Ministry for Primary Industries
Manatū Ahu Matua

Animal Products Notice

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

9 January 2017

Issued under the Animal Products Act 1999

New Zealand Government

TITLE

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

COMMENCEMENT

This Animal Products Notice comes into force on 1 March 2017 for new programmes and [to be confirmed] for existing programmes.

ISSUING AUTHORITY

This Animal Products Notice is issued pursuant to sections 45, 159 and 167 of the Animal Products Act 1999 and the Animal Products (Dairy) Regulations 2005 having had regard to the matters specified in section 44(7) and having undertaken consultation in accordance with section 163 of the Animal Products Act 1999.

Dated at Wellington this ... day of 2016

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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 specify particular requirements that apply to the manufacture, evaluation, 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 0.5% of the final product).

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

a) The Animal Products (Dairy Processing Specifications) Notice 2011:
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 18 December 2014:
d) Market-specific requirements issued as overseas market access requirements (OMARs) under Part 5 of the Animal Products Act 1999:
e) The Australian New Zealand Food Standards Code:
f) DCP 1: Animal Products (Dairy) Approved Criteria for General Dairy Processing.

Background

(1) 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.

(2) 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.

(3) 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.

(4) 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 raw materials, the formulation of the products, product and environmental testing, tracing, and audit and evaluation of manufacturing processes.

Who should read this?

(1) This Notice should be read by:

a) manufacturers of relevant product:

b) people who repack or relabel relevant product:
c) evaluators and auditors of risk management programme (RMP) of manufacturers of relevant product.

Why is this important?

(1) Manufacturers of relevant product are responsible for ensuring they meet their obligations under this Notice. A person who fails to comply with the requirements of this Notice may be committing an offence under the Animal Products Act 1999.

Part 1: Requirements

1.1 Application

(1) This Notice applies to dairy processors who operate RMPs at premises where relevant products are manufactured (in this Notice referred to as "manufacturers").

(2) The relevant products covered by this Notice are as follows:

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 product represented as intended for use in any of those products (other than ingredients that will comprise less than 0.5% of the final product).

(3) Clause 5.11 also applies to other dairy processors who store or transport relevant product but do not manufacture it.

(4) Part 7 specifically applies to evaluators and verifiers of RMPs.

(5) Any requirement of this Notice that is not specifically imposed on any person (such as requirements relating to the content of RMPs) is a requirement that a manufacturer is required to comply with or ensure compliance with.

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, typically not exceeding 24 hours, 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 measurement means any measurement (such as of weight, time, or temperature) identified in an RMP as critical for the purpose of ensuring the safety, integrity, and fitness for purpose of final product

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

a) are or may be exposed; and
b) will not subsequently be subject to heat treatment

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 food, intended for children aged between 12 and 36 months, that is specifically designed as a supplement to a normal diet to address situations where intakes of energy and nutrients may not be adequate to meet the child's requirements

heat treated means being subject to a validated heat treatment equivalent to pasteurisation

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 be subject to heat treatment is exposed:
c) any other area where raw materials that will not be subject to heat treatment 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

manufacture means the process of converting dairy material or product into relevant product, and includes all associated activities such as receiving raw materials, cleaning and maintaining equipment used during processing, and storing final product; but does not include:

a) harvesting, filtering, cooling or storing raw milk at a farm dairy; or
b) storing dairy material or dairy product where the only processing undertaken is storage and temperature control; or
c) the placing of packaged final product into labelled outer packaging at a store

manufacturer means a dairy processor who is the RMP operator of premises where relevant product is manufactured

manufacturing area means:

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

MPI means the Ministry for Primary Industries

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 packages, anything used to enclose packages, and anything packed with final product (such as scoops and re-closure lids)

raw materials means:

a) all ingredients used in the manufacture of final product:
b) any gas or water (including steam) that comes into contact with relevant product during manufacture:

c) any packaging intended for use in or as packages of final product

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

relevant product means any of the following, whether it is final product or is in the process of manufacture:

a) infant formula:
b) follow-on formula:
c) formulated supplementary food:
d) dairy material or product represented as being intended for use in infant formula, follow-on formula, or formulated supplemented food (other than any material or product that will comprise less than 0.5% of final product)

