



Code of Practice: Additional Measures for Raw Milk Products

March 2010

Prelims

Amendment 0

March 2010

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NZFSA does not accept any responsibility or liability whatsoever for any error of fact, omission, interpretation or opinion that may be present, however it may have occurred.

Website

A copy of this document can be found at: <http://www.nzfsa.govt.nz/dairy/index.htm>

Review of Code of Practice

This Code of Practice will be reviewed, as necessary, by the New Zealand Food Safety Authority. Suggestions for alterations, deletions or additions to this Code of Practice, should be sent, together with reasons for the change, any relevant data and contact details of the person making the suggestion, to:

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Amendment Record

It is important that this publication is kept up-to-date by the prompt incorporation of amendments.

To update this publication when you receive an amendment, remove the appropriate outdated pages, destroy them, and replace them with the pages from the new issue. Complete instructions will be given on the covering letter accompanying the amendment. File the covering letter at the back of the publication and sign off and date this page.

If you have any queries, please ask your auditor or verifier.

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1 Introduction

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1.1 Scope and purpose

The purpose of this Code is to provide additional technical information and establish base criteria to assist dairy processors who may be contemplating the production and processing of raw milk and raw milk products for the general population. This Code is intended to supplement the Animal Products (Raw Milk Products Specifications) Notice 2009, available on the NZFSA website at <http://www.nzfsa.govt.nz/dairy/publications/specifications/final-raw-milk-spec.pdf>

This Code is expected to serve as a reference for those involved in the evaluation, audit or verification of risk management programmes or food safety programmes developed for the processing of raw milk products.

1.2 Application

Dairy processors are required to operate under a programme that has been approved or registered by NZFSA. This Code applies to those dairy processors wishing to harvest, store or transport raw milk or dairy material for the manufacture of raw milk products, and those dairy processors wishing to manufacture raw milk products who choose to include this Code as part of their programme. This Code is not mandatory **unless** it has been included within the operator's programme.

This Code sets out **additional** measures for a programme, it is important that operator's are familiar with the requirements that apply generally to the processing of dairy material and dairy products.

The details in this Code are to be read in conjunction with all other requirements, criteria and guidelines issued under the Animal Products Act 1999, available on the NZFSA website at: www.nzfsa.govt.nz/dairy

1.3 Summary of most relevant legislation

- Animal Products Act 1999

- Animal Products (Dairy) Regulations 2005
- Animal Products (Risk Management Programme Specifications) Notice 2008
- Animal Products (Dairy Processing Specifications) Notice 2006
- Animal Products (Raw Milk Products Specifications) Notice 2009
- The Australia New Zealand Food Standards Code -
<http://www.foodstandards.gov.au/foodstandards/foodstandardscode/>
- Other specifications available on the NZFSA website -
<http://www.nzfsa.govt.nz/dairy/publications/specifications/index.htm>

1.4 Other references

- NZFSA Approved Criteria - <http://www.nzfsa.govt.nz/dairy/publications/approved-criteria/index.htm>
- Register of approved and recognised dairy maintenance compounds -
<http://www.nzfsa.govt.nz/registers-lists/dairy-maintenance-compounds>
- Market specific requirements (available on request) -
<http://www.nzfsa.govt.nz/dairy/publications/omar/index.htm>
- NZCP1: Design and operation of farm dairies -
<http://www.nzfsa.govt.nz/industry/general/cops/design-farm-dairies/>
- Interim Code of Practice for the development of a Food Safety Programme for Specialist Cheeses and Yoghurt, available on request from the NZ Specialist Cheesemakers Association - <http://www.nzscsca.org.nz/nzscsca/index.php>
- The (UK) Specialist Cheesemakers Code of Best Practice

1.5 Interpretation

Herd means, for the purposes of this Code, one or more milking animals kept together in a group and includes a flock in the case of sheep.

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

Notice means the Animal Products (Raw Milk Products Specifications) Notice 2009.

ODPM means an operator defined process measure as defined by the Notice.

Process run means each discrete and homogenous quantity of dairy material processed within a lot or batch, for example each curd set or “make” in cheese making.

Salt in moisture means salt percentage divided by moisture percentage multiplied by 100.

Shelf life means the period nominated by the operator during which a product remains fit for its intended purpose.

Start-up protocol means a document containing –

- a. details of the evidence to be collected to demonstrate the effectiveness of the programme
- b. a proposal for the retention or disposition of the product until the effectiveness of the programme has been demonstrated.

Validate means the process by which evidence is obtained to demonstrate that animal material or animal product will be fit for intended purpose, through the achievement of any regulatory limit or operator-defined limit.

2 Programme Development and Approval

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2.1 Procedure

The typical procedure for the development, confirmation, evaluation and approval/registration of a programme for the manufacture of raw milk products is set out in Appendix 1. There are some procedural differences in the registration of a risk management programme and the approval of a food safety programme. Operators should take the information provided and align it to their specific situation.

It must be noted that the measures outlined in this Code of Practice are in addition to those generally required for the processing of dairy material and dairy products.

2.2 Programme amendment

Extending the scope of a programme that covers any dairy processing activity from farm dairy through to manufacture to allow for the processing of raw milk for raw milk products is a significant amendment. The amendment will require evaluation by a suitably recognised evaluator or, for a food safety programme, assessment by a suitably qualified auditor.

3 Farm Dairies

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3.1 Identification of farm dairies

The RMP operator is required to maintain a register of all farm dairies. The farm dairies that have been confirmed as meeting the requirements for the harvesting and supply of raw milk for raw milk products must be clearly identified. Details for these farm dairies must include physical location of the farm dairy, unique company supply number or identifier, and the name and contact details of the farm dairy operator. Because urgent contact with the milk harvester may be required, RMP operators should maintain contact details for the person with day to day responsibility for milk harvesting and supply.

3.2 Quality management system

The measures set out in this part are in addition to those contained in NZCP1: Design and operation of farm dairies <http://www.nzfsa.govt.nz/dairy/publications/cop/design-farm-dairies/index.htm>

Farm dairy operators harvesting milk intended for the manufacture of raw milk products are expected to have access to, and be familiar with this Code and NZCP1.

Farm operators are required to have and operate-

- a. a quality management system covering all farm dairy activities
- b. a mastitis management plan such as the Seasonal Approach to Mastitis Management (SAMM) Plan
- c. a documented effluent management plan, if this is required under 3.7 *Effluent, waste and flooding* of this Code.

