



Proposed Labelling Requirements for Export Infant Formula, Follow-on Formula, and Formulated Supplementary Foods for Young Children

Applicable to all retail-ready exports

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1 Submissions

The Ministry for Primary Industries (MPI) invites comment from interested parties on proposals to introduce minimum labelling requirements for exports of dairy-based retail-ready infant formula products and formulated supplementary foods for young children. 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); and
- your address.

Please submit your response by 20 August 2014.

Your comments should be sent to:

MPI Infant Formula Programme

PO Box 2835

Wellington

Email: Infant.Formula@mpi.govt.nz

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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.

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2 Introduction

This paper proposes introducing minimum labelling requirements for all retail-ready infant formula, follow-on formula, and formulated supplementary foods for young children intended for export from New Zealand (other than to Australia). These labelling requirements have been made in reference to international Codex Alimentarius Standards and the Australia New Zealand Food Standards Code. The proposals include criteria for making voluntary New Zealand origin label claims for these products.

It is proposed that the minimum labelling requirements are put in place by issuing an Animal Products Act 1999 Notice. The draft Notice is attached to this paper at Appendix 2.

The objectives of the proposals in this paper are to:

- support regulatory oversight of specified labelling requirements for exported infant formula, follow-on formula, and formulated supplementary foods for young children, while maintaining flexibility for exporters to meet the requirements of different export markets;
- provide clarity to industry and to verifiers on infant formula, follow-on formula and formulated supplementary foods for young children labelling requirements regarding what is required on a label, what is prohibited, and what is permitted voluntarily;
- improve the level of compliance of labels on exports of retail ready infant formula, follow-on formula and formulated supplementary foods for young children.¹

2.1 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, a risk-based approach suggests that 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 and traceability are also particularly high for infant formula products and formulated supplementary foods for young children.

2.1.1 Current legislation that applies to the labelling of exported retail-ready dairy products

The overarching principle of New Zealand's legislation is that all food for export must meet New Zealand domestic requirements, unless the food is an animal product and is expressly exempted. The Australia New Zealand Food Standards Code (issued as a food standard under Part 2 of the Food Act 1981) sets out composition (end product) and labelling requirements for all retail-ready foods sold in Australia and New Zealand. It also applies to all exported food, except where explicitly exempted. The standard for infant formula products has specific labelling requirements, such as the requirement for a warning statement on products ('Breast milk is best for babies'), and required statements for storage and preparation.

¹ For ease of writing, this paper will refer to 'infant formula products and formulated supplementary foods for young children' to cover all formula for children aged from 0-36 months. Infant formula products covers both infant formula and follow-on formula.

Currently, all dairy products (including infant formula) are exempted from meeting any retail-ready labelling requirements in the Food Standards Code. Notices issued under section 60B of the Animal Products Act 1999 can give exemptions from New Zealand standards. Under the *Animal Products (Exemptions from Labelling Standards for Dairy Product and Dairy Material Intended for Export) Notice 2006*, all dairy products and dairy material intended for export (other than to Australia) are exempted from any requirements regarding food labelling issued under Part 2 of the Food Act 1981.² This is to enable export products to meet importing country labelling requirements.

There are other labelling requirements for dairy products, including infant formula products, which are detailed below. Many of these requirements specifically relate to outer packaging.

Animal Products (Dairy) Regulations 2005

The Animal Products (Dairy) Regulations 2005, issued under the Animal Products Act 1999 (the APA) impose various duties on persons supplying and processing dairy material and products. Two sections relate to labelling: ‘Labelling and identification requirements’ (section 18) and ‘Dairy material or dairy product not to be associated with false or misleading representation’ (section 19). These require that all dairy material and dairy product is accurately described, and that there must not be any false or misleading representation concerning, for example, the supplier’s name, the product’s nature or physical condition, origin, composition, or ingredients.

Animal Products (Export Requirements – Dairy Products) Notice 2005

This Notice primarily imposes labelling requirements on the outer packaging for any exported dairy material and product, other than to Australia. This reiterates that no dairy product or dairy material intended for export is to be labelled or marked in a way that is likely to be misleading or deceptive as to its nature, origin or composition. It also notes that all dairy products must comply with any further labelling requirements prescribed by the importing country.

The Notice specifies that the outer packaging must identify what the product is, in accordance with the importing country requirements, or if there are no importing country requirements, in compliance with the Australia New Zealand Food Standards Code (the Food Standards Code) or be labelled or defined as a dairy product in such a way as to comply with the relevant definition in the Act. The outer packaging must also specify the net contents, as well as information for traceability purposes: the name and address of the manufacturer, and either the lot identification or date of manufacture.

