

**New Zealand Food Safety Authority
P O Box 2526, Wellington, New Zealand**

NZFSA: Dairy & Plants Standard

Circular number 79

Dairy Industry Regulations 1990

107.2 Dairy Product Safety

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107.2	15 May 2003	Promulgated by Circular number 79	Director, NZFSA Dairy & Plants	

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Issue of Circular and Implementation

Regulation 59 of the *Dairy Industry Regulations 1990* allows the Director General of MAF to issue Circulars setting out criteria for matters which must be approved by, or done to the satisfaction of, the Director-General, pursuant to the *Dairy Industry Regulations 1990*.

This Circular, no. 79, containing NZFSA Standard D107.2, "Dairy Product Safety" is issued in accordance with that regulation 59.

This Circular, no. 79, takes effect on 15 May 2003.

This Standard will apply to all new Product Safety Programmes (PSPs) from the date of issue by Circular.

Existing PSPs approved under the previous regulatory requirements will need to comply with this Standard twelve months from the date of issue. Amendments to currently approved PSPs to incorporate the requirements of this Standard will require validation prior to evaluation by NZFSA/Third Party Agencies (TPAs) and approval by NZFSA.

Approval for the following NZFSA standard is withdrawn:

- NZFSA Standard D107.1, "Dairy Product Safety".

Circular number 44, containing MAF Standard D107.1, "Dairy Product Safety", is revoked.



Tim Knox
Director, Dairy and Plant Products
New Zealand Food Safety Authority
15 May 2003

(Signed under authority delegated by the Director-General of MAF pursuant to regulation 59 of the Dairy Industry Regulations 1990.)

Foreword

The *Dairy Industry Act 1952* and the *Dairy Industry Regulations 1990* establishes a framework to provide assurances that dairy products manufactured in New Zealand are safe. The establishment of food safety outcomes is a key step in achieving this objective.

NZFSA standards are intended to assist the industry by interpreting the regulatory requirements, and indicating acceptable criteria for complying with the requirements and verifying compliance.

Specifically, this Standard defines the outcome requirements that are specified in the *Dairy Industry Regulations 1990* relating to the safety of dairy products that must be managed by everyone who manufactures, transports, stores, or exports any dairy product, to ensure that the dairy product is safe for human consumption. All product safety programmes (PSPs) covering the manufacture, transportation, storage or export of dairy products must include provision for ensuring product compliance with NZFSA Dairy Standard D107, "Dairy Product Safety".

The NZFSA Standard on Dairy Product Safety has been developed to:

- outline regulatory requirements specified in New Zealand dairy legislation for product safety; and
- describe acceptable criteria (means for satisfying NZFSA that the requirements are being achieved).

Where dairy product is sold in New Zealand, the *Food Act 1981* and the *Food Regulations 1984* provide many of the safety standards that must be met. The *Food Regulations 1984* were superseded by the joint Australia New Zealand food standards from the 20th December 2002.

NZFSA have not specifically established product safety standards for export dairy product. Where an importing country specifies some or all safety standards, these are given as Importing Country Requirements (ICR's).

Memoranda of understanding (MOUs) between the New Zealand Government and other governments exist. These MOUs are designed to recognise the equivalence with New Zealand's legislation and regulatory policies and procedures. Nations that have MOUs with New Zealand audit the practices in New Zealand to confirm equivalence.

The WTO Sanitary and Phyto-sanitary (SPS) Agreement states, "*Members shall ensure that their SPS measures are based on an assessment as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organisations*".

Critical to a SPS measure is the establishment of a Food Safety Objective (FSO). The FSO is "the reason/purpose for a sanitary measure, and which includes a description of the expected/ desired extent of control of food-borne hazards resulting from application of sanitary measure(s). In the context of equivalence, a FSO should provide a rationale for how and why a sanitary measure achieves or contributes to the achievement of a country's appropriate level of protection". FSOs are determined in the risk analysis process.

