Ministry for Primary Industries
Manatū Ahu Matua

Animal Products Notice

Manufacture of Dairy Based Infant Formula Products and Formulated Supplementary Foods for Young Children

23 June 2022

Issued under the Animal Products Act 1999

New Zealand Government

TITLE

Animal Products Notice: Manufacture of Dairy Based Infant Formula Products and Formulated Supplementary Foods for Young Children

COMMENCEMENT

This Animal Products Notice comes into force on 1 July 2022.

ISSUING AUTHORITY

This Animal Products Notice is issued under section 167(2) of the Animal Products Act 1999 and supplements the Animal Product Regulations 2021.

Dated at Wellington, 23 June 2022

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(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) The purpose of this Notice is to supplement the Animal Products Regulations 2021 by specifying particular requirements that apply to the manufacture and verification of the following products (referred to in this Introduction and the Notice as "relevant products"):

a) Dairy based infant formula products (i.e., infant formula and follow-on formula):
b) Dairy based formulated supplementary foods for young children:
c) Dairy based ingredients represented as intended for use in any of those products (other than ingredients that comprise less than 5% of the final product).

Background

(1) The Animal Products Act 1999 establishes a regime for ensuring that animal products are fit for their intended purpose.

(2) The Animal Products Regulations 2021 set out the details of that regime.

(3) The World Health Organisation recommends that infants should be exclusively breastfed for the first 6 months of life to achieve optimal growth, development and health. Thereafter, to meet their evolving nutritional requirements, infants should receive nutritionally adequate and safe complementary foods while breastfeeding continues. In instances where an infant is unable to be breastfed, or where breastfeeding is not appropriate, a suitable breast-milk substitute should be used. Infant formula products are the only suitable breast-milk substitutes. The New Zealand Ministry of Health also provides guidance on the feeding of infants.

(4) As infant formula can be the sole source of nutrition for a vulnerable population group, particularly for infants aged up to 6 months, greater food safety monitoring and oversight is appropriate and generally expected. Infants and young children have special nutritional needs and a less developed immune system than healthy adults.

(5) Infant formula products, formulated supplementary foods for young children, and ingredients intended for use in those products are of high interest in international trade. Consumers reasonably expect New Zealand to ensure that all parties in the supply chain:

a) are held accountable for the fitness for purpose of products offered for sale; and
b) fulfil their responsibilities and play an appropriate role should any problems be detected.

(6) This Notice promotes consistency in the application of risk management measures applied to the production and processing of relevant products by imposing specific requirements relating to the premises and equipment used, the control of inputs, the formulation of the products, product and environmental testing, tracing, and verification and evaluation of manufacturing processes.

Who should read this?

(1) This Notice should be read by:

a) an operator of an RMP that covers the manufacture of relevant product:
b) dairy processors who manufacture relevant product:
c) dairy processors who repack and/or relabel outer packaging of relevant product:
d) dairy processors who store or transport the following product:

i) inputs intended for relevant product; or
ii) relevant product; or

e) evaluators and verifiers of risk management programme (RMP) of manufacturers of relevant product.

Why is this important?

(1) For the purposes of section 135 (1)(c) of the Animal Products Act 1999, a failure to comply with this Notice, without reasonable excuse, is an offence.

Other information

(1) The requirements in this Notice are additional to other relevant requirements that apply to dairy processors, such as:

a) the Animal Products Notice: Production, Supply and Processing;
b) the Animal Products Notice: Export Requirements for Infant Formula Products and Formulated Supplementary Foods for Young Children, issued 1 February 2016;
c) the Animal Products Notice: Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Food for Young Children, issued 28 February 2022;
d) market-specific requirements issued as overseas market access requirements (OMARs) under Part 5 of the Animal Products Act 1999; and
e) the Australia New Zealand Food Standards Code.

Part 1: Requirements

1.1 Application

(1) This Notice applies to the processing of the following (referred to as **relevant products**) whether it is final product or is in the process of manufacture:

a) dairy based infant formula for infants aged up to 6 months;
b) dairy based follow-on formula for infants aged 6 months to 12 months;
c) dairy based formulated supplementary food for children aged between 12 months to 36 months;
d) any dairy material or dairy product intended for use in any of those products (unless it will comprise less than 5% of the final product).

(2) Note that:

a) Parts 2 to 6 apply to dairy manufacturers operating under an RMP; and
b) Part 7 applies to certain other dairy processors, whether or not they operate under an RMP.

1.2 Definitions

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

Act means the Animal Products Act 1999

adequate means sufficient to accomplish the intended purpose

batch means a homogenous quantity of relevant product manufactured during a discrete period of time as part of one continuous process

buffer zone means the area in front of any entrance to a high hygiene area (as defined in this clause) that physically separates the high hygiene area from any non-high hygiene area

CIP means cleaning in place

contact surface means any surface that comes, or may come, into contact with relevant product or ingredients, and includes the surfaces of equipment and packaging

critical parameter means a parameter that is measured (such as of weight, time, or temperature) and is identified in an RMP as critical for the purpose of ensuring the safety, integrity and fitness for purpose of final product, and forms part of a critical measurement as defined in the Regulations

dry area means any area where dry ingredients or dry relevant products:

a) are or may be exposed to the processing environment; and
b) will not subsequently be heat treated

equipment –

a) means the whole or any part of a utensil, machine (including a vending machine), fitting, device, instrument, stamp, apparatus, table, article, or other thing that is used or intended for use in relation to the manufacture of relevant product; and
b) includes a utensil or machine that is used or intended for use in cleaning or sanitising equipment or facilities

final product means relevant product, whether packaged or not, in the form in which it is intended to leave the premises

follow-on formula means an infant formula product represented as either a breast milk substitute or replacement for infant formula and which constitutes the principal liquid source of nourishment in a progressively diversified diet for infants aged from 6 months

formulated supplementary food means a food specifically designed as a supplement to a normal diet to address situations where intakes of energy and nutrients may not be adequate to meet an individual's requirements

formulated supplementary food for young children means a formulated supplementary food for children aged between 12 months to 36 months

heat treated means being subject to a heat treatment, at least equivalent to pasteurisation, that is a defined heat treatment or has been validated in accordance with clause D3.19 of the Animal Products Notice: Production, Supply and Processing as if it were a defined heat treatment

high hygiene area means any of the following areas where relevant product is manufactured:

a) dry areas (as defined in this clause):
b) wet areas where relevant product that will not subsequently be heat treated is exposed:
c) any other area where ingredients that will not subsequently be heat treated are exposed:
d) any other area that the manufacturer designates in the RMP as a high hygiene area for the purpose of this Notice

