation and integrity at dairy premises

(1) All dairy material and dairy product must be:

a) stored under appropriate conditions; and
b) protected from potential contaminants, infestation and spoilage; and
c) handled under appropriate stock management systems.

(2) Dairy processors must ensure:

a) adequate facilities are provided for the storage of dairy material or dairy product, ingredients, additives, processing aids, packaging materials and non-food chemicals such as fuel, adhesives and maintenance compounds including cleaning chemicals, pesticides, fumigants and lubricants; and
b) separate, secure storage facilities are provided for odorous or hazardous substances.

(3) Dairy Processors must have adequate facilities available for storing items under the conditions specified in the RMP, for example the relative humidity or temperature. Storage conditions must be adequately controlled and monitored when the storage conditions are necessary to ensure that the dairy material remains fit for purpose:

a) ambient temperatures, airflow, and relative humidity must be controlled if this control is required to ensure the safety and suitability of raw material, dairy material or dairy product is maintained; and
b) procedures must be in place and ensure the integrity of dairy material or dairy product is maintained throughout manufacture and storage, and that:
    i) dairy material and dairy product is, and remains, clean, undamaged and free from deterioration or contamination; and
    ii) incoming dairy product and dairy material, excluding raw milk, is assessed for potential contamination, deterioration or damage; and
    iii) the growth of harmful or undesirable micro-organisms and the production of any toxins is minimised; and
    iv) where appropriate, critical limits established in HACCP plans are monitored; and
    v) any dairy material or product that fails this assessment is managed as non-conforming dairy material or product in accordance with clause 2.8.

(4) Dairy Processors must have procedures in place that ensure the separation, segregation and identification of:

a) specialty milk such as colostrum and colostrum-containing products until the manufacturer makes a decision to mix the specialty milk with other dairy material or dairy products and label all resulting dairy material or dairy product appropriately; and
b) dairy material that has not been heat treated and dairy material that has been heat treated when both are handled at the premises; and
c) conforming and non-conforming dairy material and dairy product; and
d) any raw materials or dairy products that have been determined to be unfit for purpose

(5) Dairy processors must have procedures to protect the manufacturing process from contamination, including the entry of, or contamination from, foreign matter, including:

a) the means to monitor and record all intrusive maintenance in and around processing areas, including product contact areas, and the controls necessary to ensure that product safety is not compromised during these operations; and
b) the operation and calibration of any in-line metal detectors required under the RMP, and the actions to be taken when metal is detected or the metal detector fails to operate as intended so that only dairy material or dairy product confirmed as conforming is released; and
c) regular checks of all equipment for potential sources of foreign matter; and
d) in the case of metal discovered on in-process magnets, the clear separation of acceptable findings from unacceptable findings and, for any unacceptable finding:

i) the actions to be taken to confirm whether dairy material or dairy product is adversely affected, including additional foreign matter testing if appropriate; and
ii) confirming the dairy material or dairy product adversely affected, if it is determined that dairy material or dairy product has been affected; and
iii) the considerations that must be included in any investigation and the corrective actions to be taken to protect dairy material and dairy product;

and;

e) regular checks of the equipment and processes that ensure dairy material, dairy product, and raw materials will not come into contact with anything that could cause contamination or deterioration, for example cross contamination of dairy material with non-conforming dairy material, cleaning chemicals or heat exchange media.

5.10 This section deleted - Intentionally left blank

5.11 Raw materials

(1) Dairy processors must have procedures to ensure that:

a) the fitness for purpose of dairy material, including raw milk, received for manufacture is monitored and appropriate steps taken if any dairy material is found or suspected not to be fit for the intended purpose; and
b) only conforming dairy material that is fit for the intended purpose may be used for the manufacture of dairy products, unless:

i) all dairy material and dairy product can and will be identified as non-conforming, isolated and managed in accordance with clause 2.8; or
ii) The Director-General has approved or specified the use in accordance with the Animal Products Notice: Disposal of Non-conforming Dairy Material or Dairy Product.

and;

c) only permitted raw materials are used in the manufacture of dairy products; and
d) all raw materials must be traceable to the product in which they have been used; and
e) dairy material, dairy product and raw materials are protected from contamination, deterioration, adulteration and infestation; and
f) edible material is protected from contamination by inedible materials.

5.12 Maintenance, cleaning and waste

(1) Dairy processors must have procedures to ensure that:

a) equipment and facilities are fit for their intended purpose and maintained in an appropriate state of hygiene and repair so that dairy material and products are, and remain, fit for the intended purpose; and
b) the premises, facilities, equipment and surroundings are kept clean, tidy, free from pests, and suitably hygienic for the nature of processing intended; and
c) rubbish and wastes are removed, disposed of in a safe and appropriate manner, and are not allowed to accumulate in and around the processing environment; and
d) all in-line product filters, including milk filters, strainers, sifters and magnets are cleaned and maintain; and
e) building integrity is maintained; and
f) regular assessments are made and deficiencies documented; and
g) appropriate corrective actions are completed to rectify any deficiencies.

(2) Every dairy premises must have a cleaning programme included in the RMP that ensures that premises, facilities, equipment and services such as airlines and CIP circuits are cleaned and maintained to hygiene and housekeeping standards appropriate for the nature of the process undertaken at the premises.

(3) The cleaning programme must outline how equipment and product contact surfaces are cleaned, and where appropriate sanitised and rinsed, and how the effectiveness of cleaning is monitored.