3.3 Identification of milking animals

Farm dairy operators must-

- a. ensure that each individual animal is uniquely identifiable. The manner in which this is done needs to be sufficiently robust so that there will be no confusion. Typically this will be through the use of an ear tag and a register of the animals in the herd, but in a situation with only one or two animals, alternatives may suffice
- b. keep a record of which animals are in the milking herd when milk is being supplied for the manufacture of raw milk products
- c. monitor the milking herds regularly to be sure that only those animals intended to be in the herd as identified in (b) above are indeed in the herd. This becomes particularly important if the milk from any particular animal is determined to be unfit for raw milk products and it needs to be confirmed whether the animal was or wasn't in the milking herd at a specific time.

3.4 Animal health

It is essential that farm dairy operators monitor the health and behaviour of milking animals. Animals are to be removed from the milking herd when—

- a. identified with, or suspected to have an infectious disease
- b. a teat or the udder has been injured
- c. there is any evidence of clinical mastitis
- d. the milk is observed to be abnormal.

Milk from animals affected under points a. to d. above is to be withheld from supply for any purpose until the condition has been resolved or veterinary clearance has been obtained. The affected milk is non-conforming and as such is not permitted to be used for raw milk products or heat treated (pasteurised) products. Farm dairy operators are expected to seek veterinary advice when conditions are not resolved as expected and for symptoms which are unfamiliar.

Farm dairy operators must ensure that all animals in the milking herd are subject to a veterinary inspection twice per season. One being in the period August to November and one in the period February to May. If no milk is being harvested for raw milk products during one or other of these periods then no inspection is required in that period. If no milk is being harvested in both periods then there must be an inspection within the previous six months. For example, a farm producing milk for raw milk products from September until January only requires one veterinary visit.

Farm dairy operators are to ensure that all bovine animals in the milking herd receive a *Leptospirosis* trivalent vaccination before entering the milking herd, and that milking animals of other species receive a *Leptospirosis* vaccination if a suitable vaccine is available.

Farm dairy operators must document, implement and adhere to a plan for the management of mastitis, such as the Seasonal Approach to Mastitis Management (SAMM Plan), in conjunction with veterinary advice.

Milk from milking animals of unknown health status, such as purchased animals, must be withheld until the animals are confirmed to be healthy. Confirmation may be achieved by confirming the Tb status, reviewing the Animal Status Declaration form (ASD), veterinary inspection and individual Somatic Cell Count (if the animal is milking). Records confirming the health of purchased animals, such as the Animal Status Declaration form (ASD) or veterinary inspection record, must be kept.

Controls related to bovine Tuberculosis (Tb)

Farm dairy operators must ensure that milking herds comprising cows and buffaloes -

- a. have a rating of "C5" through to "C10" under the national Tb eradication scheme
- b. are subjected to a Tb screening test each season.

If goats in the milking herd are on the same farm as cattle, buffalo, or deer then the -

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

Farm dairy operators are not to supply raw milk for the manufacture of raw milk products if any animal on the farm—

- a. returns a positive reaction to any Tb test
- b. is suspected to be affected by Tb based on veterinary diagnosis
- c. is directed to slaughter by a veterinarian or person authorised to do so under the national Tb eradication scheme.

The milk from the entire herd must be withheld from supply for raw milk products if any single animal returns a first test positive Tb result. This is irrespective of whether a confirmatory test is undertaken. If there is more than one herd on the property, then the milk from all herds must be withheld. However, the Recognised Agency accepts that the herds are managed as separate farm holdings and there is no contact between the animals.

Milk required to be withheld under the criteria above can be supplied for the manufacture of raw milk products once the status of all animals and herds are confirmed to satisfy the requirements set out in the Notice.

If the presence of Tb is confirmed in any animal from a farm by any other means (i.e. post-mortem examination), then milk from any animal in the milking herd on the farm must not be supplied for the manufacture of raw milk products. This applies until such time as the milking herd meets the requirements outlined.

3.5 Housing and environment

In situations where animals are housed, farm dairy operators must ensure that-

- a. the housing pens, bedding and associated things are designed, maintained and operated in an appropriate manner to minimise pests, contamination of feed, soiling or trampling of the udders and teats, and exposure of milking animals to pathogens
- b. the facilities are cleaned in an appropriate frequency and manner
- c. there is adequate airflow
- d. regular observations are made for disease, injury, discomfort or distress
- e. animals are removed immediately when identified as affected by, or potentially affected by, disease, injury, discomfort or distress and may only return once the condition has been resolved
- f. animals are removed immediately for the period instructed when required to do so by a veterinarian or a person authorised under the Animal Products Act or the Biosecurity Act 1993.

All holding yards, feeding yards, loafing yards, and wintering yards or pads must be operated in a manner that minimises soiling of the udder and teats as well as negative impacts on animal health, for example crowding which may lead to trampling of teats or udders.

Access ways including races, stock tracks and gateways must be maintained to minimise soiling of the udder and teats.

3.6 Animal water and feed

Farm dairy operators must ensure that-

-
- a. drinking water for milking animals is of suitable quality to minimise water-borne disease transmission. While it is not a requirement to test the water, unless there is reasonable doubt, it should be free of offensive odour and of a colour and clarity level consistent with good farming practice
 - b. milking animals have access to unsuitable water restricted. This may include water in waterways or contained water (e.g. dams) where the water is intended for other purposes such as irrigation
 - c. all feed for milking animals (including feed additives and supplements) is—
 - i. of known origin,
 - ii. traceable back to the supplier of the feed
 - iii. suitable for the milking animals
 - iv. for all feed not grown on either the property or a run-off controlled by the same farm operator, a declaration is obtained from the supplier of the feed stating that it is suitable for milking animals (noting the additional requirements for fermented feeds below).
 - d. feed production and storage facilities must be appropriate for the nature of the feed
 - e. no feed waste, silage sludge or mouldy feed is offered to or consumed by milking animals
 - f. milking animals are not fed any fermented or ensiled feeds if the milk is to be used for the manufacture of raw milk products, where the process does not reduce the level of *Listeria monocytogenes* and the manufacturer advises the farm dairy operator accordingly
 - g. milking animals should only be offered ensiled or fermented feed that has been prepared, stored and made available in a manner that minimises microbial contamination. Special consideration to be given to:
 - i. design of silos or bunkers
 - ii. production practices for silage including compaction of the stack
 - iii. controlling the quality of the fermented feed including pH reduction and sensory assessment (odour).

3.7 Effluent, waste and flooding

Effluent must be managed to ensure appropriate disposal and milking animals kept away from areas where effluent or waste is stored to minimise exposure.

If dairy effluent is applied to pasture then it must be done under a suitable, documented management plan. There must be at least 21 days between application and grazing or harvesting of feed. The milking animals and the farm dairy environment must not be exposed to spray drift when effluent is being spray irrigated.

Milking animals are not to be exposed to human waste or any other waste likely to contain pathogens of significance to human health. Waste is not to be applied to areas used to grow feed for the milking herd.

Milk must be withheld from animals exposed to areas affected by flooding or the uncontrolled application of waste material including effluent. The term uncontrolled refers to any form of effluent application or exposure that is not covered by a documented effluent management plan.