This Standard establishes interim product safety outcomes for dairy products pending the development of product safety outcomes based on FSOs.

This Standard applies to all dairy products that are:

- delivered to the retail distribution chain within New Zealand; or
- exported.

Everyone:

- who manufactures, transports, stores, or exports any dairy product;
- who is responsible for determining the conformance of dairy products to meet products safety outcomes
- who develops, evaluates or approves PSPs;

must comply with this Standard.

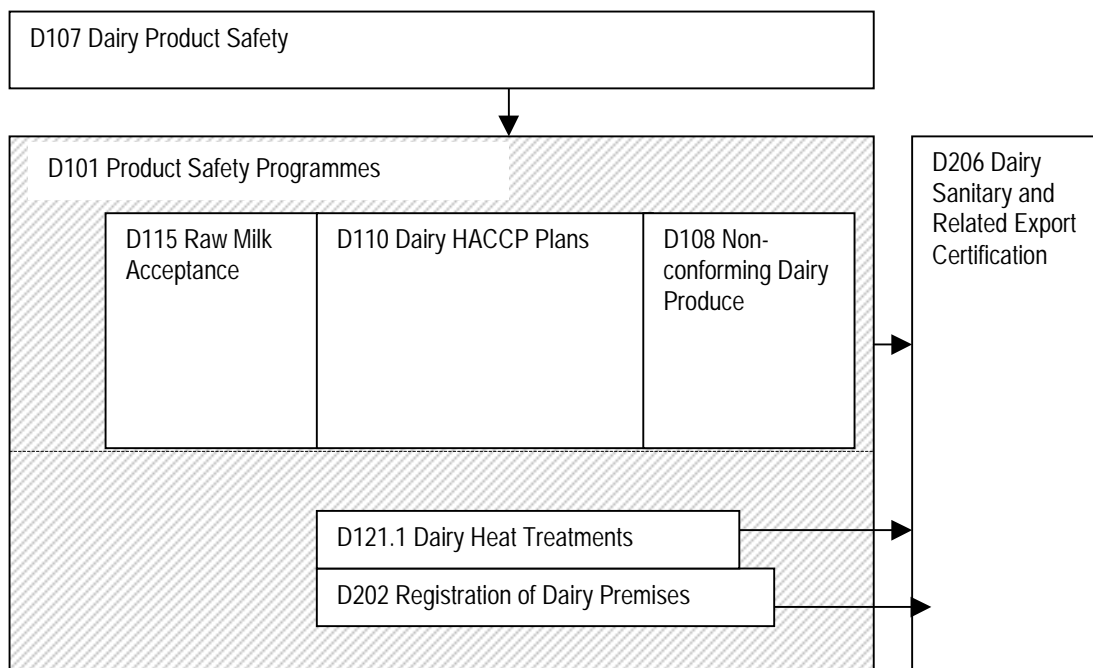
In addition, appendices to this Standard provide:

- the criteria used to assess whether the outcomes contained in the Standard are met; and
- importing country requirements relating to official assurances provided by NZFSA concerning Dairy Product Safety.

Preface

Context

This Standard specifies minimum product safety outcomes for all dairy products. As shown in the diagram below the majority of other standards are designed to provide a framework for the preparation of PSPs to ensure that these outcomes are met.



Resources

The following standards must be read in conjunction with this Standard:

- MAF Standard D101, “Product Safety Programmes”.
- MAF Standard D108, “Non-conforming Dairy Produce”.
- MAF Standard D110, “Dairy HACCP Plans”.
- MAF Standard D202, “Registration of Dairy Premises”.
- MAF Standard D206, “Dairy Sanitary and Related Export Certification”.

References

- Report to the Technical Consultative Committee (TCC) – Recommended Product Safety Limits for the New Zealand Dairy Industry. (This document is available on the NZFSA website at <http://www.nzfsa.govt.nz/dairy/publications/information-papers/tcc-psl.pdf>).