infant formula means an infant formula product 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

manufacture means the process of converting dairy material or dairy product into relevant product, and –

a) includes all associated activities such as the following:
    i) receiving inputs:
    ii) cleaning and maintaining equipment used during processing:
    iii) packing, storing, and applying labels to final product
b) does not include –
    i) harvesting, filtering, cooling or storing raw milk at a farm dairy:
    ii) storing dairy material or dairy product where the only processing undertaken is storage and temperature control:
    iii) the placing of packaged final product into outers

manufacturing area means:

a) all high hygiene areas; and
b) any other areas where inputs (packaged or unpackaged) are exposed

outers means a container or anything used to enclose packages of final product

package, in relation to ingredients or final product, means a container (whether a bulk container or a retail-ready container) that is in direct contact with the ingredient or final product, but not including containers that are used temporarily to hold ingredients or relevant product during manufacture

packing (as a verb) means the part of the manufacturing process that involves putting final product into a package; but does not include putting those packages into larger containers

packaging includes, for the purposes of this Notice, packages, anything used to enclose packages, and anything packed with final product (such as scoops and re-closure lids)

records means any written record, whether in hard copy or electronic

retail-ready means final product that is packed in the package in which it is intended to be sold to consumers

validation means the process described in Regulation 34(1)

wet area means any area liquid dairy material or liquid dairy product is processed.

(2) Any term defined in the Act, the Regulations, or the Animal Products Notice: Production, Supply and Processing and used in this Notice but not defined in this notice has the same meaning as in the Act, Regulations, or the Animal Products Notice: Production, Supply and Processing.

Part 2: Premises, equipment and personnel

2.1 Application of Part

(1) This Part applies to the processing of relevant product under an RMP that is not intended to be subsequently heat treated.

2.2 Areas to be identified in RMP

(1) Every RMP must identify all of the following:

a) the boundaries of the manufacturing area and any other areas used in association with the manufacture, handling and storage of relevant product; and
b) the boundaries of the high hygiene areas within the manufacturing area, and the function of each high hygiene area (e.g. wet areas, dry areas or buffer zones); and
c) the demarcation point between any wet area and any dry area, which must be a point at which the relevant product can reasonably be considered to be dry.

2.3 Design and construction of manufacturing areas

(1) The manufacturing area must be laid out in a way that provides an orderly process of manufacture of final product.

(2) There must be adequate space in manufacturing areas to enable manufacturing, cleaning, maintenance and inspection to be undertaken effectively.

(3) All interior building surfaces (such as walls, doors, windows, floors and ceilings) in manufacturing areas must:

a) be smooth (other than floors); and
b) be durable, resistant to fracture, and free from cracks, crevices and open joints, and minimising ledges; and
c) not enable dust and waste material to accumulate, including in wall cavities or under floors; and
d) not be a source of physical, chemical, or biological contamination.

(4) The floors of all manufacturing areas must:

a) be made of impervious material, which will withstand mechanical wear and damage; and
b) be crevice free and sealed and (in wet areas) sloped so that they are easily cleaned; and
c) be free-draining or dry readily.

(5) Where services such as pipes, wiring and ducting pass through the walls, ceilings, or floors of manufacturing areas, the gap must be sealed using appropriate materials on both the interior and exterior surfaces to prevent the entry of pests and the accumulation of dust, contaminants and (in the case of dry areas) moisture.

(6) Drains in manufacturing areas must be of adequate size and sanitary design and must not present a contamination risk.

2.4 High hygiene areas

(1) The high hygiene areas within a manufacturing area are those areas where the highest level of protection from environmental contamination is necessary in order to ensure the safety and fitness for purpose of relevant products.

(2) Each high hygiene area must be physically separated (e.g. by a wall that extends floor to ceiling or other equally effective barrier) from non-high hygiene areas, unless:

a) the manufacturer has in place a procedure that has been validated in accordance with Regulation 34; and
b) the RMP operator holds the validation information that shows the procedure is as effective as physical separation at preventing contamination of high hygiene areas.

(3) Wet areas and dry areas must by physically separated, unless:

a) the manufacturer has in place a procedure that has been validated in accordance with Regulation 34; and
b) the RMP operator holds the validation information that shows the procedure is as effective as physical separation at preventing cross-contamination between the wet and dry areas.

(4) Non-potable water lines passing through high hygiene areas must be checked regularly to confirm ongoing integrity.

2.5 Air pressure in high hygiene areas

(1) High hygiene areas must be maintained under positive air pressure at all times, except as provided in clause 3.5.

(2) Air flowing into high hygiene areas must be filtered and purified (as required) to reduce moisture, contaminants and odours to acceptable levels.

(3) Air flow must be effectively managed in high hygiene areas and must:

a) provide adequate ventilation and exhaust systems as necessary; and
b) ensure that the systems controlling air flow are designed and constructed to minimise the risk of contamination.

(4) Ventilation systems must be periodically checked to ensure that design pressures are being maintained within documented tolerances in the RMP.

(5) Inspection and maintenance procedures must be established to ensure air filtration is and remains effective, and that the air is appropriate to the particular high hygiene area.

2.6 Entry to high hygiene areas through buffer zone

(1) A buffer zone must be provided that physically separates high hygiene areas from other non-high hygiene areas.

(2) A buffer zone that allows a person to enter a high hygiene area must be designed to enable the person to change into protective clothing and footwear before entering the high hygiene area.

(3) A buffer zone is not required if:

a) the manufacturer has in place a procedure that has been validated in accordance with Regulation 34; and
b) the RMP operator holds the validation information which shows the procedure is as effective as subclause (1) and (2) at ensuring high hygiene areas are protected from the entry of pathogens or other contaminants, including those associated with people (clause 2.7) or items (clause 2.8).

2.7 People entering high hygiene areas

(1) A person may enter a high hygiene area only if the person:

a) is wearing clean protective outer clothing and footwear that:

i) is worn only in the high hygiene area or adjacent buffer zone; and
ii) is identified in the RMP as appropriate for that specific high hygiene area; and

b) has washed, dried and sanitised their hands in the adjacent buffer zone, or washes, dries and sanitises them immediately on entering the high hygiene area (providing it is not a dry area); and
c) passes through a buffer zone.

2.8 Items entering or exiting high hygiene areas

(1) All inputs and other items (such as tools and equipment, maintenance compounds and other chemicals) entering a high hygiene area must enter via a buffer zone.