2.1.2 Labelling requirements in overseas markets

Labelling requirements for infant formula products in overseas markets vary but most standards were developed with reference to the international Codex standards. In addition, many countries are signatories to the World Health Organization Code of Marketing for Breastmilk Substitutes, aspects of which (such as for warning statements on products) can be incorporated into domestic legislation. For example, Chinese labelling requirements for infant formula specify that the label should state that the most ideal food for infants for 0-6 months is breastmilk; and images of infants or women cannot appear on cans, nor any statement such as ‘like human milk, ‘like breast milk’ or similar terms.³

² MPI permits variations from the requirement to meet the composition standards (e.g. maximum and minimum levels of nutrients allowed in products) in the Food Standards Code on a case-by-case basis, under Notices under the APA. The exemptions are limited to being on a country-by-country basis, as when issuing an exemption the Director-General must give regard to the requirements of the overseas market.

³ GB 10765-2010 (National Dairy Standard for Infant Formula)

3 Problem Definition

3.1.1 Variation in the level of compliance of exported infant formula products

The purpose of food labelling is to provide information to consumers about the safety and suitability of food. This is particularly important for infant formula for the 0-6 months age group, as it can be the sole source of nutrition for this population group. Currently, all exports of infant formula are exempt from the specific labelling requirements in the Food Standards Code, apart from the labelling requirements that are stipulated for outer packaging in the Animal Products (Export Requirements – Dairy Products) Notice 2005. Products need to comply with the importing country requirements for labelling (which in many cases are similar to requirements in the Food Standards Code, as these were developed with regard to Codex standards) and provide safety and suitability information.

MPI has observed considerable variation in the labelling of export infant formula products, including in relation to nutrition and health claims, and New Zealand origin claims.

The exemption from domestic labelling requirements could be contributing to the level of variation seen on labelling of infant formula products and formulated supplementary foods for young children. Some exemptions are generally required across many markets – e.g. from the requirement to label in English (particularly if the country being exported to does not require English labelling). However, some labelling requirements (such as instructions for use and storage) directly affect safe use of the food.

3.1.2 Meeting overseas market expectations

Increasingly, overseas markets are expecting closer regulatory scrutiny of the formulation and labelling of infant formula products and formulated supplementary foods for young children, especially as they are ‘high-risk’ products and can be the sole source of nutrition for infants aged 0-6 months.

Consumers for sensitive products like infant formulas are looking for a high level of regulatory oversight for assurances about the safety and suitability of products they intend to buy for their infants and young children. This extends to government oversight of labelling, and the claims that are made on products.

In general, MPI is not required to provide official assurances in relation to the labelling of exported product. However, the variation observed in relation to labelling of export infant formula could impact on perceptions of the standard of products exported from New Zealand.

3.1.3 Lack of clarity as to what the general labelling exemption gives an exemption from

The Exemption Notice for exported dairy product is unclear as to how far the exemption applies. Operators have reported confusion about which labelling provisions in the Food Standards Code still apply, if any (e.g. if the labelling requirements contained in Standard 2.9.1 for infant formula products still apply).

MPI also receives regular queries from industry with regards to what can be put on a label, particularly nutrition content and health claims. Some countries, such as China, currently allow for nutrition content and function claims on products. New Zealand companies want to be able to do this to compete in market under the rules that apply in that market.

Question

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

4 Proposal

MPI considers that the generic exemption for labelling for all dairy products should remain in place (as contained in the Animal Products (Exemptions from Labelling Standards for Dairy Product and Dairy Material Intended for Export) Notice 2006). The exemption is necessary for exporters to be able to quickly and easily meet market access requirements (i.e. they do not need to go through a specific exemption process as for exemptions from the composition requirements of the Food Standards Code). The requirements in the Animal Products (Dairy) Regulations 2005 and Animal Products (Export Requirements – Dairy Products) Notice 2006 should also remain in place.

However, because infant formula products and formulated supplementary foods for young children are seen as a high risk product, and overseas consumers are expecting a higher degree of regulatory oversight for all aspects of its production and sale, MPI considers more clarity is needed in relation to the requirements for the labelling of these products for export. In particular, it should be made clear to manufacturers what the permissions are for nutrition content and health claims; and clear criteria is needed for New Zealand country of origin claims.

A proposed notice, to be issued under the Animal Products Act 1999 is attached at Appendix 2. The purpose of this Notice is to specify minimum labelling requirements for all dairy based infant formula, follow-on formula and formulated supplementary foods for young children in consumer-ready packages exported from New Zealand to all markets except to Australia.

Questions

2. Do you have any comments on the proposed introduction of minimum labelling requirements for all exported retail-ready infant formula, follow-on formula and formulated supplementary foods for young children?
3. If you do not agree with the introduction of minimum labelling requirements, what other ways do you consider the Government should be addressing labelling compliance for exports of these products?

4.1 LABELLING NOTICE APPLICABLE FOR ALL EXPORTED INFANT FORMULA PRODUCTS

4.1.1 General labelling requirements

The Notice specifies the information which must be on a label, but does not prescribe the format of the information – the label must be in a format that complies with the importing country requirements. It also specifies other information which must not be on a label, and information which can voluntarily be on a label, in accordance with certain criteria.

In addition, any specific importing country labelling requirements must also be met. If the requirements of the importing country and the requirements in the proposed Notice are in conflict, the importing country requirements take precedence over the requirements in this Notice.

