Ministry for Primary Industries
Manatū Ahu Matua

Proposed Specifications for the Manufacturing of Dairy Based Formulae for Infants and Young Children

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New Zealand Government

Growing and Protecting New Zealand

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1 Submissions

The Ministry for Primary Industries (MPI) invites comment on proposals to specify how certain food safety and suitability outcomes must be met for the manufacture of dairy-based formulae for infants and young children. The proposals in this paper are of a technical nature. Therefore, MPI is particularly seeking comments from those involved in the manufacture of infant formula on whether the proposals would meet the objectives, and any costs to manufacturers of implementing the proposals. MPI will analyse submissions and respond to any outstanding issues in due course.

The following points may be of assistance in preparing comments:

- Wherever possible, comment should be specific to a particular section in the document. All major sections are numbered and these numbers should be used to link comments to the document.
- Where possible, reasons and data to support comments are requested.
- The use of examples to illustrate particular points is encouraged.
- As a number of copies may be made of your comments, please use good quality type, or make sure the comments are clearly hand-written in black or blue ink.

Please include the following information in your submission:

- the title of the discussion document;
- your name and title (if applicable);
- your organisation's name (if applicable);
- a contact email address; and
- your mailing address.

Please submit your response by 12 September 2014. Please send your comments to:
MPI Infant Formula Programme
PO Box 2835
Wellington; or
Email: infant.formula@mpi.govt.nz

The Official Information Act
Everyone has the right to request information held by government organisations, known as "official information". Under the Official Information Act 1982 (the OIA), information is to be made available to requestors unless there are grounds for withholding it. The grounds for withholding information are outlined in the OIA.

If you are submitting on this discussion document, you may wish to indicate any grounds for withholding information contained in your submission. Reasons for withholding information could include that information is commercially sensitive or that the submitters wish personal information such as names or contact details to be withheld. MPI will take such indications into account when determining whether or not to release information.

Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman. For more information please visit
http://www.ombudsman.parliament.nz/resources-and-publications/guides/official-information-legislation-guides

2 Introduction

This paper sets out proposals to specify how certain food safety and suitability outcomes must be met for the manufacture of dairy-based formulae for infants and young children from 0 to 36 months of age.

The proposals (proposed specifications) aim to increase consistency in how risk management principles and practice are applied by manufacturers across the New Zealand infant formula manufacturing industry. We expect that specifications would improve clarity for manufacturers and would make it easier for the Ministry for Primary Industries (MPI) and Recognised Agency[1] verifiers to check that infant formula manufacturers are consistently meeting relevant food safety and suitability requirements. MPI also considers that the specifications would help to communicate the New Zealand standards that apply to the production of infant formula to overseas regulatory authorities, and thereby support ongoing market access for New Zealand exports.

The proposed specifications have been developed with reference to international standards where appropriate, and cover topics such as:

- premises zoning;
- ingredient reception;
- re-work;
- blending and homogeneity;
- validation of foreign matter detection systems;
- stock and dispensary management;
- trial or "mock" recalls;
- cleaning.

The proposed specifications would apply to all manufacturers of dairy-based infant formula, follow-on formula, and formulated supplementary foods for young children (collectively called 'dairy-based formulae for infants and young children') from 0 to 36 months, and manufacturers of dairy ingredients specifically intended for use in those products, for both the domestic and export markets. Any other relevant requirements for dairy processors under the Animal Products Act 1999 (the APA) would still apply. MPI expects that New Zealand infant formula manufacturing companies would already meet most of the proposed specifications.

[1] 'Recognised Agencies' are third party entities that are recognised by MPI under the Animal Products Act 1999 to undertake evaluation and verification of Risk Management Programmes. Currently, there are three Recognised Agencies for dairy manufacturing (including infant formula): AsureQuality, Eurofins, and MPI Verification Services.

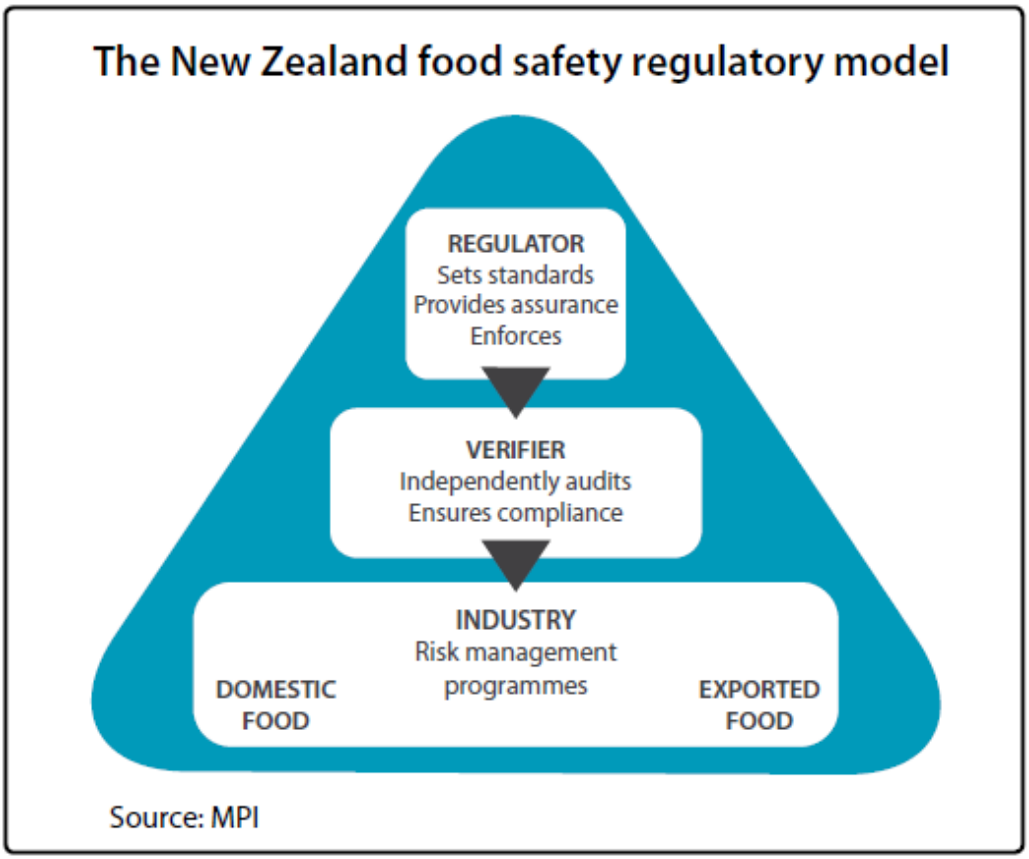
3 Background

The World Health Organization (WHO) recommends that infants should be exclusively breastfed for the first six 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 up to two years of age or beyond (WHO/UNICEF, 2003). 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.

As infant formula can be the sole source of nutrition for a vulnerable population group, particularly for the age range 0-6 months, stronger food safety monitoring and oversight is appropriate for infant formula products than for dairy products for adult consumers. Infants have special nutritional needs and lower immunity than adults. Market expectations for safety are also particularly high for infant formula and formulated supplementary foods for young children.

3.1 CURRENT RULES FOR THE MANUFACTURE OF INFANT FORMULA

The manufacture and export of dairy-based formulae for infants and young children is regulated under the APA. The general approach of the APA is described in the 'Regulatory Model' outlined in below:



- MPI (the regulator) sets outcome-based standards.
- Manufacturers (the industry) must identify and manage risks specific to their premises, production processes, products, personnel, and intended consumers through their Risk Management Programmes (RMP) (or Food Safety Programmes, if operating under the

Food Act 1981). RMPs must be evaluated by a Recognised Agency, and approved by MPI.

- Recognised Agencies are responsible for ongoing verification that manufacturers are operating in accordance with their RMP. Under the APA, performance-based verification applies. The minimum verification frequency for manufacturers producing dairy products for export is quarterly (once every three months).
- MPI monitors the regulatory system through its system audit capacity, can take enforcement action where non-compliance is identified, and undertakes continuous improvements of regulatory standards.

Manufacturers are best placed to manage risks related to the products they produce. This approach is consistent with the principles of Hazard Analysis and Critical Control Points (HACCP).

Generally, there may be a number of different ways to meet relevant outcome-based food safety requirements. To assist manufacturers, MPI may publish one particular method that it has analysed and considers to be adequate, while being open to alternative approaches where the approaches meet the same outcomes. [2] In some cases, there may only be one method available to consistently meet an outcome-based food safety requirement, or MPI may consider it necessary to specify how all manufacturers must meet an outcome. The Act provides for these situations by enabling MPI to establish 'specifications' that set out how a manufacturer must meet an outcome-based food safety requirement (for example, the Animal Products (Dairy Processing Specifications) Notice 2011).[3]

Currently infant formula manufacturing is covered by the general requirements that apply to dairy production. Manufacturers producing infant formula are required to manage all relevant risks to the intended consumer and to meet any specific food safety outcomes required by MPI.

