Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Labelling of retail-ready dairy-based infant formula products and formulated supplementary food for young children intended for export

9 May 2018

A guidance document issued by the Ministry for Primary Industries

New Zealand Government

Title

Guidance Document: Labelling of retail-ready dairy-based infant formula products and formulated supplementary food for young children intended for export

About this document

The Ministry for Primary Industries (MPI) publishes a variety of guidance documents. Typically these documents either explain the applicable requirements, assist stakeholders to comply with the applicable legal requirements, explain MPI's view of good industry practice, explain MPI's role, or help stakeholders to provide documentation to MPI that will enable the issuance of approvals, official assurances and other documents.

Any guidance on how to comply with the applicable requirements may not be the only way to achieve compliance with those requirements. Stakeholders are encouraged to discuss departures from the approaches outlined in this guidance document with MPI to avoid expending resources on the development of alternative approaches which may later be considered unsuitable.

The term "must" is not typically used in guidance. In this particular document the term "must" is simply used in the context of quoting or paraphrasing the requirements set out in the related Animal Products (Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Foods for Young Children) Notice 2014.

Related requirements

The purpose of this document is to provide guidance to those in the infant formula manufacturing industry who label retail-ready exports of infant formula products and formulated supplementary food for young children, to help achieve compliance with the Animal Products (Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Foods for Young Children) Notice 2014.

Other labelling requirements for export dairy products (including outer product) also apply, and are contained in the Animal Products (Dairy) Regulations 2005 and the Animal Products (Export Requirements – Dairy Products) Notice 2005.

Document history

Version Date	Section Changed	Change(s) Description
18 December 2014	NA	New document
May 2018	5.1.2 Protein Source	Clarification for single and multiple protein sources.
	5.1.3 List of Ingredients	Clarification regarding listing bovine and non-bovine dairy products
	5.1.13 Statement regarding the importance of breast feeding	Clarifying that statements are required for infant formula and follow-on formula and that the two statements must be contained together
	5.1.14 Statement on suitability	Clarifying statements on suitability required for all products to indicate the age range of intended consumer

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Disclaimer

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1 Purpose

The purpose of this document is to provide guidance to those in the infant formula manufacturing industry who label retail-ready exports of infant formula products and formulated supplementary food for young children to help them achieve compliance with the Animal Products (Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Foods for Young Children) Notice 2014 ("the Notice").

It also provides guidance to Recognised Agencies, which are required to undertake verification activities under the Notice.

2 Background

The Animal Products (Labelling Requirements for Exports of Dairy Based Infant Formula Products and Formulated Supplementary Foods for Young Children) Notice 2014 puts in place minimum labelling requirements for retail-ready infant formula products (including follow-on formula) and formulated supplementary foods for young children intended for export from New Zealand to any market other than Australia.[1]

All dairy products, including dairy-based infant formula products and formulated supplementary food for young children, intended for export from New Zealand are exempt from the labelling requirements of the Australia New Zealand Food Standards Code.[2] In general, importing country or market requirements apply to the labelling of these products. Infants have special nutritional needs and lower immunity than adults, and market expectations for safety and traceability are particularly high for infant formula products and formulated supplementary foods for young children. Therefore, the Notice introduces minimum labelling requirements for these products when produced for export from New Zealand.

The Notice specifies the information that 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's or market's requirements. The Notice also specifies other information that cannot appear on a label of infant formula, follow on formula, or formulated supplementary food for young children, and information that can be voluntarily included on a label in accordance with certain criteria set in the Notice. In addition to the requirements set out in the Notice, any specific importing country or market labelling requirements must also be met in order to be lawfully sold in that country. If the requirements of the importing country or market as set out in regulation or equivalent documents or in executive directives are in conflict with the requirements in the Notice, the Notice provides that the importing country or market requirements take precedence. Evidence of importing country or market requirements should be held by manufacturers to demonstrate compliance with this provision of the Notice.

Infant formula products and formulated supplementary food for sale in New Zealand (whether produced in New Zealand or imported) must comply with the Australia New Zealand Food Standards Code.