Effective changes¹

This Standard will introduce the following changes to the previously existing situation:

- Generic Microbial Product Safety Limits (PSLs) rather than Product Specific Microbial Limits resulting in changes to the required outcomes for some products.
- Microbial testing required to be commenced within seven days of manufacture.
- Removal of the previous requirements relating to heavy metals. The requirements for heavy metals are now contained in the Australia New Zealand Food Standards Code (FSC) (www.foodstandards.govt.nz).
- Changes to the vitamin product safety outcomes based on Codex requirements.
- Changes to the residue product safety outcomes referenced to MRL's.
- Radionuclides are to be monitored under a regulated control scheme.
- Product outcomes are to apply throughout the shelf life of the product.
- Use of results from retesting of product previously found to contain pathogens in excess of limits contained in this Standard is not permitted.

Future intentions

Work has commenced on amending the *Animal Products Act 1999* (APA) to include dairy operations in the scope of that legislation. The APA places an increasing emphasis on HACCP as the means of managing hazards, such as pathogenic micro-organisms in human food and animal feeds. The validated HACCP plan is the platform for an operator's Risk Management Programme (which is the APA version of a PSP).

¹ This section is provided to assist manufacturers to ascertain the extent of the changes that this Standard introduces. The information in this section is advisory and in all cases the Standard takes precedent.

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NZFSA Standard D107.2, “Dairy Product Safety”

1.0 Scope

This Standard defines the outcomes for ensuring that safe and wholesome dairy products are produced.

This Standard applies to all dairy products that are:

- delivered to the retail distribution chain within New Zealand; or
- exported.

Everyone who:

- manufactures, transports, stores, or exports any dairy product;
- is responsible for determining the conformance of dairy products to meet product safety outcomes;
- develops, evaluates or approves PSPs;

must comply with this Standard.

Commentary

- *Criteria for demonstrating how the outcomes have been met are provided in Appendix One.*
- *Importing country and export certification requirements may place additional requirements on dairy product safety. Further information about some of these additional requirements is provided in Appendix Two.*

2.0 Definitions

NZFSA: Dairy and Plant Products Group definitions of terms can be found in the “Glossary of Terms,” available on the Dairy & Plants website (www.nzfsa.govt.nz/Dairy).

These definitions must be read in conjunction with the interpretations in the *Dairy Industry Act 1952* and the *Dairy Industry Regulations 1990*.

Codex – The Codex Alimentarius, published by the Food and Agriculture Organisation (FAO) and World Health Organisation (WHO).

Compliance – General term to refer to all aspects of confirming that products, facilities, people, programmes, and systems meet regulatory requirements and, where applicable, importing country official requirements.

Dairy produce – Milk, cream, butter, cheese, and any other product of milk or cream.

Dairy product – Dairy produce intended for sale in, or export from, New Zealand for human consumption;

- (a) includes raw milk or cream intended for sale in New Zealand for human consumption as raw milk or cream; but
- (b) does not include raw milk or cream intended to be processed before sale in New Zealand for human consumption.

Export – Transport of goods outside New Zealand’s territory (i.e. beyond the “twelve mile limit”).

Foreign matter – Any extraneous thing:

- (i) that is injurious to health or harmful; or
- (ii) that is offensive; or

- (iii) the presence of which would be unexpected or unreasonable in food of that description prepared or packed for sale in accordance with good trade practice.

NZFSA: Dairy & Plants – The Dairy and Plant Products Group of NZFSA, reporting to the Executive Director, Dairy & Plant Products.

Manufacture – In relation to dairy product, means all activities involved with converting dairy produce into dairy product (with or without other substances or ingredients), and its preparation in a product factory for sale; and includes receipt or deposit of the dairy produce from which it is manufactured.

Non-conforming – In relation to dairy produce, any that is suspected or known not meet regulatory requirements.