3.8 Milk filtering, cooling and storage

Milk must be filtered and, unless manufacture commences within two hours from the completion of milking, immediately cooled using primary cooling as described in NZCP1 and then either–

- a. cooled to 7°C or below within three hours from the completion of milking if the milk is stored for no more than 24 hours
- b. cooled to 6°C or below within two hours from the completion of milking.

The milk must be held at or below the appropriate temperature from (a) above until it is removed from the farm bulk milk tank or until the next milking.

Milk should be collected daily unless there is a technologically justified reason for holding longer. It must not be held for more the 48 hours before manufacture commences.

To minimise microbiological growth, farm dairy operators should cool milk quickly and hold at 4°C with sufficient, gentle agitation to maintain even heat distribution and avoid icing or freezing.

3.9 Milking plant and facilities

Farm dairy operators must ensure that appropriate hand washing facilities are available for milk harvesters.

The bulk milk tank used to store the raw milk must only be used for the storage of conforming milk. All bulk milk tanks must be clearly labelled to identify the nature of the milk.

Milk that is not suitable for either raw milk products or heat treated products (i.e. calf milk), is not to be stored at the farm dairy and must be at least 20 metres from the milking area, milk receiving area, milk storage room/area and milk collection point.

When not in use the bulk milk tank must be closed and protected from soiling or other contamination.

The milking plant and bulk milk tank must be—

- a. rinsed with cold water and then cleaned using a NZFSA approved detergent with hot water immediately following each milking
- b. sanitised using a NZFSA approved sanitiser following each clean
- c. sanitised using a NZFSA approved sanitiser immediately prior to use, and then rinsed or drained as appropriate.

Milking machines, when used, must be tested each season by a competent person, for example, Milk Pumping Trade Association (MPTA) member.

The bulk milk tank is to be located in an enclosed milk room or, if located outside, must be fully enclosed and have the facility to continuously monitor the temperature of the contents.

3.10 Farm dairy water

Water used to clean, sanitise, rinse and maintain the milking plant, for cleaning of the teats and for hand washing must be free of pathogens and is to be monitored for E. coli to confirm absence in 100 mls—

- a. every season in conjunction with a farm dairy assessment
- b. whenever there is a change to the water supply that might impact on its microbiological status.

3.11 Dairy yard

The dairy yard must be of solid construction as set out in NZCP1, and must be cleaned after each milking using water of suitable quality. The wash water is not required to be tested but should be free of objectionable odour and should not leave a residue on the yard. The water must be from a suitable water supply and not recovered from effluent.

3.12 Milk harvesting

The milking plant must be clean and must be sanitised, rinsed and drained immediately before milking animals for the supply of raw milk for raw milk products.

The milking of animals that require their milk to be withheld, including those identified under section 3.4, must be delayed until milking of the milking herd has been completed and the milk delivery line has been removed from the bulk milk tank. The milking plant must then be cleaned and sanitised prior to harvesting milk for human consumption.

All teats must be clean and dry at the point of milking. If they are not clean and dry then:

- a. for bovine, if the teat and udder are dry then brushing the teat may be sufficient, otherwise the teats are to be washed and dried with a single service towel
- b. for caprine and ovine, the teats are to be wiped.

Monitoring for mastitis

Milk harvesters must have a mastitis management plan and must document the routine and periodic steps taken to monitor for mastitis in the milking herd.

If there is any indication that an animal may have mastitis then the foremilk from each teat/gland is to be stripped immediately prior to milking and assessed for defects, including—

- a. visual observation for clots or flakes, watery appearance or unusual colour or consistency, ropiness
- b. undertaking a rapid mastitis test (e.g. California mastitis test or conductivity).

All the milk from the animal must be withheld if any teat is found to have abnormal milk.

Monitoring for mastitis is to include—

- a. observations of animal behaviour, particularly indications of udder discomfort or resistance to milking

- b. observation of the teats and udder at each milking for injury or damage, heat or swelling
- c. inspecting the milk filter
- d. activity monitoring trends in the bulk milk supply somatic cell count result
- e. routine stripping of foremilk from each animal, according to a documented routine. For larger herds it is recommended that foremilk be stripped from one teat of each animal on selected days of the week. For example, strip milk from the front right teat every Monday, front left every Tuesday etc. this way every gland of every animal will be monitored each week.

Note: milk harvesters should avoid the transfer of pathogenic bacteria from one animal to another, for instance by rinsing gloved hands in sanitising solution between animals

If the somatic cell count for the farm supply exceeds 240,000 cfu/ml for cows then action is to be taken to reduce the level by:-

- a. reviewing routine procedures and discussing these with any staff involved to ensure the procedures are being followed as intended
- b. stripping the foremilk milk from each individual animal and assessing it for defects
- c. reviewing individual animal herd test data, if herd testing
- d. removing animals identified under a. and b. above and treating them in accordance with veterinary advice.

To prevent infection, teats are to be sanitised immediately after milking. Only a teat spray approved for use prior to milking may be used for this purpose, and the teats should be clean, have sufficient contact time with the sanitiser, and be wiped dry before the cups are applied.

Milk harvesters–

- a. must ensure that hands and forearms are kept clean during milking
- b. should wear new, clean, latex-type gloves at each milking
- c. when milking by hand, ensure gloves are changed or hands are washed between animals.

3.13 Colostrum

Colostrum is not to be used for the manufacture of raw milk products. Milk is to be withheld for at least eight full milkings and four full days from giving birth, and should be extended to twelve full milkings and six days for heifers (first time calvers).

3.14 Automated or unconventional milking systems

Automated milking systems and any novel or unconventional milk system or farm dairy designs are not to be used for harvesting raw milk intended for raw products unless the specific designs have been submitted with the risk management programme (RMP) for evaluation. The RMP operator is expected to maintain records regarding the farm dairy design and milking system used at each farm dairy.

3.15 Avoiding cross contamination

Milk intended for raw milk products must be segregated from milk not intended for raw products. This means ensuring that

- a. any raw milk intended for raw milk products must not come into contact with either raw milk that is not intended for raw milk products, or raw milk that does not meet all the requirements for the manufacture of raw milk products
- b. the milking plant, bulk milk tanks and any other contact surfaces are cleaned before harvesting milk intended for raw milk products to ensure there is no opportunity for cross contamination to occur.

3.16 Monitoring of farm milk supply

The nature and frequency of the monitoring plan for each raw milk supplier will depend upon–

- a. any additional acceptance testing undertaken by the manufacturer of the raw milk products
- b. the type of validation undertaken (challenge study, predictive modelling, etc)
- c. the pathogen degree to which pathogen growth might occur
- d. whether raw milk acceptance, process hygiene and food safety criteria are met consistently.