3 Application

The Notice applies to dairy based infant formula products and formulated supplementary foods for young children intended for export from New Zealand to any market, excluding Australia. It applies to both the powdered and ready to consumer liquid versions of these products.

[1] Food exports to Australia must comply with the Australia New Zealand Food Standards Code and the Trans Tasman Mutual Recognition Act 1997, as relevant.
[2] This is provided by the Animal Products (Exemption from Labelling Standards for Dairy Product and Dairy Material Intended for Export) Notice 2006.

The Notice does not apply to ingredients products (e.g. infant formula base powders), or to foods for infants standardised under Standard 2.9.2 of the Australia New Zealand Food Standards Code or foods other than formulated supplementary foods for young children intended for use by young children 12-36 months of age.

If the importing country or market does not permit the category of product that is referred to in the Notice as "formulated supplementary food for young children", the Notice does not constitute a permission to sell this category of product in that country or market. If the importing country or market regulates products for young children in the same category as follow-on formula products (e.g. has a regulatory category 6-36 months), then the follow-on formula provisions of the Notice apply to products intended for those age groups to those markets.

Please note, the term 'formulated supplementary foods for young children' is used in the Notice. The Notice defines this as product intended for young children aged 12-36 months.[3] This category of formulated dairy-based products may be known by different terms in other markets.

4 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 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 formulae formula product of 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

[3] This is different to the age ranges for this product category in the Australia New Zealand Food Standards Code of 1-4 years (i.e. up to 48 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

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.

5 Information required on labels

The Notice requires several labelling elements to be included on all labels of exported retail-ready infant formula products and formulated supplementary foods for young children. The required labelling elements are based on the relevant international Codex standards. These requirements are contained in clauses 2.3(1) for infant formula, 2.4(1) for follow-on formula, and 2.5(1) for formulated supplementary foods for young children.

The required labelling elements for infant formula and follow-on formula are the same, apart from clause (m) ‘statement on suitability’. There are fewer required labelling elements for formulated supplementary food for young children. In particular, identification of the protein source and including a statement about the importance of breastfeeding are not required for these products, unless required by an importing country or market.

The specific format of the required labelling elements is not prescribed. For example, a product label must include nutrition information labelling, but the specific format (e.g. a table or panel) is not prescribed. The format of the required labelling elements will depend on the requirements of the importing country or market. Operators should hold evidence of importing country or market labelling requirements (e.g. regulations, standards, product registrations) for these products for verification purposes.

5.1 Guidance on required labelling elements

Guidance on each of the required labelling elements is provided below. The context of the whole label must be considered to ensure truthfulness of labelling.

5.1.1 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

The name of the food used will be dependent on the requirement of the importing country or market (e.g. 'infant formula', or 'follow-on formula' or 'follow-up formula'). If the importing country or market does not require a prescribed or particular name to be used, the terms 'infant formula', 'follow-on (or 'follow-up') formula', or 'formula for young children' should be used. The term 'infant formula' can only be used on products suitable as breast milk substitutes for infants from birth.

5.1.2 Protein source

The Notice requires that labels for infant formula and follow-on formula must identify the protein source i.e. whether the formula is derived from cow, goat or sheep milk.

For infant formula and follow-on formula based on a single protein source it is sufficient to communicate the protein source in the ingredient list, so long as declaration by this method does not mislead the consumer. A total absence of any reference is not acceptable.

Where multiple protein sources are present the labels for infant formula and follow-on formula should contain information of all protein sources.

For formulated supplementary food for young children intended for export, there is no explicit requirement to state the protein source, however there is a requirement to have a name or description of the food sufficient to indicate the true nature of the food – therefore, for example, a sheep milk derived product should clearly identify this somewhere on the label.

5.1.3 List of ingredients

The Notice requires that labels of infant formula products and formulated supplementary food for young children intended for export include a list of ingredients. All ingredients, including food additives should be identified.

The format of the list of ingredients should meet the format requirements of the importing country or market.

The most common way of listing ingredients is to use the common name of the ingredient and list in descending order of ingoing weight. The method for labelling any food additives, vitamins and minerals should comply with importing country or market requirements.