Specific areas of the Notice are canvassed below.

4.1.2 Proposed mandatory requirements on a label

It is proposed that several labelling elements should be required on all labels. The list has been made with reference to the relevant Codex standards, and the Australia New Zealand Food Standards Code. These mandatory requirements are contained in clauses 2.3(1), 2.4(1), and 2.5(1).

The lists are presented in a way as to not specify exact requirements, for example, a product must have nutrition information labelling, but the specific format is not prescribed. Also, statements on infant formula and follow-on formula are required noting the superiority of breastfeeding or breast milk, and a statement that the product should only be used on the advice of an independent health worker. This enforces in law New Zealand's commitments as signatory to the WHO Organization Code of Marketing for Breastmilk Substitutes.

Question

4. Do you have any comments on the proposed mandatory requirements?

4.1.3 Proposed prohibitions on a label

Idealisation of infant formula

The Notice prohibits pictures of infants, pictures that idealise the use of infant formula, and the words 'humanised' or 'maternalised' or any word or words having the same or similar meaning. This incorporates the World Health Organization Code of Marketing for Breastmilk Substitutes (of which New Zealand is a signatory), which aims to contribute to providing safe and adequate nutrition for infants by protecting and promoting breastfeeding. Many other countries around the world have signed up to this Code.

Government emblems and logos

The use of names and emblems of New Zealand State agencies and organisations is restricted under the Flags, Emblems and Names Protection Act 1981. Labels of infant formula (or any other food export) should not display any logo or emblem of, or refer to, a New Zealand Government department unless specifically permitted or required by the relevant department as part of that department's administration of its functions under legislation delegated by Parliament.

Health claims on infant formula for infants aged 0-6 months, unless expressly permitted

The notice prohibits health claims on infant formula for infants aged 0-6 months, unless expressly permitted by the importing country. This recognises that health claims on products intended for infants 0-6 months old have the potential to undermine public health messages about the importance of breastfeeding.

Question

5. Do you have any comments on the proposed prohibitions on labels?

4.1.4 Proposed voluntary information on a label

Nutrition and health claims

The use of nutrition and health claims on infant formula products is a controversial area. The Codex Guideline 'Nutrition and Health Claims (CAC/GL 23-1997) states that nutrition and

health claims shall not be permitted for foods for infants and young children, except where specifically provided for in relevant Codex standards or national legislation. This guidance recognises the risk that the use of nutrient content and health claims on infant formula products could undermine global public health promotion of breast feeding. It also recognises that different countries have different approaches to the regulation of nutrient content and health claims on infant formula products.

Under New Zealand legislation, it is clear that nutrition and health claims are not permitted on infant formula products for infants aged 0-12 months. Nutrition content claims are permitted on products for infants aged over 12 months, in accordance with certain specified criteria.

The approach taken under this Notice is to:

- prohibit health claims on infant formula intended for infants aged 0-6 months unless a claim is expressly permitted by the importing country (as outlined above);
- Permit nutrition claims on infant formula, follow-on formula and formulated supplementary foods for young children where such claims are accepted by the importing country, are not misleading, and do not imply that the product is nutritionally equivalent or superior to breastmilk.
- Permit health claims on follow-on formula and formulated supplementary foods for young children where such claims are accepted by the importing country, are not misleading, and do not imply that the product is nutritionally equivalent or superior to breastmilk.

This allows New Zealand exporters to meet importing country requirements while ensuring that New Zealand's obligations under the World Health Organization Code of Marketing are considered.

Manufacturers and exporters are responsible for interpreting and meeting importing country rules in relation to labelling and claims, and are reminded that where express permissions are not provided in the importing country, they carry nutrition and health claims on products at their own commercial risk.

Question

6. Do you have any comments on the proposed approach for nutrition and health claims?
7. If your company was currently putting claims on products, would you be able to continue to do so, or would this activity become restricted under these proposals?

Proposed criteria for New Zealand origin claims

It is voluntary to make a New Zealand origin label claim on products for sale in New Zealand, or exported, for the purposes of marketing. However, the claim cannot be false or misleading.

To support consumers' and regulators' ability to identify authentic New Zealand infant formula products or formulated supplementary foods for young children in offshore markets, this paper proposes criteria for certain New Zealand origin claims on these products. The criteria would apply to the following claims, or any claim that is substantially similar:

- Product of New Zealand/100% New Zealand
- Made in New Zealand
- Made in New Zealand using/from local and imported ingredients

Table 1 sets out the proposed criteria for New Zealand origin label claims. Appendix 1 outlines how the proposed criteria were developed, and explains how the proposed criteria would apply in relation to trademarks and rules of origin.