[2] For example, the Dairy Processing Criteria 3: Animal Products (Dairy) Approved Criteria for the Manufacturing of Dairy Material and Product. See http://www.foodsafety.govt.nz/elibrary/industry/3-animal-products-approved-criteria/dpc3-approved-criteria-for-the-manufacturing-of-dairy-material-and-product.pdf

[3] Available here: http://www.foodsafety.govt.nz/elibrary/industry/Animal_Products_Dairy-Requirements_Material-2011.pdf

4 Problem Definition

Infant formula can be the sole source of nutrition for a vulnerable population group. It is a complex product containing multiple and highly processed ingredients. Infant formula manufacturing is a complex process and small changes in product composition or the introduction of contaminants can have direct impact on product safety and suitability. Therefore, it is particularly important that every infant formula manufacturing premises can meet safety and suitability outcomes, and that this can be consistently verified.

4.1 SUPPORTING COMPLIANCE AND VERIFICATION

The recent report of the Government Inquiry into the Whey Protein Concentrate Contamination Incident recognised that New Zealand's dairy food safety systems are as good as any in the world. However, it is important to periodically review the food safety system to ensure it continues to support the production of consistently safe and suitable products. There are a number of factors that have prompted this review of MPI's specifications for infant formula manufacturing, including:

- MPI has observed that infant formula manufacturers use a variety of different food safety management processes in the manufacture of infant formula, and manage risks in a variety of ways.
- Infant formula products and process innovation has occurred at an uncommonly fast pace in recent years and several businesses have begun manufacturing infant formula in the last two years.

These factors have led to a degree of variability in the application of risk management practices across the infant formula industry. This variability poses challenges for verifiers who are responsible for ensuring manufacturers are operating in compliance with RMPs and meeting a consistent standard.

4.2 MEETING OVERSEAS MARKET EXPECTATIONS

Increasingly, major export markets are developing more prescriptive approaches to regulating the manufacture of infant formula. For example, the United States and the People's Republic of China have recently introduced infant formula manufacturing standards that prescribe how certain outcomes must be met on specific matters including, for example, premises and equipment design. These requirements have been developed in response to the high expectations consumers have for the safety and suitability of infant formula in those markets.

Overseas regulators often expect to see similar approaches to regulation in the countries that export infant formula to them. While it is not necessary or advisable to replicate regulatory provisions that apply in different countries, it is important that New Zealand can clearly demonstrate how our regulatory standards can satisfy importing country and overseas consumer expectations. If we cannot, there is potential for markets to impose additional prescriptive requirements, or for overseas consumers to reject New Zealand infant formula.

Consultation Questions

1. Do you have any comments and suggestions on the problems identified above?

5 Objectives

The objective of the proposed specifications is to support the sustainable growth of New Zealand infant formula exports by:

- Increasing consistency in the application of risk management measures across the New Zealand infant formula manufacturing industry.
- Clearly articulating New Zealand's regulatory standards for the production of infant formula, to more effectively demonstrate how New Zealand's standards meet importing country expectations.
- Supporting effective and efficient verification of infant formula manufacturers by Recognised Agencies.

Consultation Questions

2. Do you have any comments on the objectives identified above?

6 Proposals

MPI proposes to issue specifications under the APA setting out how certain food safety and suitability outcomes must be met for the manufacture of dairy-based formulae for infants and young children (aged 0-36 months). The proposed specifications would apply to those manufacturing formulae for infants and young children, and those manufacturing dairy ingredients specifically intended for use in formulae for infants and young children. Current outcome requirements and any market-specific requirements would continue to apply.

Draft specifications have been developed with reference to:

- Codex Recommended International Code of Practice: General Principles of Food Hygiene (CAC/RCP 1-1969).
- Codex Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004).
- Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008).
- Standards of comparable countries and trading partners (e.g. the United States and China).

Key aspects of the draft specifications are summarised below, and the full draft specifications are attached to this paper in Appendix 1.

The draft specifications have been developed by MPI with input from an industry working group established by the Dairy Products Safety Advisory Council for that purpose. MPI is now seeking feedback from all interested parties. The proposed specifications are highly technical. MPI encourages those manufacturing infant formula and dairy ingredients for use in infant formula to consider the proposals and provide feedback.

Key elements of the specifications are described below at a high level. When considering comments, please refer to and comment on the text in the attached draft specifications.

6.1 ESTABLISHMENT DESIGN AND FACILITIES

The design of an infant formula manufacturing establishment is an important contributor to meeting expected food safety and suitability outcomes. A key aspect of establishment design is zoning (e.g. standard care and high care zones)

Environmental factors in different areas of an establishment must already be managed in a way appropriate to the products manufactured in those areas.

MPI considers that for infant formula, physically separating zones is the only practical way to effectively manage the different processing environments. We propose to set limits for air pressure differential between zones.

To maintain the integrity of zones MPI proposes to set out ways that movement of raw material, product, and staff between zones must be managed.

6.2 SUPPORTING SYSTEMS

Supporting systems for infant formula manufacturing include product contact utilities, cleaning (including ‘clean in-place (CIP) and pest management programmes), and HACCP.

In relation to cleaning, MPI proposes to specify features that all cleaning programmes must include to ensure the consistency and effectiveness of cleaning procedures.

6.3 RAW MATERIALS

MPI proposes to specify criteria or restate existing requirements in relation to raw materials including, raw milk acceptance criteria, material acceptance programmes, reprocessing of dairy material, storage and disposal of ingredients and dairy materials, and traceability of all materials used in the production of infant formula (including requirements for annual trace forward and trace back exercises).

6.4 FORMULATION

MPI proposes to specify that each manufacturer must keep a formulation register, and each formulation must be backed up with documentation that demonstrates its suitability. This would enable more effective monitoring by verifiers and MPI of the suitability of each product formulation. In addition, the draft specifications include requirements in relation to shelf life, composition and contaminants, and dispensary management (e.g. the weighing and measuring of ingoing ingredients).

6.5 MANUFACTURE

MPI proposes to set specific requirements or restate existing requirements in relation to process hygiene (including batch processing records), monitoring of product conformance (for example, sampling and testing programmes for nutritional and microbiological parameters), identification and treatment of non-conforming ingredients, recall procedures, processes to document complaints received, packaging, storage and transport.

6.6 EVALUATION AND VERIFICATION

MPI proposes to establish some specific requirements for evaluation and verification of infant formula manufacturing operations. This includes assessing and maintaining competency of operators, evaluators and verifiers. Specific requirements are also proposed to increase the audit intensity of infant formula manufacturing operations. Due to the vulnerability of the intended consumer, infant formula operators should expect more intense audit scrutiny. This is best achieved through more intense audits, rather than more frequent audits. We do not propose any change to the existing "ceiling" (or minimum) frequency for performance-based verification of once every three months.

Consultation Questions

3. With reference to the detail in the draft specifications (attached), do you have any comments or suggestions relating to any particular sections?

4. Are there specific aspects of the drafting in particular sections that should be changed? Please provide suggested changes and the reason for the suggested change.

5. If you do not agree with the proposed specifications for particular matters, please identify other ways that to meet the objectives of those matters.

6. Do you consider there are any areas that need to be addressed that are not already covered?

7. Please identify any potentially unintended consequences of particular specifications.

7 Options

The options discussed in this paper are either to maintain the status quo or proceed with the proposed specifications (set out in full in Appendix 1).

7.1 OPTION 1: STATUS QUO

This option would retain the current settings for infant formula manufacturing as described in the background and problem definition sections above.

7.2 OPTION 2: PROCEED WITH THE PROPOSED SPECIFICATIONS

Under this option, MPI would issue the proposed specifications, taking into account feedback received during consultation. Implementation of the specifications could lead to some increased costs for businesses. Potential costs are outlined below.

7.2.1 Costs to meet specifications

MPI is seeking information on any costs to infant formula manufacturers of complying with the proposed specifications, and the scale of such costs. This paper has identified potential costs, and grouped them by those that may be relevant to some or only few manufacturers of dairy based formulae for infants and young children, or manufacturers of dairy materials intended for use in those products.

We anticipate that some infant formula manufacturers may need to:

- update risk management documentation;
- carry out additional validation work;
- update their records; and
- update their cleaning programmes and associated documentation.

We anticipate that a few infant formula manufacturers may need to:

- alter their facilities or equipment setup;
- develop additional monitoring and testing programmes;
- update business practises with regard to re-work;
- calibrate equipment and record new calibration data; and
- develop additional cleaning parameters.

Consultation Questions

8. Are there any other costs that MPI has not identified?

9. What is the scale of any additional costs on your business that would result from the proposed specifications?

10. What changes could be made to the proposed specifications to avoid particular costs while still meeting the objectives?

7.2.2 Transition Period

MPI proposes that there would be transition arrangements for existing manufacturers to comply with the proposed specifications. MPI proposes that all existing operators should conform to the specifications within 6-12 months from the date of issue of the proposed notice.

Any new applications for RMP approval received after the date of issue of the proposed notice would need to comply with the notice.