(2) A buffer zone that allows for the entry of inputs and other items must be set up as an airlock, UV tunnel or any other suitable arrangement provided that the buffer zone ensures that the inputs and other items do not contaminate the environment of the high hygiene area.

(3) A buffer zone that allows the exit of items must be designed to ensure that the high hygiene area is protected from contamination.

(4) If a buffer zone that controls the entry or exit of items into or out of the high hygiene area in rapid succession, and the buffer zone is not set up as an airlock, the opening into or out of the high hygiene area must be the minimum size necessary to allow the passage of the items and, when not in use, steps must be taken to protect the high hygiene area from contamination.

(5) Any other items entering a high hygiene area must be:

a) clean and, if practicable, sanitised before entry; and
b) accounted for at all times.

(6) Gases (including steam and compressed air) used in high hygiene areas must be suitably filtered or purified to eliminate contaminants, and the RMP must set out:

a) procedures for the periodic confirmation that all gases are of suitable quality; and
b) the procedures, and records to be kept, if problems are detected.

(7) Wood must not be used in or introduced into high hygiene areas unless all of the following are met:

a) there is no practical alternative;
b) the use of wood is reviewed to confirm that it will not pose a contamination risk;
c) the wood is inspected to ensure it is in good condition and meets the criteria in the RMP for ensuring that high hygiene areas are protected from contamination;
d) the people coming into contact with the wood have no direct contact with inputs or relevant product;
e) the procedures for handling and inspecting the wood are documented and confirmed to be effective.

2.9 Specifications for dry areas

2.9.1 Physical separation of dry areas

(1) Any dry area within a high hygiene area must be physically separated from other parts of the high hygiene area, unless:

a) the manufacturer has in place a procedure that has been validated in accordance with Regulation 34; and
b) the RMP operator holds the validation information that shows the procedure is as effective as physical separation at keeping water, moisture, dust and other sources of potential contamination out of the dry area.

2.9.2 Air temperature

(1) In dry areas, the air temperature must be maintained at a level that ensures that:

a) inputs and relevant products are not adversely affected; and
b) personnel working in the area are not affected in a way (for instance, by sweating) that could adversely affect the product.

(2) The RMP must set out the acceptable limits of air temperatures for dry areas.

2.9.3 Relative humidity

(1) In dry areas, the maximum relative humidity must not exceed:

a) 65%; or
b) a higher limit set out in the RMP.

(2) A manufacturer may only adopt a higher alternative maximum relative humidity in subclause (1)(b) if:

a) the higher relative humidity level is unavoidable; and
b) a validation in accordance with Regulation 34 has confirmed that the higher level will not adversely affect the final product.

2.9.4 Deviations from air temperature or humidity requirements

(1) The RMP must set out the steps to be taken if the air temperatures or relative humidity deviate from the levels specified in this Notice or the RMP.

(2) Relevant product that is in process when the air temperature or relative humidity deviates from the specified levels may still be treated as conforming product if:

a) an investigation by the manufacturer confirms that the product has not been adversely affected by the deviation; and
b) the manufacturer took the steps described in the RMP as soon as practicable; and
c) a record of the steps taken is kept.

2.9.5 Cleaning

(1) In dry processing areas, water and liquid cleaning solutions (including alcohol) must not to be used unless:

a) the area ceases production to permit full cleaning, sanitising and drying; or
b) there is no valid alternative, and the solution is securely sealed when not in use, and the use is documented.

2.9.6 People entering dry areas

(1) Before a person enters a dry area from any place that is not another dry area, the person must change outer clothing, in a buffer zone, into outer clothing specifically provided for use in dry areas.

2.10 Construction of CIP systems

(1) Every CIP system must be constructed and operated in such a way that CIP solutions, materials and substances cannot intermix with inputs and relevant product.

2.11 Personnel

(1) A dairy manufacturer must ensure that there are enough suitably skilled people who have the necessary qualifications and practical experience to ensure that the responsibilities and duties placed on any one individual do not compromise the manufacturing process or the final product.

(2) A dairy manufacturer must:

a) have and maintain training procedures and records; and
b) ensure that personnel who work in high hygiene areas have additional training on the specific contamination risks in high hygiene areas.

2.12 Equipment

(1) Equipment in manufacturing areas must be used only for its intended purpose.

(2) Equipment or area that is used to manufacture a product that is not intended for human consumption and will not meet human consumption conformance standards must not be used in the manufacture of relevant product unless:

a) the equipment or area has undergone comprehensive cleaning and sanitising before it is used to manufacture relevant product; and
b) the cleaning and sanitising procedure has been validated to confirm that a suitable level of hygiene has been achieved.

(3) All equipment in the manufacturing area must be designed and fabricated using materials that allow for regular cleaning, sanitising and maintenance of both the internal and external equipment surfaces.

(4) The following surfaces of equipment in the manufacturing area must be made of materials that will not adversely affect final relevant product:

a) contact surfaces:
b) any other surface that comes into contact with any water, steam, gas, or cleaning solution that comes, or may come, into contact with relevant product or ingredients.

Part 3: Cleaning and maintenance

3.1 Application of Part

(1) This Part applies to the processing of relevant products under an RMP.

3.2 Cleaning procedures

(1) Every dairy manufacturer must have cleaning procedures that ensure that premises and equipment are cleaned and maintained to a standard appropriate for the nature of the processes undertaken at the premises.

(2) The cleaning procedures must identify all of the following:

a) the equipment and places to be cleaned;
b) the frequency for each type of cleaning, sanitising or maintenance activity including CIP, clean out of place and manual cleaning;
c) the cleaning cycle (for example, rinse-alkali-rinse-acid-drain) for equipment;
d) the maintenance compounds used to clean, sanitise and maintain, along with the permissible range of chemical strengths and the means by which the strength is confirmed (for example, conductivity sensors);
e) the equipment required to be manually cleaned or cleaned out of place;
f) the equipment and areas to be dry cleaned, and the cleaning procedures and materials to be used;
g) which cleaning, sanitising and maintenance items are permitted in the manufacturing area;
h) how maintenance may or must be undertaken;
i) which process lines must be cleared between batches when dried powders are processed;
j) the means by which the effectiveness will be confirmed.

(3) The cleaning procedures must ensure that all of the following are met:

a) manufacture in a dry area can only commence once the area and the equipment in it are confirmed to be dry;
b) cleaning and maintenance items are labelled and stored correctly;
c) where equipment is used to produce successive batches of the same relevant product, the equipment is cleaned sufficiently often to ensure that there will be no degradation of material or accumulation of material (such as fat, protein or biofilms) on or in the equipment;
d) the cleaning process will restore the environment and all equipment to the required hygienic state, without adversely affecting adjacent areas;
e) equipment in high hygiene areas that is not in routine use is maintained in an adequate hygienic state that prevents contamination of the environment, equipment and relevant product in the high hygiene area;
f) records of all cleaning, sanitising and maintenance undertaken show (as appropriate) the date, time, equipment, cleaning circuit and the person who performed or initiated the cleaning.