Table 1: Production scenarios and claims					
#	Production scenario	New Zealand origin claim	Product of New Zealand/ 100% New Zealand	Made in New Zealand	Made in New Zealand using local and imported ingredients
1.	<ul style="list-style-type: none"> The product must be manufactured using all New Zealand origin constituents including vitamins and minerals (but not necessarily food additives); All or virtually all processes involved in the product's manufacture, (whether through a <i>wet</i>, <i>combined</i> or <i>dry-mix</i> process) must be carried out in New Zealand; and All packaging of the product must be carried out in New Zealand. 		Yes	Yes	Yes
2.	<ul style="list-style-type: none"> The product must be manufactured in a <i>wet-mix</i> or <i>combined</i> process carried out in New Zealand; All or virtually all⁴ the dairy protein constituents in the product must be of New Zealand origin; and The final blending and packaging must be carried out in New Zealand. 		No	Yes	Yes
3.	<ul style="list-style-type: none"> The product must be manufactured in a <i>wet-mix</i> or <i>combined</i> process carried out in New Zealand; Some, but not all of the dairy protein constituents in the product must be produced in New Zealand; and The final blending and packaging must be carried out in New Zealand. 		No	No	Yes ⁵

Any claim expressly required by an importing country government agency would be exempt from the requirements. The claim 'Country of Origin: New Zealand' would be exempted, if:

- it was located on the rear of the product's label;
- it was necessary or desirable to meet requirements of the importing country government.

⁴ 'or virtually all' in this instance intends to cater for situations where there may be a small amount of residual protein in lactose for example.
⁵ Under scenario 3 a 'Made in New Zealand' claim should be qualified with, for example, '...from/using local and imported ingredients'.

To carry 'Country of Origin: New Zealand' on its label, the product would still need to meet any relevant requirements relating to the *rules of origin* of the importing country. These are explained in Appendix 1.

Questions

8. Do you have any comments on the proposed criteria for New Zealand origin label claims?
9. How easy or difficult do you consider it would be for your company to make a claim under this criteria?

4.1.5 Verification and compliance requirements

It is proposed that manufacturers must have documented systems to ensure compliance with the requirements of this Notice, and verification will be undertaken by Recognised Agencies or Persons, as part of routine verification checks. It will be up to the verifier to determine how often the checks are undertaken, but it will be not less than annually. As happens now under performance based verification, there is scope for verifiers to determine what is checked at each visit and an operator that has more non-conformances or non-compliances in this area may warrant extra attention.

Where a manufacturer is meeting importing country requirements, instead of the requirements of this Notice, then the manufacturer must hold documentary evidence of the relevant importing country requirement. This means (in the case of making a health claim on infant formula for infants aged 0-6 months, as express permission is required) holding an English language version on the importing country's standard. For other health or nutrition claims, the evidence must be that it will be accepted by the importing country (e.g. an email from an official, or from a customer confirming that a health or nutrition claim can be present on the label).

If labels are not in English, in order to demonstrate compliance, a manufacturer must have a certified translated version of the label available for a verifier to check.

Questions

10. Do you consider that the proposed verification requirements are workable? If not, why not?
11. Do you consider there are other ways to meet the requirements for translation?

4.2 TRANSITION PERIOD

It is proposed there is an 18 month transition period between the issuing of the Notice and the Notice coming into force, to allow for any changes that operators need to make to be made as part of the cycle of usual labelling changes.

Question

12. Do you consider an 18 month transition period is workable, or do you think more or less time would be required?

Appendix 1: Development of New Zealand Origin Labelling Criteria for Exported Infant Formula Products and Formulated Supplementary Foods for Young Children

This section outlines how the proposed criteria for New Zealand origin claims were developed, and explains how the proposed criteria would apply in relation to trademarks and rules of origin.

Substantial Transformation

The international Codex Alimentarius General Standard for the Labelling of Pre-packaged Foods (1-1985)[1] states that:

- The country of origin of the food shall be declared if its omission would mislead or deceive the consumer.
- When a food undergoes processing in a second country which changes its nature, the country in which the processing is performed shall be considered to be the country of origin for the purposes of labelling.

In this paper, for the purposes of country of origin labelling for marketing, the term *substantial transformation* describes the processing of a product *which changes its nature*. For dairy based infant formula products or formulated supplementary foods for young children, a *substantial transformation* occurs in New Zealand when protein, fat, and carbohydrate constituents are combined in liquid phase and dried in New Zealand.

After considering Canadian and Australian examples, and consulting relevant government departments, MPI does not consider that mixing all ingredients together in dry form is a *substantial transformation* for the purposes of New Zealand origin labelling.

To help define a substantial transformation this paper draws on the Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008) which defines wet-mix, dry-mix, and combined processes:

- Wet-mix is defined as a ‘manufacturing process by which all constituents of the infant formulae are handled in a liquid phase, and may involve homogenization, heat-treatment, concentration by evaporation, and then dried.’

For the purposes of this paper MPI considers that in a *wet-mix* process any ingredients that are added in the fluid bed (the secondary drying stage immediately after spray-drying) are added in liquid phase.

- Combined is defined as a ‘manufacturing process by which some of the constituents of the infant formulae are wet processed and dried and other ingredients are added in a dry form after the heat treatment.’