5.13 Pest management

(1) Dairy processors, other than farm dairy operators, who manufacture or store dairy material or dairy product must have procedures for pest management in the RMP to ensure that:

a) pests do not infest, spoil or contaminate dairy material, dairy product, ingredients, packaging or associated things; and
b) the storage, use and application of pesticides and other chemical or microbiological compounds in and around the premises does not contaminate the processing environment, equipment, packaging or food material and that dairy material and dairy product will not be adversely affected; and
c) there is routine monitoring of the manufacturing environment, process, dairy material and dairy product to confirm that pests are controlled effectively.

5.14 Pathogen management

(1) Dairy processors who manufacture dairy product must:

a) have an environmental pathogen management plan that consists of documented procedures for monitoring the manufacturing environment and adjacent areas, manufacturing processes and equipment to confirm that pathogens are effectively controlled within manufacturing areas; and
b) manage the risk of pathogen contamination in dairy material and dairy product by implementing good operating practices and appropriate surveillance as required through the development of the Hazard Identification and Analyses or the HACCP plan under clause 2.7; and
c) have documented procedures for monitoring dairy material or dairy product to confirm that it is fit for the intended purpose in accordance with clause 2.9 and clause 2.10; and
d) ensure that any testing for pathogens or hygiene indicator microorganisms undertaken to satisfy this clause is performed by a laboratory registered by MPI under the Animal Products Notice: Specifications for Laboratories and is using a test method that is accepted under that Notice.

(2) The environmental pathogen management plan must be designed to provide early warning that microbial contamination within the manufacturing environment has occurred and that exposed material is at risk of contamination unless corrective action is taken immediately to remedy the situation, and must include procedures for ensuring:

a) that the opportunities for pathogens to gain entry to the manufacturing areas, processes, raw materials or dairy products are minimised; and
b) appropriate control of people, equipment and consumables appropriate to the nature of the processing undertaken; and
c) that materials which may be introduced into critical hygiene areas are identified as well as how each is to be handled; and
d) that the use or introduction of wood within critical hygiene areas is not permitted except for situations where the use is essential and suitable procedures are in place and validated as adequate. If wood is introduced, the HACCP plan must demonstrate how the associated hazards are controlled.

(3) The environmental pathogen management plan must include:

a) what is to be monitored, when, and how; and
b) the procedures for sampling and the location of sampling points; and
c) the clear separation of acceptable results from unacceptable results for each parameter tested; and
d) the steps to be followed in the event of an unacceptable result, including:

i) increased surveillance of the environment, adjacent areas, dairy product or any other items that may be relevant; and
ii) when it will be necessary to undertake an investigation into the cause; and
iii) taking specified corrective actions.

(4) The requirement in clauses 5.14(1) to (3) do not apply to dairy processors who only relabel packaged dairy material or dairy product or repack packaged dairy material or dairy product into new outer packaging and have procedures in place that describe the process and ensure the integrity of the inner packaging will not be compromised.

5.15 Defined dairy heat treatments

(1) This section specifies the heat treatment and associated processing requirements for:

a) thermisation for cheese-making; and
b) pasteurisation; and
c) ultra high temperature (UHT) treatment.

(2) The RMP operator must ensure the RMP sets out procedures to:

a) ensure the requirements for heat treatments specified in this Notice are met where:

i) there is a legal requirement for the dairy material to have received a defined heat treatment; or
ii) heat treatment has been identified as a CCP under the HACCP plan; or
iii) there is a label claim for a defined heat treatment; or
iv) export certification requirements in a notice issued under Part 5 of the Act requires that the dairy material has received a defined heat treatment.

b) ensure defined heat treatments and associated heat treatment equipment is effective and reduces the number of pathogenic micro-organisms to an acceptable level to ensure dairy product is fit for the intended purpose when combined with:

i) the nature of packaging; and
ii) the stated storage conditions and shelf life; and
iii) other complementary measures.

(3) Dairy material does not require further heat treatment if it has received a defined heat treatment in accordance with this Notice and following the heat treatment it is handled, transported, stored and manufactured in accordance with an RMP that ensures the dairy material is effectively protected from contamination and maintains the heat treatment status that was applied.

(4) The RMP must contain a heat treatment plan if it covers a defined dairy heat treatment, and dairy processors must follow all heat treatment plans that apply to their dairy processing activities.

(5) The heat treatment plan must contain or incorporate by reference documents that cover:

a) identification of the equipment used for defined heat treatments including "as built" drawings of the equipment; and
b) confirmation the heat treatment equipment is designed, constructed and installed in a way that allows heat treatment to be readily validated, evaluated and verified; and
c) description of how particle size and dairy material or dairy product composition is controlled, when necessary, to ensure complete heat treatment of all particles; and
d) description of how the minimum heat treatment temperature and minimum holding time are consistently and uniformly achieved, measured and monitored; and
e) technical specifications and information about any computer control system used for defined heat treatment control; and
f) equipment performance parameters; and
g) the critical limits with regards to heat treatment in the HACCP plan; and
h) change management procedures in regards to defined heat treatment equipment, operating characteristics and, if applicable, computer control equipment and software. These procedures must include the requirement to notify the recognised agency of any significant changes; and
i) procedures for keeping operating records relating to defined heat treatments.