(4) The cleaning procedures must be validated in accordance with Part 6 of this Notice.

3.3 Specifications for CIP systems

(1) The cleaning procedures must:

a) describe the performance characteristics of the CIP system; and
b) set out how the dairy manufacturer determines whether the CIP system is functioning as intended.

(2) Dry compounds used in a CIP system for cleaning or flushing must:

a) be food grade; and
b) be subject to periodic checks at a frequency specified in the cleaning procedures, to ensure the compounds do not become a source of contamination.

3.4 Monitoring effectiveness of cleaning

(1) The RMP must set out:

a) how often cleaning effectiveness under routine processing conditions is monitored; and
b) the steps to be taken when the measurement of critical parameters relating to cleaning are not complied with.

(2) Routine checking of cleaning effectiveness is to be directed to areas or points in the process where contamination or inadequate cleaning is more likely to occur.

(3) A dairy manufacturer must have procedures that ensure any failure to apply effective cleaning, as required by the RMP, is recorded, investigated and remedied as soon as possible.

3.5 Maintenance in high hygiene areas

(1) Maintenance within a high hygiene area must be undertaken only in accordance with procedures set out in the RMP, and those procedures must ensure:

a) that the entry of maintenance items into high hygiene areas is controlled so that the entry of foreign matter and pathogens, and (in dry areas) moisture, is minimised (by, for example, cleaning and sanitising the items); and
b) that steps are taken to minimise dust being generated within high hygiene areas; and
c) that all maintenance items taken into high hygiene areas during maintenance are accounted for after the work is completed; and
d) if normal air pressure and air flow requirements cannot be maintained during the maintenance work, that after the work is complete the air pressure and air flow requirements are re-established and checked before manufacture recommences; and
e) that records of all maintenance work are kept.

3.6 Environmental pathogen monitoring plan

(1) For high hygiene areas where relevant product is or may at any time be processed, the environmental pathogen monitoring plan must provide for the ongoing monitoring of environmental samples for Salmonella spp.

(2) For high hygiene areas where infant formula, or relevant product intended for infant formula (i.e. product intended for infants aged up to 6 months) is or may at any time be processed, the environmental pathogen monitoring plan must provide for the ongoing monitoring of environmental samples for *Cronobacter* spp, directly or Enterobacteriaceae as an indicator for *Cronobacter*, regardless of whether that product is being manufactured at the time.

(3) In the event that Enterobacteriaceae is used as an indicator for *Cronobacter* and an unfavourable result is identified, the operator must take action as specified in the environmental pathogen monitoring plan. This must include testing directly for *Cronobacter* in place of Enterobacteriaceae.

(4) The environmental pathogen monitoring plan must also provide for the monitoring of:

a) air quality (by using, for instance, exposure plates for relevant hygiene indicators); and
b) product contact surfaces (such as wet or dry swabs as appropriate from strategic locations, or powder residue samples when equipment is opened for cleaning, inspection or maintenance); and

c) non-contact surfaces (such as swabs or dust/powder samples from a selection of different locations throughout the processing area at different times).

(5) Any sampling procedures set out in an environmental pathogen monitoring plan must avoid bias, such as in the timing of sampling.

3.7 Maintenance compounds and other chemicals

(1) Dairy manufacturers must keep records of all maintenance compounds used.

(2) No unlabelled chemicals and solutions, including water in a container, may be present in manufacturing areas.

(3) Other chemicals may be used within a manufacturing area only in accordance with procedures set out in the RMP, and must be stored at locations identified in the RMP when not in use.

(4) Containers of maintenance compounds or other chemicals that are suitable for re-use may be reused only to store the same compound or chemical.

(5) In this clause, "other chemicals" includes any compound that is not an ingredient or maintenance compound, but that is used in connection with the manufacture of relevant product (such as the ink used on packages).

3.8 Pest management

(1) As part of the pest control procedures required under clause C1.12(2) of the Animal Product Notice: Production, Supply and Processing, a dairy manufacturer must include procedures that ensure high hygiene areas are only operated in a manner that prevents the entry of pests.

(2) The RMP must set out a schedule of inspection for pest activity and the required response to findings of pests or evidence of pests.

(3) If pest control stations are used, dairy manufacturers must:

a) comply with procedures that ensure that pests are removed from pest control stations at a frequency appropriate to the target pest; and
b) keep a record of observations relating to pest incursions.

3.9 Waste

(1) Waste must be removed from high hygiene areas regularly, and until removal, must be suitably contained and clearly labelled.

3.10 Protection from intentional adulteration

(1) The RMP operator must ensure that the RMP includes a plan for the protection of relevant product from contamination through intentional adulteration.

3.11 Safeguards against presence of foreign matter

(1) Every RMP must describe how the dairy manufacturer safeguards final product from the presence of foreign material during manufacture, and the measures taken to test for the presence of foreign material (such as, using sifters or filters, inline magnets, metal detectors, or x-ray).

(2) If a dairy manufacturer uses calibration control items such as test pieces or similar to confirm either on-going calibration of equipment or whether the safeguards are effective, then:

a) the test pieces must be clearly labelled and controlled to ensure they do not end up in final product; and
b) the size of the test pieces must be recorded; and
c) when validating equipment performance, any test pieces used must be located at the point where they will be most difficult to detect.

(3) If foreign material is found in relevant product during manufacture then, in addition to the actions required for non-conforming product, the frequency of sampling and testing must be reviewed and, if necessary, increased to ensure that non-conforming product is identified.

3.12 Calibration

(1) In addition to clause C1.10 of the Animal Products Notice: Production, Supply and Processing, RMPs must identify which equipment is used to measure critical measurements.

(2) A dairy manufacturer must:

a) ensure the calibration status of equipment used to measure critical measurement is clearly indicated and verifiable; and
b) maintain records of all required calibrations.

(3) If critical measurements are found to have been measured using equipment that does not have a current calibration, is not accurate, is no longer functioning as intended or has been subjected to unauthorised adjustments, then the dairy manufacturer must do the following:

a) investigate the matter;
b) report the non-compliance to the RMP verifier in accordance with Chapter D, subpart 3 of the Animal Products Notice: Production, Supply and Processing;
c) comply with clause 3.13(3).