For the purposes of this paper MPI considers that in a *combined* process:

- dry ingredients are added to the formula in the fluid bed.
- dry infant formula base is mixed with additional dry ingredients, provided that all the protein, fat and carbohydrate constituents in the base were mixed with each other in the liquid phase.

- Dry-mix is defined as a ‘manufacturing process by which all constituents of the infant formulae are processed dry and blended to obtain the desired final formula.’

For the purposes of this paper MPI considers that in a *dry-mix* process protein, fat or carbohydrate constituents such as skim milk powder and whey protein concentrate are obtained in dry phase then blended in the dry phase.

Therefore, a *substantial transformation* would occur in New Zealand where product was processed in a *wet-mix* or *combined* process, but not a *dry-mix* process. Mixing all constituents in dry form using existing technologies is not a *substantial transformation*. However, if all or virtually all the dry constituents including vitamins and minerals were themselves wholly produced in New Zealand, and any other relevant criteria were met, then a ‘Made in New Zealand’ or a ‘Product of New Zealand’ claim could be made.

Characterising component

In the context of this paper the characterising component of an infant formula product or formulated supplementary food for young children is the dairy protein component. MPI considers that dairy protein is usually associated with dairy based infant formula products or formulated supplementary foods for young children by consumers. The protein component of the formula is commonly what determines whether a formula is marketed as cow or goat milk formula for example, and if it were to be substituted with protein from a plant source the product would no longer be dairy based.

Essential constituents

In the context of this paper the essential constituents would be those required by the importing country to meet compositional requirements for infant formula products or formulated supplementary foods for young children. Essential constituents include: proteins, fats, carbohydrates, and other nutrients such as vitamins and minerals. A variety of ingredients can be used to meet compositional requirements.

MPI is not aware of any New Zealand manufacturers of infant or follow-on formula manufacturers that use all New Zealand essential constituents. Most countries have highly prescribed compositional requirements for infant formula, follow-on formula, and sometimes formulated supplementary foods for young children. Therefore, it would be difficult for New Zealand manufacturers to meet the threshold to claim ‘Product of New Zealand’, or similar those products.

Qualification of Claims

A qualifier is the latter part of a claim such as ‘Made in New Zealand from local and imported ingredients’. A qualifier, regarding the origin of certain constituents for example, can be made and may be necessary to avoid making a false or misleading claim.

Rules of Origin

Rules of origin in the context of this paper are the laws, regulations and administrative rulings applied by governments to determine the country of origin of goods for the purpose of tariff considerations. An infant formula product or formulated supplementary food for young children that qualifies as a New Zealand origin product under an overseas country’s rules of origin will not necessarily be able to make a New Zealand origin marketing claim on its label. In some instances it is necessary or desirable, for the purposes of Rules of Origin considerations, to include the statement ‘Country of Origin: New Zealand’ on the rear of a product’s label. In these instances, MPI does not consider this statement to be a marketing claim.

Trade Marks

Country of origin claims forming part of a trade mark, registered or not, must still meet the requirements of relevant legislation.

Products Sold in Australia and New Zealand

For origin labelling rules in Australia refer to the Australia New Zealand Food Standards Code and the Competition and Consumer Act 2010. For New Zealand refer to the Fair Trading Act 1986 and/or the Animal Products Act 1999 and associated legislation.



Draft for Consultation

**Labelling Requirements for
Exports of Dairy Based
Infant Formula Products
and Formulated
Supplementary Food for
Young Children**

TITLE

[Animal Products Notice: Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Food for Young Children]

COMMENCEMENT

[This Animal Products Notice comes into force on ..]

ISSUING AUTHORITY

[This Animal Products Notice is issued under sections 60 and 167(1)(ja) of the Animal Products Act 1999, being satisfied of the matters specified in section 60(1)(c) of the Act.]

Dated at Wellington this [...] day of [..... 2014]

Tim Knox
Director, Market Assurance
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)
Regulations and Assurance Branch
Food Assurance
PO Box 2526,
Wellington 6140
Email: food.assurance@mpi.govt.nz

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Introduction

This introduction is not part of the Animal Products Notice, but is intended to indicate its general effect.

Purpose

- (1) The purpose of this Notice is to specify minimum labelling requirements for all dairy based infant formula products and formulated supplementary foods for young children in retail ready packages exported from New Zealand to all markets, except to Australia.
- (2) This Notice specifies information that must be on a label, but does not prescribe the format of the information. It also specifies other information which must not be on a label; and which can voluntarily be on a label, in accordance with certain criteria.

Background

- (1) Currently, all exported dairy products are exempt from the labelling requirements of the Australia New Zealand Food Standards Code. This is to allow exporters to meet the labelling requirements of the importing country. However, as infant formula products have particular labelling requirements reflecting the special dietary needs for this group, and acknowledging the World Health Organization Code of Marketing of Breastmilk Substitutes, this Notice imposes basic labelling requirements on infant formula, follow-on formula and formulated supplementary foods for young children intended for export.
- (2) The basic labelling requirements have been made with reference to the following Codex Standards: 72-1981 'Standard for Infant Formulas and Formulas for Special Medical Purposes Intended for Infants'; 1-1985 'General Standard for the Labelling of Prepackaged Foods'; and 156-1987 'Standard for Follow-up Formula', and the Australia New Zealand Food Standards Code.