Consultation Questions

11. Do you consider a transition period of 6-12 months for existing manufacturers is workable? If possible, please provide specific reasons for the need for a shorter or longer period (e.g. capital works that would need to be undertaken at a particular site)

Ministry for Primary Industries
Manatū Ahu Matua

Animal Products Notice

Animal Products (Dairy Based Formulae for Infants and Young Children) Notice 2014

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An animal products notice issued under the Animal Products Act 1999

New Zealand Government

TITLE

Animal Products Notice: Animal Products (Dairy Based Formulae for Infants and Young Children) Notice 2014

COMMENCEMENT

It is anticipated that this Animal Products Notice will come into force on [to be determined] for new programmes and [to be determined – between 6-12 months from issue] for existing programmes

ISSUING AUTHORITY

This Animal Products Notice is issued

Dated at Wellington this ... day of 2014

[to be determined]
Manager, Animal Products
Ministry for Primary Industries
(acting under delegated authority of the Director General)
A copy of the instrument of delegation may be inspected at the Director General's office.

Contact for further information
Ministry for Primary Industries (MPI)
Regulation and Assurance Branch
Animal Products
PO Box 2526,
Wellington 6140
Email: animal.products@mpi.govt.nz

Contents

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 set out additional requirements for the manufacture, evaluation and verification of dairy based formulae for infants and young children from the age of 0 to 36 months.

(2) The notice is intended to promote consistency in the application of risk management measures applied to the production and processing of dairy based formulae for infants and young children, and dairy ingredients intended for use in these products.

Background

(3) The World Health Organization (WHO) recommends that infants should be exclusively breastfed for the first six 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 up to two years of age or beyond. 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.

(4) As infant formula can be the sole source of nutrition for a vulnerable population group, particularly for the age range 0-6 months, stronger food safety monitoring and oversight is appropriate for dairy based formulae for infants and young children than for dairy products for adult consumers. Infants and young children have special nutritional needs and lower immunity than adults. Market expectations for safety are also particularly high for infant formulae and formulated supplementary foods for young children.

Who should read this Animal Products Notice?

(5) This notice will be of interest to:

a) Dairy processors manufacturing dairy based formulae for infants and young children.
b) Operators of risk management programmes covering the manufacture of:
    i) dairy based formulae for infants and young children, whether bulk or in consumer packs;
    ii) dairy based infant formulae powder that is formulated or partially formulated
    iii) dairy material or product represented as being intended for use in infant formulae
c) Persons supplying ingredients, packaging and other materials or services intended for use in the manufacture of dairy based formulae for infants and young children.
d) Agencies and Persons recognised to evaluate and verify risk management programmes for the manufacturing dairy based formulae for infants and young children.
e) Exporters of dairy based formulae for infants and young children.

Why is this important?

(6) In many cases Infant Formula is the sole source of nutrition for the developing infant, and as such must deliver the nutrients essential for health and development. The other formulae products covered by this Notice are also important sources of nutrition, while being supplemented by other foods.

(7) In addition to nutritional considerations infants are particularly vulnerable to pathogens. As such manufacturers must apply a higher level rigor to ensure that the products they supply will consistently meet all safety criteria.

Contacts

(8) [to be completed after consultation]

Other information

(9) These specifications are in addition to the general dairy processing requirements issued under the Animal Products Act.

Part 1: Preliminary Provisions

1.1 Application

(1) This notice applies to:

a) Dairy processors manufacturing dairy based formulae for infants or young children.

b) Operators of Programmes covering the manufacture of:

i) dairy based formulae for infants or young children, whether bulk or in consumer packs;

ii) dairy based formulae for infants or young children powder that is formulated or partially formulated

iii) dairy material or product represented as being intended for use in dairy based formulae for infants or young children

c) Agencies and Persons recognised to evaluate and verify risk management programmes for the manufacturing of dairy based formulae for infants or young children.

1.2 Definitions

(1) In this notice, unless the context otherwise requires, -

Act means the Animal Products Act 1999

Airlock means an enclosed space with two or more doors, and which is interposed between two or more rooms, e.g. of differing class of cleanliness, for the purpose of controlling the air-flow between those rooms when they need to be entered. An air-lock is designed for use by either people or goods.

Batch means a homogenous quantity of dairy material or dairy product manufactured during a discrete period of time, typically not exceeding 24 hours, as part of one continuous process, and Lot has the same meaning.

Blend means an individual sub unit within a batch that, immediately prior to packing, has been handled as a discrete unit of product.

Combined process - manufacturing process by which some of the constituents of the infant formula are wet processed and dried and other ingredients are added in a dry form after the heat treatment.

Medium Hygiene Area means the enclosed area in which heat treated product will or may be exposed and handled, prior to and including the point of packaging.

Standard Hygiene Area means the general processing environment and includes storage areas.

Dairy based formulae means, for the purpose of this Notice, all formulae for infants and young children aged 0 to 36 months that is based on dairy components.

Dairy Maintenance Compound has the same meaning as that given in the Animal Products (Dairy) Regulations 2005.

Dry mix process means manufacturing process by which all constituents of the infant formulae are processed dry and blended to obtain the desired final formula.

Follow On Formula has the meaning given to it in the Australia New Zealand Food Standards Code.

Formulated Supplementary Food for Young Children has the meaning given to it in the Australia New Zealand Food Standards Code.

High Hygiene Area means the enclosed area in which dry products and ingredients will or may be exposed to the environment, including blending and packing areas.

Indicator Nutrient means a nutrient whose concentration is measured during manufacture to confirm accurate and complete addition to, and/or uniform distribution in, an in-process batch or final product blend or batch.

Infant has the meaning given to it in the Australia New Zealand Food Standards Code.

Infant Formula has the meaning given to it in the Australia New Zealand Food Standards Code.

Infant Formula Product has the meaning given to it in the Australia New Zealand Food Standards Code.

Ingredient means all material included in the infant formulae including dairy material, non-dairy ingredients, additives and processing aids.

In-process batch means a dairy material in combination with any added ingredients at any point in the manufacturing prior to final packaging.Manufacture means all dairy processing activities at a physical location associated with the processing of dairy to modify the nature of dairy material, to package and to label dairy material or product. Manufacture includes storage of dairy material and product at the same physical location as the processing activities identified, but does not include milk harvesting, filtering, cooling and storage at a farm dairy and does not include storage when the only processing undertaken is storage, temperature control and repacking and labelling into outer packaging.

MPI Accepted Test Method means a test method that satisfies the criteria set out in the Animal Products (Dairy Recognised Agency and Persons Specifications) Notice.

Raw Material means all consumable items used to construct the packaged infant formulae product including ingredients, packaging and services such as gas and steam intended for direct contact the ingredients or product.

Operator Verification has the same meaning as given in the Animal Products (Risk Management Programme Specifications) Notice 2008.

Packing means the placing of dairy material or dairy product into a container or container inner where the dairy material or dairy product is in direct contact with the container or container inner. Packing is a manufacturing process.

Pathogen means a disease causing organism.

Programme means Risk Management Programme or Food Safety Programme (where production is for domestic market only).

Reprocessing means the processing of dairy material or dairy product that has already undergone and exited the process concerned, and would not be expected to re-enter the process..

Significant change means any change made to key staff, environment, premises, equipment, facilities, process, cleaning systems, product including formulation, packaging or label, which may affect the fitness for the intended purpose of the dairy material or dairy product.

Standard Hygiene Area means the general processing environment where heat treated material and product, and any ingredients not receiving heat treatment, will not be exposed.

Validation means, for the purposes of this Notice, the process by which the operator ensures that the programme or a discrete part of the programme is complete, and meets the requirements of the Act and any relevant animal product regulations and specifications; and when implemented, will consistently achieve the required outcomes of the programme or the discrete part of the programme.

Validation Protocol means, for the purposes of this Notice, a plan developed by the operator that describes the steps to be undertaken to confirm that a process or activity is valid, as provided for under the Animal Products (Risk Management Programme Specifications) Notice 2008.

Validation Report means, for the purposes of this Notice, a report that summarises the findings from a validation protocol and will establish whether an activity is valid, not valid or requires further investigation.

Validation Study means, for the purposes of this Notice, a study undertaken prior to a process step or activity being introduced, to confirm that the process or activity is valid, for example the validation of heat treatment.

Wet mix process - manufacturing process by which all constituents of the infant formula are handled in a liquid phase, and may involve homogenisation, heat-treatment, concentration by evaporation and then dried.

(2) Any term or expression that is defined in the Animal Products Act 1999, the Animal Products (Dairy) Regulations 2005 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 Notice.

Part 2: Premises and Equipment Design

2.1 Design and Construction

2.1.1 Plant Layout

(3) Premises should preferably be laid out in such a way as to allow the production to take place in areas connected in a logical order corresponding to the sequence of the operations and to the requisite cleanliness levels.

(4) The adequacy of the working and in-process storage space must permit the orderly and logical positioning of equipment and materials so as to minimise the risk of confusion between different products or their components, to avoid cross-contamination and to minimise the risk of omission or wrong application of any of the manufacturing or control steps.

(5) When exposed to the processing environment, interior surfaces including walls, floors and ceilings:

a) must be smooth, free from cracks and open joints,

b) must permit easy and effective cleaning and, if necessary, disinfection, and

c) must not shed particulate matter.