Any bolding or highlighting specific ingredients in the ingredient list must comply with importing country or market requirements.

Where the formula is clearly of bovine origin, and this is evident from the listing of cows' milk in the ingredient list, it is not necessary to state that each of the dairy ingredients are of bovine origin. However where dairy ingredients are derived from other (non-bovine) sources this should be clearly stated.

If a goat or sheep milk based product contains dairy ingredients derived from cow's milk (e.g. lactose) this should be declared on the product label to avoid false and misleading representations. Note however that lactose may not be considered a dairy product by some markets e.g. China.

5.1.4 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

MPI recommends that advisory or warning statements are used on any product that contains ingredients known to cause hypersensitivity and allergic reaction. This is required by the Notice if required by the importing country or market. Operators should hold evidence to demonstrate they have reviewed importing

country or market requirements to determine whether a warning statement or declaration for allergens is required by the importing country or market.

5.1.5 Declaration of nutritive value (e.g. nutrition information labelling) in a format required by the importing country or market

The Notice requires that the nutritive value (e.g. energy content, the amount of protein, fat and carbohydrate, vitamins, minerals and any other nutritive substance) must be declared on the label. The format used for the declaration should meet the importing country or market requirements. Where the importing country or market does not have specific format requirements, a 'nutrition information panel' as required in the Australia New Zealand Food Standards Code is used.

For some markets (including New Zealand and Australia), the inclusion of non-mandated nutrients in the nutritional information is viewed as a nutrition claim. The inclusion of reference to voluntarily added nutrients and nutritive substances in the nutrition information and any bolding or highlighting of specific nutrients or nutritive substances in the declaration of nutritive value must comply with nutrition content claims provisions of the Notice, that is, they must be accepted by the importing country or market.

5.1.6 Date marking information

The Notice requires date marking information to be included on the label. This should usually be a "use by" date indicating the date after which the product is no longer suitable for consumption by the intended consumer. To be in compliance with the Notice, and the general provisions of the Animal Products Act, the "use by" date identified on the product label must accord with the shelf life validation for the product.

5.1.7 Storage directions and instructions for use

The Notice requires instructions for use to be included on the label. This is a very important element to support the safe use of infant formula products. The directions and instructions should cover storage of the package once it is opened, as well as how to make up the formula (e.g. number of scoops, amount of water). Most countries prescribe the format and text for the storage directions and instructions for use. If an importing country or market does not prescribe the text and format for this information, MPI recommends that the provisions of the Australia New Zealand Food Standards Code be followed.

5.1.8 Statement of safe preparation and storage once made up

The Notice requires a statement of safe preparation and storage for powdered infant formula. As in (5.1.7) above, this is a very important element to support the safe use of infant formula products. The statement should cover how to prepare the formula safely (e.g. requirements relating to the water used to reconstitute the product) and how to store the formula once water has been added to prepare the final product.

Most countries prescribe the format statement on safe preparation and storage. If an importing country or market does not prescribe the text and format for this information, MPI recommends operators follow the provisions of the Australia New Zealand Food Standards Code.

5.1.9 Net weight of the product

This should be expressed in units as specified by the importing country or market.

5.1.10 Name and business address of supplier

The Notice requires the name and address of the supplier of the product to be identified on the label. The supplier is the business or entity that can be contacted by the regulator for recall and product tracing purposes, and by the consumer for product information. It is a minimum traceability requirement.

5.1.11 Lot identification

Information to identify the lot or batch of product must be included on the product label (i.e. artwork) or on the retail packaging itself (e.g. jet coded on the base of a can). If appropriate, and in accord with an operator's

RMP, date marking may be used for lot identification purposes unless other requirements apply in an importing country or market.

Please note that some markets may require the lot identification on the label artwork. This is not a requirement of the Notice, but may be a market requirement.

5.1.12 Manufacturing premises identification

The Notice requires that the manufacturing premises is identified on the product label. This may be on the label artwork or elsewhere visible on the retail package (e.g. jet coded on the bottom of the can).The premises should be identified by the Unique Location Identifier as assigned by MPI of the final premises of manufacture. For infant formula products and formulated supplementary foods for young children this will most likely be the premises where the product is packed into retail ready packaging, and should be the same premises identification as appears on the export certificate. This is consistent with the Codex traceability principles (CAC GL 60-2006).