Regulations means the Animal Product (Dairy) Regulations 2005

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

RMP means a risk management programme; and in relation to a manufacturer, means the RMP of the premises where the manufacturer manufactures relevant product

significant amendment, in relation to an RMP, means an amendment of a type described in the section 25 of the Act

verifier means an MPI recognised RMP verifier

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

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

Guidance
Examples of terms defined elsewhere include:
- Ingredient (defined in the Regulations)
- Dairy processor (defined in the Act)

1.3 Transitional provisions

(1) This clause applies to manufacturers whose RMP for premises where relevant product is manufactured is registered before the date on which this Notice comes into force.

a) For manufacturers whose RMP for relevant product is registered before the date on which this Notice is issued, 1 March 2017:
b) For manufacturers whose RMP for relevant product is registered on or after the date this Notice is issued, or on the date the RMP is registered.

(2) This Notice applies on 1 September 2017.

(3) However, manufacturers need not comply with the requirements of clauses 2.3, 2.5, 2.6 and 2.7 until 1 September 2020 if:

a) the manufacturer has a premises improvement plan that describes the capital works to be done, the manner in which the premises improvement plan will address deficiencies, and the timeline (including steps for evaluating and registering proposed significant amendments to the manufacturer's RMP); and

b) the premises improvement plan is agreed to by the verifier by 1 September 2017.

Part 2: Premises, equipment, and personnel

2.1 Application of Part

(1) This Part applies to manufacturers of relevant product that is represented as being fit for purpose without further heat treatment.

2.2 Areas to be identified in RMP

(1) Every RMP must identify the boundaries of the manufacturing area and any other areas used in association with the manufacture of relevant product.

(2) Every RMP must further identify 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).

(3) Every RMP must clearly identify the demarcation point between any wet area and any dry area, which must be a point at which the 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) All interior building surfaces (such as walls, doors, windows, floors and ceilings) in manufacturing areas must:

a) be smooth (other than floors);
b) be durable, resistant to fracture, and free from cracks, crevices and open joints; and
c) enable and withstand effective cleaning and, where necessary, disinfection; and
d) not enable dust and waste material to accumulate, including in wall cavities or under floors; and
e) not be a source of physical, chemical, or microbiological contamination.

(3) The floors of all manufacturing areas must:

a) be made of impervious material; and
b) be sealed and (in wet areas) sloped so that they are easily cleaned; and
c) be free-draining or dry readily.

(4) 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.

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

(6) The design of manufacturing areas, and the location of equipment within manufacturing areas, must allow the effective cleaning and inspection of the premises and equipment.

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

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 from non-high hygiene areas, unless the manufacturer has in place a validated procedure that is as effective as physical separation at ensuring that there is no cross contamination into high hygiene areas.

(3) Wet areas and dry areas must by physically separated, unless the manufacturer has in place a validated procedure that is as effective as physical separation at ensuring that there is no 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 3.4.

(2) Air flowing into high hygiene areas must be filtered and purified 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.

(5) Inspection and maintenance programmes 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 area, unless the manufacturer has in place a validated procedure that is as effective as physical separation at ensuring that there is no cross contamination into high hygiene areas.

2.7 People entering high hygiene areas

(1) A person may enter a high hygiene area only if he or she:

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 and dried his or her hands in the adjacent buffer zone, or washes and dries them immediately on entering the high hygiene area (providing it is not a dry area).

(2) Buffer zones allowing people into a high hygiene area must enable people to change into protective clothing and footwear before entering the high hygiene area.

2.8 Things entering high hygiene areas

(1) All raw materials 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) Buffer zones allowing the entry of raw materials and other items must be set up as an airlock, UV tunnel or other arrangement that ensures that the raw materials and other items do not contaminate the environment of the high hygiene area.

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

(4) 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.

(5) Gases (including steam) 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.

(6) Wood that is not intended to be subject to a validated heat treatment must not be used in or introduced into high hygiene areas unless:

a) there is no practical alternative; and
b) the use of wood is reviewed to confirm that it does not and will not pose a contamination risk; and
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; and
d) the people coming into contact with the wood have no direct contact with raw materials or relevant product; and
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) Each dry area within a high hygiene area must be physically separated from other parts of the high hygiene area, unless the manufacturer has in place a validated procedure that 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) raw materials 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 range of air temperatures for dry areas, along with the justification for those temperatures.