(6) Pipe work, light fittings, ventilation points and other services must be designed and sited to avoid the creation of recesses which are difficult to clean. As far as possible, for maintenance purposes, they should be accessible from outside the manufacturing areas.

(7) Where any pipe, wire or duct passes through any ceiling, floor or wall, the gap, whilst allowing for possible pipe expansion, should be sealed to prevent water seepage, harbourage of pests and the entry of insects and vermin from either side. Electrical ducting should be sealed to prevent the access of insects and rodents.

(8) Where product lines, service lines, ducting and trunking pass through walls, ceilings or floors, they should be flashed and sealed (using appropriate materials) to eliminate crevices on both the interior and exterior surfaces.

(9) Adequate space must be provided to enable processing activities to be undertaken as well as maintenance and inspection.

(10) Floors must be made of impervious material and be sufficiently smooth and sloped so that they are easily cleaned and free draining.

(11) Drains in wet processing areas must be of adequate size, kept clean, and must not present a contamination risk to the processing environment.

2.1.2 Hygiene Zones

(1) The manufacturing premises must be physically separated into designated hygiene zones according to the nature of processing.

(2) The following zones must be clearly documented within the programme–

a) Standard Hygiene Areas
b) Medium Hygiene Areas,
c) High Hygiene Areas

(3) Where the programme operator can justify locating processes in a Standard Hygiene Area due to the inherent safety of the design and operating characteristics, this must be clearly documented in the

programme and validated. Examples include UHT or similar processing equipment that is totally enclosed.

(4) All wet mix processing up to, but not including packing areas, must be separated from dry mix processing. The programme must ensure that direct access from wet areas to dry areas is prevented, and that water or moisture cannot inadvertently flow into the dry mix processing area.

(5) People must not move from wet to dry areas without appropriate change of protective clothing and controlled re-entry consistent with entry from an external area.

(6) Physical separation must be provided for areas where the nature of processing may affect other processing activities.

(7) Material storage areas must provide the required environmental conditions for the material stored, including temperature, light and humidity, and physical separation of -

a) packaging materials;
b) ingredients in a concentrated form;
c) other conforming ingredients;
d) all non-conforming materials; and
e) chemicals

(8) The dispensary for ingredients that will not undergo any bacterial reduction treatment must be in a designated High Hygiene Area.

(9) There should be defined areas or other control systems for the following activities:

a) Receipt, identification, sampling, and quarantine of incoming materials, pending release or rejection; and
b) Holding rejected materials before further disposition (e.g., return, reprocessing or destruction).

(10) Where lids are applied in a Standard Hygiene Area after the package has been sealed, the steps taken to protect the lids from contamination must be documented

2.1.3 Controlled Entry

(1) Access by personnel to Medium and High Hygiene Areas should only be via a personnel changing facility.

(2) Routine entry of plant, equipment, ingredients, chemicals, packaging, etc. to Medium and High Hygiene Areas should be via a buffer area such as an airlock that will protect the higher hygiene area from lower hygiene area.

(3) Buffer areas should have provision for cleaning items expected to pass through. Openings from Medium and High Hygiene Areas through which drums, cartons, cans, bags etc. are handled in rapid succession, that make the use of an airlock impractical, must be protected by suitable means such as properly constructed flaps, strips or air curtains. These openings must only be the minimum size necessary to allow passage of the containers, and when not in use steps must be taken to maintain air pressure differentials and protect against the entry of vermin and insects. This will typically require that conveyors have a removable section at the door.

(4) Medium and High Hygiene Areas must be part of the routine cleaning and sanitising programme and are not to be used for storage of items.

(5) Removal of outer packaging and decontamination of materials entering Medium and High Hygiene Areas should occur within the buffer area unless there is a technological reason that this cannot be achieved.

2.1.4 Air

(1) Positive air pressure

a) Air must not flow from lower hygiene zones to higher hygiene zones
b) High Hygiene, Medium Hygiene and Standard Hygiene Areas should always operate at a minimum positive air pressure of 40 Pa (4 mm water gauge). A design pressure of 60 Pa (6 mm water gauge) is generally considered adequate to achieve this.
c) When the one facility contains High Hygiene, Medium Hygiene and Standard Hygiene Areas, the pressure differentials must ensure correct airflow is maintained.
d) All production areas must be maintained under positive pressure outside processing times.
e) Ventilation systems should be balanced and periodically checked to ensure that design pressures are achieved.

(2) Inspection and maintenance programmes must be established to ensure air filtration is and remains effective and that the air is appropriate for the particular hygiene zone.

(3) Air must be filtered to ensure the removal of airbourne particles including bacteria and bacterial spores, odours if present, moisture and any other contaminants.

(4) Adequate ventilation, air filtration and exhaust systems are to be provided as appropriate for the area. These systems must be designed and constructed to minimise the risk of contamination and cross-contamination and should include control of air pressure, microorganisms , dust, odours, humidity, and temperature, as appropriate for the nature of processing being undertaken

(5) Air Temperature

a) In dry areas where product is exposed the air temperature must be maintained at a level that ensures all materials including ingredients will not be affected and, for manual handling of exposed product, operator comfort is maintained.

(6) Relative Humidity

a) In dry areas with product exposed the relative humidity must not exceed 65%. In situations where the relative humidity may exceed 65% the programme operator must set out a clear remedial actions to be taken, records of such actions, and justification with suitable evidence to demonstrate that product will not be adversely affected.

2.2 Equipment and Materials

2.2.1 General requirements

(1) All equipment must be of a design that is intended for the purpose for which it is used.

(2) Equipment for the manufacture of infant formula products must only be used for the processing of dairy material and dairy products intended for human consumption.

(3) All direct contact surfaces as well as indirect contact surfaces used for services such as water, steam, cleaning solutions and gases must be made using suitable materials that will not adversely affect the product.

(4) Fabrication of non-food contact surfaces must allow for regular cleaning and sanitising.

(5) Wood should not be used or introduced to the Critical Hygiene Area or High Hygiene Area unless:

a) There is no practical alternative
b) The use of wood is thoroughly reviewed to confirm that it does not and will not pose a contamination risk
c) Any wood that does enter a Critical Hygiene Area is inspected first to ensure that the wood is in good conditions and meets the minimum standard required to protect the processing environment

d) The personnel coming into direct contact with wood have no direct contact with product.

2.2.2 Repairs and Maintenance

(1) All intrusive maintenance must be undertaken in accordance with documented procedures and records kept.

(2) Equipment within processing areas must be maintained and must pose a risk to the suitability of the material being processed. Equipment that is no longer suitable for use must either be moved out of the processing area or clearly marked in a way that will ensure that it cannot be used.

Part 3: Supporting Systems

3.1 Product contact Utilities

(1) All utilities, including steam, gases, compressed air, heating, ventilation, air conditioning, must be suitably filtered or purified to remove particulates and eliminate contaminants such as oil and moisture (excluding steam) to ensure that product will not be adversely affected.

(2) Procedures must provide for the periodic confirmation that all utilities, including steam, gases, compressed air, heating, ventilation and air conditioning are of suitable quality with corrective actions taken when necessary.

3.2 Water

Note: Requirements for the suitability of water used within dairy processing are covered within DPC3.

3.3 Cleaning

(1) Cleaning

a) Processors must have procedures describing the overall cleaning regimes to be applied including, as appropriate, the:

i) Frequency
ii) Cleaning cycle, for example rinse-alkali-rinse-acid-rinse-drain in wet processes
iii) Chemicals and permissible chemical strengths
iv) Cleaning time and temperature at each step for cleaning solutions and sanitizers
v) Flow rates
vi) Dry cleaning
vii) Minimum drying times for dry process equipment and facilities to dry
viii) Means by which cleaning is confirmed, such as conductivity sensors
ix) Clear identification of equipment subject to cleaning out of place and equipment subject to cleaning in place.

b) Information must be held identifying all compounds used to clean, sanitise and maintain equipment and facilities. For compounds that are not MPI recognised the processor must assess the compound and confirm that it is suitable for the intended use and will not affect or contaminate the product, and will not cause accelerated deterioration of the processing components.

c) Where equipment is assigned to continuous production or campaign production of successive batches of the same product, equipment should be cleaned at appropriate intervals to prevent build-up and carry-over of contaminants and the development of biofims (e.g. degradation products or accumulation of minor ingredients, microbial growth).

d) Cleaning processes must be designed to restore the equipment and facilities to the required hygienic state while minimising the spread of dust and other wastes.

e) Equipment not in routine use must be cleaned to a suitable sanitary level before and after production to prevent contamination.

f) Records of major equipment use, cleaning, sanitization and/or sterilization and maintenance should show the date, time (if appropriate), product, and batch number of each batch processed in the equipment, and the person who performed the cleaning and maintenance.

g) Cleaning procedures must include the steps to be taken to ensure that cleaning items are stored correctly so that they will not be a source of contamination and will perform as intended.

h) Procedures must ensure that water and liquid cleaning solutions are to not be used in dry processing areas unless either:
   i) the area ceases production to permit full cleaning and sanitising, or
   ii) there is a valid technological reason and the use is documented.

i) Drying times for all equipment and facilities in dry areas must be established, and checks undertaken following a controlled wet clean to confirm that all parts are completely dry prior to production recommencing.

