Labelling guideline for RMP manufacturers of colostrum products

January 2011

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1 Preamble

The purpose of this guideline is to assist operators to achieve compliance with regulatory requirements for labelling of colostrum products.

2 History

Verification of labelling performed by NZFSA in 2009 highlighted significant breaches of the Food Standards Code, Dietary Supplement Regulations and the Animal Products (Export Requirements – Dairy Products) Notice 2005 by many operators. These breaches undermine the integrity of the official assurances programme (OAP).

In light of these findings NZFSA put in place the requirement for verification checks to be carried out at point of certification on labelling of all colostrum products (from January 2010), prior to consignment based certificates being issued in MP Ecert, until such time that the Recognised Agency (RA) was satisfied that labelling requirements are consistently being met by the operator.

Since this requirement was been in place, NZFSA continued to receive a number of applications for certification of colostrum products with non-compliant labels.

3 Legal requirements

Colostrum product manufacturers must first identify the intended consumer. Once this has been established, the applicable standards should be referenced to confirm compliance with the specified outcomes.

This section outlines the legislative requirements which apply to dairy material and dairy product labelling that colostrum product manufacturers should be aware of, with the significant aspects (such as key terms) in bold or underlined.

3.1 Animal Products (Dairy) Regulations 2005

3.1.1 Reg 18 (Labelling and identification requirements)

(1) **Dairy material** and **dairy product** must be labelled or identified in accordance with any relevant specifications.

(2) Any labelling or identification required by specifications must—

(a) Clearly relate to the dairy material or dairy product to which it applies; and

(b) Contain information that accurately describes or differentiates the dairy material or dairy product to which it applies;

3.1.2 Reg 19 (Dairy material or dairy product not to be associated with false or misleading representation)

(1) **Dairy material**, **dairy product** or any **ingredient** added to dairy material or product, must not be associated with a false or misleading representation of any kind concerning—

(a) The supplier's name or the unique identifier of the processing premises:

(b) The lot identifier of the product or product identification:

(c) The fitness of the material or product for its intended purpose:

(d) Its nature and physical condition:

(e) Its origin:

(f) Its composition:

(g) Its ingredients:

(h) The proportions of its ingredients or other constituents:

(i) The type of treatment applied to the material or product:

(j) Its net contents.

3.2 Australia New Zealand Food Standards Code

The Food Standards Code is applicable to dairy products categorised as food (excluding products categorised as Supplemented Foods or Dietary Supplements) manufactured in New Zealand and includes infant and follow on formulas.

For clarification, "manufacture" means all activities involved with converting dairy material into dairy product (with or without other substances or ingredients), and its preparation in a dairy factory for sale. This includes receipt or deposit of the dairy material from which it is manufactured and the packaging for final sale.

Refer to the below links to the Food Standards Code and the NZFSA Food Labelling Guide for further clarification.

Australia New Zealand Food Standards Code

NZFSA Food Labelling Guide

3.3 New Zealand Food (Supplemented Food) Standard 2010

This standard was created to regulate "food-type" dietary supplements that were formally regulated under the Dietary Supplements Regulations 1985 ("DSR"). The Supplement Food Standard is in two parts. Part 1 provides the new regulatory requirements for supplemented foods. Part 2 replicates the existing provisions of the DSR as they apply to "food type" products, as a transitional tool. Manufacturers of supplemented foods can choose to comply exclusively with either Part 1 or Part 2 of the Supplemented Foods Standard until 30 March 2012 by which time all supplemented foods must comply with Part 1.

Any operator introducing a new product to the market in the transition period does so in the knowledge that on 31 March 2012, the new provisions of the Standard apply. That means from this date, all foods intended for consumption by infants or children under four years must comply with the Food Standards Code. It is recommended that manufacturers introducing new supplemented foods to the market should comply with Part 1 of the Supplemented Foods Standard. The Supplemented Food Standard is available on the NZFSA website at the link below:

http://www.foodsafety.govt.nz/elibrary/industry/Zealand_Food-Regulations_Regulations.pdf

In developing the Supplemented Food Standard, the Government noted that it is not intended to provide for the management of risks to vulnerable population groups. As infants and children less than four years of age are a vulnerable population group, Part 1 of the Standard does not permit the formulation and marketing of supplemented foods to this age group. Risks to this age group are managed by standards set out in the Food Standards Code.