2.9.3 Relative humidity

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

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

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

a) the higher relative humidity level is unavoidable; and
b) a validation process 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 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) are 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, 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 cannot intermix with raw materials and relevant product.

2.11 Personnel

(1) Manufacturers must ensure that there are enough 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) Manufacturers must:

a) have an organisation chart; and
b) have job descriptions for any personnel with responsibilities relating to the RMP; and
c) have and maintain training procedures and records; and
d) ensure that personnel who work in high hygiene areas have additional training on the specific contamination risks in high hygiene areas.

(3) Manufacturers must ensure that anyone who undertakes an internal audit or the review of a RMP has the appropriate skills and knowledge to do so.

2.12 Equipment

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

(2) Equipment used to manufacture something that is not intended for human consumption must not be used in the manufacture of relevant product.

(3) Equipment that is used to manufacture a product that is for human consumption but is not relevant product may be used at the premises only if the manufacturer has and complies with a validated procedure for cleaning and sanitising the equipment before it is used in the relevant product.

(4) All equipment in the manufacturing area must be designed and fabricated using materials that allow for regular cleaning, sanitising and maintenance.

(5) 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.

Guidance

For clarification, relevant product that is redirected for other purposes, such as other food products or animal feed, as part of the manufacturing process, is permitted.

Examples include sifter overs or line flushings.

Part 3: Cleaning and maintenance

3.1 Cleaning programme set out in RMP

(1) Every manufacturer must have a cleaning programme included in the RMP that ensures 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 programme must identify:

a) the equipment and places to be cleaned; and
b) the frequency for each type of cleaning, sanitising or maintenance activity including CIP, clean out of place and manual cleaning; and
c) the cleaning cycle (for example, rinse-alkali-rinse-acid-drain) for equipment; and
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); and
e) the cleaning time, temperature and flow rates for each CIP solution used; and
f) the equipment required to be manually cleaned or cleaned out of place; and
g) the equipment and areas to be dry cleaned, and the cleaning procedures and materials to be used; and
h) the means by which cleaning effectiveness is confirmed; and
i) which cleaning and maintenance items are permitted in the manufacturing area; and
j) when, where, and how maintenance may be undertaken, and the associated records to be kept; and
k) which process lines must be cleared between batches when dried powders are processed, the means by which the effectiveness will be confirmed, and
l) the records to be kept.

(3) The cleaning programme must ensure that:

a) manufacture in a dry area can only commence once the area and the equipment in it are confirmed to be dry; and
b) cleaning and maintenance items are labelled and stored correctly; and
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; and
d) the cleaning process will restore the environment and all equipment to the required hygienic state, without adversely affecting adjacent areas; and
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; and
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 programme must be validated in accordance with Part 6 of this Notice.

3.2 Specifications for CIP systems

(1) The cleaning programme must:

a) describe the performance characteristics of the CIP system; and
b) set out how the 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 programme, to ensure the compounds do not become a source of contamination.

3.3 Monitoring effectiveness of cleaning

(1) The RMP must set out:

a) how, and how often, cleaning effectiveness under routine processing conditions is monitored; and
b) the steps to be taken when critical measurements 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.

Guidance

Equipment cleanliness can be monitored by testing and by visual examination, where feasible. Visual inspection can allow detection of contamination limited to small or difficult to access areas that might otherwise go undetected.

Effective monitoring of cleanliness includes confirming that rinsing has been effective in removing chemical residues.

Options to confirm the effectiveness of cleaning include:

- monitoring the cleaning, sanitising, and maintenance chemical strength and flow rate at the start, end, and/or within the CIP circuit:
- swabbing surfaces, product contact, non-contact, and people-contact surfaces:
- obtaining samples of material or product at pre-determined points of the process, monitoring for appropriate hygiene indicators, and assessing against predetermined action limits.

3.4 Maintenance in high hygiene areas

(3) 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.

3.5 Environmental monitoring programme

(1) The environmental monitoring programme must be designed to provide early warning that microbial contamination in the premises has occurred and that exposed relevant product is at risk of contamination unless corrective actions are taken immediately to remedy the situation.