(2) Cleaning In Place (CIP)

a) Procedures must detail the minimum performance characteristics of the CIP system and the means by which the manufacturer will determine that the CIP has functioned as intended.

b) The processing system and CIP system must be constructed and controlled to positively prevent the intermixing of the product and any CIP solution.

c) Dry compounds used for cleaning or flushing in a dry process must be of food grade and subject to any appropriate checks to ensure equipment will not be contaminated.

(3) Validation of cleaning processes

a) Cleaning, sanitising and maintenance programmes must be documented and validated before acceptance into routine use to confirm that they will consistently achieve the intended outcome and ensure that surfaces and the processing environment will be clean and free from contamination.

b) Equipment cleaning must consider physical residues from the ingredients processed as well as microbiological contamination.

c) Validation of cleaning procedures should reflect actual equipment usage patterns. If various dairy material and products are manufactured using the same equipment and the equipment is cleaned by the same process, cleaning validation must consider these other materials and products, particularly those that are more likely to challenge the cleaning regime such as high protein, high fat and viscous material.The cleaning validation study or protocol should describe:

   i) the equipment to be cleaned;
   ii) the cleaning matrix including strengths, temperatures and flow rates;
   iii) the procedures, including which items are to be cleaned manually, by CIP or by other means;
   iv) parameters to be monitored during CIP to confirm complete cleaning such as conductivity, level/proximity sensors and/or solution strengths at the completion of cleaning;
   v) visual and sensory assessments to be undertaken;
   vi) the methods to be used to confirm cleaning effectiveness, including the type of samples to be collected, how samples will be collected and handled, and the analytical testing to be undertaken; and
   vii) where appropriate, the means by which removal of chemical residues is achieved.

(4) Revalidation

a) The cleaning regime must be revalidated should any changes be made to the process that render the existing validation invalid. This includes changes to equipment or the CIP cycle, or changes to the flow of material.

b) Reduction in time/temperature/chemical strength will require revalidation.

c) Supplier recommendations cannot be used as a substitute for validation.

d) Should an item be replaced on the basis of like for like, then re-validation is not required provided that the two items are for all intents and purposes identical.

(5) Operator verification of cleaning effectiveness

a) Cleaning procedures must be monitored at appropriate intervals after validation to ensure that these procedures are effective when used during routine production. Equipment cleanliness can be monitored by testing and visual examination, where feasible. Visual inspection can allow detection of contamination concentrated in small areas that could otherwise go undetected by sampling and/or analysis.

b) The programme must describe the programmed steps to be taken to confirm the ongoing effectiveness of cleaning procedures, including manual cleaning, CIP and equipment maintenance. Options include;

i) Monitoring of cleaning, sanitising and maintenance chemical strength and flow rate at the start, end and/or within the CIP circuit.
ii) Swabbing of surfaces, product contact, non-product and people contact surfaces
iii) Sampling flushings or the first product post cleaning.
iv) Obtaining samples of material or product at pre-determined points of the process, monitoring for appropriate hygiene indicators, and assessing against predetermined action limits.

c) Routine confirmation of cleaning effectiveness should be directed to areas or process steps where contamination or poor cleaning is more likely to occur.
d) The programme must identify the applicable limits that apply to the monitoring under subclause (a) as well as the steps to be taken to ensure that control is restored if limits are exceeded. Any potentially non-conforming product produced while limits weren't met must be identified. A multiple tier approach may be adopted, and product will only be deemed potentially non-conforming when the applicable limit has been breached.
e) For clarity, confirming effectiveness includes effective rinsing to remove chemical residues.

(6) Wastes must be removed from the processing environment regularly and any wastes stored temporarily within the processing environment must be placed into vessels or containers that are clearly labelled and appropriately contained to protect the processing environment.

(7) Maintenance and Housekeeping

a) The programme must identify which equipment items for cleaning and maintenance are permitted to be present in the processing environment.
b) To ensure that items are only used in the designated areas, all equipment used for cleaning and maintenance purposes must be assigned a unique identifying mark, such as an identifier and colour code to clearly indicate the item and the acceptable location for storage and use.

(8) Responses to failures

a) Any failure to apply effective cleaning as required by the programme must be recorded, investigated as a non-conforming event, and remedied as soon as possible.
b) Any and all ingredients and product that may have been adversely affected by the failure must be identified and managed as non-conforming product unless it can be shown that the ingredients or product can be shown to be unaffected..
c) Should the failure be identified before any further material is processed, and the area and equipment concerned is subject to a further compliant cleaning cycle, then no material or product is to be deemed non-conforming.

Note: Cleaning Validation must include:

- Consideration of drying times (dry areas)
- Consideration of cleaning compound suitability
- Vacuum – discrete vs. central (which is higher risk). The selection must be justified as equivalent
- Hoses
- Cleaning material grades

3.4 Calibration

(1) Control, weighing, measuring, monitoring and test equipment that is critical for ensuring product safety, integrity and suitability must be calibrated according to written procedures and an established schedule.

(2) Equipment calibration referred to in subclause 1 must be made against standards traceable to certified standards if they exist.

(3) Calibration records must be maintained. Current calibration status of critical equipment must be known and verifiable. Instruments not meeting calibration criteria or that do not have current calibration must not be used.

(4) Deviations from approved standards of calibration on critical instruments must be investigated to determine if these could have had an impact on any dairy material and/or product processed since the last successful calibration, andcorrective action taken to restore the calibration status.

3.5 Pest and Pathogen Programmes

(1) Pathogen management

a) The process and processing environment must be designed to minimise the introduction and proliferation of micro-organisms.

b) The hygienic status of the processing environment in High Hygiene Areas and Medium Hygiene Areas where product is exposed must be monitored regularly. The monitoring programme must be designed to provide an early warning that microbial contamination might occur if corrective actions aren't taken, and should consider–

i) Exposure plates monitoring for relevant hygiene indicators,
ii) Assessing contact surfaces and non-contact surfaces that personnel will contact to assess hygiene,
iii) Assessing contact surfaces after cleaning to confirm that the surfaces are free from residual material including fat/oil and protein, and
iv) Visual inspection of equipment, contact surfaces and the processing environment.

c) The programme must set out the frequency of monitoring, the escalated monitoring to be undertaken should unfavourable results be identified, and the location and procedures for sampling.

d) Procedures must ensure that access to High Hygiene Areas and Medium Hygiene Areas is restricted and that:

i) Personnel only enter through appropriate clothing change and sanitation control facilities.
ii) Outer clothing, including footwear, worn in High Hygiene Areas and Medium Hygiene Areas must be appropriate for the nature of processing within that area, and must ensure that product and contact surfaces are protected from contamination from personnel and the clothing. Outer clothing worn in wet areas must not be worn in dry High Hygiene Areas.
iii) Hand washing and, where appropriate, drying facilities must be provided prior to entry into Medium and High Hygiene Areas, and hand sanitising facilities should be provided after the clothing exchange or within the processing area as appropriate.

(2) Tools and equipment entry

a) Procedures must ensure that the opportunity for foreign matter or pathogen entry is minimised through cleaning and sanitising of items

b) All intrusive maintenance must be undertaken in accordance with documented procedures and records kept.

Note: Programmes:

- Need to consider air particles as well as airborne bacteria and surface hygiene
- Guidance to include the selection of monitoring points
- Environmental and in process monitoring to be integrated with escalations

Note: Staff health procedures and controls should be outlined – and should be event based rather than assessment when healthy (e.g. once per year). This supports the existing approach in the Dairy Regulations.

(3) Pest Management

a) Premises should be designed and equipped to protect the internal environment from the entry of insects and other pests.
b) There must be a regular programme of inspection for evidence of pest activity, with action taken to remedy deficiencies and both findings and corrective actions recorded. The frequency and intensity of inspections should be appropriate for the hygiene status of the environment.
c) When used, pest control stations must be subject to regular inspection and observations recorded.

Note: Pest management requirements are set out in the Animal Products (Dairy Processing Specifications) Notice.

3.6 Programme Validation

(1) The RMP operator is responsible for ensuring that validation is undertaken when the programme is first developed, and when changes to the programme are made that may impact on manufacture or the programme.

(2) When required, validation must provide objective, documented evidence that a particular process or activity, when operated within specified parameters, will perform effectively to produce material that consistently meets predetermined specifications and attributes.

(3) All processes under the programme must be validated, with validation procedures documented and records kept, including:

a) manufacturing process including carryover of material of differing formulations,
b) sanitation of items entering High Hygiene Areas
c) cleaning procedures,
d) sampling and sample handling procedures,
e) in-process control test procedures,
f) environmental monitoring,
g) computerized recording and control systems,
h) product formulation,
i) homogeneity of the packed product,
j) determination of shelf life and stability,
k) conditions for extending shelf life of any ingredient
l) packing processes, and
m) labelling.