- e. the nature of product that will or may be manufactured.

The farm dairy programme operator will need to discuss the situation and the options with the manufacturing programme operator.

Monitoring of individual farm supplies should also take into account–

- a. the process hygiene criteria that apply at the start of manufacture (Aerobic Plate Count (APC) not to exceed 300,000 cfu/ml immediately prior to manufacture commencing)
- b. the microbiological parameters specified in Standard 1.6.1 of the Food Standards Code
- c. the product safety limits specified in DPC1: Animal Products (Dairy) Approved Criteria for Dairy Processing
- d. the food safety criteria in the Notice
- e. identification and analysis of hazards in accordance with section 17(3) of the Animal Products Act.

Table 1 of Appendix 2 sets out the minimum monitoring required for individual farm supplies along with acceptance standards. Monitoring must increase to each consignment if an acceptance limit is exceeded and is to continue on each consignment basis until three consecutive supply days meet the acceptance standard.

It should be noted that minimum specified parameters, limits, monitoring frequency and response to unfavourable results are subject to on-going review and additional minimum requirements may be recommended or stipulated if considered necessary.

3.17 Disposal of non conforming raw milk

Milk that has not been harvested and stored in accordance with a RMP registered for the harvesting milk for raw milk products or is suspected to be unfit for the manufacture of raw milk products must be withheld and either:

- a. disposed of appropriately on farm
- b. redirected to supply for the manufacture of heat treated products provided that the milk meets the requirements for such supply.

Whenever milk is withheld the farm dairy operator is to record the use or fate of the milk.

3.18 Farm dairy assessment

The RMP operator must ensure that farm dairy assessments are undertaken twice per season, one being in the period August to November and one in the period February to May. The farm dairy assessor undertaking the assessments must be a suitably qualified and competent person who is free from any conflict of interest.

If no milk is being harvested for raw milk products during one (but not both) of these periods then no inspection is required for that period.

If no milk is being harvested during both periods then an inspection is required within the previous six months.

For example, the affect of the above requirement is that a farm producing milk for raw milk products from September to December will only require one farm dairy assessment, assuming that operations comply with requirements.

In any situation where the farm dairy operations are not able to be confirmed as suitable for the harvesting of raw milk products or any situation where a serious compliance failure is identified:

- a. the farm dairy assessor is to advise the farm dairy operator and RMP operator immediately
- b. no raw milk harvested at the farm dairy is to be used for the manufacture of raw milk products until the situation has been resolved
- c. any affected milk already supplied must be identified and the circumstances investigated and reported in accordance with section 3.19
- d. supply may only resume once the condition has been resolved.

Milk failing to meet the requirements for raw milk products may be acceptable for processing with heat treatment, this is expected to be identified as part the farm dairy assessment findings.

3.19 Reporting

The risk management programme operator must ensure that:

- a. the farm dairy operator is advised of any unsatisfactory milk collection temperatures and unsatisfactory test results of the farm milk supply without delay

- b. dairy processors receiving raw milk are advised immediately of any non-conformance or non-compliance that has or may affect the status of the raw milk supplied
- c. the risk management programme verifier is advised and appropriate actions taken in accordance with regulation 5 of the Animal Products (Dairy) Regulations 2005 and clause 5 of the Animal Products (Dairy Processing Specifications) Notice 2006. It should be noted that any milk non-conformance or any failure on the part of the RMP or farm dairy operator to comply with the requirements set out in the RMP is likely to mean that any manufactured raw milk product is deemed non-conforming.

3.20 Communication between farm dairy operator and manufacturer

Farm dairy operators supplying milk for the manufacture of raw milk products should be supplying milk under a written contract or agreement. The agreement must clearly set out any special requirements or considerations that farm dairy operator must comply with. This may be due to the nature of the processes used or products that the manufacturer intends to make. This may include such things as restrictions on the types of feed, the milk storage temperature parameters, etc.

4 Transport

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4.1 Transfer to processing premises

Milk intended for raw milk products must be segregated from milk not intended for raw products. This means ensuring that:

- a. raw milk intended for raw milk products does not come into contact with either raw milk that is not intended for raw milk products or raw milk that does not meet all the requirements for the manufacture of raw milk products
- b. raw milk intended for raw milk products is transported with the same controls that apply to the transport of heat treated dairy material
- c. heat treated milk is not contaminated through contact with raw milk (whether or not it is intended for raw milk products)
- d. tanks, hoses and other contact surfaces are cleaned and sanitised to ensure there is no opportunity for cross contamination to occur between different types of dairy material.

Before accepting milk for collection, the temperature of the milk must be checked to ensure it meets the criteria specified by the manufacturer, based on:

- a. the frequency of collection
- b. the time from the completion of milking
- c. the expected start of manufacture.

The collection time and milk temperature are to be recorded. If the milk is above the permitted temperature then it must not be accepted. The details must be documented and the farm dairy operator and RMP operator advised.

From the point of collection through to delivery to the manufacturing premises the temperature of the milk must not exceed 8°C.

The transport conditions must maintain the microbiological integrity of the raw milk.

The vessel or tank used to transport raw milk or dairy material for the manufacture of raw milk products are to meet the same criteria applied to vessels or tanks used to transport heat treated liquid dairy material intended for further processing – refer to the Operational Guideline: Design and Construction of Dairy Premises and Equipment, available at <http://www.nzfsa.govt.nz/dairy/publications/guidelines/designandconstruction.htm>

5 Manufacture

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5.1 General requirements applicable at all stages of processing

Raw milk products must be manufactured–

- a. using raw milk that-
 - i. has been specifically harvested, stored and transported under an approved/registered programme with the intention of manufacturing raw milk products
 - ii. is suitable for the nature of the intended product.
- b. using procedures, cleaning programmes and equipment of a design that do not permit cross contamination such as the inadvertent mixing of-
 - i. raw milk or dairy material with treated dairy material or product
 - ii. raw milk intended for raw milk products with milk that is not eligible for raw milk products.
- c. following documented procedures that protect the dairy material from contamination throughout manufacture and ensuring that the processing of raw milk products does not adversely affect the processing of heat treated dairy products.

5.2 HACCP

Operators are reminded of the importance of developing a HACCP Plan following the steps set out in DPC1: *Approved criteria for general dairy processing*. This will include identification of the pathogens of significance given the Operator Defined Process Measures (ODPM) that will be applied and the compositional characteristics of the raw milk product.

5.3 Milk acceptance and storage

Upon receipt at the manufacturing premises, raw milk intended for the manufacture of raw milk products are held at 6°C or below until the commencement of manufacture unless-

- a. manufacture commences within two hours when held at the farm dairy
- b. manufacture commences within four hours of acceptance at the manufacturing premises, in which case the milk temperature must not exceed 8°C.