3.13 Failure to meet dairy conformance standards

(1) Any failure to apply effective cleaning that results in, or may result in, relevant product being adversely affected must be reported to the RMP verifier in accordance with Chapter D, subpart 3 of the Animal Products Notice: Production, Supply and Processing, with records of all such failures retained by the dairy manufacturer.

(2) Any ingredient or relevant product of which the fitness for its intended purpose may have been adversely affected by a failure to clean effectively must be identified and managed as non-conforming product, unless or until the verifier confirms that the ingredient or product is unaffected.

(3) If a relevant product may have been affected by a failure to comply with the requirements for measuring critical parameters, the product must be treated as non-conforming product, unless or until the verifier confirms that the product is unaffected.

Part 4: Inputs and formulation

4.1 Application of Part

(1) This Part applies to the processing of relevant products under an RMP.

4.2 Procurement of inputs

(1) Every dairy manufacturer must:

a) set out in the RMP the acceptance criteria to be used in the selection of inputs and suppliers of inputs; and
b) ensure that a list is kept of accepted suppliers of inputs and the inputs they supply along with a record of the manner in which the suitability of each supplier was confirmed; and
c) ensure that procurement records are kept for each input, showing the intended use of the input and its critical specifications.

(2) To confirm the suitability of inputs, dairy manufacturers must review any associated reports from laboratories accredited to ISO/IEC 17025, certificates of analysis, and declarations from other dairy manufacturers or suppliers of inputs.

(3) Any certificates of analysis, supplier declarations or assurances, or any other documented safeguards used by suppliers to confirm that inputs meet requirements must be retained by the dairy manufacturer to support the dairy manufacturer's determination of suitability.

(4) Dairy manufacturers must ensure that suppliers will consistently supply inputs that are suitable for the intended use. For this purpose, dairy manufacturers must hold relevant information on each supplier of inputs, such as that obtained by carrying out supplier audits, reviewing audits of suppliers by third parties, reviewing equivalent endorsements, or any other appropriate process.

(5) If a supplier fails to meet the dairy manufacturer's acceptance criteria for the input supplied, the dairy manufacturer:

a) must raise the issue with the supplier and record the outcome; and
b) if the acceptance criteria continue not to be met, must deem the supplier to no longer be suitably qualified for the input concerned.

(6) If a supplier is not the person who manufactured the input, the dairy manufacturer must be satisfied that:

a) they know who the original dairy manufacturer of the input is; or
b) they are satisfied the supplier has reliable and robust systems in place to ensure the integrity of inputs.

4.3 Input acceptance

(1) The RMP must set out the procedure for recording the following in relation to the receipt of inputs:

a) the input received and the quantity;
b) who supplied it;
c) when it was received at the premises.

(2) Every RMP must set out the procedures for checking that:

a) inputs are only accepted from suppliers on the list of accepted input suppliers referred to in clause 4.2(1) b); and
b) the integrity of each input consignment has been maintained and its outer packaging has not been compromised; and

c) all inputs used for relevant product meet the dairy manufacturer's acceptance criteria and are fit for purpose.

(3) Dairy material and dairy product intended for inclusion in relevant product must either be:

a) conforming dairy material or product; or
b) dairy material or product for which consent has been obtained from the Director-General under the Animal Products Notice: Disposal of Non-conforming Dairy Material or Dairy Product for the intended use, and all specified conditions have been met.

(4) If an input is received from a supplier with a problem that might adversely affect relevant product (such as having the potential to cause contamination, or having its composition misrepresented), the RMP operator must report the matter to the verifier without delay if the problem with the input could reasonably be expected to:

a) result in relevant product being non-conforming; and
b) affect other dairy manufacturers receiving the product for use in relevant product.

(5) Dairy manufacturers must:

a) identify in the RMP which testing of inputs they will undertake, and when tests will be done; and
b) regularly compare their own test results with any supplier statements concerning the inputs.

(6) Underweight or overweight relevant product, and start of run relevant product, may be treated as conforming material if it is managed in accordance with a process set out in the RMP.

4.4 Milk and other liquid dairy material

(1) Immediately before heat treatment, raw milk used to manufacture relevant product must be no older than 72 hours unless an alternative age, along with any additional control criteria, has been validated in accordance with regulation 34 and is specified in the RMP.

(2) The RMP sampling and testing plan must include the following:

a) the process hygiene tests to be applied at the start of manufacture and the level at which action must be taken, such as aerobic plate count (30°C /72 hours) with a maximum 300,000 cfu/ml;
b) the point of sampling;
c) the frequency of sampling;
d) the actions to be taken if the action level specified under subclause (2)a) are exceeded.

(3) Every RMP must set out procedures and criteria, including time and temperature, for the storage and transport of milk and other liquid dairy material, to ensure it does not deteriorate.

4.5 Storage and unpacking of inputs

(1) Inputs used to manufacture relevant product must be:

a) clearly identifiable at all times; and
b) stored away from things that are poisonous, harmful, odorous, volatile, corrosive, offensive or that might otherwise adversely affect the input or its packaging; and
c) stored in a place and manner that protects the input from contamination and deterioration; and
d) stored in a place and manner that protects the packaging of inputs from damage and deterioration; and
e) adequately spaced so as to permit inspection during storage.

(2) Inputs must not be stored in buffer zones, but may be kept in buffer zones temporarily pending use.

(3) The removal of outer packaging (if any) from inputs, and the decontamination of inputs, must occur before the input enters a high hygiene area, unless:

a) the manufacturer has in place a procedure that has been validated in accordance with Regulation 34; and
b) the RMP operator holds the validation information that shows the procedure is as effective at preventing the introduction of pathogens or other contaminants into a high hygiene area as the removal of outer packaging from inputs and decontamination of inputs before their entry into a high hygiene area.

(4) As far as practicable, the following must be stored apart from each other, in a manner that minimises the risk of cross-contamination and ensures that one thing is not mistaken for another:

a) packaging materials;
b) bulk dairy material;
c) ingredients in concentrated form;
d) maintenance compounds;
e) chemicals not for use as ingredients.

4.6 Ingredient shelf life

(1) For each ingredient, the dairy manufacturer must know and record:

a) its shelf life while in its package; and
b) its shelf life once its package is open (i.e. the shelf life of the unpackaged ingredient).

(2) If a final product has a shelf life that takes it beyond the shelf life of an ingredient (as at the time it is incorporated), the dairy manufacturer must document the justification for the shelf life applied to the product.