5.1.13 Statement regarding the importance of breast feeding

New Zealand is a signatory to the World Health Organization Code of Marketing for Breastmilk Substitutes (the WHO Code). Under the WHO Code countries have undertaken to require statements on infant formula products to indicate the superiority of breastfeeding or breast milk to infant and maternal health, and that the product should only be used on the advice of an independent health worker.

The Notice requires these statements to be included on infant formula and follow-on formula. The statements are required even where the importing countries legislation does not specifically mandate this (see also Section 8.2 of this Guidance).

The wording and format of the statements should follow importing country or market requirements or guidelines where these are specified.

Where the importing country or market does not have specific requirements for inclusion of the statements, or for the wording or format of them, MPI recommends that operators follow the provisions of the Australia New Zealand Food Standards Code. i.e. a heading that states ‘Important Notice’ (or words to that effect), with under it the statement—‘Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice’.

The two statements; concerning superiority of breast feeding, and using on the advice of an independent health worker, must be contained together on the label under the heading Important Notice. It is not permissible to separate the two statements.

A statement not to change the proportions when making up the formula without advice from a health professional is not sufficient in fulfilling the requirement that there be a statement that product should only be used on advice of an independent health worker.

5.1.14 Statement on suitability

The Notice requires that labels for all infant formula, follow-on formula and formulated supplementary food for young children include a statement of suitability to indicate the age range of the intended consumer. Suitability statements are important on all three product types to differentiate nutritionally complete infant formula from other products.

For infant formula a suitability statement that the product is 'suitable for use from birth' is recommended however other wording representations are acceptable if the same meaning is conveyed. For example, '0-6 months' conveys the same meaning as "product may be used from birth", as the important public health and safety aspect is that it is suitable from birth.

For follow-on formula labels are required to contain two statements; 'should not be used for infants under the age of 6 months', and 'infants over the age of six months should be offered foods in addition to formula'. Alternative wording to similar effect may be used.

For formulated supplementary foods for young children the suitability statement must make it clear that the product is an addition to a normal diet and not the other way round.

6 Information prohibited on labels

6.1 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. These provisions reflect New Zealand's obligations as a signatory to the World Health Organization Code of Marketing for Breastmilk Substitutes. Similar provisions apply in most of New Zealand's major markets.

Examples of what is **not** allowed:

a) Pictures of mother and baby together
b) Pictures of a baby

6.2 Government emblems and logos

It is unlawful to use the names and emblems of New Zealand State agencies and organisations on product labels or in advertising (including on websites) unless specifically authorised. Holding a Risk Management Programme (RMP) or an animal products exporter registration is not authorisation to use the logo or name of MPI or its predecessor agencies (e.g. NZFSA) on labels or in advertising.

The use of names and emblems 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.

The Notice restates the restrictions in the Flags, Emblems and Names Protection Act 1981 so that compliance with the restrictions can be included as part of routine verification of infant formula manufacturing.

Examples of what is **not** allowed:

a) Ministry for Primary Industries logo
b) New Zealand Food Safety Authority logo
c) New Zealand Food Safety logo

6.3 Health claims on infant formula suitable for infants from birth

The Notice defines a health claim as: 'any representation that states, suggests, or implies that a relationship exists between a food or constituent of a food and health. Health claims include nutrient function claims, other

function claims concerning specific beneficial effects of the consumption of the food or its constituents in the context of the total diet on normal functions or biological activities of the body, or reduction of disease risk claims'.

Examples of health claims include:

a) "Calcium is good for strong bones"
b) Product "supports brain and eye development"
c) Product "supports healthy digestion"
d) "Fish oil may support cognitive development"
e) "Lutein may support eye health"

The Notice prohibits health claims (including nutrient function claims) on infant formula suitable for infant from birth, unless there is an *express permission* in the importing country's or market's legislation or executive directive for health claims (or a class of health, for example, nutrient function claims) in general, or a specific health claim in particular (clause 2.3(2)(e)).