Raw milk that is above 6°C on receipt but does not exceed 8°C must be either-

- a. held at or below 8°C provided that manufacture commences within four hours
- b. cooled to 6°C within one hour of receipt and held at 6°C or below until manufacture commences.

The raw milk must be no older than 48 hours at the start of manufacture. However the raw milk should be no older than 24 hours at the start of manufacture unless–

- a. the milk has been sampled and is being held pending the outcome of the test result
- b. the milk is intended for the manufacture of hard or extra hard cheese.

The incoming milk is to be sampled prior to the commencement of manufacture and tested according to a documented plan at sufficient frequency to ensure that process hygiene criteria and food safety criteria will be met. Appendix 2 sets out a recommended monitoring plan.

For traceability raw milk should be used on a batch basis and not a continuous 'feed and bleed' basis.

5.4 Dairy material temperature

The temperature of milk and other dairy material must be controlled throughout processing to minimise the opportunity for pathogens to grow. The acceptable temperatures are to be specified and monitored periodically to show that control is maintained.

If milk is required to be conditioned at a temperature above 6°C for any period of time then this should be included as an ODPM.

5.5 Starter cultures

Starter cultures (either added directly to the raw milk or used for bulk starter preparation in heat treated milk) must be free from pathogens and must be from an operator approved supplier. Each batch of culture must be traceable to the batches of product, in which, they are used.

It is not acceptable to use whey or material obtained from previous manufacture when manufacturing a raw milk product.

In most situations use of a starter culture will be part of an ODPM, for example to produce acid and reduce pH. If this is the case then the starter culture strain(s) and quantity added must be capable of achieving the required level of acidification within the time allowed, and these parameters are to be defined for the specified ODPM.

5.6 By-products and loss streams

The programme must identify any by-products (cream or whey) or recovered waste/loss streams (i.e. cheese fines or trims) and the intended use. Typically these will be suitable as animal feed without further processing and may be suitable for human consumption products following further processing with a defined heat treatment provided that—

- a. they have been recovered and stored under suitable conditions
- b. further processing commences without excessive delay.

5.7 Environmental pathogen management

The programme for manufacturers of raw milk products must include an environmental pathogen management plan for the monitoring and control of pathogens in the manufacturing environment. This plan will identify the manner in which monitoring occurs, the acceptance thresholds, and the actions to be taken if acceptance thresholds are breached - refer to the Animal Products (Dairy Processing Specifications) Notice 2006 and DPC3 for further information.

5.8 Operator defined process measures

The programme is to contain a description of the manufacturing process, including inputs and outputs, in conjunction with a process flow diagram. From this each ODPM must be clearly identified, including-

- a. the process steps that alone, or in combination, make up the ODPM (i.e. defining the ODPM)
- b. the acceptable operational (process) tolerance criteria that applies for each measure, for example minimum and/or maximum temperature and time, minimum pH or titratable acidity, acceptable compositional range (e.g. salt and moisture percentage)

- c. the manner in which the process measures will be monitored, including sampling frequency, testing method and accept/reject determinants
- d. the actions to be taken should any operator defined process measure fail to be applied as intended. This must include both actions to remedy the loss of control as well as the steps to be taken to identify and contain potentially affected dairy material and product.

Equipment used to make measurements must be fit for the purpose and properly calibrated, for example—

- a. thermometers used to monitor the process must be calibrated for the range of temperatures encountered
- b. pH meters must be calibrated using suitable buffer solutions that cover the routine working range (i.e. one higher and one lower than the pH range routinely measured)
- c. acidity measurements made using properly standardised solutions.

Records - the programme must provide for the details of all samples taken and the results obtained to be recorded and made available on request.

5.9 Failure to apply an ODPM

Dairy material and raw milk product are deemed to be non-conforming if the operator fails to apply any ODPM as set out in the programme. Operators need to be aware that failure to apply each ODPM or a failure to act on unacceptable findings may result in more products becoming affected indirectly and the sub sequential impact may therefore be much greater.

5.10 Failure to meet food safety criteria

In the event that product fails to meet any applicable microbiological limits, including food safety criteria, the product is deemed non-conforming and the standard procedures for reporting and managing the product apply. This will include identification of all product and dairy material that may be affected, including loss streams. The operator is also expected to review incoming raw milk data, in-process monitoring data and records from each ODPM.

If all monitoring results and ODPM records indicate conformance should have been achieved then the operator should—

- a. impose more stringent monitoring of the raw milk supply unless there is data to show the raw milk supply was not a likely factor

- b. review the manner in which samples are taken and handled, with particular focus on the point of sampling and the assumptions made on the basis of the sample.

5.11 Confirmation of programme validity

The programme operator is required to determine whether the proposed manufacturing process will produce a raw milk product that consistently meets the applicable microbiological limits and food safety criteria.

Further information on the development and content of a protocol for confirming the validity of a programme can be found in Section 4.4 of the Risk Management Programme Manual, available at: <http://www.nzfsa.govt.nz/industry/general/rmp/documents/manuals/risk-management-programmes/amdt-3.pdf>

Appendix 3 sets out options for confirming the validity of a programme for the manufacture of raw milk products. The range of potential products and the manufacturing processes used to make them are extremely diverse. The resources available to operators will vary based on the size and nature of their operations. It is not practical to establish one fixed protocol for confirming the validity of the process and product. A range of options are provided to assist operators.

Some of the options, for example challenge studies, have a greater burden prior to commercial manufacture commencing. They provide certainty of outcome and ensure the financial commitment for facilities, plant, resources, raw materials, ingredients etc is justified. Some of the other options may appear to be less rigorous, but they still require technical justification and carry a higher commercial risk on the part of the programme operator should the process/product combination not be confirmed as capable of meeting the required outcome.

Sampling and testing

5.12 Monitoring

To ensure that raw milk products are fit for purpose, there must be a suitable monitoring plan in place that includes sampling and testing for relevant pathogens and other microbiological parameters. The design of the plan will vary depending on the nature of the operation, the processes and the product. The plan must be capable of showing that process hygiene criteria are being satisfied and food safety criteria are met.

Operators need to take a risk based approach when developing a monitoring plan. The plan should start with the raw milk product (the food) and working back through the process to the raw milk as received. Refer to sections 5.13 to 5.16 of this Code.

5.13 The final product (end of manufacture and throughout shelf life)

The operator is expected to-

- a. identify all food safety and microbiological parameters and limits that apply to the particular food product through out the shelf life
- b. consider the nature of the product and the results of any validation study that shows the fate of pathogens during processing and throughout the shelf life of the product
- c. make allowance for any potential growth from the end of manufacture through to the end of the products shelf life. This may require predictive modelling or extrapolation from known data.