(6) The RMP must contain training and operating procedures to ensure that operators of heat treatment equipment and contractors (as appropriate):

a) have the knowledge and skills necessary to understand the hazards managed by the heat treatment; and
b) understand the heat treatment and how it operates; and
c) operate, check and maintain the heat treatment including monitoring and taking timely and appropriate corrective action(s) when there is a loss of control; and
d) carry out calibration of equipment used to measure, monitor and control defined heat treatment equipment, parameters and critical limits; and
e) record keeping to confirm that heat treatment operators have been trained and are competent persons.

(7) Dairy material used for the manufacture of dairy products is considered to have received a defined heat treatment when it has been heat treated using properly designed, installed, operated, and maintained heat treatments that meets:

a) the applicable requirements for heat treatment and the management of dairy material in this Part; and
b) the heat treatment procedures and recording requirements the contained in the RMP or heat treatment plan.

(8) Heating and holding steps in manufacturing processes that provide the required heat treatment conditions are considered to provide the defined heat treatment when:

a) the defined heat treatments and associated requirements provided in clause 5.15 are demonstrated to be met during the manufacturing process; and
b) all other requirements for the defined heat treatments are met as provided in clauses 5.15.

(9) Further to clause (7), heating and holding steps, which may provide heat treatment with the same process performance characteristics as pasteurisation, include evaporation in the production of milk powder, cream treatment processes such as vacreation in butter making, and deodorisation in anhydrous milk fat (AMF) manufacture.

(10) The minimum equipment design standards and process performance requirements for defined dairy heat treatments must meet those set out in Table 5.1.

Table 5.1: Heat Treatment 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 <1000 µm 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 (ø)	<200 µm ø	200 to 500 µm ø	800 to <1000 µm ø	<200 µm ø	200 to 500 µm ø	800 to <1000 µm ø	
Minimum holding time (seconds)	Minimum temperature (ºC)						
1.0	81.6	-	-	84.4	-	-	-
2.0	79.0	81.6	-	81.8	84.4	-	-
3.0	77.6	79.0	-	80.4	81.8	-	-
4.0	76.5	77.6	81.6	79.3	80.4	84.4	-
5.0	75.7	76.5	79.0	78.5	79.3	81.8	-
6.0	75.1	75.7	77.6	77.9	78.5	80.4	-
7.0	74.6	75.1	76.5	77.4	77.9	79.3	-
8.0	74.1	74.6	75.7	76.9	77.4	78.5	-
9.0	73.7	74.1	75.1	76.5	76.9	77.9	-
10.0	73.3	73.7	74.6	76.1	76.5	77.4	85.5
11.0	73.0	73.3	74.1	75.8	76.1	76.9	-
12.0	72.7	73.0	73.7	75.5	75.8	76.5	-
13.0	72.4	72.7	73.3	75.2	75.5	76.1	-
14.0	72.1	72.4	73.0	74.9	75.2	75.8	-
15.0	72.0	72.1	72.7	74.8	74.9	75.5	79.5
30	70.2	70.8	70.9	73.5	73.6	73.7	-
60	69.4	69.4	69.5	72.2	72.2	72.3	-
Minimum holding time (minutes)	Minimum temperature (ºC)						
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	-

(11) Thermisation for cheese-making, pasteurisation, and UHT treatment must be undertaken using heat treatments that are designed, installed, operated and maintained in a manner that ensures that:

a) no untreated or partially treated dairy material passes forward or cross contaminates heat treated dairy material; and
b) heat treated dairy material and dairy product is not contaminated from services, including coolants, heat exchange media or cleaning solutions.

5.15.1 Thermisation for cheese making

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

(2) Thermisation for cheese-making is:

a) rapidly heating liquid dairy material containing low numbers of pathogenic micro-organisms to a temperature of no less than 64.5°C, and retaining it at that temperature for no less than 16 seconds; and
b) prior to leaving the control of the dairy manufacturer:

i) storing the cheese at a temperature of not less than 7°C for a period of not less than 90 days from the date of commencement of manufacture; and
ii) demonstrating that pathogens do not exceed acceptable levels in the cheese.

5.15.2 Pasteurisation

(1) Pasteurisation is:

a) rapidly heating every particle of milk to a temperature of no less than 72°C and retaining it at that temperature for no less than 15 seconds; or
b) rapidly heating milk to a temperature of no less than 63°C and retaining it at that temperature for no less than 30 minutes; or
c) rapidly heated and held using a temperature and holding time combination with the same process performance as pasteurisation for the dairy material concerned. Temperature and holding time combinations with the same process performance parameters as pasteurisation for a range of liquid dairy material including milk, high fat milk, milk with added sweeteners, concentrated dairy material and ice-cream are specified in Table 5.1

5.15.3 Ultra high temperature (UHT) treatment

(1) UHT treatment of liquid dairy material is:

a) the application of heat to continuously flowing liquid dairy material using such temperatures for such time that renders the dairy material commercially sterile at the time of processing; and
b) aseptic packaging resulting in commercially sterile product.

5.15.4 Management of dairy material immediately post heat treatment

(1) At the end of the heat treatment and prior to further processing or storage, the dairy material must be immediately heated or cooled to a temperature that maintains the wholesomeness of dairy material or product either until further processed or for the duration of its shelf life.

5.15.5 Dairy processor validation of heat treatment

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

(2) As part of the RMP validation, the responsible person is responsible for ensuring that the heat treatment is validated.