An *express permission* means that the permission is written into the laws or regulations or executive directives of the importing country or market. To demonstrate compliance with this requirement, manufacturers should hold an English language copy of the relevant importing country or market requirement and this should be made available to a verifier or MPI on request. Product registration or an email or letter from an overseas Government agency is not considered sufficient for the purposes of an *express permission*.

Guidance on permissions for health claims for products intended for ages 6-36 months is provided in section 7 below.

7 Information that can be included on labels voluntarily

7.1 Health claims and nutrition claims

7.1.1 Definitions

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

Examples of health claims include:

a) "Calcium is good for strong bones"
b) Product "supports brain and eye development"
c) Product "supports healthy digestion"
d) "Fish oil may support cognitive development"
e) "Lutein may support eye health"
f) Product "promotes sound sleep"

The Notice defines a nutrition claim as 'any representation which states, suggests or implies that a food has particular nutritional properties, including and not limited to the energy value and to the content of protein, fat, carbohydrates, as well as the content of vitamins and minerals. In the Australia New Zealand Food Standards Code, these are called 'nutrition content claims'.

Examples of nutrition claims include:

a) "Product contains omega 3"
b) "Product is a good source of vitamin C"

7.1.2 Products intended for use by infants from birth

The Notice prohibits health claims on infant formula products intended for use by infants from birth (e.g. for ages 0-6 months), unless there is an express permission in the importing country's or market's legislation or executive directives for health claims in general, or a specific health claims in particular (clause 2.3(2)(e)).

The Notice permits nutrition claims on infant formula intended for use by infants from birth 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.

To demonstrate compliance with this provision of the Notice, the operator should hold evidence that a nutrition claim is *accepted* by the importing country or market. This can be in the form of legislation or regulation that expressly permits the specific claim or nutrition claims in general, or evidence of acceptance of the product label by the import or regulatory authorities of the relevant market (e.g. a communication from a relevant official), or by product registration. A communication from a customer in-market is not considered sufficient evidence that a claim is accepted by the importing country or market.

Acceptance by an importing country or market is not the only criteria for permitting nutrition claims on these products. In addition to being accepted by the importing country or market, claims must not be misleading or imply that the product is nutritionally equivalent or superior to breastmilk. Examples of nutrition claims that would **not** be permitted even if it is accepted by the importing country or market are:

a) "This product has the same nutritional profile as human milk"
b) "Product contains more lutein than human milk"
c) "Contains vitamin C" – when there is no vitamin C in the product

For verification of this provision, evidence for acceptance of a nutrition claim can be provided after samples or initial shipments have been sent to market for product acceptance or product registration purposes. In such cases, a verifier can note the product and label for follow up verification at a later date.

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

7.1.3 Products intended for use by infants aged 6-12 months (follow-on formula)

The Notice permits health claims and nutrition claim on follow-on formula 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.

To demonstrate compliance with this provision of the Notice, the operator should hold evidence that a health claim or a nutrition claim is *accepted* by the importing country or market. This can be in the form of legislation or regulation that expressly permits the specific claim or nutrition claims in general, or evidence of acceptance of the product label by the import or regulatory authorities of the relevant market (e.g. a communication from a relevant official), or by product registration. A communication from a customer in-market is not considered sufficient evidence that a claim is accepted by the importing country or market.

For verification of this provision, evidence for acceptance of a nutrition claim can be provided after samples or initial shipments have been sent to market for product acceptance or product registration purposes. In such cases, a verifier can note the product and label for follow up verification at a later date.

Acceptance by an importing country or market is not the only criteria for permitted health and nutrition claims on these products. In addition to being accepted by the importing country or market, claims must not be misleading or imply that the product is nutritionally equivalent or superior to breastmilk. Examples of claims that would **not** be permitted even if accepted by the importing country or market include:

a) "This product provides the best start in life for babies"
b) "Product provides the same nutrition for brain development as human milk"
c) "Product contains the more lutein than human milk"

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

7.1.4 Products intended for use by young children aged 12-36 months (formulated supplementary food for young children)

The Notice permits health claims and nutrition claim on formulated supplementary food 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.