4.7 Ingredient management

(1) The RMP must set out procedures to ensure that:

a) any ingredient that will not be further heat treated meets the microbiological limits that apply to the relevant product in which it is used, unless the RMP specifies an alternative microbial limit for that ingredient; and
b) critical nutrients are of known composition, homogeneity and stability so that they will be present at the correct level in the packaged product.

(2) Ingredients that will not be subsequently heat treated may be dispensed only in a high hygiene area.

(3) Ingredients must be weighed, measured and used under conditions that do not adversely affect their suitability for use.

(4) Measuring or subdividing operations that are identified in the RMP as critical must be witnessed or subject to an equivalent form of independent confirmation (such as electronic data logging).

(5) If an ingredient is subdivided for later use, the container holding the ingredient must be suitable and be identified in a manner that enables the following information to be readily determined:

a) ingredient name and/or item code;
b) ingredient batch identifier and expiry date (if any);
c) actual or estimated weight or measure of ingredient remaining.

4.8 Disposal of unused inputs

(1) Any input that does not meet its acceptance criteria or is otherwise unwanted must be identified and stored in a manner that prevents its inadvertent use.

(2) All dairy material or product that is non-conforming or is intended to be redirected to another process must be clearly identified and removed from high hygiene areas as soon as practicable.

(3) Dairy manufacturers must keep records of the following for all inputs that were intended for use in relevant product but are unused (whether because they do not comply with their acceptance criteria, or are unsafe, or for any other reason):

a) the name of the material;
b) the supplier of the material;
c) the batch identifier of the material;
d) the date on which the material was received at the premises;
e) the quantity of material received at the premises on that date;
f) the quantity of unused material;
g) the reason why the material is unused.

(4) Dairy manufacturers must retain control of unused pre-printed packaging through to the point of destruction, unless the packaging is returned to its supplier.

4.9 Formulation

(1) The dairy manufacturer of relevant product is responsible for:

a) determining that each relevant product manufactured at the premises is fit for its intended purpose; and
b) ensuring that the formulation of each relevant product is suitable and uses only ingredients that meet the dairy manufacturer's acceptance criteria identified in clause 4.2(1); and
c) ensuring that the following are confirmed by a suitably skilled person as fit for purpose:

i) the product formulation for each relevant product;
ii) labelling of any retail-ready product;
iii) the market conformance of all relevant products, including in relation to their formulation, ingredients, packaging, labelling and any codings or markings.

(2) In considering the suitability of a formulation, dairy manufacturers must take into account:

a) the ingredients used; and
b) the process, packaging, and packing method, as they relate to shelf life and stability.

(3) The dairy manufacturer must keep a record of:

a) the attributes of each relevant product that are critical to food safety, suitability and regulatory conformance; and
b) any tolerance limits applying to those critical attributes that can be applied when doing routine monitoring; and
c) who provided advice or opinion, and their qualifications, skills and experience, to the dairy manufacturer when the dairy manufacturer was doing the things referred to in clause 4.10(1); and
d) how product suitability and stability is confirmed.

4.10 Records of formulations of final product

(1) Every dairy manufacturer must maintain a history of each final product produced at the dairy manufacturer's premises, by keeping up-to-date records of the following:

a) the name or product code of the product;
b) the intended age range, market and packaging type or types;
c) the formulation recipe and packaged product composition;
d) the tolerance limits for essential nutrients;
e) the specifications for any formulated ingredients (such as base powders and blended ingredients);

f) the processing and packaging method (including, for instance, any use of gases);
g) the label.

(2) The records must be able to be collated so that they can show the full history of the product, including the date on which changes are made to any of the matters listed above.

4.11 Shelf life of final product

(1) The shelf life must be established and validated for:

a) each final product, in each form of packaging in which it leaves the premises; or
b) a representative of each group of final products, in which case the dairy manufacturer must document why the products are treated as a group and the justification for selecting that product as representative of the group for the purposes of establishing shelf life.

(2) The shelf life of a packaged final product may be longer than the shelf life of an ingredient of the product if:

a) the RMP operator determines that final product will be unaffected by the incorporation of the ingredient, during the whole of its shelf-life, by one of the following methods:

i) the proposed use has been validated in accordance with Regulation 34(1) or (2);
ii) an appropriate, independent study or academic paper confirms suitability of the ingredient when used as proposed;
iii) information has been obtained from the manufacturer of the ingredient; and

b) the dairy manufacturer keeps a record of the validation, study or information.

(3) Subject to the Standard 1.2.1 of the Australia New Zealand Food Standards Code, the date mark shown on final product that has been packed may be altered (other than to correct an error) only if a dairy product disposition request is raised with the RMP verifier and written approval is received.

(4) The dairy manufacturer must monitor each relevant product, or representative of a group of relevant products, over its shelf life and check whether the product remains within specifications under the labelled storage conditions for the duration of its shelf life.

Part 5: Manufacture

5.1 Application of Part

(1) This Part applies to the processing of relevant products under an RMP.

5.2 During manufacture

(1) During the manufacture of relevant product, all exposed ingredients and relevant product, and all contact surfaces, must be protected from contamination.

(2) Contact between people and ingredients, relevant products, and contact surfaces must be minimised.

5.3 Wet processing

(1) In wet processing (i.e. when constituents of the relevant product are processed in a liquid phase) ingredients must be added either:

a) before being heat treated and before the filter controlling particle size during heat treatment; or
b) in the case of pasteurisation, at a point beyond the heat treatment holding tubes.

5.4 Keeping processing records

(1) The RMP must have procedures that ensure the following records are kept for each batch of relevant product:

a) the name or product code of the relevant product manufactured;
b) dates and times of the start, end, and any suspension of manufacture, and any significant intermediate stages;
c) the identity of the responsible process operator or operators at each significant stage of the process and, where applicable, the identity of any person cross-checking actions or making critical measurements;
d) the batch identifier or analytical control identifier of each batch of relevant product manufactured, as well as the quantity of each input actually measured and the amount of any recovered or reprocessed material added;
e) the processing activity as described in the RMP and (for traceability purposes) the processing lines used;
f) a record of the in-process controls, the initials of any person carrying them out, and the results obtained;
g) for a dry mix process (i.e. when constituents of the relevant product are combined in a dry state), a mass balance check obtained at specific points identified in the RMP; and
h) notes on any processing problems, with a signed authorisation for any deviation from the manufacturing formula and processing instructions.

5.5 Sampling and testing plan

(1) The RMP must contain a sampling and testing plan that covers all relevant matters including:

a) input acceptance;
b) in-process monitoring;
c) environmental pathogen monitoring (noting that the sampling and testing plan may reference details held in the environmental pathogen monitoring plan);

d) confirmation of shelf life determination; and
e) final product conformance testing.