(3) The validation of heat treatments includes the assessment within a specific manufacturing process of:

a) the time/temperature combination is consistently applied; and
b) the particle size stated in the heat treatment plan is met; and
c) the equipment sanitation is effective; and
d) the equipment layout allows ease of access; and
e) the equipment performance and reliability; and
f) any variations to processes or product formulations that could affect the efficacy of the heat treatment; and
g) the procedure to ensure no contamination of the heat treated dairy material occurs; and
h) the dairy material or dairy product is sufficiently heated or cooled to maintain it in a wholesome condition; and
i) the monitoring and corrective action procedures.

(4) Validation is required when:

a) a new heat treatment is developed; or
b) new heat treatment equipment is installed; or
c) existing heat treatment equipment is relocated; or
d) a significant change is made to an existing heat treatment.

(5) The validation must be carried out by a person or a team of people who have:

a) a relevant tertiary qualification or demonstrated competence as a technical professional in food processing engineering; and
b) relevant and current knowledge of dairy heat treatment equipment or processes; and
c) adequate knowledge of food safety.

(6) Validation of defined heat treatments must be performed against an appropriate protocol which may reference appropriate technical criteria such as, the (MPI) Heat Treatment Code of Practice.

5.15.6 Heat treatment evaluation

(1) All heat treatments covered by this Notice, other than stove top heat treatment, must be evaluated by a person recognised for heat treatment evaluation as part of an RMP evaluation when they:

a) are new; or
b) are relocated; or
c) have undergone a significant change.

(2) Stove top heat treatments must be evaluated by a recognised RMP evaluator or a person recognised for heat treatment evaluation, as part of an RMP evaluation when they:

a) are new; or
b) have undergone a significant change.

(3) Heat treatment evaluation is required to ensure:

a) compliance with this Notice, and
b) confirmation that those means of complying with this Notice that are either specified or referenced within the heat treatment plan or elsewhere in the RMP can be, or are being, followed, prior to the processing of dairy material for the manufacture of dairy products.

(4) Heat treatment validation and heat treatment evaluation may occur concurrently but must be carried out by different individuals.

(5) Finished product manufactured from dairy material heat treated during commissioning of a heat treatment, prior to the completion of the heat treatment evaluation and the resolution of any critical non-compliances, must either:

a) be covered by a validation programme under a registered RMP or RMP amendment; or
b) managed as non-conforming dairy material under clause 2.8; or
c) appropriately labelled and directed to domestic animal feed use or non-edible use provided the RMP provides adequate controls and provisions to manage the dairy material or product.

(6) All critical non-compliances must be resolved prior to heat treating any dairy material used for the manufacture of dairy products intended for human consumption or export.

5.15.7 Non-conforming heat treatments

(1) Heat treatments are non-compliant if they fail to:

a) comply with the requirements of this Part; or
b) follow the heat treatment provisions within the RMP and heat treatment plans; or
c) resolve heat treatment critical non-compliances identified by the RMP evaluator or RMP verifier.

(2) If a heat treatment is determined to be non-compliant:

a) any dairy material or dairy product processed using the non-compliant heat treatment is non-conforming and must be managed in accordance with clause 2.8; and
b) all dairy material or product treated by the heat treatment since the last recorded demonstration of compliance by that heat treatment must be identified and managed as non-conforming dairy material in accordance with clause 2.8.

5.15.8 Release of pasteurised dairy product

(1) This clause applies in situations where pasteurised dairy product is released and may be consumed before test results are received for any required microbiological testing under clause 2.9.

(2) Where clause 5.15.8(1) applies dairy processors must ensure that:

a) an alkaline phosphatase test is completed prior to release of the dairy product and gives a negative result; and
b) the alkaline phosphatase test is completed by a competent person, using a test method that is suitable for the type of pasteurised dairy material; and
c) details of the testing undertaken are recorded.

(3) The alkaline phosphatase testing under this clause is considered to be a process control test and as such is not required to be undertaken by a recognised laboratory.

5.16 Packaging

(1) Product packaging must be hygienic, clean and made from materials that are non-toxic and will not contaminate dairy material or product.

(2) The RMP must set out procedures for:

a) ensuring the integrity, cleanliness, and freedom from contamination of raw materials upon receipt; and
b) maintaining the materials' integrity, cleanliness and freedom from contamination during storage and prior to use.

5.17 This section deleted - Intentionally left blank

5.18 Conformance monitoring

(1) Dairy processors that manufacture dairy material or dairy products must have procedures to ensure that:

a) sampling and testing is carried out in accordance with a documented monitoring plan to confirm conformance to the RMP and this Notice, and to verify that the resultant dairy material or dairy product is truthfully labelled and represented; and
b) samples are representative of the lot or part lot from which they have been derived; and
c) samples are correctly labelled so that the material lot or part lot from which they have been derived can be readily determined; and

d) the sampling activity does not contaminate the dairy material, either directly or indirectly; and
e) the sampling and testing plans for monitoring conformance and truth of labelling parameters specify:

i) the test methods to be used; and
ii) the sampling procedures to be followed; and
iii) the sampling frequency to be followed under routine monitoring and also the frequency to be applied should unfavourable results be indicated; and
iv) for each parameter measured, the tolerance limits to be applied and the action to be taken should the tolerance limits be exceeded.

(2) Conformance testing must be undertaken in accordance with clause 2.9.