To demonstrate compliance with this provision of the Notice, the operator should hold evidence that a health claim or a nutrition claim is *accepted* by the importing country or market. This can be in the form of legislation or regulation that expressly permits the specific claim or nutrition claims in general, or evidence of acceptance of the product label by the import or regulatory authorities of the relevant market (e.g. a communication from a relevant official), or by product registration. A communication from a customer in-market is not considered sufficient evidence that a claim is accepted by the importing country or market.

For verification of this provision, evidence for acceptance of a nutrition claim can be provided after samples or initial shipments have been sent to market for product acceptance or product registration purposes. In such cases, a verifier can note the product and label for follow up verification at a later date.

Acceptance by an importing country or market is not the only criteria for permitted health and nutrition claims on these products. In addition to being accepted by the importing country or market, claims must not be misleading or imply that the product is nutritionally equivalent or superior to breastmilk. Examples of claims that would **not** be permitted even if accepted by the importing country or market include:

a) "This product provides the same nutrition for brain development as human milk"
b) "This product contains the more lutein than human milk"

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

7.2 New Zealand origin claims

7.2.1 Background

It is voluntary to make a New Zealand place of origin label claim for marketing purposes on food products, including infant formula, for sale in New Zealand or for export.

Origin statements and claims cannot be false or misleading. This requirement is set out in provisions of the Fair Trading Act 1986, the Food Act 1981, the Food Act 2014,[4] and the Animal Products (Dairy) Regulations 2005.[5]

The Notice provides clear criteria for making "Product of New Zealand" and "Made in New Zealand" (or equivalent) claims on infant formula products and formulated supplementary foods for export. The Notice applies only to these products. All other dairy products for export must comply with the general provisions of the Animal Products (Dairy) Regulations 2005.

Decisions on whether a New Zealand place of origin claim can be made for a product have to be taken on a product-by-product basis.

[4] Most provisions of the Food Act 2014 will come into force in March 2016 and will replace the Food Act 1981.
[5] The relevant provision are found in the Fair Trading Act 1986 section 13(j), Food Act 1981 section 10(1)(a), Food Act 2014 sections 227 and 228(1)(b), and the Animal Products (Dairy) Regulations section 19(1)(e).

MPI strongly recommends that businesses seek legal advice on the appropriateness of New Zealand place of origin claims on their products.

The New Zealand Commerce Commission is the Government agency with responsibility for enforcing the Fair Trading Act. The Commerce Commission has developed guidance on making claims about the place of origin of foods. This is available on the Commerce Commission website www.comcom.govt.nz.

7.2.2 New Zealand origin claims on dairy based infants formula products and formulated supplementary food for young children intended for export

The Notice clarifies the existing general provisions of the Animal Products (Dairy) Regulations 2005 as they apply to dairy based formula for infants and young children intended for export, and removes doubt about when certain origin claims on these products can be made.

The Notice applies only to dairy based infant formula products and formulated supplementary foods for young children intended for export from New Zealand to countries other than Australia. It does not affect the application of the existing general legislative provisions in relation to false and misleading claims on foods for export (other than dairy based formula for infants and young children), or food for sale on the New Zealand or Australian market. As noted above, these general provisions are set out in the Fair Trading Act 1986 and regulations made under the Animal Products (Dairy) Regulation 2005, and the Animal Products Regulations 2000.

"Product of New Zealand" claims on dairy based dairy based infants formula products and formulated supplementary food for young children

The claim that a food is "produced" in a place of origin, or is the "product" of that place of origin is considered to be a comprehensive claim about the origin of the material constituents of the food, and the processes involved in its production. These elements are important to determining where the *essential character* of a food is created.

Infant formula products and formulated supplementary foods for young children are complex, highly processed products, with multiple ingredients that tend to be sourced from a number of countries. In addition, most countries have regulations in place to specify the essential composition of infant formula and follow-on formula, and some key aspects of formulated supplementary foods for young children. These regulations ensure that products are suitable for vulnerable consumers.