New Zealand origin claims

- (3) This Notice puts in place criteria for certain New Zealand origin label claims on retail-ready infant formula, follow-on formula, and formulated supplementary foods for young children intended for export. The criteria are contained in Part 3. The criteria are necessary to support regulators' and consumers' ability to identify authentic New Zealand products in overseas markets.
- (4) New Zealand origin claims in addition to those detailed in this Notice can continue to be used but must be truthful and not misleading as to the origin of the product and its constituent ingredients.
- (5) Manufacturers and exporters are reminded that, in addition to this Notice, the Animal Products (Dairy) Regulations 2005 require that dairy material, dairy product, or any ingredient added to dairy material or product, must not be associated with any false or misleading representation concerning, for example, the product's origin, composition, or ingredients.

Nutrition and Health Claims

- (6) The Codex Guideline 'Nutrition and Health Claims (CAC/GL 23-1997) states that nutrition and health claims shall not be permitted for foods for infants and young children, except where specifically provided for in relevant Codex standards or national legislation. This Guidance recognises the risk that the use of nutrition and health claims on infant formula products could undermine global health promotion of breast feeding. It also recognises that different countries have different approaches to the regulation of nutrition and health claims on infant formula products.
- (7) This Notice prohibits health claims on infant formula intended for infants aged 0-6 months unless a claim is expressly permitted by the importing country.
- (8) This Notice permits nutrition claims on infant formula, follow-on formula, and formulated supplementary foods for young children where such claims are accepted by the importing country, are not misleading, and do not imply that the product is nutritionally equivalent or superior to breastmilk.

- (9) This Notice permits health claims on follow-on formula and formulated supplementary foods for young children where such claims are accepted by the importing country, are not misleading, and do not imply that the product is nutritionally equivalent or superior to breastmilk.
- (10) Manufacturers and exporters are responsible for interpreting and meeting importing country rules in relation to labelling and claims, and carry any commercial risks associated with making nutrition and health claims.]

Who should read this Animal Products Notice?

- (11) [All manufacturers and exporters of retail-ready infant formula products and formulated supplementary foods for young children and Recognised Agencies and Persons who undertake verification of such activities.]

Why is this important?

- (1) [Operating other than in accordance with this Notice may result in a product being ineligible for export.
- (2) For the purposes of section 135(1)(c) of the Animal Products Act 1999, a failure to comply with this Notice, without reasonable excuse, is an offence.]

Contacts

- (1) [For all matters relating to operation of this Notice, please dial MPI's general inquiry line 0800 00 8383 (local) or +64 4 894 0100 (overseas), and request to be put through to the Food Assurance Team.
- (2) Alternatively, you can write to us at the address provided at the bottom of page 1 of this Notice.]

[Other information

- (1) This Notice does not contain an exhaustive list of prerequisite requirements for the export eligibility of Infant Formula Products, and Formulated Supplementary Foods for Young Children. It is the responsibility of dairy operators to ensure familiarity with the Animal Products Act 1999 and all legislation issued under it that are of relevance to the subject matter.]

Part 1: Preliminary Provisions

1.1 Application

- (1) This Notice applies to all manufacturers and exporters who label retail-ready infant formula, follow-on formula and formulated supplementary foods for young children prepared for export from New Zealand (other than to Australia.)
- (2) The requirements in clauses 4(3); 4(4) and 4(5) of this Notice apply to Recognised Agencies and Persons.
- (3) The contents of this Notice apply to the products listed above, despite the existence of the Animal Products (Exemption from Labelling Standards for Dairy Product and Dairy Material Intended for Export) Notice 2006.

1.2 Definitions

Act means the Animal Products Act 1999

Australia New Zealand Food Standards Code means the current joint food standards code established under the Australia-New Zealand Joint Food Standards Agreement

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

Dairy based means the formula contains, as its predominant protein constituent, protein derived or processed from milk extracted from a milking animal such as a cow, goat or sheep

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

Exporter means a person who exports infant formula, follow-on formula or formulated supplementary foods for young children from New Zealand (other than to Australia)

Infant formula and **follow-on formula** has the same meaning as Standard 2.9.1 of the Australia New Zealand Food Standards Code, or any future standard which may replace this standard. Infant formula is product formulated to be used from birth. Follow-on formula is product formulated to be used from the age of six months

Formulated Supplementary Foods for Young Children has the same meaning as Standard 2.9.3 of the Australia New Zealand Food Standards Code, or any future standard which may replace this standard, with the exception that it is product formulated to be used for children aged 12 to 36 months

Health claim means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Health claims include nutrient function claims; other function claims concerning specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body; or reduction of disease risk claims

Manufacturer means any operator who manufactures and/or labels retail-ready infant formula products or formulated supplementary foods for young children