(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 monitoring programme must require ongoing monitoring 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 monitoring programme. This must include testing directly for *Cronobacter* in place of Enterobacteriaceae.

(4) The environmental monitoring programme must provide for the monitoring of:

a) air quality (by using, for instance, exposure plates for relevant hygiene indicators); and
b) all surfaces (by, for instance, taking swabs, dust samples and powder residue samples from a selection of different surfaces (both contact and non-contact) throughout the whole area at different times).

(5) The environmental monitoring programme must specify:

a) what gets monitored, when, and how; and
b) the procedures for any sampling and the location of sampling points; and
c) what happens if unfavourable results are identified, which must include:

i) increasing sampling, as set out in the programme; and
ii) investigating the cause; and
iii) taking specified corrective action.

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

3.6 Maintenance compounds and other chemicals

(1) All maintenance compounds used anywhere within the boundaries of the premises covered by the manufacturer's RMP must:

a) be approved by MPI for the specific use; or
b) have been assessed by the manufacturer as:

i) suitable for its intended use; and
ii) not going to affect or contaminate the relevant product; and
iii) not going to accelerate the deterioration of the processing equipment or components.

(2) All maintenance compounds and other chemicals must be used in accordance with their label and instructions for use.

(3) Manufacturers must keep records of all maintenance compounds used to clean, sanitise or maintain the premises or equipment.

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

(5) All maintenance compounds and other chemicals in a manufacturing area must be clearly labelled with a label that shows:

a) the name of the product; and
b) its intended use; and
c) any warnings provided on or with the maintenance compounds or other chemical (except that, if it is impractical to include the warning on the label, the warning may instead be set out in a clearly visible form at the place where the maintenance compound or other chemical is stored).

(6) 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.

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

(8) 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 labels).

3.7 Pest management

(1) Premises must be operated in a manner that protects them from 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, manufacturers must:

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

3.8 Waste

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

3.9 Protection from intentional adulteration

(1) Every manufacturer must ensure that, within 30 days after this Notice comes into force, the RMP includes a plan for the protection of relevant product from intentional adulteration.

3.10 Safeguards against presence of foreign matter

(1) Every RMP must describe how the manufacturer safeguards final product from the presence of foreign material, 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 manufacturer uses test pieces to test whether the safeguards are effective:

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 locate.

(3) If foreign material is found in relevant product, corrective action (as set out in the RMP) must be taken and the frequency production testing must be reviewed.

3.11 Calibration

(1) RMPs must:

a) identify which equipment is used to make critical measurements; and
b) include the procedures and a schedule for calibrating all equipment used to make critical measurements.

(2) Manufacturers must maintain records of all calibrations.

(3) The calibration status of equipment used to make critical measurements must be clearly indicated and verifiable.

(4) Manufacturers must not use equipment to make critical measurements if the equipment does not meet calibration criteria or does not have current calibrations.

(5) If critical measurements are found to have been made using equipment that does not have a current calibration, the manufacturer must:

a) investigate the matter; and
b) report the findings to the verifier.

3.12 Response to failures

(1) Any failure to apply effective cleaning as required by the RMP is a non-compliance and must be recorded, investigated, and remedied as soon as possible.

(2) Any failure to apply effective cleaning that results in, or may result in, relevant product being adversely affected must be reported immediately to the verifier, and records of all other such failures must be retained by the manufacturer.

(3) Any ingredient or relevant product that 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.

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

Part 4: Raw materials and formulation

4.1 Procurement of raw materials

(1) Every manufacturer must:

a) set out in the RMP the acceptance criteria to be used in the selection of raw material and raw material suppliers; and
b) ensure that records are kept of accepted raw material suppliers, the raw materials supplied, and the manner in which the suitability of each supplier was confirmed; and
c) ensure that procurement records are kept for each raw material, showing the intended use of the material and its critical specifications.

(2) Manufacturers must review any reports from accredited laboratories, certificates of analysis, and manufacturer's declarations to assess the suitability of raw materials.

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

(4) Manufacturers must ensure that suppliers of raw materials are and remain suitable, and for this purpose must carry out audits, review of third party audits, reviews of equivalent endorsements, or any other process that provides an equivalent level of confidence.