Importantly, a product cannot be an infant formula if it does not meet the essential nutritional needs of infants as a sole source of nutrition (a breastmilk substitute) as reflected in the essential compositional requirements for these products. On this basis, and in MPI's view, the *essential character* of an infant formula, a follow-on formula, or a formulated supplementary food for young children can be defined by the constituents of the product used to meet the essential compositional requirements for these products as set out in regulation.

For infant formula and follow on formula, the essential compositional requirements are contained in Standard 2.9.1 of the Australia New Zealand Food Standards Code (the Food Standards Code). For formulated supplementary foods for young children, the essential composition requirements are contained in Standard 2.9.3 of the Food Standards Code. Relevant export exemptions made under section 60B of the Animal Products Act also apply. Essential composition requirements for infant formula and follow on formula are set out in Division 2 of Standard 2.9.1. Essential composition requirements for formulated supplementary foods for young children are set out in Division 4 of Standard 2.9.3.

Typically, infant formula products and formulated supplementary food for young children, made in New Zealand, contain a high proportion of imported ingredients, including imported vegetable oils, vitamins and minerals. Despite this, MPI has observed a number of export infant formula products claiming to be "product of New Zealand" or "100% New Zealand".

In MPI's view, such claims on a typical infant formula product are likely to be misleading given the proportion of imported essential ingredients in these products.

For this reason, the Notice makes it clear that a claim that a dairy based formula for infants or young children is "produced in New Zealand" or is the "product of New Zealand" can only be made if all the ingredients used

to meet the essential compositional requirements for that product are produced in New Zealand. MPI considers that a "made in New Zealand" claim, or equivalent, is more appropriate for infant formula products that are manufactured in New Zealand (see further details in 7.2.2.2 below).

Verifiers should pay very close attention to any dairy based formula for infants or young children that makes a "Product of New Zealand", or similar, place of origin claim.

The Notice and this guidance apply to the following claims that MPI considers equivalent or sufficiently similar in meaning to "Product of New Zealand":

a) Produced in New Zealand
b) Wholly New Zealand made

The statement "Produced in a NZ factory" should be avoided, as it is not one of the listed examples for origin claims, and could be misleading.

In MPI's view, a claim that a dairy based formula for infants or young children is "100% New Zealand" can only imply that all of the product constituents are produced in New Zealand. The use of this claim on an infant formula manufactured in New Zealand is likely to be considered false and misleading under the Animal Products (Dairy) Regulations 2005.

"Made in New Zealand" claims on dairy based dairy based infants formula products and formulated supplementary food for young children

A claim that a food is "made" or "manufactured" in a particular place, indicates that a substantial manufacturing process has been undertaken, and that the resulting food is distinctly different from the raw materials used to produce it.

The production of dairy based infant formula products and formulated supplementary foods for young children generally involves a "wet blend" or "combined process" where many or all of the major constituents are blended in a wet phase, and subsequently dried into powder. In a "combined process" additional dry ingredients are added to a wet blended "base powder" to complete the product formulation. The addition of dry ingredients to the wet blended base powder may take place at the same premises, or at a different premises. Retail ready products also require packaging and labelling.

The Notice makes it clear that dairy based infant formula products and formulated supplementary foods for young children processed and packaged in New Zealand using a "wet blend" or "combined process" can make a "made in New Zealand" place of origin claim.

The Notice and this guidance apply to claims that are sufficiently similar in meaning to "Made in New Zealand". Examples of such claims include:

a) New Zealand Made
b) Manufactured in New Zealand

Dairy based infant formula products and formulated supplementary food for young children produced using a "dry mix" process, or packaged in New Zealand using imported "base" powder cannot make a "made in New Zealand" placed of origin claim.

Other place of origin claims such as "packed in New Zealand from local and imported ingredients" may be used as long as they are not false and misleading. Where such a claim is made the reference to local ingredients should be second to imported if the majority of the mix is imported. If local ingredients are not included, they should not be referenced in the statement.

MPI recommends operators seek legal advice when considering use of New Zealand place of origin claims.