Party – Person or Organisation subject to regulatory control pursuant to the *Dairy Industry Act 1952*.

Product Safety Programme (PSP) – An NZFSA-approved document detailing the means by which organisations will comply with regulatory requirements, including dairy industry legislation. (Note: Criteria for recognition of equivalent programmes such as Food Safety Programmes (FSP's) and Risk Management Programmes (RMP's) will be established longer term).

Satisfactory – In relation to any dairy produce, means:

- not having in it or on it any harmful or injurious substances;
- not being, or containing, decomposed, dirty, rotten, spoiled or diseased substances;
- not affected by disease;
- not affected by any objectionable taint or smell;
- not containing any foreign matter; and
- not condemned under Section 9 of the *Dairy Industry Act 1952*.

Safe – In relation to any dairy product, “safe” means satisfactory, fit for human consumption, and not having in it or on it any pathogenic organisms

- (a) that are present in an amount that makes the product harmful or injurious to the health of the people who may eat or drink it; or
- (b) that
- (i) are not present in an amount that makes the product harmful or injurious to the health of the people who may eat or drink it; but
 - (ii) by virtue of their ability to reproduce, to produce toxins, or both, make the product potentially harmful or injurious to the health of the people who may eat or drink it.

In relation to any dairy produce that is not a dairy product, “safe” means satisfactory, and fit for the manufacture of dairy products.

Shelf Life – Shelf life of a product is the period nominated by the manufacturer during which the product maintains its safety and suitability at a specific storage temperature and at other specified conditions.

Third Party Agency (TPA) – Organisation approved by NZFSA to carry out evaluation and/or verification services.

Unsafe –

- In relation to dairy produce, any that is not satisfactory.
- In relation to dairy products, any that is unfit for human consumption, or that is or may be harmful or injurious to the health of people who may eat or drink it.

- In relation to raw materials, ingredients, or product contact materials, any that contains microbiological, chemical, or physical contaminants which, if used in manufacture, could result in the production of unsafe dairy products.
- In relation to trends, any trends in environmental, process, or product testing that indicate the potential for unsafe dairy produce/products to be produced, e.g. continuing level 3 pathogen environmental surveillance results, continuing low levels of *E. coli* in product.

Wholesome – Means that the dairy product does not contain or have attached to it, enclosed with it, or in contact with it anything that is offensive, or whose presence would be unexpected or unusual in product of that description.

3.0 Outcomes

To comply with this Standard:

- All dairy products and dairy manufacturers must comply with section 14 of the *Dairy Industry Act 1952* and regulations 3, 4, 6, 8, 9, 10, 13 and 37 of the *Dairy Industry Regulations 1990*.
- All dairy products must be safe and wholesome
- Every person who manufactures, transports, or stores any dairy product must take all reasonably practical steps to ensure that it is safe and stays safe.
- All manufacturers of dairy products, and operators of stores and transporters who handle dairy products must operate in accordance with a product safety programme (PSP) approved by NZFSA in compliance with MAF Standard D101, "Product Safety Programmes". The PSP must document procedures to ensure that dairy products manufactured, sampled, examined, tested, stored and transported are safe and can be demonstrated to be safe.
- All non-conforming dairy product must be managed in compliance with MAF Standard D108, "Non-conforming Dairy Produce".
- Manufacturers must demonstrate the achievement of the outcomes set out in this Standard through the implementation of an appropriate hazard based management system as described in NZFSA Standard D110, "Dairy HACCP Plans".

Acceptable criteria by which a manufacturer may be judged to have satisfactorily achieved the outcomes described in section 3 of this Standard are specified in Appendix One. A Product Safety Programme (PSP) that includes procedures for ensuring that each of these criteria is satisfied and meets all other relevant PSP requirements will be approved by NZFSA.

Routine testing of product safety attributes may not be required where a HACCP Plan (refer NZFSA D110, "Dairy HACCP Plans") can demonstrate an equivalent level of confidence in meeting these product safety outcomes.