(4) The parameters and attributes important to food safety and wholesomeness are to be identified and tolerance limits established based upon:

a) regulatory and nutritional requirements;
b) established process variability; and
c) test measurement uncertainty.

(5) Validation must be undertaken to ensure that the processes, systems and procedures are fit for the intended purpose, and must include:

a) a definition of the product in terms of its important product attributes,
b) a description of process parameters that could affect important product attributes,
c) the tolerance range for each critical process parameter expected to be used during routine processing activities, and how they are measured and monitored.

(6) In addition to subclause (4), each validation study must be documented and include:

a) the design and purpose of the study,
b) the competencies of persons undertaking validation
c) the findings including results,
d) an outline of the point at which any change will require re-validation.
e) the conclusions, and
f) any recommended changes required to correct deficiencies identified.

(7) For clarity, validation is not limited to identified CCPs and must include all activities determined to be important product fitness for purpose.

Validation Documentation

(8) For each programme element requiring validation that cannot be validated prior to manufacture commencing there must be a written validation protocol that specifies how each of those programme elements will be validated. Each validation protocol must be reviewed by suitably qualified technical and quality personnel.

(9) Each validation protocol must define the scope of activity being validated, the associated process control measures and the acceptance criteria associated with each process control measure.

(10) A validation report based on the validation protocol must be prepared once validation is complete. The validation report must summarise the results obtained, provide comment on any deviations observed, and present appropriate conclusions, including any recommended changes required to correct deficiencies identified.

Review of Validated Systems

(11) Systems and processes must be periodically reviewed to confirm that they are still operating in accordance with the validated performance criteria.

(12) Where no significant changes have been made to the system or process, and a review confirms that the system or process is consistently producing material meeting its specifications, there is no need for revalidation.

(13) Systems and processes must be 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 the validated performance criteria.

(14) Significant amendments to the programme which may affect the product, including items listed under subclause (2), must be revalidated.

Note: Validation competencies: competencies or qualifications will be set out in guidance material.

3.7 Chemicals and Maintenance Compounds

(1) All dairy maintenance compounds used must either be recognised by MPI for the specified use, or have passed assessment by the manufacturer.

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

(3) All maintenance compounds and other chemicals including inks must be clearly labelled with:-

a) the name of the product
b) the intended use
c) any warnings that may be required to clearly identify any restriction on permitted use.

(4) Chemical use within the manufacturing premises must be controlled and in accordance with documented procedures and label instructions.

(5) Chemical containers may only be re-used to store the same chemical or maintenance compound.

(6) All items including chemicals within the processing environment must be stored at designated locations when not in use.

3.8 Personnel Competencies

(1) Manufacturers must have:

a) a sufficient number of suitably qualified and competent personnel to carry out or supervise all tasks and functions.
b) The manufacturer must have an adequate number of personnel with the necessary qualifications and practical experience so that the responsibilities and duties placed on any one individual will not compromise risk management activities .
c) The manufacturer must have an organisation chart. People in responsible positions should have specific duties recorded in written job descriptions and adequate authority to carry out their responsibilities.
d) Job descriptions for all staff with specific responsibilities related to the programme.
e) Training records must be kept. Personnel in High Hygiene Areas should have additional training specific to the contamination hazards in that area.

(2) There must be sufficient technical expertise available to enable the manufacturer or RMP Operator to confirm that any product formulation will be suitable for the intended purpose, and how this will be met must be documented within the programme.

(3) Persons undertaking internal audits must be suitably qualified audit, and those undertaking periodic review of the programme, including HACCP Plan or Hazard ID and Analysis must be technically qualified to undertake the review.

(4) Manufacturers must ensure that only fit and proper persons are assigned key responsibilities under the programme.

3.8.1 Security

(1) Manufacturers must put in place procedures to prevent the entry of unauthorised people to any processing area.

(2) Production, storage and quality control areas should not be used as a right of way by personnel who do not work in them.

3.9 HACCP

(1) The Hazard Identification and Analysis or HACCP Plan is an essential component of the programme and the Programme operator must determine whether any Critical Control Points exist within the manufacturers processing activities.

3.9.1 Critical Control Points

(1) The following operations must be considered for inclusion as CCPs, and the rational for inclusion or exclusion documented:

a) Addition of ingredients relied upon to meet essential nutritional requirements
b) Heat Treatment
c) Confirmation that the correct product is placed in the correctly labelled package.
d) Foreign Matter control such as sifter, metal detector and/or X-ray
e) Ingredient receipt
f) product formulation

3.9.2 Foreign matter

(1) Foreign matter intervention measures may be either a CP or CCP. This will be determined through the hazard identification and analysis process while progressing through the HACCP principles.

(2) Use of intervention must be considered and the rational validated, including the use of–

a) inline magnets to remove metal
b) metal detectors for ferrous and non-ferrous metal
c) X-ray for the detection of non metallic foreign matter.

(3) Test Piece validation using product including pass/fail criteria

a) Operators must use ferrous and non-ferrous test pieces, size of the test pieces to be determined by the operator and recorded in their programme.
b) Test piece items should be located within packaged product being monitored at that point that is most difficult to detect.
c) Where a test piece is placed into packaged product, the packaged product must be clearly labelled and controlled in such a way that prevents it continuing through the process.

Note: MPI will define foreign matter standards.

Part 4: Raw Materials

4.1 Raw Milk Acceptance Criteria

(1) Raw milk intended for infant formula manufacture is to be;

i) heat treated within 72 hours of milking, and eithernot more than 10°C at delivery to the manufacturing site, or
ii) processed within 4 hours of receipt or cooled to 6°C or below.

(2) The following process hygiene tests are to be applied to the raw milk at the start of manufacture through periodic testing, and corrective actions taken and recorded if the process hygiene limits are exceeded–

a) Aerobic Plate Count (30°C/72 hours) maximum 300,000 cfu/ml
b) Titratable acidity 0.18% maximum.

(3) Raw milk that cannot be shown to meet the criteria in clause (1) may be used provided that steps are taken to show that the milk met the criteria set out in clause (2).

(4) Manufacturers must establish the storage tolerances for heat treated milk and liquid dairy material prior to drying, including time and temperature, to ensure the quality of the milk or dairy material is maintained.

4.2 Material Acceptance Programme

(1) Preferred Suppliers

a) Manufacturers must:

i) have documented procedures that set out the rationale and criteria to be used in the selection, acceptance and rejection of preferred suppliers, and the materials procured from those suppliers.
ii) ensure that preferred suppliers meet the capability, suitability and integrity criteria set out in the documented procedures under sub clause i) above, for example by way of audits or review of third party audits or review of an equivalent endorsement
iii) maintain a list of preferred suppliers, the steps taken to assess suitability, and the findings from that assessment
iv) audit or remove suppliers that fail to maintain the criteria set out under sub clause i)
v) maintain specification requirements for all raw materials to ensure they are fit for the intended purpose, and the means by which raw material conformance will be assessed.

(2) Material Acceptance Programme

a) Manufacturers must have the procedures and criteria for raw material receipt documented in their acceptance programme, including:

i) Confirming that the supplier is on the current preferred supplier list
ii) Confirming suitability, including:

1) Intended use and, where required, country eligibility
2) Testing, CoAs and lab accreditation
3) Integrity of packaging
4) Sensory assessment of the material by a suitably qualified person

b) Dairy processors must confirm that ingredients meet documented specifications suitable for dairy based formulae manufacture.

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c) The name and address of the manufacturer of all ingredients must be known. Reliance on third parties to supply materials and ingredients without disclosing the source is not permitted.
d) Materials should be purchased against an agreed specification, from a supplier or suppliers which have been approved
e) Changing the source of supply of relied upon raw materials requires a requalification of the raw material.

4.2.1 Sampling and Testing of Raw Materials

(1) Manufacturers must have a documented sampling and testing programme for raw materials that is designed to ensure all ingredients are fit for their intended purpose.

(2) The sampling and testing programme must ensure that–

a) the microbiological quality of ingredients not subjected to further validated pathogen elimination meet the microbiological requirements for the finished product.
b) relied upon macro and micro nutrients will be present in every item of packaged product at the correct level. Consideration must be given to:

i) evidence of ingredient composition for all relied upon ingredients, and
ii) ingredient homogeneity and stability

(3) All CoAs, supplier declarations or assurances, and other documented procedures and safe guards employed by the suppliers of ingredients to confirm ingredient conformance must be retained to support the manufacturers own determination of suitability.

(4) To confirm the accuracy of the information provided by ingredient suppliers, manufacturers must undertake their own testing periodically and compare the results obtained with the levels advised by the ingredient supplier. Where unreasonable deviations occur action must be taken to remedy the situation and all details recorded.

(5) Monitoring of non-food materials that may contact food materials or product must be documented and must be appropriate taking into consideration the nature of the material, its use within the process, and any confirmation of suitability that is obtained.

(6) The intensity of raw material testing must consider the intended intensity of final product testing, testing of market macro and micro nutrients being required per blend when adequate details are not known of the ingredients used.

4.3 Reprocessing

(1) Product and material intended to be reprocessed must be clearly identified and regularly removed from the processing area.