5.19 Changes to premises, ownership and operating status

(1) RMP operators and dairy processors must ensure that no significant changes are made to the premises, equipment, or facilities unless:

a) the change has been registered as an amendment to the risk management programme by the Director-General under section 25 of the Act in the manner prescribed in the Animal Products (Risk Management Programme) Specifications Notice 2008 as may be amended or replaced from time to time; and
b) the change is carried out in a manner that, in the opinion of the Director-General, ensures that the fitness for intended purpose of dairy product is not compromised during and subsequent to the change; and
c) work on the change is undertaken in accordance with:

i) the RMP; and
ii) the registered amendment to an RMP; and
iii) any validation protocol that may apply; and
iv) any conditions applied by the Director-General under section 22 of the Act or directions given under section 81 of the Act.

(2) The RMP operator must advise the Director-General in writing before:

a) any dairy processor using premises covered by the RMP ceases to use the premises as a dairy premises; or
b) the ownership or right of possession of all or part of the premises changes.

(3) Every person who acquires or surrenders ownership of a dairy premises must advise the Director-General, in writing, without delay so that that the unique location identifier details can be updated. This requirement applies irrespective of whether the dairy activities carried out come under another person's RMP.

Part 6: Transport

6.1 Object of this Part

(1) The object of this Part is to:

a) set out measures that must be addressed by dairy processors who transport dairy material or dairy product along with risk management programmes that cover the transport dairy material or dairy product; and
b) ensure transport units and loading equipment are constructed, maintained and operated in a manner that maintains the fitness for purpose of dairy material or dairy product; and
c) ensure raw milk suspected not to be fit for intended purpose is managed appropriately; and
d) ensure dairy material or dairy product that has received a defined heat treated is transported in a manner that maintains its heat treated integrity and is protected from contamination.

6.2 Application of this Part

(1) This Part applies to:

a) RMPs and operators of RMPs that cover the transport of dairy material or dairy products; and
b) dairy processors who transport dairy material or dairy product; and
c) dairy material and dairy product.

6.3 General Requirements

(1) When transport of dairy material or dairy product is covered by an RMP, the operator of that programme must have procedures to ensure that the dairy processors covered by their RMP met their obligations under this Part.

(2) Dairy processors must ensure:

a) the integrity of dairy material and dairy product and its packaging is maintained; and
b) dairy material and dairy product is handled in a manner that minimises:

i) the risks of contamination, spoilage or deterioration; and
ii) the proliferation of micro-organisms; and
iii) the development of toxins;

and;

c) The hygiene and behaviour of persons involved in the transportation of dairy material or dairy product must be such that the contamination and deterioration of dairy material or dairy product from this source is minimised.

(3) In relation to facilities, equipment, maintenance and housekeeping, dairy processors must that ensure:

a) hygienic standards are maintained and dairy material and dairy product is protected from contamination, deterioration and adulteration; and
b) transport units, equipment and any facilities are maintained; and
c) the method and conditions of transport for dairy material or dairy products is suitable given the nature of the material or product so that it is protected from contamination and will remain fit for its intended purpose; and
d) ensure dairy material or dairy product that has received a defined heat treated is transported in a manner protects it from contamination and maintains its heat treated integrity; and
e) the method and regime for cleaning vehicles and for cleaning, sanitising and maintaining containers, equipment and dairy material and dairy product contact surfaces is documented; and

f) the effectiveness of the measures under clause 6.3(c) is monitored to confirm that satisfactory hygienic standards are met; and
g) regular assessments are made by suitably competent persons at a frequency that ensures a satisfactory state of repair and hygiene is maintained; and
h) deficiencies identified during any assessment are documented and rectified; and
i) appropriate corrective action is taken in the event of any non-compliance.

6.4 Design and construction

(1) Transportation units and loading equipment must be designed, constructed, equipped and operated to maintain the status of dairy material and dairy product as fit for intended purpose and to minimise exposure to hazards and associated risk factors.

(2) Temperature measuring devices used to make critical measurements must be calibrated.

6.5 Transport of dairy material or dairy product

(1) Dairy material or dairy product that is conveyed together with any other thing that may be a source of contamination must be adequately separated and protected from that source in a manner that prevents cross-contamination.

6.6 Raw milk not fit for purpose

(1) If, in the opinion of the transport operator, any raw milk at a farm dairy is suspected of not being fit for intended purpose, the transport operator must:

a) refuse to accept or transport that milk; and
b) advise the farm dairy operator and any affected risk management programme operators that the milk is suspected of not being fit for its intended purpose.

(2) Clause 6.6(1) does not apply where:

a) the RMP sets out an alternative procedure to ensure that milk suspected of not being fit for its intended purpose is isolated and disposed of in a accordance with the Animal Products Notice: Disposal of Non-conforming Dairy Material or Dairy Product; or
b) the RMP operator receiving the raw milk designates an alternative use for the milk, such as animal feed, following procedures documented within the RMP.

(3) Where clause 6.6(2) applies the transport operator must ensure that all milk contact surfaces are cleaned, sanitised and rinsed prior to handling further dairy material or dairy product.

(4) The operator of an RMP covering the transport of raw milk is responsible for making dairy processors aware of any non-conforming raw milk that may have been delivered to them.

6.7 Records to be kept

(1) Records must be kept for all dairy material or dairy product handled, including:

a) its source and when it was collected or received; and
b) its destination, and when it was delivered or left the transport operators control.

Guidance

Transport operators may elect to operate under one of the following options as an alternative to operating under an RMP:

(a) the exemption under section 8B(3) of the Animal Products (Exemptions and Inclusions) Order 2000 an RMP for the transporting of dairy material or dairy product for animal consumption, for export without official assurances or for the domestic market; or
(b) the Animal Products Notice: Regulated Control Scheme – Transportation and Handling of Products for Export with an Official Assurance.