Proposals for alternative criteria will be accepted by NZFSA, provided it can be demonstrated, to NZFSA's satisfaction, that the required outcomes will be achieved. A guide to the information required in these proposals and the procedures used by NZFSA to assess proposals can be obtained from NZFSA.

4.0 Verification (external)

External verification of compliance with the outcomes described in section 3 of this Standard is undertaken by NZFSA or a NZFSA-approved Third Party Agency (TPA) as part of a PSP assessment.

4.1 Compliance

The manufacturer is compliant with the outcomes described in section 3 of this Standard if:

- the means to deliver the outcomes described in section 3 of this Standard are documented in NZFSA-approved PSPs; and
- the parties operate in accordance with that NZFSA-approved PSP.

Parties operating in compliance with the outcomes described in section 3 of this Standard and an NZFSA-approved PSP are entitled to:

- produce milk or cream intended for the manufacture of dairy products;
- transport or store dairy produce;
- manufacture, transport, or store dairy products for sale and/or export.

4.2 Non-compliance

Non-compliance with the outcomes described in section 3 of this Standard (including selling or exporting dairy products not manufactured in accordance with an approved PSP) constitutes an offence under regulation 49 of the *Dairy Industry Regulations 1990*.

If a dairy manufacturer does not operate in accordance with the requirements in this Standard:

- a Notice may be issued by a NZFSA Inspector to remedy any defects;
- export certification and/or use of any NZFSA marks may be suspended;
- approval of the PSP may be withdrawn; and/or
- prosecution for this and other offences may occur.

Appendix One: Acceptable Criteria

NZFSA: Dairy and Plant Products Group recognises that a Product Safety Programme (PSP) holder can meet the outcomes in section 3 of this Standard in a number of different ways.

Following are criteria by which a dairy PSP holder may be judged to satisfactorily achieve the outcomes described in section 3 of this Standard. A PSP that includes procedures for ensuring that each of these criteria is satisfied and meets all other relevant PSP requirements will be approved by NZFSA: Dairy and Plant Products Group.

A PSP holder may provide proposals for alternative criteria, which are other ways of delivering the outcomes in this Standard. NZFSA will approve these proposals provided it can be demonstrated to NZFSA's satisfaction that the required outcomes will be achieved. A guide to the information required in these proposals and the procedures used by NZFSA to assess proposals can be obtained from NZFSA: Dairy and Plant Products Group.

Similarly industry sectors may develop codes of practice that contain means of satisfying these criteria, and/or alternative means of achieving the outcomes described in section 3 of this Standard. NZFSA will approve these industry codes of practice for use by the sector concerned provided it can be demonstrated to NZFSA's satisfaction that the required outcomes will be achieved.

1.0 Product Safety

The following product outcomes apply to all dairy products and are not exceeded at any point during the product's shelf life, when handled and stored in accordance with manufacturer's specifications.

As stated in the standard "***Routine testing of product safety attributes may not be required where a HACCP plan (refer NZFSA D110, "Dairy HACCP Plans") can demonstrate an equivalent level of confidence in meeting these product safety outcomes.***"

1.1 Wholesomeness and Foreign Matter

All dairy products

- are wholesome and
- do not contain any foreign matter that constitutes a food safety hazard.

The manufacturer's PSP defines what constitutes a food safety and non food safety hazard for the products manufactured within the scope of the PSP.

1.2 Pathogenic micro-organisms

This section lists microbial Product Safety Limits (PSLs).

Key Points are as follows:

- The limits described are not exceeded at any time during the product's shelf life (assuming the product is handled and stored according to the manufacturer's guidelines).
- Where a PSP documents the requirement for routine pathogen testing, the testing is initiated as soon as possible, and not later than seven days after the completion of product manufacture².
- The manufacturer's HACCP plan, developed in accordance with the NZFSA Standard D110 "Dairy HACCP Plans", is used to provide the basis for the sampling and testing plan for the parameters described in Table A1.1.