(5) If a supplier fails to meet the manufacturer's acceptance criteria for raw material supplied, the 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 remove the supplier from the list of accepted raw material suppliers.

(6) If a supplier is not the manufacturer of the raw material, the manufacturer must be satisfied that:

a) the manufacturer knows who the original manufacturer of the raw material is; or
b) the supplier has reliable and robust systems in place to ensure raw material integrity.

4.2 Raw material acceptance

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

a) raw materials are only accepted from suppliers on the list of accepted raw material suppliers referred to in clause 4.1(1) b); and
b) the integrity of the consignment and outer packaging has not been compromised; and
c) all raw materials used for relevant product meet the manufacturer's acceptance criteria and are fit for purpose.

(2) Dairy material and product intended for inclusion in relevant product must be conforming dairy material or product, or material for which consent has been obtained from the Director-General under Regulation 5 of the Regulations.

(3) If raw material is received from a supplier in a state that, were the raw material used in final product, the product would be non-conforming, the problem with the raw material must be reported to the verifier within 48 hours of being detected.

(4) Manufacturers must:

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

(5) 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.

4.3 Milk and other liquid dairy material

(1) Immediately before heat treatment, raw milk used to manufacture relevant product must be no older than:

a) the age specified and validated in the RMP; or
b) if no age is specified, 72 hours.

(2) Manufacturers must ensure that process hygiene tests, as defined in the RMP, are applied to raw milk at the start of manufacture.

(3) The RMP must specify for the tests:

a) the point of sampling; and
b) the frequency of sampling; and
c) the accepted tolerances; and
d) any corrective actions to be taken if acceptable tolerances are exceeded.

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

Guidance

Process hygiene testing will typically include aerobic plate count (30°C every 72 hours) with a maximum 300,000 cfu/ml at the start of manufacture.

4.4 Monitoring raw materials at the premises

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

a) any ingredient that is not to be heat treated meets the microbial 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 macro and micro nutrients are of known composition, homogeneity and stability so that they will be present at the correct level in the packaged product.

Guidance

The intensity of raw material testing will vary depending on the intended intensity of final product testing, the outcome from historic testing of material from the manufacturer and hazard analysis, and the intended use of the raw material.

4.5 Storage and unpacking of raw materials

(1) Raw materials 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 raw material or its packaging; and
c) stored in a place and manner that protects the raw material from contamination and deterioration; and

d) stored in a place and manner that protects the packaging of raw material from damage and deterioration; and
e) spaced so as to permit inspection.

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

(3) The removal of outer packaging, and the decontamination of raw materials, must occur before the raw materials enter a high hygiene area, unless an alternative validated procedure for bringing specific raw materials into a high hygiene area is set out in the RMP.

(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 manufacturer must know and record:

a) its shelf life while in its package; and
b) its shelf life once its package is open (ie, the shelf life of the unpackaged ingredient); and
c) how long it remains stable once incorporated into relevant product.

(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 manufacturer must document the justification for the shelf life applied to the product.

4.7 Ingredient management

(1) Ingredients that will not undergo any subsequent pathogen heat treatment may be dispensed only in a high hygiene area.

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

(3) 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).

(4) 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 raw materials

(1) Any raw material 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) Manufacturers must keep records of the following for all raw materials 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) 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 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 manufacturer's acceptance criteria identified in clause 4.1(1):
c) ensuring that the following are confirmed by a suitably qualified 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, 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 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 manufacturer when the manufacturer was doing the things referred to in clause 4.9(1); and
d) how product suitability and stability is confirmed.

Guidance

In setting tolerance limits, the manufacturer will need to consider the established process variability and test measurement uncertainty, meaning that the tolerance limits are likely to be tighter than absolute regulatory limits.

4.10 Register of formulations of final product

(1) Every manufacturer must maintain a history, as from the date that this Notice applies, of each final product produced at the 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 stated shelf life must be 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 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 stated shelf life of a packaged final product may be longer than the shelf life of an ingredient of the product if:

a) a study, or information obtained from the manufacturer of the ingredient, confirms that the final product will be unaffected, during the whole of its shelf-life, by the incorporation of the ingredient; and
b) the manufacturer keeps a record of the study or information.