In determining the best option operators should review their contractual obligations and consult the dairy processors and businesses for whom they intend to transport dairy material or dairy product as coverage by an RMP may be required for other reasons.

Part 7: Raw milk products

7.1 Object of this Part

(1) The object of this part is to:

a) set measures for the processing activities related to raw milk products that apply in addition to those set out elsewhere in this Notice; and
b) ensure that raw milk products are safe to consume due to the nature of processing, the controls applied at each processing step, and the intrinsic product characteristics.

7.2 Application of this Part

(1) This Part applies to:

a) operators of RMPs that cover the processing of dairy material for raw milk products; and
b) dairy processors who process dairy material for raw milk products, including farm dairy operators, transporters and dairy manufacturers.

7.3 Interpretations

(1) For the purpose of this Part:

milking herd means the milking animals kept and milked for the purpose of supplying raw milk for the manufacture of raw milk products.

7.4 Restriction on raw milk supply

(1) Raw milk for the manufacture of raw milk products may only come from farm dairies that:

a) are under an RMP that has the harvesting and supply of raw milk for raw milk products within its scope; and
b) have been assessed by the RMP operator and confirmed to meet the requirements in this Part.

7.5 Identification of eligible farm dairies

(1) An RMP that covers the harvesting and supply of raw milk for the manufacture of raw milk products must identify eligible farm dairies and maintain a register of that includes:

a) the unique farm dairy identifier, such as supply number; and
b) the farm dairy operator; and
c) the location of the farm dairy; and
d) the date that the farm dairy became eligible to supply raw milk for raw milk products, and if applicable, the date that the farm dairy ceased to be eligible to supply milk for raw milk products.

7.6 Milking animal identification

(1) Farm dairy operators must implement an identification system to ensure each animal in the milking herd is uniquely identifiable.

(2) Records must be kept that enable the farm dairy operator to identify which animals are part of the raw milk products milking herd.

7.7 Animal health

(1) Raw milk for raw milk products may only be harvested from outwardly healthy animals that have been subjected to veterinary observation within the previous six months.

(2) Farm dairy operators must ensure that milking herds comprising cows and buffaloes are:

a) Tb clear; and
b) in the case of replacement animals, sourced from herds that are Tb clear.

(3) If goats in the milking herd come into contact with cattle, buffalo, or deer then the:

a) cattle, buffalo, and deer herds must be classified as Tb clear; and
b) goats must be tested for Tb each season and not give a positive reaction.

(4) Farm dairy operators must not supply raw milk for the manufacture of raw milk products from any animal on the farm that:

a) returns a positive reaction to any Tb test, including first test positive but has not been confirmed as Tb negative; or
b) is suspected to be affected by Tb based on veterinary diagnosis; or
c) is directed to slaughter by a veterinarian or person authorised to do so under the national Tb eradication scheme.

(5) Animals in the milking herd must not come into contact with any animals that are required to have their milk withheld under clause 7.7(4).

(6) If any animal on the farm is confirmed to be a Tb reactor the farm dairy operator must not supply raw milk for the manufacture of raw milk products until the criteria in clauses 7.7(2) and (3) are confirmed to have been met

(7) If the presence of Tb is confirmed in any animal on or from a farm by any means, including post-mortem inspection, then no milk from any animal on that farm can be supplied for the manufacture of raw milk products until such time as the milking herd the requirements set out in clauses 7.7(2) and (3) are met.

7.8 Water and feed for animals in the milking herd

(1) Farm dairy operators must ensure that water and feed made available to animals in the raw milk products milking herd is of suitable quality and is not a vector for pathogens.

7.9 Milk harvesting

(1) The teats of milking animals must be clean and dry at the time milk is harvested.

(2) If teats are not clean and dry they must be:

a) for bovine animals, washed and dried with a single service towel; or
b) for other species, wiped clean.

(3) Milk harvesters must:

a) strip and observe the foremilk from each teat immediately prior to milking:

i) at a frequency determined by the farm dairy operator that ensures abnormalities will be detected; and
ii) when there is reason to suspect that the milk may be abnormal, for example due to signs of clinical mastitis or elevated somatic cell counts;

and;

b) withhold all the milk from any animal in the milking herd found to have visibly abnormal milk from any teat.

(4) Except as provided under clause 7.9(5), farm dairy operators must ensure that raw milk that is intended for the manufacture of raw milk products doesn't not come into contact with any milk that is not intended for the manufacture of raw milk products, except as per 7.11(2)c).

(5) Raw milk that is intended for the manufacture of raw milk products may come into contact with raw milk harvested under the Animal Products Notice: Raw Milk for Sale to Consumers Regulated Control Scheme.

7.10 Operator monitoring of farm milk supply

(1) The RMP operator must document the manner in which the raw milk supply will be monitored, including but not limited to:

a) the parameters to be monitored, including to, APC, *E. coli*, sensory evaluation, and somatic cell count; and
b) the frequency at which they are to be monitored; and
c) the acceptable limits; and
d) the actions to be taken if those limits are exceeded.

7.11 Disposal of non-conforming raw milk

(1) RMP operators must document the procedures for managing raw milk that has not been harvested in accordance with this notice, or for any other reason is not fit for the manufacture of raw milk products.

(2) the procedures under clause 7.11(1) must provide for:

a) withholding milk on-farm in accordance with clause 3.18; or
b) managing milk as non-conforming product in accordance with clause 4.10; or
c) presenting milk for supply for heat treated dairy products only, provided that it is suitable for that purpose.