Based on the information available the operator must document the maximum acceptable limit for each microbiological parameter and, if necessary, the point at which it applies. If growth is likely to occur after manufacture then the limit to be applied at the time of sampling must make allowance of the maximum expected increase during shelf life.

The operator then proposes the test parameters to monitor and selects a NZFSA recognised dairy laboratory that has a suitable NZFSA approved dairy test method available. In some situations there may be more than one test method available and so operators should discuss their requirements with the recognised laboratory when developing a programme to ensure an appropriate method is selected. If the product is intended for export then the test method to be used may be stipulated by the importing country.

The operator must determine a suitable sampling frequency. In doing so consideration is to be given to-

- a. the nature of the process and the product
- b. the nature of the operator validation undertaken and the depth of information available
- c. the frequency and nature of in process testing
- d. the extent and intensity of raw milk testing.

If minimal validation data is available then a higher sampling frequency will be expected unless there is significant raw milk and in-process testing for pathogens. Table 3 of Appendix

2 provides standard sampling frequencies as well as higher frequency sampling required during confirmation of process validity.

The monitoring programme is to include provision for increased sampling and testing frequencies should unfavourable results be obtained from the testing of raw milk, environmental, in-process or final product samples. As an example, the programme might provide for the automatic increase in sampling from standard frequency to high frequency.

The proposed sampling and testing programme to monitor product must be agreed by the programme evaluator or auditor.

5.14 In-process testing

In-process testing is used to monitor ODPMs, to demonstrate that the process is in control and confirm that the final product can be expected to meet food safety and microbiological limits.

Appropriate sampling points will be determined by ODPMs, the point in the process where pathogens are likely to be at their maximum, and the ability to obtain a suitable sample.

Consideration should be given to all the factors that contribute to the process, including secondary factors such as brine concentration, whey acidity.

For in-process testing the operator may determine tolerance limits that differ from those in the food safety criteria, but in such cases details of the rationale will need to be documented and retained.

5.15 Raw milk at the commencement of processing

Sampling and testing of the consolidated raw milk should occur prior to each manufacturing run, as outlined in Table 2 of Appendix 2. While results will not be available at the time manufacture commences regular monitoring confirms that the milk continues to be suitable for the process. Where a result can be obtained within 24 hours indicating the suitability of the raw milk, assuming milk is collected/used daily, the operator may elect to sample and hold the milk so that an accept/reject decision can be made. For most parameters this isn't possible and the results will be used to-

- a. confirm ongoing suitability of the milk supply and the handling procedures up to the point of sampling
- b. confirm that the milk is suitable for the intended process/product combination

- c. support in-process and end product monitoring results.

Sufficient sampling must be undertaken so that failures in the raw milk supply will be identified.

The number of samples required will depend on how the milk is received and held prior to manufacture. Each mixed raw milk silo is expected to be sampled, as set out in Table 2 of Appendix 2.

5.16 Individual farm raw milk supplies

Where the farm dairy is controlled by the manufacturing processor, monitoring of the farm supply and monitoring at the commencement of processing would typically be combined, with the parameters determined from the combined requirements for each.

Where milk is being purchased from another operator then the acceptance criteria should form part of a supply agreement. It is in the interests of the manufacturer to only accept milk suitable for the intended process/product.

The expected minimum sampling and testing regime is set out in Table 1 of Appendix 2.

5.17 Process hygiene failures

The programme must identify the steps to be taken in the event of a process hygiene failure. This is to include investigation and review of:

- a. test and temperature data for each individual farm supply
- b. the hygiene status and cleaning records for vessels used to transport raw milk
- c. temperature data for each consignment of milk received
- d. the hygiene status, cleaning records, temperature data and any in-process data from receipt through to the point of sampling for the process hygiene parameter concerned.

5.18 Operator competency

The suitability of any proposed process and product combination design is to be reviewed and confirmed as acceptable by a person with appropriate skills, knowledge, competence and experience. The programme operator is responsible for ensuring that each person with designated responsibilities under the programme is sufficiently competent to fulfil their

responsibilities. Records are to be kept of relevant experience, qualifications and any training that has been provided.

The programme must specify the competencies needed by individuals to enable the effective operation of the programme.

The programme must provide for the keeping of records, in an easily accessible form, demonstrating that the competencies identified under this clause have been achieved and maintained.

5.19 Non-conforming dairy material and dairy product

Any raw milk, dairy material, or raw milk product that has not been harvested, transported, stored or manufactured in accordance with the programme must be managed as non-conforming dairy material in accordance with regulation 5 of the Animal Products (Dairy) Regulations 2005.

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 a heat treatment provided the-

- a. procedure for managing and tracing the dairy material is set out in the programme
- b. dairy material is suitable for the nature of the process and product.

The procedure must specify-

- a. the nature of the failure (for example the incoming milk failing to meet the operators acceptance criteria)
- b. any specific actions that need to be taken to confirm that the material is-
 - i. still conforming dairy material
 - ii. suitable for further processing by the intended process.
- c. the remedial actions that need to be taken to prevent a recurrence.

5.20 Significant change

A significant change and the associated programme amendment must be evaluated or re-audited **before** processing commences under the amended conditions.

Examples include a new raw milk product or product variant, or any change to the ODPMs for an existing product (including a change to the acceptable limits).

5.21 Programme verification

On-going verification of the programme will be at the frequency deemed appropriate by the auditor or verifier. For product manufactured in premises that export dairy products the Animal Products (Export Verification Requirements) Notice 2009 will apply.

5.22 Risk organism response plans

It is recommended that all manufacturers have a risk organism response plan, as set out in the Animal Products (Risk Organism Response Plans) Notice 2008, to mitigate the risk of being affected by a risk organism response. The plan should include provision for all milk to be suitably treated (for example pasteurised, double pasteurised or acidified) should the need arise. Manufacturers should expect that during an incursion response the manufacture of raw milk products will be suspended and manufactured product may be condemned or require reprocessing with a defined heat treatment. Having such a plan in place will minimise the interruption to operations.

Labelling

5.23 Labelling

It is recommended that raw milk products are labelled with a voluntary advisory statement to the effect that they contain unpasteurised milk, for example "made with unpasteurised milk". This applies to raw milk products sold or prepared for sale in New Zealand.

This recommendation will be reviewed when Food Standards Australia New Zealand (FSANZ) has completed its work on proposal P1007 Primary Production and Processing Requirements for Raw Milk Products (Australia only). While this is an 'Australia only' proposal any labelling outcomes would apply to Australia and New Zealand

Manufacturers should take note of clause 26 of the Animal Products (Raw Milk Products Specifications) Notice 2009 which state that, by way of explanation—

- a. clause 4 of Standard 1.2.4 of the food standards code requires ingredients to be declared using the common name of the ingredient, or a name that describes the true nature of the ingredient, or if applicable a generic name; and

- b. that requirement means that in relation to food made from raw milk, the ingredient declaration should include a statement that the milk is raw or unpasteurised.