²For Cheese manufacture, where a PSP documents the requirement for routine pathogen testing, the testing is initiated as soon as possible, and not later than seven days after the completion of initial processing, which includes brining (where appropriate), but does not include the cheese maturation period.

- In the event that pathogenic micro-organisms do exceed the limits in Table A1.1, the product is deemed to be non-conforming under D108.
- **Retesting After Issue of Final Laboratory Result:** Use of results from retesting of product previously found to contain pathogens in excess of limits contained in this Standard is not permitted. However additional testing may be carried out on previously untested product to establish limits of non-conformance in a product lot (e.g. where determination of cut-off points is required).
- **Retesting prior to issue of final Laboratory Result:** Where the laboratory has unequivocal evidence that the 'suspect' result arises from a failure of its internal systems (NB this requires clear documentation) then the use of retest results may be permitted. This is regarded as a 'laboratory internal retest' and each instance is reported as per NZFSA Standard D302 "Registration of Dairy Laboratories".
- All dairy products manufactured in New Zealand, for sale in New Zealand or Australia also comply with microbiological limits specified in the Australia New Zealand Food Standards Code (FSC) (refer to www.foodstandards.govt.nz for the current food standards).

Table A1.1 PSLs for Pathogenic Bacteria

Pathogen	General PSLs (1, 3)	Specific PSLs (2, 3)	Explanatory Notes / Comments
<i>Salmonella spp.</i>	ND/25g	ND/250g	<ul style="list-style-type: none"> ▪ ND = not detected in the volume tested ▪ Composite of samples collected throughout the production run as defined by the manufacturer's PSP
<i>L. monocytogenes</i>	ND/25g ⁽⁴⁾	ND/25g	<ul style="list-style-type: none"> ▪ ND = not detected in the volume tested ▪ Composite of samples collected throughout the production run as defined by the manufacturer's PSP
<i>Coagulase Positive Staphylococci (S. aureus)</i>	1000/g	100/g	<ul style="list-style-type: none"> • It is critical that sampling and testing are performed in a way that correctly estimates the maximum number of <i>S. aureus</i> reached in a product. This is important because the risk posed by released enterotoxin is 'estimated' by the bacterial load
<i>B. cereus</i>	1000/g	100/g ⁽⁵⁾	
<i>E. coli</i>	100/g	10/g	

(1) **General PSLs:** For product to be consumed by the general population.

(2) **Specific PSLs:** For products that are specifically designated for, and are likely to form, a substantial part of the dietary intake of more susceptible members of the population (i.e. infants and young children, the old, pregnant and immuno-compromised).

(3) **Sampling Rates:** If testing is required, the rate of sampling for each organism/product combination should be decided as part of a HACCP analysis performed on the manufacturing process (refer to NZFSA Standard D110, "Dairy HACCP Plans").

(4) **Listeria monocytogenes:** A figure of 100/g has been proposed by the Joint FAO/WHO Food Standards Programme, Codex Committee on Food Hygiene in the "Draft Guidelines for the Control of *Listeria monocytogenes* in Foods" and is obtaining increasingly wide acceptance. In the future, it may be appropriate to adopt a PSL of 100/g in circumstances where it can be shown that growth is extremely unlikely to occur during the life of the product. However, before this occurs, NZFSA and the dairy industry will need to be convinced that the 100/g figure has become accepted by reputable food safety authorities worldwide.

(5) **Bacillus cereus:** This limit only applies to product designated as infant formula.

1.3 Residues of agricultural compounds and veterinary medicines.

Dairy products manufactured in New Zealand for sale in New Zealand do not contain any residues exceeding the limits specified in the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2002*.

In addition dairy products manufactured for export do not contain any residues exceeding the limits specified by Codex.