(3) A record must be kept for non-conforming milk including the volume, reason and where the milk went.

7.12 Farm dairy assessment

(1) Raw milk may only be harvested for raw milk products if a farm dairy assessment has been undertaken by a recognised farm dairy assessor within the previous 6 months, with an acceptable outcome.

(2) If the operations of a farm dairy are not able to be confirmed as suitable for the harvesting of milk for the manufacture raw milk products, or any situation where a critical non-compliance is identified:

a) the farm dairy assessor is to advise the farm dairy operator and RMP operator without delay; and
b) all raw milk supplied for the manufacture of raw milk products must be managed as non-conforming milk until the situation has been resolved.

7.13 Transfer to processing premises

(1) Dairy processors who transport raw milk intended for the manufacture of raw milk products must ensure that:

a) equipment, facilities, and storage areas protect the raw milk from contamination; and
b) milk does not come into contact with milk that is not for the manufacture of raw milk products; and

c) the temperature of the raw milk does not exceed 8°C at any time from collection at the farm dairy through to acceptance at the manufacturing premises.

7.14 General requirements for raw milk product manufacture

(2) Raw milk products must be manufactured:

a) from raw milk that:

i) is suitable for the nature of the intended raw milk product; and
ii) has been harvested and handled in accordance with this notice;

and;

b) using procedures and equipment of a design that ensure cross contamination will not occur.

7.15 Milk acceptance and storage

(1) Raw milk used for the manufacture of raw milk products must:

a) be held at or below 6°C until the commencement of manufacture unless manufacture commences within 4 hours of receipt at the manufacturing premises, in which case the milk temperature must not exceed 8°C;
b) be no older than 48 hours at the commencement of manufacture; and
c) be monitored:

i) as part of the sampling and testing plan under clause 2.9;
ii) at sufficient frequency to confirm that process hygiene and food safety criteria are routinely met; and
iii) prior to the commencement of manufacture unless the manufacturing premises is at the same place as the farm dairy.

7.16 Operator defined process measures (ODPMs)

(1) In addition to any critical control point identified as necessary under clause 2.7, the manufacturer must document:

a) the operator defined process measures to be applied during the manufacture of the raw milk product that alone, or in combination, are necessary to ensure the food safety criteria is met; and
b) the manner in which the operator defined process measures will be monitored; and
c) the actions to be taken should any operator defined process measures fail to be applied as intended.

Guidance

The MPI Code of Practice: Additional Measures for Raw Milk Products provides additional detail regarding operator defined process measures and how they are applied.

7.17 Milk treatment and preparation

(1) The temperature of raw milk and dairy material must be controlled within the parameters specified in the RMP and monitored in order to minimise the opportunity for pathogens to grow.

(2) Temperatures above 6°C that are applied to milk or dairy material during processing, including storage and maturation or ripening, must be technologically necessary for the process and nature of the raw milk product manufactured.

7.18 Starter cultures

(1) Any starter culture used as part of an operator defined process measure must be capable of achieving any required acidification within the time allowed.

(2) Whey or material derived from previous dairy product manufacture must not be added as a starter culture.

7.19 Monitoring dairy product conformance

(1) The RMP operator must ensure that raw milk products:

a) are monitored for relevant pathogens or other microbiological parameters at a frequency appropriate to the nature of the raw milk product and process; and
b) satisfy the process hygiene criteria requirements contained in clause 7.20; and
c) meet the microbiological food safety criteria in clauses 2.10 and 7.21.

(2) Any raw milk product that fails to meet the food safety criteria is non-conforming and must be managed in accordance with clause 2.8.

Guidance

The MPI Code of Practice: Additional Measures for Raw Milk Products sets out more detail for the parameters to include and the frequency of monitoring.

7.20 Process hygiene criteria

(1) The raw milk or raw milk products listed in column 2 of Table 7.1 must comply with the microbiological limits under column 3 set in relation to the applicable microbiological tests under column 1 at the time the criterion listed in column 4 applies.

(2) If raw milk or raw milk product listed column 2 of Table 7.1 does not meet the microbiological limits under column 3 set in relation to that raw milk product then the dairy processor must take the corrective action specified in column 5.

Table 7.1 – Raw milk products: Hygiene acceptance criteria

Micro-biological tests	Dairy Material	Maximum Acceptable Level	Criterion Applies	Corrective Action Required
Aerobic Plate Count – 72 hours at 30ºC	Raw milk	300,000 cfu/ml	Raw milk immediately prior to the commencement of manufacture	Improve transport and premises hygiene and monitor individual raw milk supplies.

7.21 Food safety criteria

(1) In addition to the microbiological product safety limits in clause 2.10, the raw milk products listed in column 2 of Table 7.2 must comply with the limits set in column 3 set in relation to the relevant micro-organism or biological toxin listed in column 1.

Table 7.2 – Raw milk products: Product safety limits

Micro-organism or biological toxin	Raw milk product	Product Safety Limit
Salmonella	All	Absence in five 25g samples taken over the lot
Listeria monocytogenes	All	Absence in five 25g samples taken over the lot while under the control of the manufacturing processor
Staphylococcal enterotoxins	All	Not detected in five 25g samples taken over the lot

7.22 Operator defined process measure failures

(1) Dairy material and raw milk product are deemed to be non-conforming if there is a failure to apply any operator defined process measure as set out in the RMP.