Nutrition claim means any representation which states, suggests or implies that a food has particular nutritional properties, including, but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals

Supplier means the packer, manufacturer, vendor or importer

Retail-ready means product which is in a form ready to be sold to consumers, and may or may not need to be reconstituted prior to use. This excludes trade samples, i.e. product not in a form intended to be sold or provided to the consumer

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

Draft for Consultation

Part 2: Labelling Requirements

2.1 General provisions

- (1) All labels of retail-ready infant formula, follow-on formula and formulated supplementary foods for young children that is to be exported must contain the information set out in clauses 2.3(1), 2.4(1), and 2.5.(1) of this Notice, and the information must be in a format that complies with the importing country requirements.
- (2) In addition, any specific importing country labelling requirements must also be met.
- (3) If the requirements set out in this Notice and the importing country requirements are in conflict, the importing country requirements, as expressly detailed in the importing country's laws, take precedence over the requirements in this Notice.

2.2 Language requirements

- (1) Labels must be in -
 - a) the language or languages of the importing country; or
 - b) English; or
 - c) dual language: in both the language of the importing country, and in English.
- (2) Where a label is dual language, the information must be consistent in each language.

2.3 Labelling requirements for infant formula

- (1) All labels of retail-ready infant formula to be exported must contain the following information -
 - a) A name or description of the food sufficient to indicate the true nature of the food, or the name of the food as used in the importing country (e.g. infant formula):
 - b) Protein source:
 - c) List of ingredients:
 - d) A warning statement or declaration of the foods and ingredients known to cause hypersensitivity (e.g. allergens), if required by the importing country:
 - e) Declaration of nutritive value (i.e. nutrition information labelling), in a format as required by the importing country:
 - f) Date marking information (i.e. use by date):
 - g) Storage directions and instructions for use:
 - h) Statement on safe preparation and storage once made-up (if powdered):
 - i) Net weight of the product:
 - j) Name and business address of supplier:
 - k) Lot identification:
 - l) Under the heading 'Important Notice' (or equivalent), a statement: 'Breast milk is the best food for your baby', or similar statement as to the superiority of breastfeeding or breast milk, and a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of its use:
 - m) Statement on suitability (e.g.: 'Product may be used from birth').
- (2) Labels of retail-ready infant formula to be exported must *not* contain the following information -
 - a) Pictures of an infant:
 - b) Pictures that idealise the use of infant formula:
 - c) The word 'humanised' or 'maternalised' or any word or words having the same or similar meaning:

- d) Any emblem or logo of a New Zealand government department or agency, or depiction that could be confused with any form of government endorsement (e.g. Ministry for Primary Industries or its predecessors), without the express permission of the responsible agency or agencies:
 - e) A health claim, unless expressly permitted by the importing country.
- (3) Labels of retail-ready infant formula to be exported may contain the following information -
- a) New Zealand origin label claims, in accordance with specified criteria in Part 3 of this Notice:
 - b) Nutrition claims where these are accepted by the importing country, are not misleading, and do not imply the product is nutritionally equivalent or superior to breastmilk.

2.4 Labelling requirements for follow-on formula

- (1) All labels of retail-ready follow on formula to be exported must contain the following information -
- a) A name or description of the food sufficient to indicate the true nature of the food, or the name of the food as used in the importing country (e.g. follow on formula, or follow-up formula):
 - b) Protein source:
 - c) List of ingredients:
 - d) A warning statement or declaration of foods and ingredients known to cause hypersensitivity (e.g. allergens), if required by the importing country:
 - e) Declaration of nutritive value (i.e. nutrition information labelling), in a format as required by the importing country:
 - f) Date marking information (i.e. use by date):
 - g) Storage directions and instructions for use:
 - h) Statement on safe preparation and storage once made-up (if powdered):
 - i) Net weight of the product:
 - j) Name and business address of supplier:
 - k) Lot identification:
 - l) Under the heading 'Important Notice' (or equivalent), a statement: 'Breast milk is the best food for your baby', or similar statement as to superiority of breastfeeding or breast milk and a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of its use:
 - m) Statement on suitability (e.g.: 'Should not be used for infants aged under 6 months; and infants over the age of 6 months should be offered foods in addition to formula.')
- (2) Labels of retail-ready follow-on formula to be exported must *not* contain the following information -
- a) Pictures of an infant:
 - b) Pictures that idealise the use of infant formula:
 - c) The word 'humanised' or 'maternalised' or any word or words having the same or similar effect:
 - d) Any emblem or logo of a New Zealand government department or agency, or depiction that could be confused with any form of government endorsement (e.g. Ministry for Primary Industries or its predecessors), without the express permission of the responsible agency or agencies.
- (3) Labels of retail-ready follow-on formula to be exported may contain the following information -
- a) New Zealand origin label claims, in accordance with specified criteria in Part 3 of this Notice:
 - b) Nutrition and health claims where these are accepted by the importing country, are not misleading, and do not imply the product is nutritionally equivalent or superior to breastmilk.

