



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

18 December 2014

TITLE

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 18 June 2016.

ISSUING AUTHORITY

This Animal Products Notice is issued under sections 45 and 167(1)(h), and 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 18th. day of December 2014

[Signed]

Allan Kinsella
Director, Systems Audit, Assurance and Monitoring
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.

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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 the 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 of retail ready packages, 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.
- (3) This Notice only applies to dairy based infant formula products and formulated supplementary foods for young children. Products derived from non-dairy sources (e.g. soy) are not covered by this Notice.

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 or market. 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 or market in its laws or executive directives.

- (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 or market, 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 or market, 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 or market 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?

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?

Operating other than in accordance with this Notice may result in a product being ineligible for export.

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

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.

Alternatively, you can write to us at the address provided at the bottom of page 1 of this Notice.

Other information

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 4.1(3); 4.1(4) and 4.1(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

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

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 formula product or formulated supplementary food for young children 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 formula product or formulated supplementary food for young children are processed dry and blended to obtain the desired final 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);

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

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

formulated supplementary food for young children means a formulated supplementary food for children aged 12 months 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;

infant formula means an infant formula product represented as a breast milk substitute for infants and which satisfies the nutritional requirements of infants aged up to four to six months;

infant formula product means a product based on milk or other edible food constituents of milk origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants, and includes infant formula and follow-on formula;

label means any tag, brand, mark or statement in writing or any representation or design or descriptive matter on or attached to or used in connection with or accompanying any food or package;

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;

package—

- a) includes anything in or by which food for carriage or for sale may be wholly or partly encased, covered, enclosed, contained, or packed; and, for food sold or carried or intended for sale or carriage in more than 1 package, includes every such package; but
- b) does not include any of the following:
 - i) bulk cargo containers:
 - ii) pallet overwraps:
 - iii) crates and packaging that do not obscure labels on the food:
 - iv) craft and vehicles

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;

supplier means the packer, manufacturer, vendor or importer;

unique Location Identifier means a unique identification code to indicate the location or premises within a risk management programme; and

wet-mix process is a manufacturing process by which all constituents of the infant formula product or formulated supplementary food for young children are handled in a liquid phase, and may involve homogenization, heat-treatment, concentration by evaporation, and then dried.

- (2) Unless the context otherwise requires, any term or expression that is defined in the Animal Products Act 1999, or regulations made under that Act and used, but not defined, in this notice has the same meaning as in that Act or regulations.

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 or market requirements.
- (2) In addition, any specific importing country or market labelling requirements must also be met.
- (3) If the requirements set out in this Notice and the importing country or market requirements are in conflict, the importing country or market requirements, as expressly contained in the importing country's or market's laws or executive directives, 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 market; or
 - b) English; or
 - c) dual language: in both the language of the importing country or market, 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 or market(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 or market:
 - e) declaration of nutritive value (i.e. nutrition information labelling), in a format as required by the importing country or market:
 - 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 contents of the product (either volume or weight), as required by the importing country or market:
 - j) name and business address of supplier:
 - k) lot identification:
 - l) manufacturing premises identification (Unique Location Identifier)
 - m) 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:
 - n) 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 or market in its laws or executive directives.
- (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 or market, 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 or market (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 or market:
 - e) declaration of nutritive value (i.e. nutrition information labelling), in a format as required by the importing country or market:
 - 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 contents of the product (either volume or weight), as required by the importing country or market:
 - j) name and business address of supplier:
 - k) lot identification:
 - l) manufacturing premises identification (Unique Location Identifier)
 - m) 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:
 - n) 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 follow-on 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 or market, 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 or market (e.g. growing up milk; toddler milk; formula for older infants and young children; follow-on formula):
 - 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 or market:
 - d) declaration of nutritive value (i.e. nutrition information labelling), in a format as required by the importing country or market:
 - 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 contents of the product (either volume or weight), as required by the importing country or market:
 - i) name and business address of supplier:
 - j) lot identification:
 - k) manufacturing premises identification (Unique Location Identifier)
 - l) 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 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 or market, 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
 - b) Made in New Zealand

3.2 Exemptions

A claim is exempt from the requirements of clause 3.1 if:

- a) it is made in accordance with an express requirement of a relevant importing country government agency or importing market authority in its laws or executive directives; 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 or importing market authority.

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 or market requirements where a manufacturer is complying with an importing country or market 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 or market requirements, instead of the requirements of this Notice, then the documentary evidence held by the manufacturer of the relevant importing country or market 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 that the translation is correct.
- (3) Despite sub clause (2), a manufacturer may undertake the translation, provided that the translation is certified as correct by an external party, independent of commercial clients and of the manufacturer.
- (4) 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

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 	<ul style="list-style-type: none"> The ingredients used in the product to meet the essential compositional requirements (i.e. relating to energy, fats/lipids, proteins (including amino acids), vitamins, minerals and electrolytes) for infant formula, follow-on formula or formulated supplementary foods for young children as set out in the Australia New Zealand Food Standards Code or any relevant Section 60B notice issued under the Animal Products Act 1999 must be produced in New Zealand; 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 process in New Zealand, or a combined process in which both the wet and dry processing components are carried out in New Zealand; and The final blending and packaging of the product must be carried out in New Zealand.