6 Appendix 1: Programme Development and Approval

Amendment 0

March 2010

Process for the development, evaluation and approval of a programme for the manufacture of raw milk products.

Operator
RA / Auditor
NZFSA

Design

Step 1	<p>The operator confirms (to her/his own satisfaction) that the intended product is likely to be an acceptable raw milk product based on available data indicating that—</p> <ul style="list-style-type: none"> (i) the process doesn't include pathogen elimination of at least log⁵ (ii) the product is not liquid drinking milk and does not contain colostrum (iii) the product is expected to meet Food Safety Criteria (from the Specifications) and microbiological limits (from the Food Standards Code) 	
Step 2	<p>Defining the manufacturing process and drafting programme outline</p> <p>The programme operator—</p> <ul style="list-style-type: none"> (i) determines the manufacturing conditions, the compositional characteristics of the product and sets out a process flow for each intended raw milk product (ii) develops a HACCP Plan (as for all dairy processing) (iii) determines the Operator Defined Process Measures (iv) undertakes all other general steps required for dairy processing (v) prepares an initial draft of the Programme/Programme amendment 	

Confirm

Step 3	<p>The operator confirms the product is a valid raw milk product. This requires evidence that the nature of the product and the processes used in its manufacture meet the requirements of the Notice and ensure that the product</p>	
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Method 1	<p>meets the Food Safety Criteria (from the Specifications) and microbiological limits (from the Food Standards Code).</p> <p>This can be done in several ways, including:</p> <p>The operator confirms that the product meets the compositional acceptance criteria set out under 8.3.3, Method 1 in Appendix 3 of this Code of Practice.</p>
Method 2	<p>The operator uses a predictive mathematical model that is accepted by NZFSA as valid for the purpose. It is possible that such a model may only validate the suitability of the product and process for some rather than all pathogens of interest. For the remaining pathogens one of the other validation options will be required.</p>
Method 3	<p>The operator undertakes (or commissions) a challenge study to validate the suitability of the product/process following the NZFSA guideline.</p>
Method 4	<p>The operator obtains reliable information that demonstrates the suitability of the product and process. Such data may come from variety of sources including:</p> <ul style="list-style-type: none"> (i) other manufacturers (ii) papers published by research or academic organisations (iii) the operator's experience with a similar process and product

Complete Programme

Step 4	<p>Operator completes development of the Programme or Programme amendment, incorporating:</p> <ul style="list-style-type: none"> (i) manufacture of raw milk products in the scope (ii) identification of the raw milk product(s) to be manufactured, and for each <ul style="list-style-type: none"> a. the process flow, and b. identification of the Operator Defined Process Measures and the management controls associated with each (what measurement is made at what point, and the criteria for accept/reject decisions) (iii) appropriate controls regarding the raw milk supply (iv) the additional manufacturing requirements from the Notice and Code specifying labelling text to meet requirements.
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Evaluate

Operator
 RA / Auditor
 NZFSA

Step 5	Operator submits the Programme or Programme amendment to an NZFSA recognised auditor/evaluator.	Operator
	Evaluator assesses the Programme or Programme amendment against all relevant requirements.	RA / Auditor
	Evaluator provides the Operator with an evaluation report including a recommendation.	RA / Auditor
	If the evaluation report indicates that more work is required the Operator addresses the issues (and/or goes back through Steps 1-4) to remedy the deficiencies if necessary) and then submits the revised Programme or Programme amendment at Step 5. If the evaluation report indicates the Programme is recommended for registration the Operator proceeds to Step 6.	Operator

Register

Step 6	Operator applies to NZFSA to have the Programme or Programme amendment registered.	Operator
Step 7	NZFSA considers the application and, if satisfied with the application, registers the Programme.	NZFSA

Manufacture Commences

Step 8	The operator may commence manufacture, adhering to the procedures set out in the programme and undertaking final confirmation of programme validity under routine processing conditions. During this period the operator must follow the start-up protocol provisions, that is: (i) no product is to leave the operator’s control until all data related to the batch has been received and confirmed as acceptable, including all test results and measures to confirm that the operator defined process measures were applied correctly; (ii) sampling and testing is undertaken in accordance with 8.3.4 of Appendix 3; (iii) the operator accepting the commercial risk should the process not be confirmed as valid, in which case:	Operator
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Operator
 RA / Auditor
 NZFSA

	<p>a. the product subject to the protocol is deemed non-conforming and must not be released for human consumption, and</p> <p>b. depending on the segregation controls in place, any other products that may also be affected are also deemed non-conforming and managed accordingly;</p> <p>(iv) no product manufactured during the start-up confirmation period is directed to export.</p>	
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Verify

Ongoing	The operator ensures that on-going audit/verification of the Programme occurs at the required frequency.	
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7 Appendix 2: Monitoring Criteria for Raw Milk Products

Amendment 0

March 2010

Table 1: Monitoring criteria and acceptance limits for individual farm dairy raw milk supplies

Species	Parameter	Sample	Minimum Frequency	Acceptable Limit
Bovine	Somatic cell count ¹	Farm dairy bulk milk tank at time of collection or acceptance	One test per week per farm	400,000 cells/ml.
Other	Somatic cell count ¹	Farm dairy bulk milk tank at time of collection or acceptance	One test per week per farm	1,000,000 cells/ml.
All	Aerobic plate count at 30°C/72 hours or Bactoscan®	Farm dairy bulk milk tank at time of collection or acceptance	One test per week per farm	100,000 cfu/ml.
All	<i>E coli</i>	Farm dairy bulk milk tank at time of collection or acceptance	One test per week per farm	100 cfu/ml.
All	<i>L monocytogenes</i>	Farm dairy bulk milk tank at time of collection or acceptance	According to operator's programme	Set by the operator

¹ Except in situations where all milking animals are monitored for somatic cells using a suitable test with results recorded and milk discarded when above the applicable acceptance limit.

Table 2: Monitoring criteria and acceptance limits for raw milk at the start of manufacture

Species	Parameter	Sample	Standard Frequency ²	Acceptable Limit
All	APC	Representative sample of each bulk raw milk silo taken at the time of use	Each raw milk silo at the time of manufacture	300,000 cfu/ml
All	<i>E coli</i>	Representative sample of each bulk raw milk silo taken upon receipt once contents are mixed	Each raw milk silo	100 cfu/ml
All	<i>L monocytogenes</i>	Representative sample of each bulk raw milk silo taken upon receipt once contents are mixed	Each raw milk silo	Set by the operator (Absence in 1ml. unless evidence to support an alternative)

² Operator may be able to justify a reduced frequency once sufficient data has been obtained.