(2) The sampling and testing plan must:

a) specify what must be tested, and at what frequency; and
b) set out the frequency that each parameter is scheduled to be tested; and
c) differentiate between process hygiene and product conformance testing; and
d) set out the response to unfavourable results or trends which, in addressing clause D1.12(1)e) of the Animal Products Notice: Production, Supply and Processing, must include:

i) increased investigational sampling and other monitoring activities; and
ii) appropriate corrective and preventative actions and procedures; and reporting requirements.

(3) In addition, the following testing is required and must be included in the RMP sampling and testing plan:

a) *Salmonella* testing of relevant products, unless aseptically packaged and commercially sterile:
b) *Cronobacter* spp testing of packaged infant formula (0-6 months).

(4) When developing the RMP sampling and testing plan the RMP operator must consider the following:

a) ingredients and the testing required to confirm suitability for use;
b) microbiological parameters and pathogens relevant to the nature of the relevant product and the processing methods;
c) chemical residues and contaminants;
d) compositional parameters, including:

i) nominated nutrients to be used to confirm batch conformity; and
ii) confirmation of batch homogeneity;

e) foreign matter that may be objectionable or reflect unacceptable processing conditions;
f) intentional adulterants.

(5) The sampling and testing plan must be designed to ensure that a dairy manufacturer can confirm that essential macro and micro nutrients will be present in every packaged item of final product.

(6) The sampling and testing plan must include a procedure for recording and reporting laboratory results in a way that allows for easy review of the results, for example, trend analysis.

5.6 Testing of samples

(1) 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 this clause:

a) food safety;
b) product conformance;
c) wholesomeness;
d) standard of identity;
e) RMP compliance, including with the environmental monitoring programme;
f) to satisfy relevant Overseas Market Access Requirements (OMAR).

(2) Testing must be undertaken in a laboratory:

a) recognised by MPI under the Animal Products Act 1999; and
b) using test methods covered under the laboratory's ISO/IEC 17025 scope of accreditation; and
c) where required, use any method specified under the Act.

(3) However, testing does not have to be done as required by clause 5.6(2) if that testing is not commercially available within New Zealand, provided the overseas laboratory uses test methods covered by its scope of accreditation to ISO/IEC 17025.

5.7 Retention samples

(1) Retention samples must be collected from each batch of retail-ready product as follows:

a) a minimum of three 200g samples be collected per batch each day (and if the batch extends beyond a 24-hour period, then one sample must be collected during each additional 8-hour period in which any processing occurs);
b) the retention samples collected must include one sample collected at each of the following points:

i) the start of the batch;
ii) the middle of the batch;
iii) the end of the batch.

(2) The retention samples collected under clause 5.7(1) must be retained for the shelf life of the relevant product, unless the verifier approves earlier release.

5.8 Non-conforming batches

(1) A batch of relevant product is non-conforming if any of the following apply:

a) the batch fails to meet the product homogeneity requirements documented in the RMP:
b) any sample taken from the batch:

i) fails to meet regulatory requirements for composition; or
ii) fails to meet applicable chemical contaminant or residue limits; or
iii) fails to meet applicable microbiological criteria; or
iv) is not wholesome;

c) the batch is in retail-ready packaging and one or more of the packages at the point when the package leaves the control of the manufacturers' RMP:

i) is not adequately sealed; or
ii) does not provide protection from contamination; or
iii) does not provide the intended internal atmosphere; or
iv) contains unacceptable foreign matter, objectionable material or adulterants;

d) the batch has been manufactured using ingredients that are not permitted, are non-conforming, or are otherwise unsuitable:
e) the batch has otherwise not been manufactured or packed in accordance with the RMP.

5.9 Packaging used for retail-ready product

(1) Retail-ready relevant product must be sealed in its packaging.

(2) The packaging used must:

a) be appropriate for the pack size; and
b) be waterproof; and
c) protect the product from contamination; and
d) not easily break or tear under expected handling conditions.

(3) For dry relevant product, the residual oxygen within the retail-ready package must be:

a) at or below the level specified in the RMP; and
b) consistent with the level specified when establishing shelf life; and
c) monitored at a frequency specified in the RMP to confirm conformance with the RMP.

(4) Any packaging that forms part of the final product and is likely to come into contact with the contents of the package at some time (such as lids or measuring aids) may only be incorporated into the package while in a high hygiene area, unless:

a) the manufacturer has in place a procedure that has been validated in accordance with Regulation 34; and
b) the RMP operator holds the validation information that shows the procedure is as effective at ensuring the packaging will be free from contamination when incorporated while in a non-high hygiene area.

(5) The RMP must include procedures for:

a) ensuring that the correct product is contained in any labelled retail-ready product, and the procedures must include record-keeping requirements; and
b) confirming the integrity of the seal on retail-ready product, through routine inspection and testing at minimum frequencies specified in the RMP; and
c) confirming the compositional conformance of retail-ready product, including the marker compounds to be monitored.

5.10 Disposal of retail-ready product that is not for human consumption

(1) An RMP must include procedures to ensure that:

a) all retail-ready product (whether conforming or not) that is redirected to animal consumption is managed in such a way that it cannot re-enter the human food chain; and
b) all retail-ready product (whether conforming or not) that is redirected to destruction remains under the control of the manufacturer through to the point of destruction, and that appropriate evidence is retained.

5.11 Tracing forward and back

(1) The traceability procedures set out in Regulation 103(1)(a) must also provide for the tracing of all inputs.

(2) Dairy manufacturers must ensure that full traceability is maintained by keeping records showing:

a) where inputs come from; and
b) what happens to the input (for instance, whether it is used in a product, is rejected, or becomes waste); and
c) what happens to anything that the input is used in (such as final product or waste) when it leaves the premises.

(3) Dairy manufacturers must be able to trace both forward and back, that is:

a) forward, from the receipt of a particular input through to anything that contains or may contain that input; and
b) back, from any package of final product back to the inputs used in or associated with its manufacture.

(4) Traceability must be maintained on the basis of one step forward and one step back, and include the following:

a) what products an input went into, or how it was disposed of;
b) when that product or disposed material left the premises;
c) where, or to whom, the product was dispatched.

(5) If any dairy material or product that is not relevant product leaves the dairy manufacturer's control, the dairy manufacturer must keep a record of what went, where it went, and when.