New Zealand related symbols also considered as "made in NZ" place of origin claims

The use of "NZ made" logos or images and symbols such as stylised kiwi, silver ferns, maps of New Zealand, or the New Zealand flag are taken to be claims of New Zealand origin, and should conform to the criteria for "made in NZ" place of origin claims provided in the Notice, unless a contextual statement (e.g. "blended and packed in New Zealand") is provided.

8 Verification and record keeping

Manufacturers must have documented systems to ensure compliance with the requirements of the 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 checks to determine compliance with this Notice are undertaken, but it must not be 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 a history of non-conformances or non-compliances in this area may warrant extra attention.

8.1 Verification of labels

Verification of labels is part of performance based verification of manufacturers. Verification is not label approval. Labels do not need to be verified prior to first export.

A sample of at least five labels must be checked annually. This can be spread over several verification visits in a year. This is a minimum and more than five labels can be checked at the discretion of the verifier. If less than five labelled products are produced by the manufacturer, then all labels should be subject to verification within the annual period.

The label verification should check that:

a) each required labelling element is present on a label, as detailed in clauses 2.3(1); 2.4(1) or 2.5(1) of the Notice.
b) there is no prohibited information on the label, as detailed in clauses 2.3(2); 2.4(2) and 2.5(2) of the Notice.
c) for any voluntary information and claims on labels, the criteria has been met (as detailed further in section 7 of this guide).

Any non-compliance with the Notice identified through performance based verification should be treated as a non-conformance with the operator's RMP and corrective action taken. Non-conformance with the required labelling elements or the prohibited information provisions should be considered as a non-conformance. Consideration of product disposition following non-conformance reporting will take place on a case-by-case basis and will depend on the specific non-conformance. Repeated labelling non-conformances can result in operators moving down a step in performance based verification.

Given label preparation and printing can be costly and time intensive there is a clear incentive for manufacturers to ensure the labels on products produced at their premises comply with the Notice.

8.2 Meeting importing country or market requirements where these conflict with the Notice

Where an importing country or market requirement is in conflict with a requirement of the Notice, the manufacturer should hold a copy or version in English of the relevant importing country or market regulation, standard, legislation or executive directive. An email from an official alone is not sufficient evidence of a conflict. In cases where the importing country or market regulation is not reasonably accessible to the manufacturer in English, a translation of the relevant provisions of the regulation can be held as sufficient evidence.

The absence of a specific requirement in an importing country's or market's regulation is not considered a conflict with the Notice. In cases where the importing country or market does not have requirements for the labelling of infant formula, or is silent on some labelling matters (such as health claims on infant formula suitable from birth), the Notice applies.

"Label approval" by an overseas regulatory authority (e.g. product acceptance for import, or product registration) is not sufficient to comply with the Notice in full.

8.3 Translations

The Notice requires that if labels are not in English, a certified translation of product labels is held by the operator and made available for verification.

A certified translation is a translation that has been undertaken by a service in New Zealand independent of the manufacturer and/or the brand owner/customer, and is certified (signed) by a person with responsibility for that translation. Contact details for the translation service, and identification of the individual translator should be on record and available for verification.

Where translation expertise in a specific language cannot reasonably be obtained in New Zealand, an overseas independent translation service may be used. However, the operator should have a documented procedure to show how it has verified the accuracy of the translation (for example, software used for secondary translation). For clarity, MPI considers that translations from Chinese Mandarin, Arabic, Hindi, Thai, Malay, Bahasa, Vietnamese, and Cambodian can be reasonably obtained in New Zealand.

For dual language labels, a signed declaration that attests to the consistency between the English and foreign language versions of the same information on the label from a translation service independent to the manufacturer or brand owner/customer should be held by the manufacturer and available for verification. For some dual language labels, only some of the information will be in both languages. A certified translation is required for information in a foreign language that does not also appear on the label in English.

9 Miscellaneous

9.1 Advertising

Advertising in overseas markets is outside the scope of the Notice and MPI's jurisdictions. However, manufacturers and exporters are reminded that they need to comply with any requirements of the importing country or market and should be aware of their ethical obligations under the WHO Code of Marketing for Breastmilk Substitutes to not promote in any way infant formula products as an equivalent or superior alternative to breastmilk.