(2) Reprocessing of dairy material from one batch or blend into another batch or blend of dairy material intended for dairy based formulae without further heat treatment must be approved by the Director General as if it were non conforming product under regulation 5 of the Animal Products (Dairy) Regulations 2005.

(3) Proposals to reprocess product into dairy based formulae must be supported by the manufacture of the product to be reprocessed. Proposals must include;

a) The conformance status of the material or product,
b) The process to be undertaken,
c) Confirmation that the process is covered by the programme, and
d) Justification that the final product will remain fit for purpose

(4) The requirements of sub clause (2) and (3) do not apply where the following activities are clearly outlined in the programme and undertaken within an appropriate period:

a) Underweight or overweight product, and
b) Start of run product, excluding flushings.

Note: Only conforming ingredients intended for dairy based formulae for infants or young children may be used and ingredients or formulae that become non-conforming are to be disqualified.

4.4 Storage and Disposal

(1) Manufacturers must ensure that–

a) raw materials are clearly identified at all times
b) procedures describe how raw materials will be managed upon opening, including labelling and storage conditions and records of quantities consumed and when
c) records of material use must be kept, including date opened and the date/s and quantities consumed.

(2) Management of material and product not intended for dairy based formulae

a) All dairy material, product or other materials to be redirected to general human consumption product, animal consumption, non-edible processing or disposal must;

i) be clearly identified,
ii) be stored in such a way that the material will not contaminate the immediate processing environment
iii) not be stored in packaging that may result in the material being mistaken as conforming product
iv) be removed regularly from Medium and High Hygiene Areas

(3) Product and ingredient items must:

a) be stored under appropriate conditions with consideration to temperature and humidity,
b) not be stored with any goods that are poisonous, harmful, odorous, volatile, corrosive or offensive, and
c) for materials stored in fiber drums, bags, or boxes, be stored off the floor and suitably spaced to permit inspection and, if necessary, cleaning.

(4) Disposal of packaged product must meet the following requirements;

a) Product redirected to stockfood must be relabelled or have the existing label obliterated sufficiently so that the product would not reasonably be redirected to human consumption, appropriate records must be maintained including volumes and recipient.
b) For destruction, the product must remain under the control of the manufacturer through to the point of destruction with appropriate evidence retained for traceability purposes. For example photos and landfill receipts.

(5) Disposal of packaging must remain under the control of the manufacturer through to the point of destruction with appropriate evidence retained for traceability purposes.

Note: MPI to further consider controls in relation to discarding containers/packaging

4.5 Traceability

(1) Full traceability must be maintained

a) Traceability for all materials, including packaging, must be maintained on the basis of one step forward, one step back, namely, the identities of the supplier and the recipient and when the items were received or despatched.
b) All packaged product and waste material must be labelled or marked in a manner that enables the unique identity of the product and waste material to be determined. This must include, as a minimum, the Batch ID and ULI of the final manufacturer to pack and/or label.
c) For retail ready consumer packs, each individual item must have, as a minimum, the Batch ID and ULI of the manufacturer. This marking does not need to be on the face of the label but must meet the requirements of the intended market.
d) Processors must be able to trace both forward and back, that is, from raw material receipt through to all dairy material, product and waste streams and from any single product item back to the materials and processing records associated with the manufacture of that product.
e) Records to support tracing of dairy material and product must be held electronically to facilitate rapid tracing.

Note: Scope of traceability systems: the system should cover material handled by the operator (manufacturer). For example, the system should include products supplied by a third parties for toll manufacture

(2) Tracing forward and recall exercises

a) Processors must complete a tracing and mock recall exercise at least annually, based a nominal raw material or ingredient being non-conforming.
b) Records must be kept for the tracing and recall exercise, including the time taken from initiating the exercise until all product is deemed to be identified and the company would be in a position to initiate the recall.
c) Should the tracing and recall exercise take longer than 48 hours then the operator must document the actions to be taken to ensure the exercise can be completed within 48 hours and run a further exercise must be undertaken within 3 months.

(3) Tracing back exercise

a) Processors must complete a trace back exercise at least annually, based a nominal non-conforming manufactured product.
b) Records must be kept for the trace back exercise, including the time taken from initiating the exercise until all materials used to manufacture the product have been identified.
c) Should the trace back exercise take longer than 48 hours then the operator must document the actions to be taken to ensure the exercise can be completed within 48 hours and run a further exercise must be undertaken within 3 months.

(4) All disposal of ingredients must be recorded with all inwards and outwards items accounted for.

(5) Items entering and exiting the Critical Hygiene Area and High Hygiene Area must–

a) be clearly labelled
b) be subject to stock control, and
c) for housekeeping items, be coded to clearly indicate acceptable location and use.

Part 5: Formulation

5.1 Formulation Suitability

(1) The programme must ensure that each infant formula product is identified on a register maintained by the operator and must include:

a) the product name,

b) product and package type(s),

c) formulation (recipe) and anticipated product composition,

d) processing and packaging method (including gases),

e) label, and

f) the period in which the details are, or were, valid.

(2) A new record must be made when any change is made to any of the required parameters.

(3) The manufacturer must have a procedure to confirm formulation suitability and hold evidence that demonstrates consistent conformance to compositional standards.

(4) To satisfy sub clause (3) the manufacturer must take into consideration–

a) recipe,

b) ingredients, and

c) the packaging and packing method, as they relate to shelf life and stability.

(5) The RMP Operator is responsible for determining that the product will be fit for the intended purpose and for ensuring that the formulation uses compliant ingredients. Responsibility cannot be transferred to a third party regardless of any commercial arrangements that may be in place, but advice can be taken from suitably qualified individuals as part of the RMP Operators determinations.

(6) Where the manufacturing process is packing only, the packer is responsible for confirming that the product is fit for purpose.

5.2 Shelf Life

(1) The shelf life and stability (fitness for purpose) of ingredients prior to and post opening must be documented, and records must be kept as the ingredients are consumed.

(2) The validation of manufactured product shelf life and stability must be undertaken for each different product.

(3) The shelf life of the final product should not be longer than the shortest remaining shelf life of any ingoing processed dairy material or other ingredients unless a validation study has been undertaken to support any shelf life extensions anticipated by the manufacturer.

(4) Manufacturers intending to extend the shelf life of any ingredient must be able to clearly demonstrate that the extended shelf life is valid for the product. This may be achieved by way of:

a) Validation studies on the raw material, ingredient and/or final packaged product
b) Information provided by the manufacturer or supplier of the raw material or ingredient that is relevant to the stability of the final packaged product.

(5) For dry mix processes, the maximum permitted residual oxygen level in the packaged product must be defined by the operator for each product if the level of residual oxygen will impact on shelf life. If a level

is required to be set then the level in packaged product must be monitored and recorded at sufficient frequency to ensure that each packaged item is within the defined threshold.

(6) The purpose of the on-going stability programme is to monitor the product over its shelf life and to determine that the product remains, and can be expected to remain, within specifications under the labelled storage conditions.

5.3 Composition and Contaminants

(1) Fully formulated products and dairy material must meet the following chemical contaminant limits:

Parameters	**Maximum Permitted Level**	**Applies to**
Lead	0.02 mg/kg	all products (ready to eat basis)
Aflatoxin M_1 plus B_1	500 ug/kg	all products
Ash	3.6%	Fully formulated product only

Note that the contaminant limits set out above may be issued under *DPC1: Animal Product (Dairy) Approved Criteria for General Dairy Processing*

(2) Raw milk and milk powder used as raw materials must meet the following criteria;

Species		
Bovine	0.18% Titratable Acidity maximum	milk and reconstituted powder prior to formulation
Caprine and Ovine	0.16% Titratable Acidity maximum	milk and reconstituted powder prior to formulation

5.4 Dispensary Management

(1) Raw materials must be weighed or measured under appropriate conditions that do not affect their suitability for use

(2) Weighing and measuring devices must be of suitable accuracy for the intended use.

(3) If a material is subdivided for later use in production operations, the container receiving the material must be suitable and identified in a manner that will enable the following information to be readily determined:

a) Material name and/or item code;
b) Receiving or control number;
c) Weight or measure of material in the new container; and
d) Re-evaluation or retest date if appropriate.

(4) Critical weighing, measuring, or subdividing operations must be witnessed or subjected to an equivalent control. Prior to use, production personnel should verify that the materials are those specified in the batch record.

Note: Dispensary management guidance: Ingredients must be added either prior to pasteurisation before the filter controlling pasteurisation particle size, or at a point beyond the heat treatment holding tubes. No ingredients are to be added between the filter and the end of the holding tubes.

Part 6: Manufacture

6.1 Process hygiene

(1) Wherever possible direct contact must be avoided between the operator and the exposed product or any part of the equipment and packaging that comes into contact with the products.

(2) In cases where dust is generated (e.g. during sampling, weighing, mixing and processing operations, packaging of dry products), specific provisions should be taken to avoid cross-contamination and facilitate cleaning.

(3) There must be procedures describing the manner in which lines will be cleared between batches when processing dried powders and records must be kept.