The manufacturer's HACCP plan, developed in accordance with the NZFSA Standard D110 'Dairy HACCP Plans', is used to provide the basis for a sampling and testing plan for the parameters described in Codex and the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2002*. In the event that residues do exceed the limits, the product is deemed to be non-conforming under D108.

Maximum residue limits (MRLs) and extraneous residue limits (ERLs) published by Codex and the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2002* can be found on the NZFSA website.

Commentary

It is proposed that the National Chemical Contaminant Program in conjunction with current inhibitory substance testing will monitor for the compounds listed by Codex and the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2002. In the interim, monitoring of product for residues of agricultural compounds and veterinary medicines will be covered by specific incident reports, raw milk and finished product inhibitory substance testing and current multi residue analysis for pesticides e.g. DDE, DDT, Lindane, others.

1.4 Toxic Trace Metal

The levels of toxic trace metals in dairy product do not exceed the limits specified in the FSC (refer to Volume Two Standard 1.4.1 Contaminants and Natural Toxicants (refer to www.foodstandards.govt.nz)).

The manufacturer's PSP contains a sampling and testing plan for these substances that has been developed in accordance with NZFSA Standard D110, "Dairy HACCP Plans".

In the event that toxic trace metals do exceed the limits specified in the FSC, the product is deemed to be non-conforming.

1.5 Nutrient Fortification

This section lists fortification standards as given by Codex (refer to Codex Standard 72, 1981 "Infant formula" and Codex Standard 156, 1987 "Follow-up formula").

Table A1.2 Codex Standard for Nutrient Fortification*

Ingredient	Infant formula		Follow-up formula		Notes
	/100 kcal	/100 kJ	/100 kcal	/100 kJ	
Vitamin A	500 I.U. or 150µg	120 I.U. or 37µg	750 I.U. or 225µg	180 I.U. or 54µg	
Vitamin D	100 I.U. or 2.5µg	25 I.U. or 0.63µg	120 I.U. or 3µg	30 I.U. or 0.75µg	1,2
Sodium	63mg	15mg	88mg	21mg	2
Potassium	209mg	50mg	Not specified	Not specified	2
Chloride	146mg	35mg	Not specified	Not specified	2

Notes

- In the case of Vitamin D, product exceeding the nutritional standard is considered non-conforming product and will be disposed of in accordance with MAF Standard D108 “Non-conforming Dairy Produce”.**
- Should product exceed the limit for individual components the potential renal solute load and osmolarity should be calculated to determine if product is safe.
- The following points should be noted:
 - kJ is calculated by (fat x 37) + (protein x 17) + (carbohydrate x 17).
 - kcal is calculated by (fat x 9) + (protein x 4) + (carbohydrate x 4).
 - Infant means a person not more than 12 months of age.
 - Young children means persons between the age of 12 months and three years.
 - Follow-up formula means a food intended for use as a liquid part of the weaning diet from the 6th month on and for young children.

1.6 Radionuclides

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

2.0 Non-conforming dairy products

Where product is identified as non-conforming:

- Appropriate corrective action(s) as stipulated in the PSP is actioned.
- Dairy product is treated as ‘suspect’ and is managed in accordance with MAF Standard D108, “Non-Conforming Dairy Produce”.

* This table is correct as at 24/01/03. For current limits refer to Codex Standard 72, 1981 “Infant formula” and Codex Standard 156, 1987 “Follow-up formula”, available on the Codex website: http://www.codexalimentarius.net/standard_list.asp

Appendix Two: Importing Country Requirements

It is the responsibility of the exporter to identify and comply with all importing country requirements; non-compliance is at their commercial risk.

Importing country requirements, which have been officially confirmed, can be obtained from the NZFSA: Dairy and Plant Products Group website (www.nzfsa.govt.nz/Dairy).

Where NZFSA provides official assurances to competent authorities of importing countries, the statements to which NZFSA attests must be verifiable. Relevant requirements are described in MAF Standard D206, "Dairy Sanitary and Related Export Certification".