(3) The shelf-life shown on final product that has been packed may be extended only if:

a) the manufacturer's RMP includes procedures for extending the shelf-life of final product; and
b) the extension is done by the manufacturer in accordance with those procedures before the product leaves the manufacturer's control; and
c) the verifier approves each specific extension if the final product for which the shelf life is being extended is retail-ready infant formula.

(4) The 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 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 process operators and ingredients, relevant products, and contact surfaces must be minimised.

5.2 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 pasteurisation and before the filter controlling pasteurisation particle size; or
b) at a point beyond the heat treatment holding tubes.

Guidance
The effect of this rule is that no ingredients are to be added between the filter and the end of the holding tubes.

5.3 Keeping processing records

(1) Manufacturers must ensure that the following are included in the process records 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 critical measurements:
d) the batch identifier or analytical control identifier of each batch of relevant product manufactured, as well as the quantity of each raw material 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:
h) notes on any processing problems, with a signed authorisation for any deviation from the manufacturing formula and processing instructions.

5.4 Sampling and testing programme

(1) Every RMP must specify (whether in the HACCP plan or elsewhere) a sampling and testing programme, and document the rationale for the programme.

(2) The programme must set out what gets tested, where, and when.

(3) The programme must, in particular, cover the following matters:

a) raw material acceptance:
b) in-process monitoring:
c) equipment hygiene:
d) the environment in the manufacturing area:
e) water:
f) CIP solutions:
g) final product:

(4) For each of those matters, the sampling and testing programme must:

a) specify sampling and sample handling procedures; and
b) specify what must be tested, and at what frequency; and
c) set out the parameters and frequencies for routine sampling and testing; and
d) specify the acceptance tolerances for each parameter; and
e) differentiate between process hygiene and product conformance testing; and
f) set out the response to unfavourable results or trends, which must include:

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

(5) In addition, the following must be tested as set out in the sampling and testing programme:

a) raw materials:
b) *Salmonella* testing of dried products and environmental samples taken from high hygiene areas:
c) *Cronobacter* spp testing of packaged infant formula:
d) *Cronobacter* spp testing of environmental samples taken from high hygiene areas in which infant formula is at any time intended to be manufactured (except as provided in clause 3.5(2)).

(6) The sampling and testing programme must be designed taking the following into consideration:

a) microbiological parameters and pathogens relevant to the nature of the relevant product and the processing methods:
b) chemical residues and contaminants:
c) compositional parameters, including:

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

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

(7) The sampling and testing programme must be designed to ensure that essential macro and micro nutrients will be present in every packaged item of final product.

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

Guidance

In determining what gets tested, when, and where, manufacturers must consider the following:

- the intensity of raw material monitoring:
- the number and size of batches or blends produced in a 24 hour period:
- the results from environmental monitoring:
- the results from confirmation of cleaning effectiveness:
- the nature of the manufacturing process (wet or dry):
- the results from historic and recent trend data from the wider monitoring programme, including final product testing, in-process and environmental monitoring, and hygiene indicators.

5.5 Testing of samples

(1) Analysis of dairy material, dairy product, and environmental samples 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.

(2) Testing to satisfy market access requirements must, unless the Director-General approves an alternative, also be conducted as required by clause 5.5(1).

(3) Testing must be undertaken in a laboratory:

a) recognised by MPI; and
b) using test methods covered under the laboratory's ISO17025 scope of accreditation; and
c) using MPI specified test methods in situations where MPI specifies the method to be used.

(4) However, testing does not have to be done as required by clause 5.5(3) if that testing is not available within New Zealand, provided the overseas laboratory uses test methods covered by its scope of accreditation under ISO17025.

(5) The verifier may approve an alternative to the requirements of this clause if he or she considers that those requirements are not necessary or appropriate for product safety.

5.6 Retention samples

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

a) a minimum of three 200 g samples must 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 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) Samples collected under clause 5.6(1) must be retained for the shelf life of the relevant product, unless the verifier approves earlier release.

Guidance
It is advisable to collect retention samples more frequently within a batch as it may minimise product losses if an issue is subsequently identified with the product or process.
It is also recommended that composite samples across all or segments of the batch (including all blends) are collected and retained.

5.7 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-reading packaging and one or more of the packages:

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.