Table 3: Microbiological monitoring of raw milk products

Parameter	Sample	Standard Frequency	High Frequency	Acceptable Limit
<i>E coli</i>	Raw milk product	one sample per lot	one sample per process run or make	100 cfu/g
<i>L monocytogenes</i>	Raw milk product	one sample per lot	one sample per process run or make	Absence in 5 x 25g (tested as a composite)
<i>Coagulase positive Staphylococci</i>	Raw milk product ³	one sample per lot	one sample per process run or make	1,000/gm (refer to Staphylococcal enterotoxins)
Staphylococcal enterotoxins	Raw milk product	When <i>Coagulase positive Staphylococci</i> exceeds 1,000/gm	When <i>Coagulase positive Staphylococci</i> exceeds 1,000/gm	Not detected in 5 x 25g
<i>Salmonella</i>	Raw milk product	one sample per lot	one sample per process run or make	Absence in 5 x 25g (tested as a composite)

³ It is critical that sampling and testing are performed in a way that accurately estimates the maximum number of coagulase positive Staphylococci reached during the manufacture and/or life of the product.

8 Appendix 3: Options for Confirming Programme Validity

Amendment 0

March 2010

8.1 Introduction

Operators must confirm that the product, when manufactured in accordance with the documented process using raw milk harvested and transported in accordance with a programme that satisfies this Code and the Notice, will consistently meet applicable food safety criteria and conforms to the definition of a raw milk product. This requires evidence that the nature of the product and the processes used in its manufacture meet the requirements of the Notice and will ensure that the product meets the Food Safety Criteria in the Specifications and microbiological limits contained in the Food Standards Code.

Conformation of validity also requires the assumptions made in the design of a process to be confirmed, such as the ability for a process to operate as described and to have the intended effect on the raw milk, dairy material or product.

It is recognised that the suitability of raw milk product manufacturing processes can be confirmed in several ways. Four acceptable methods are described under 8.3.3.

8.2 Confirming a product is a raw milk product

The first step is for the operator to confirm (to her or his satisfaction) that the intended product is likely to be an acceptable raw milk product based on available data, that is:

- a. the process doesn't include validated pathogen elimination of at least log⁵
- b. the product is not liquid drinking milk and does not contain colostrum
- c. the product is expected to meet Food Safety Criteria (from the Specifications) and microbiological limits (Food Standards Code and DPC1 product safety limits).

8.3 Confirming suitability

8.3.1 Raw milk harvesting, storage and transport

For raw milk harvesting, storage and transport the standard principles for confirming programme suitability are to be applied in the same manner as when the milk is intended for heat treated products.

8.3.2 Manufacture

Operators must confirm that the ODPMs as set out in the programme are sufficient to produce a conforming raw milk product. Four methods for confirming the suitability of a dairy product and the associated manufacturing process are set out under 8.3.3. An operator may be able to “mix and match” in order to satisfy the confirmation requirements. For example, a mathematical model may be able to demonstrate safety for some pathogens (method 2), challenge study data may be available for some pathogens under conditions replicating the process (method 3), and a scientific study may be available with sufficient data to that confirm that remaining pathogens will be controlled appropriately.

It should be noted that these are provided to assist operators and are only applicable to a programme for the manufacture of raw milk products.

The operator must also confirm the suitability of the full programme, including the ability to monitor and maintain control of the process as described in the programme.

For further information it is recommended that operators refer to the Codex “Draft Guidelines for the validation of food safety control measures” and the Risk Management Programme Manual for Animal Product Processing, Section 4 *Checks and Validation* available on the NZFSA website at:

<http://www.nzfsa.govt.nz/animalproducts/publications/manualsguides/rmp/rmp-manual/index.htm>

8.3.3 Options for confirming suitability of a manufacturing programme

Method 1

The operator confirms that the product meets at least one of the following compositional criteria throughout its shelf life:

Parameter	Compositional Criteria
pH	less than 4.4
Salt in moisture	Greater than 10%
Water Activity (Aw)	Less than 0.92

Method 2

The operator uses a predictive mathematical model that is acceptable to NZFSA as valid for the purpose. It is possible that such a model may only confirm the suitability of the product and process for some rather than all pathogens of interest. For the remaining pathogens one of the other validation options will be required.

Currently there are models under development; however access to sufficient, reliable data limits may restrict the practicality of this option for some time.

Method 3

The operator undertakes (or commissions) a challenge study to validate the suitability of the proposed product and process. It is recommended that operators discuss the suitability of this option with their evaluator, auditor or NZFSA before committing to such a study.

Method 4

The operator obtains reliable information that demonstrates the suitability of the proposed product and process. Such data may come from variety of sources including:

- current manufacturers (domestic or international)
- papers published by reputable research or academic organisations
- the operator's experience with a similar product and process.

General note

Regardless of the method elected to confirm suitability the operator must accept all commercial risk should the process fail to be confirmed as valid, in which case manufacture of the product must cease and previously manufactured product will be deemed non-

conforming and must be managed accordingly. Depending on the segregation controls in place, other product may also be affected and deemed non-conforming regardless of any heat treatment it may have received or may require additional testing to confirm conformance.

8.3.4 Monitoring during the manufacture confirmation period (“start-up protocol”)

During the confirmation period all process controls, including the OPDMs, must be monitored to confirm that the parameters and acceptance tolerances set out in the programme are appropriate and are met. The operator must also review all procedures outlined in the programme and confirm that they are being undertaken and records maintained as required.

Both the raw milk and the final product are to be sampled and tested for each parameter in column one of Table 3 in Appendix 2. Sampling is to be at the high frequency as shown in column four.

For the raw milk, a representative (mixed) sample is to be taken from each raw milk silo after mixing but prior to manufacture commencing.

Final product is to be sampled and tested according to the requirements and frequency shown in column four. Sampling and testing for coagulase positive Staphylococci must accurately estimate the maximum number expected to be present throughout the shelf life of the product when stored according to label conditions.

The start-up confirmation protocol continues in place until such time as there is sufficient evidence to show that pathogens, when present in the raw milk, are controlled and food safety criteria will be consistently met.

Further information on the development and content of a protocol for confirming the validity of a programme can be found in Section 4.4 of the Risk Management Programme Manual, available at: <http://www.nzfsa.govt.nz/industry/general/rmp/documents/manuals/risk-management-programmes/amdt-3.pdf>

Once the programme auditor or verifier confirms in writing that sufficient data has been obtained and that the start-up confirmation period is complete the operator can reduce from high frequency sampling to standard frequency, as set out in column three of Table 3 in Appendix 2.

8.3.5 Control of product during the confirmation period

The operator must have procedures to ensure that product manufactured during the confirmation period-

- a. does not leave their control until all microbiological test results related to the batch have been received and are within acceptance limits
- b. is not exported.