7.23 Non-conforming dairy material and dairy product

(1) Any raw milk, dairy material, or raw milk product that has not been harvested, transported, stored, manufactured, or otherwise processed in accordance with this notice, must be managed as non-conforming dairy material in accordance with section 2.8.

(2) Notwithstanding clause 7.23(1), raw milk or dairy material that is identified as not being suitable for the intended raw milk product may be redirected for further processing with an appropriate heat treatment provided the:

a) intended dairy material or dairy product and its processing is covered by the RMP or applicable risk based measure under the Food Act 2014 along with procedures for managing and tracing the dairy material; and
b) dairy material is suitable for the nature of the process or product.

Part 8: Export requirements

8.1 Object of this Part

(1) The object of this Part is to:

a) set additional measures that are necessary to provide for the export of dairy material or dairy product; and
b) clarify responsibilities; and
c) provide an exemption from the labelling requirements under the Australia New Zealand Food Standards Code for exported dairy products not intended for New Zealand or Australia.

8.2 Application of this Part

(1) This Part applies to:

a) operators of RMPs that cover the processing of dairy material or dairy products intended to be eligible for export; and
b) dairy processors that process dairy material or dairy product intended for export; and
c) dairy exporters.

8.3 Responsibilities of dairy processors, RMP operators and exporters

(1) All RMP operators or dairy processors who process dairy material or dairy product intended for export are required to:

a) identify within the scope of their RMP the export markets for which their dairy material is intended to be eligible; and
b) be aware of, have access to, and meet export requirements issued by Notices issued under section 60 (167(1)) of the Act that are within the scope of their dairy processing activities; and
c) maintain an RMP or documented system demonstrating compliance with relevant export requirements; and
d) have their RMP or documented system:
    i) evaluated when required by this Notice; and
    ii) in the case of dairy processors operating under an RMP, verified against any relevant export requirements by their Recognised Agency for RMP verification; and
    iii) in the case of dairy processors operating under a risk based measure under the Food Act 2014 who only export Australia, their RMP verifier.

Guidance

The extension of the scope of an RMP from New Zealand only to cover the processing of dairy material intended for export other than to Australia is a significant amendment requiring registration in accordance with section 25 of the Act.

8.4 Chemical residues and contaminants

(1) Dairy material and dairy product intended for export other than to Australia must not contain levels of chemical contaminants or residues that exceed limits specified by the intended importing country or, in the absence of a specified limit, the limit specified by Codex as follows:

a) Codex Alimentarius List of Codex Pesticide residues in Food: Extraneous Maximum Residue Limits; or
b) Codex Alimentarius List of Codex Maximum Residue Limits for Veterinary Drug Residues in Food.

8.5 Responsibilities of recognised agencies and recognised persons

(1) Recognised agencies and appropriately recognised persons must evaluate when required, and verify that dairy processors and RMP operators comply with this Part and any other export requirements issued by notice under section 60 (167(1)) of the Act that apply to the dairy processor or RMP operator, either through procedures under the RMP or separate documented systems.

8.6 Dairy independent verification programme (IVP)

(1) Dairy manufacturers operating under an RMP and intending to manufacture any dairy products for export must participate in the MPI independent verification programme for dairy products, and provide production information when requested by their recognised agency or MPI.

8.7 Labelling and product designation

(1) The requirements under this clause do not apply to dairy material and dairy products intended for Australia.

8.7.1 General labelling requirements

(1) All required labelling information must be clearly presented and must not be removed, defaced or obliterated unless the Director-General has provided an exemption in writing.

(2) Dairy product or dairy material must not be labelled or marked in any way that is likely to be misleading or deceptive as to its nature, origin or composition.

(3) All dairy products or dairy material intended for export must comply with any additional labelling requirements prescribed by the importing country.

8.7.2 Product designation

(1) The outer packaging of all dairy products intended for export must be labelled:

a) with a product designation that complies with a standard of identity prescribed by the importing country (including both words and pictures); or
b) where the importing country does not prescribe a standard of identity for the dairy product:
    i) in such a way as to comply with the Food Standards Code; or
    ii) as a dairy product in such a way as to comply with the relevant definition in the Act, interpreted as necessary using terms consistent with the Codex Standard 206-1999 General Standard for the use of Dairy Terms and the milk and milk product standards adopted by the Codex Alimentarius Commission.

8.7.3 Information concerning net contents

(1) The net contents (by weight or volume) of any dairy material or dairy product intended for export, other than to Australia, must be stated either:

a) on a label affixed to its outer packaging; or
b) in the documentation accompanying the dairy product or dairy material.

8.7.4 Information to enable traceability

(1) Sufficient information is to be provided on a label affixed to the outer packaging of any dairy material or product intended for export to ensure traceability. This must include:

a) the unique location identifier assigned by MPI or the name and address of the final premises of manufacture; and either:

i) lot identification, such as a batch identifier, bag number, box number or quality unit number of the product; or
ii) the date of manufacture or the date of packaging in code or in plain text.

(2) Sufficient information is to be provided with each packaged item so that it can be identified and traced if necessary.

8.8 Exemption from labelling standards

(1) This clause applies to all dairy product and dairy material that is intended for export from New Zealand and is not sold in New Zealand except in the course of, or for the purpose of, export.

(2) Exemptions in this clause do not apply to dairy product and dairy material intended to be exported to Australia, unless otherwise notified by the Director-General in accordance with section 60B of the Act.

(3) Dairy product and dairy material to which this clause applies is exempt from the requirements of any food standards issued under the Food Act 2014 concerning food labelling.