2.5 Labelling requirements for formulated supplementary foods for young children

- (1) All labels of retail-ready formulated supplementary foods for young children to be exported must contain the following information -
- a) A name or description of the food sufficient to indicate the true nature of the food, or the name of the food as used in the importing country (e.g. growing up milk; toddler milk; formula for older infants and young children):
 - b) List of ingredients:
 - c) A warning statement or declaration of foods and ingredients known to cause hypersensitivity (e.g. allergens), if required by the importing country:
 - d) Declaration of nutritive value (i.e. nutrition information labelling), in a format as required by the importing country:
 - e) Date marking information (i.e. use by date):
 - f) Storage directions and instructions for use:
 - g) Statement on safe preparation and storage once made-up (if powdered):
 - h) Net weight of the product:
 - i) Name and business address of supplier:
 - j) Lot identification:
 - k) Statement on suitability (e.g. must indicate the role of the food as a supplement to a normal diet, to address situations where intakes of energy and nutrients may not be adequate.)
- (2) Labels of retail-ready formulated supplementary foods for young children to be exported must *not* contain the following information -
- a) Any emblem or logo of a New Zealand government department or agency, or depiction that could be confused with any form of government endorsement (e.g. Ministry for Primary Industries or its predecessors), without the express permission of the responsible agency or agencies.
- (3) Labels of retail-ready formulated supplementary foods for young children to be exported may contain the following information -
- a) New Zealand origin label claims, in accordance with specified criteria in Part 3 of this Notice:
 - b) Nutrition and health claims where these are accepted by the importing country, are not misleading, and do not imply the product is nutritionally equivalent or superior to breastmilk.

Part 3: New Zealand Origin Label Claims

3.1 Claims must be made in accordance with criteria

- (1) Any of the claims in sub clause (2) or any claim which is substantially similar to those in sub-clause(2) must be made in accordance with the criteria specified in Schedule 1, unless otherwise exempted in clause 3.2.
- (2) New Zealand origin claims -
 - a) Product of New Zealand or 100% New Zealand
 - b) Made in New Zealand
 - c) Made in New Zealand from local and imported ingredients

3.2 Exemptions

- (1) A claim is exempt from the requirements of clause 3.1 if:
 - a) it is expressly required by a relevant importing country government agency; or
 - b) it is a claim of 'Country of Origin: New Zealand'; and
 - i) is located at the rear of the product label; and
 - ii) is necessary or desirable in order to satisfy any requirements of a relevant importing country government agency.

Part 4: Verification and Record Keeping

4.1 General provisions

- (1) A manufacturer must have documented systems to ensure compliance with the requirements of this Notice.
- (2) A manufacturer must keep records for a minimum of four years that are readily available and verifiable, and demonstrates compliance with this Notice, including documentary evidence of relevant importing country requirements where a manufacturer is complying with an importing country requirement, instead of the requirements of this Notice.
- (3) Verification of compliance with this Notice must be undertaken by a Recognised Agency or Persons, as part of routine verification checks, not less than annually.
- (4) A verifier must check:
 - a) the system a manufacturer has in place to ensure compliance with the requirements of this Notice; and
 - b) a sample of at least five labels annually; and
 - c) where a manufacturer is meeting importing country requirements, instead of the requirements of this Notice, then the documentary evidence held by the manufacturer of the relevant importing country requirement.
- (5) Where significant non-compliances to this Notice are detected during verification, the verifier may increase the frequency of verification.

4.2 Translations

- (1) If the labels are not in English, in order to demonstrate compliance, a manufacturer must have a translated version of the label available for a verifier to check.
- (2) A manufacturer must obtain a certified translation from external sources independent of commercial clients and of the manufacturer.
- (3) If labels are dual language (i.e. English and another language), then an operator must have a certified document stating that the content of the English version and the other language are consistent.

Schedule 1 – Criteria for New Zealand origin label claims

(4) Claims made under Part 3 of this Notice must meet the criteria as outlined below.

	Claims	Criteria
1	<ul style="list-style-type: none"> Product of New Zealand 100% New Zealand 	<ul style="list-style-type: none"> The product must be manufactured using all New Zealand origin constituents including vitamins and minerals (but not necessarily food additives); and All or virtually all processes involved in the product's manufacture (whether through a wet, combined or dry-mix process) must be carried out in New Zealand; and All packaging of the product must be carried out in New Zealand.
2	<ul style="list-style-type: none"> Made in New Zealand 	<ul style="list-style-type: none"> The product must be manufactured in a wet-mix or combined process carried out in New Zealand; and All or virtually all the dairy protein constituents in the product must be of New Zealand origin; and The final blending and packaging of the product must be carried out in New Zealand.
3	<ul style="list-style-type: none"> Made in New Zealand from local and imported ingredients 	<ul style="list-style-type: none"> The product must be manufactured in a wet-mix or combined process carried out in New Zealand; and Some, but not all of the dairy protein constituents in the product must be produced in New Zealand; and The final blending and packaging of the product must be carried out in New Zealand.

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