5.12 Tracing exercises

(1) Dairy manufacturers must complete at least 1 trace-back forward-tracing exercise and 1 forward-tracing exercise (which may be in conjunction with a real or simulated recall) each dairy season, based on a nominal input intended for relevant product that, for the purposes of the exercise, has been determined to be non-conforming for food safety or suitability reasons.

(2) The following records must be kept for tracing exercises:

a) for a trace-back exercise, the time taken from the initiation of the exercise until the time when either all inputs used to manufacture the product have been identified or the exercise is concluded (which must be longer than 48 hours);
b) for a forward-tracing exercise, the time taken from the initiation of the exercise until the time when either all relevant product has been identified or the exercise is concluded;
c) identification of all inputs and all relevant product manufactured at the premises that was not able to be traced successfully.

(3) If a forward tracing or trace-back exercise takes longer than 48 hours, the dairy manufacturer must:

a) investigate and implement remedial actions to reduce the time taken for future tracing exercises; and
b) record the outcome of the investigation and the subsequent remedial actions; and
c) inform the verifier at the next on-site verification of the actual time the tracing exercise took.

(4) If a forward tracing or trace-back exercise fails to account or all inputs or all relevant product manufactured at the premises, the dairy manufacturer must:

a) investigate and implement remedial actions to reduce the time taken for future tracing exercises; and
b) record the outcome of the investigation and the subsequent remedial actions; and
c) inform the verifier at the next on-site verification of the actual time the tracing exercise took.

5.13 Complaints to dairy manufacturer

(1) A dairy manufacturer must keep a record of all complaints made to the dairy manufacturer concerning any final product provided by the dairy manufacturer.

(2) The dairy manufacturer must investigate and document all complaints that the dairy manufacturer considers are valid, and must record the observations made during the investigation and any corrective and preventative actions taken.

(3) The RMP must have procedures to ensure that any failure by the dairy manufacturer to meet dairy conformance standards identified as a consequence of the complaint or investigation is notified and managed in accordance with Regulation 36 and the applicable parts of the Animal Products Notice: Production, Supply and Processing.

Part 6: Validation and operator verification

6.1 Application of Part

(1) This Part applies to the processing of relevant products under an RMP.

6.2 Validation to be undertaken

(1) A dairy processor must validate:

a) the processing activities covered by the RMP, to ensure that the facilities, processes, product formulation, supporting systems and procedures are fit for the intended purpose.
b) the activities that contribute to, or may adversely affect, the fitness for purpose of any relevant product manufactured by the manufacturer.

(2) In particular, the following must be validated:

a) the procedures for changing from manufacturing one product to manufacturing another;
b) procedures for ensuring that items entering high hygiene area are in an adequately hygienic state;
c) cleaning procedures;
d) procedures for sampling, and sample handling procedures, when testing inputs and relevant product;
e) environmental pathogen monitoring;
f) the effectiveness of the blending process, and how to ensure that it will result in homogeneity within a specified range across each batch of relevant product;
g) the shelf life of ingredients before incorporation into relevant product, and the shelf-life of the final product;
h) packing processes;
i) drying times following wet cleaning of dry areas.

6.3 Validation protocol where pre-manufacture validation is not possible

(1) In addition to addressing Regulation 34(2), a validation protocol must set out:

a) what is to be validated; and
b) the outcomes intended to be achieved by that thing; and
c) why, or on what basis, the manufacturer chose that method of validation.

6.4 Validation report

(1) On completion of a validation (whether done before or after manufacturing starts), a validation report, summarising the validation information, must be prepared and include the following:

a) what was validated;
b) what relevant products it relates to;
c) the outcomes required from the thing that was validated;
d) the competencies of the persons undertaking the validation;
e) for any critical process parameter, the acceptable tolerance range and how it was established;
f) the findings, including any test results;
g) any deficiencies or deviations identified, along with any proposed amendments and revalidation;
h) the conclusions of the study.

6.5 Validation of cleaning programme

(1) The validation of cleaning programmes set out in Part 3 must provide evidence to confirm the effectiveness of the cleaning programme, and must consider:

a) all inputs and relevant products that may be processed; and
b) the most difficult parts of the equipment to be cleaned.

(2) The cleaning programme validation information must describe or reference all the following:

a) the equipment or area cleaned;
b) the cleaning regime followed, including working solution strengths, temperatures and flow rates;
c) the procedures for CIP and any cleaning out of place;
d) the parameters monitored to confirm complete cleaning, such as conductivity, level or proximity sensors and solution strengths at the completion of cleaning;
e) visual and sensory assessments undertaken;
f) the methods used to confirm cleaning effectiveness, including the type of samples taken, the analytical testing undertaken, and the results;
g) where appropriate, confirmation that cleaning compounds are effectively removed from contact surfaces.

(3) For manufacturing equipment that is routinely subject to a dry clean only, the volume of cleaning material, such as sugars, retained within the processing equipment must be quantified for each type of cleaning programme, along with the quantity of flush material required to remove retained material.

(4) Cleaning programmes must be revalidated if any changes are made that mean that the existing validation can no longer be relied upon.

6.6 Operator verification

(1) Anything that has been validated must be periodically reviewed as part of operator verification under Regulation 22 to confirm that it is still achieving the required outcomes in accordance with its original validation.

Part 7: Miscellaneous provisions

7.1 Application of Part

(1) This Part applies whether or not the activities covered by this Part are done under an RMP.

7.2 Repacking and relabelling outers

(1) A dairy processor who relabels or repacks relevant product or relabels the outers of final product or repacks final product into new outers **at somewhere** other than the original manufacturer's premises must:

a) record the original place of manufacture of the product; and
b) keep all other records necessary to ensure full traceability.

7.3 Transport and storage

(1) A dairy processor must ensure that milk, bulk liquid dairy material, and other bulk liquid that is, or is intended for use in, a relevant product are transported and stored only in tanks, vessels or containers that:

a) are clean and only used for ingredients and foods for human consumption; and
b) do not adversely affect the milk or other liquid in them; and
c) do not permit cross-contamination; and
d) are subject to periodic monitoring, that is recorded, to confirm that the requirements above are complied with.

(2) A dairy processor must ensure that relevant products, inputs and their packaging:

a) are protected from contamination and deterioration; and
b) are kept away from goods that are harmful, odorous, volatile, corrosive, offensive, or that may otherwise affect the product; and
c) in the case of dry relevant product and dry inputs, are kept in dry conditions.

(3) A dairy processor must ensure that inputs that are not, or are no longer, intended for use in or as relevant product are:

a) clearly identified so that they will not be mistaken as suitable for use in or as relevant product; and
b) stored and transported in such a way that they will not present a risk to inputs intended for relevant products or to the premises.