5.8 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 handing 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 the manufacturer has in place a validated procedure that confirms that the packaging will be free from contamination if it is incorporated while is 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.

5.9 Re-packing by someone other than the manufacturer

(1) Every person who, at somewhere other than the original manufacturer's premises, relabels final products or repacks it into new outers, must record the original place of manufacture of the product and keep all other records necessary to ensure full traceability.

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

(1) RMPs must include procedures to ensure that:

a) Retail-ready product that is redirected to animal consumption is managed in such a way that it cannot re-enter the human food chain; and

b) Retail-ready product 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 Storage and transportation

(1) This clause applies to any dairy processor who transports or stores the following products:

a) raw materials intended for relevant product; or
b) relevant product; or
c) any other dairy material or product produced at the manufacturer's premises.

(2) Milk, bulk liquid dairy material, and other bulk liquid that is, or is intended for use in, a relevant product must be transported 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.

(3) Dairy processors must ensure that products referred to in clause 5.11(1) 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, are kept in dry conditions.

(4) Dairy processors must ensure that products referred to in clause 5.11(1) 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 raw materials intended for relevant products or to the premises.

5.12 Tracing forward and back

(1) Manufacturers must ensure that full traceability is maintained by keeping records showing:

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

(2) Manufacturers must be able to trace both forward and back, that is:

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

(3) Traceability must be maintained on the basis of one step forward and one step back, which involves recording:

a) what the raw material is; and
b) who supplied it; and
c) when it was received at the premises; and
d) what products it went into, or how it was disposed of; and
e) when that product or disposed material left the premises; and

f) where, or to whom, the product was dispatched.

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

(5) Records that support the tracing of raw materials, products, and waste must be readily available at all times, to facilitate rapid tracing.

Guidance
The scope of traceability systems should cover all raw materials handled by the manufacturer. To support rapid tracing, all records that support tracing of product should be held electronically. Batch ID may be represented in any effective form, such as manufacture date, best-before date, or cypher.

5.13 Tracing exercises

(1) Manufacturers must complete at least 2 tracing exercises each year, based on a nominal raw material intended for relevant product that has been determined to be non-conforming for food safety or suitability reasons.

(2) The exercises must include at least 1 forward-tracing exercise and 1 trace-back exercise.

(3) Records of the tracing and recall exercise must be kept and must include the time taken from the initiation of the exercise until all affected product is identified and the manufacturer would be able to effect a recall of affected product.

(4) Records must be kept for the trace-back exercise, including the time taken from the initiation of the exercise until the time when all raw materials used to manufacture the product have been identified.

(5) If a forward tracing or trace-back exercise takes longer than 48 hours, the 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 verification audit of the actual time the tracing exercise took.

5.14 Recall procedures

(1) Every RMP must include procedures that ensure that:

a) outline the actions to be taken in the event of a recall; and
b) that all reporting obligations are met.

(2) Manufacturers must complete a mock recall exercise at least once annually.

(3) During any recall, manufacturers must ensure that:

a) all reporting obligations are met; and
b) all recipients of affected product are notified; and
c) if the recall is for product within New Zealand, the requirements for recall under the Food Act 2014 are met.

5.15 Complaints to manufacturer

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

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

(3) If an investigation identifies a failure by the manufacturer to comply with the RMP or any regulatory requirements, the failure must be notified to the verifier or auditor in an exception report.

Part 6: Validation

6.1 Requirements of validation

(1) All validation undertaken for the purposes of this Notice must use objective evidence to demonstrate that:

a) the thing being validated will consistently deliver the required outcomes when operated as described; and
b) the resulting relevant product will consistently meet the food safety, wholesomeness, and compositional criteria specified in the RMP.

(2) Validation must be done as required by clause 18 of the Animal Products (Risk Management Programme Specifications) Notice 2008, supplemented by the requirements of this Notice.

(3) Validation must be undertaken by way of a validation study completed either before manufacture begins or in accordance with a validation protocol (in the case of something that cannot be validated before manufacture begins).

(4) Supporting validation information that is provided by a supplier may be used for validation purposes, but mere recommendations cannot.

6.2 Validation to be undertaken

(1) A manufacturer 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 to 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 raw materials and relevant product:
e) environmental monitoring:
f) the effectiveness of the blending process, and in particular 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 and after incorporation into relevant product:
h) packing processes:
i) drying times following wet cleaning of dry areas.