(4) The outer packaging of ingredients should be removed when possible and the remaining packaging must be in a clean state before moving into the High Hygiene Area.

6.1.1 Batch Processing Records

(1) Batch processing records must include:

a) the name of the product;
b) dates and times of commencement, cessation and suspension of manufacture, and of significant intermediate stages;
c) the name of the person responsible for each stage of production;
d) the identity of the process operator at each significant process step and, where appropriate, the identity of any person cross checking actions and/or measurements such as weights;
e) the batch number and/or analytical control number as well as the quantities of each starting material actually weighed (including the batch number and amount of any recovered or reprocessed material added);
f) the processing activity as described in the programme and, for traceability purposes, the major equipment items used.
g) a record of the in-process controls and the initials of the person(s) carrying them out, and the results obtained;
h) dry mix, the amount of product yield obtained at different and pertinent stages of manufacture;
i) notes on special problems including details, with signed authorisation for any deviation from the manufacturing formula and processing instructions.

6.2 Monitoring dairy product conformance

6.2.1 Sampling and Testing Programme

(1) As part of HACCP, manufacturers must define their sampling and testing programme for final product, taking into consideration;

a) The intensity of inwards ingredients monitoring (including packaging),
b) The number and size of batches or blends produced per 24 hour period,
c) The results from environmental monitoring,
d) The results from confirmation of cleaning effectiveness,
e) The nature of the process, and

(2) 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. In addressing subclause (1) the design of the sampling and testing programme must;

a) specify sampling and sample handling procedures,
b) set out the parameters and frequencies for routine sampling and testing,
c) specify the acceptance tolerances for each parameter,
d) differentiate between process hygiene and product conformance testing,
e) set out escalation frequencies should unfavourable results or trends be identified,
f) identify actions to be taken in the event of unfavourable results or trends to rectify the situation,
g) identify the reporting requirements.
h) consider;

i) Microbiological parameters and relevant pathogens,
ii) Chemical residues and contaminants,
iii) Compositional parameters, including indicator nutrients, and
iv) Extraneous matter that may be objectionable or reflect unacceptable processing conditions.

(3) The testing programme must be designed in a way that will ensure the relied upon macro and micro nutrients will be present in every packaged item at the correct level. To achieve this confirmation of blend homogeneity must be considered and documented.

(4) Notwithstanding sub-clause (1) and (2), the rationale for inclusion or exclusion of salmonella, cronobacter spp. (infant formula only), and enterobacteriaceae must be documented.

(5) For clarity, unfavourable results for process hygiene parameters must trigger appropriate remedial actions but the dairy material or product under test remains conforming.

(6) Analysis of dairy material and product for food safety, wholesomeness and market access purposes must be undertaken in a laboratory recognised by MPI for that testing, using MPI accepted test methods.

(7) Analysis of other parameters required under the programme must be undertaken in a laboratory accredited to ISO 17025 with the test concerned coming under the scope of accreditation.

6.3 Retention Samples

(1) Official samples must be collected from each batch of dairy material and product manufactured and retained for MPI use as follows:

a) A minimum of three samples per batch must be collected each day. If the batch extends beyond a 24 hour period then there must be three samples collected per 24 hour period.
b) The three samples are to comprise start, middle and end of the batch or 24 hour processing period, whichever is shortest.
c) Samples must be retained for the shelf life of the product.

Note: Collecting retention samples more frequently within a batch may minimise product losses if an issue is identified with the product or process. It is also recommended that composite samples across all batch and blend are collected and retained.

6.4 Non conformance

(1) For clarity, dairy based formulae and dairy material intended for dairy based formulae must be deemed non-conforming if:

a) the batch fails to meet the product homogeneity requirements documented in the programme;
b) any individual product item or sample fails to meet either:
i) regulatory requirements for compositional,
ii) applicable chemical contaminant or residue limits,
iii) wholesomeness requirements,

iv) packaging integrity, or
v) contains unacceptable foreign or objectionable material;

c) the product has been manufactured using ingredients that are not permitted or are non-conforming; or
d) the product or any component has not been processed in full compliance with the programme and requirements issued under the Animal Products Act.

6.5 Non-conforming Ingredient

(1) Any ingredient or material, that is not covered section 6.4, including packaging, intended for use in the manufacture or packing of infant formula products that is determined to non-conforming or unsuitable must be clearly recorded, including all details related to product, supplier, batch, receipt, quantity and the nature of the fault.

(2) Should the non-conformance identified under sub-clause (1) be sufficiently significant that the packaged product would represent an immediate threat to public health, and then the nature of the non-conformance must be reported to the recognised agency within 48 hours in accordance with exception reporting.

6.6 Recall Procedures

(1) The programme must contain procedures to ensure that any dairy material or product which has left the dairy processor's control and is subsequently determined to be non-conforming is recalled, and the programme operator must-

a) notify recipients of all affected material or product
b) take immediate steps to recall product that has entered the retail chain
c) fulfil reporting obligations
d) ensure that the recall procedures satisfy the Food Act. for product in the New Zealand retail chain.

6.7 Complaints

(1) All valid food safety and product conformity complaints must be documented along with a record of the subsequent investigation including all relevant observations made during the investigation, and the corrective actions taken.

(2) Should an investigation identify a failure by the manufacturer to comply with the programme or any regulatory requirement then the failure must be notified to the Recognised Agency by way of an exception report.

6.8 Packaging and Identification

(1) Packaging

a) Retail ready consumer packs must be sealed and documented programme procedures or systems must ensure that the integrity of the seal is subject to regular inspection.
b) The packaging must be appropriate for the pack size, must be waterproof and must not break or allow contamination.
c) For dry products, the residual oxygen of the pack must be reduced to the level defined by the programme operator. This may be achieved through gas flushing with nitrogen or carbon dioxide, or the use of vacuum.

(2) Product contact gases must be of a suitable grade and must be filtered and treated to ensure removal of moisture, oil, particulates and other contaminants.

(3) Packaging materials must be inert and must not result in chemical migration that would render the product unfit for its intended purpose.

6.8.1 Finished Product integrity

(1) As part of the packing process, systems must ensure that the labelled package is checked to confirm that the correct product has been packed into the correct packaging item.

(2) The integrity of the packaged product must be confirmed through routine inspection and testing, with procedures and frequencies documented in the programme.

6.8.2 Repacking

(1) When packaged products are relabelled or repacked into new outers at another premises, then full traceability details must be maintained, including the identity of the premises undertaking the relabeling or repacking.

(2) Notwithstanding clause (1), the identity of the premises that packed and sealed the product must be retained and clearly evident.

6.9 Storage

(1) Dairy material and packaged product must:

a) be stored under appropriate conditions, including those set out under section 4.1 Raw Milk Acceptance Criteria
b) be stored under dry conditions if dry, and
c) not be stored with any goods that are poisonous, harmful, odorous, volatile, corrosive, offensive or that may otherwise affect the dairy material or packaged product.

6.10 Transport

(1) During transportation the dairy material, product and its packaging must be protected from hazards that may affect the dairy material, product and its packaging, and must not come into contact with goods that are poisonous, harmful, odorous volatile, corrosive, offensive or may otherwise affect the dairy material or product.

(2) Transport of dairy material or other liquid ingredients must be made in tanks, vessels or containers that:

a) are clean
b) do not adversely affect the dairy material or ingredient, and
c) do not permit cross-contamination, and are subject to periodic monitoring to confirm the provisions in this section are met.

Part 7: Evaluation and Verification

7.1 Suitable persons

(1) Programme Evaluators must assess operator competence as part of the programme evaluation

7.2 Duties

(1) Verifiers to confirm the competence of the programme operator and each individual premises.

(2) Persons that undertake evaluators, verification or audit of programmes covered by this Notice must periodically attend relevant calibration and competency exercises convened by MPI for evaluators, verifiers and/or auditors.

7.3 Additional Verification Requirements

(1) Label conformance

a) Labels of retail ready packaged infant formula must be checked to ensure that the nutritional information panel is consistent with the requirements of the Food Standards Code or any applicable 60B exemptions.

7.4 Audit Intensity

(1) Premises that manufacture dairy based powders or dairy based formulae must receive at least one non-notified audit per dairy season. Non-notified audits will normally be inspection based.

(2) When undertaking routine performance based verification audits, the verifier must consider all requirements set out in this Notice in conjunction with all other requirements imposed under the APA.

(3) In situations where–

a) required information proves difficult to obtain,
b) key individuals are not available to provide the information required, or
c) initial findings indicate a need for more in-depth assessment;

The verifier is required to extend the onsite audit, or to record the failure to provide information and schedule a revisit to occur within 30 days unless information is provided within 2 working days that meets the verifier's requirements.

Note: Infant formula processors should expect more intense audit scrutiny, which is best achieved through more intense audits rather than more frequent audits.

During audits, information is expected to be provided within two working days though most information should be available immediately. An inability to provide information brings into question the ability for day-to-day staff to fulfil their responsibilities.

Recognised Agencies, evaluators and verifiers must meet prescribed competency requirements which will be considered for inclusion in the Animal Products (Dairy Recognised Agency and Persons Specifications) Notice.