6.3 Validation protocol where pre-manufacture validation not possible

(1) If something that is required to be validated cannot be validated before manufacture begins, the manufacturer must prepare a validation protocol for it that describes how the manufacturer intends to confirm, once manufacture has begun, whether the thing achieves the intended outcomes.

(2) A validation protocol must set out:

a) what is to be validated (for example, a process, procedure, or critical measurement); and
b) the outcomes intended to be achieved by that thing; and

c) how the manufacturer intends to validate whether the thing achieves the required outcomes; and
d) why, or on what basis, the manufacturer chose that method of validation.

(3) Every validation protocol must be reviewed by a suitably competent person.

Guidance
In setting tolerance limits, the manufacturer:

- Must first consider regulatory and nutritional requirements, and then tighten the limits as appropriate to provide for the cumulative effect of established process variability and measurement uncertainty
- will need to consider the established process variability and test measurement uncertainty, meaning that the tolerance limits are likely to be tighter than absolute regulatory limits.

6.4 Validation report

(1) On completion of a validation (whether done before or after manufacturing starts), a validation report must be prepared that includes 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 Review of validation

(1) Anything that has been validated must be periodically reviewed to confirm that it is still achieving the required outcomes in accordance with its original validation.

(2) If significant amendments to the RMP may affect relevant product, anything that has been validated that might change as a result of the amendments must be revalidated.

(3) Validated processes, procedures, and critical measurements must also be reviewed following minor changes, such as like-for-like replacement of equipment components, to confirm that they are still operating in accordance with their validation.

(4) However, revalidation is not required if changes to a process, procedure, or critical measurement are not significant and a review confirms that the resulting relevant product still meets its specifications.

6.6 Validation of cleaning programme

(1) The validation of cleaning programmes must confirm the effectiveness of the cleaning regime set out in the programme, and must consider:

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

(2) The validation report following validation of any cleaning procedures 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 powders retained within the processing equipment must be quantified for each type of clean, along with the quantity of flush material required to remove previously retained material.

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

Guidance
Revalidation will generally be required:
- for changes to equipment, the CIP cycle, or the flow of material (other than like for like):
- following a reduction in time, chemical strength, temperature, or flow rate.

Part 7: Evaluation and verification

7.1 Requirement for specialist expertise

(1) When evaluating or verifying a manufacturer's RMP for compliance with this Notice or any part of it, the evaluator or verifier must have access to whatever additional technical expertise is necessary to check compliance.

(2) As part of the evaluation process, RMP evaluators must assess the suitability of the premises and equipment for the intended uses.

7.2 Unannounced verification audits

(1) Premises that manufacture infant formula products must receive at least one unannounced verification audit each dairy season.

(2) Notice may be given to the manufacturer not more than 24 hours before an unannounced verification audit, in order to ensure access to the premises and that key personnel can be present.

(3) An unannounced verification audit may be inspection based if key personnel are not available.

7.3 Increased verification audit intensity

(1) This clause applies if, during an audit:

a) Required information proves difficult to obtain; or
b) Key personnel are not available to provide required information; or
c) Initial findings indicate a need for more in-depth assessment.

(2) If this clause applies, verifiers must:

a) Extend the onsite audit; or
b) Unless any required information is provided within 2 working days of being requested, either:
   i) Record a failure to provide the required information (if applicable); or
   ii) schedule a revisit to occur within 30 days of the original audit visit.

Guidance
Manufacturers should expect more intense verification audit scrutiny than other dairy processors. This is best achieved by more intense verification audits rather than more frequent verification audits.
During verification audits, information is expected to be made available immediately or, for archived information, within 2 working days.

7.4 Verification audit frequency

(1) This clause applies to any manufacturer who is not covered by the Animal Products Notice: Export Verification Requirements, and is for the purpose of ensuring that those manufacturers are subject to the same frequency of verification audit as manufacturers who are covered by that Notice.

(2) Manufacturers to whom this clause applies must be verified:

a) once a month; or
b) at intervals, determined by the verifier, of no more than 3 months, but only if the manufacturer continues to achieve an acceptable verification outcome.