The transition period provides time for operators to re-formulate and re-label products as necessary in order to comply with the Part 1 provisions of the Supplemented Food Standard. However, it should be noted that NZFSA considers that Part 2 of the Supplemented Food Standard (the transitional provisions) does not contain risk management provisions for foods intended for consumption by infants or children under four years of age, nor does it give effect to New Zealand obligations under the WHO International Code of Marketing of Breast Milk Substitutes. As noted above, risk management provisions and provisions to give effect to New Zealand's obligations in respect to infant feeding are contained in the Food Standards Code.

For these reasons, NZFSA advises operators that although it may be technically lawful for an operator to market a supplemented food to infants or children under the age of four, it considers there to be a commercial and reputational risk (arising from insufficiently assessed risks to infants) in marketing and exporting foods intended for consumption by infants and children under four years under the transitional (Part 2) provisions of the Standard.

NZFSA considers that the feeding of any significant amount of 'supplementary' Food to Infants, other than breast milk and / or Infant Formula Products, to infants less than 4 months of age whether in New Zealand or any other country has the very real potential to displace the use of the breast milk or its substitutes, and thus significantly disrupt the nutritional balance of the supplemented infants. Accordingly the use of these supplements constitutes a risk to the health of infants aged less than 4 months.

NZFSA also considers that any label on any package of Food For Infants that includes a recommendation, whether express or implied, that the food is suitable for infants less than 4 months of age to meet the criteria of being considered to be substantively False and Misleading with respect to "fitness for purpose", and furthermore also not to be in accordance with the World Health Organisation undertakings New Zealand has entered into in this area.

NZFSA has also provided a user guide to help with clarifying the food/supplemented food interface:

http://foodsafety.govt.nz/elibrary/industry/zealand-supplemented-foods-standard-user-guide/index.htm

3.3.1 Labelling of supplemented foods

Part 1 of the Supplemented Food Standard (the new provisions) incorporates the food labelling standards from the Food Standards Code. The Food Standards Code standards that are incorporated into the Supplemented Food Standard are listed in the Standard.

In addition, the Supplemented Food Standard prohibits the making of therapeutic claims in relation to supplemented foods.

3.4 Dietary Supplement Regulations 1985

These regulations, formerly administered by NZFSA, are now administered by the Ministry of Health (MoH). Operators may need to assess whether a dairy product falls within the definition of a “dietary supplement” in the DSR. The DSR contain specific labelling requirements for products that meet the definition of dietary supplement.

In addition, it is important to note that the DSR (reg 11) prohibit dietary supplements from making *therapeutic claims* on their labelling (or accompanying advertising or information):

11 Therapeutic claims

Except as permitted by the Medicines Act 1981 and any regulations made under that Act, no dietary supplement or package or container containing a dietary supplement shall be advertised or labelled with a statement relating to any of the following matters:

(a) treating or preventing disease:

(b) diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition:

(c) altering the shape, structure, size, or weight of the human body:

(d) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way"

The presence of therapeutic claims may mean that the supplement could be a "related product" under the Medicines Act 1981, and therefore becomes subject to approval as a "new related product" under s20 of that Act; with proof of safety and efficacy testing (see s94, Medicines Act 1981).

Any queries relating to compliance with these regulations for animal products should be referred to NZFSA (via the Recognised Agency).

3.5 Animal Products (Export Requirements – Dairy Products) Notice 2005

3.5.1 Part 3 (Labelling requirements): clause 11

(2) **No dairy product or dairy material intended for export may be labelled or marked in any way that is likely to be misleading or deceptive** as to its nature, origin or composition.

3.5.2 Part 3 (Labelling requirements): clause 12

The outer packaging of all dairy products intended for export must be labelled with:

(a) A product designation that complies with a standard of identity prescribed by the importing country (including both words and pictures); or

(b) **Where the importing country does not prescribe a standard of identity** for the dairy product, the outer packaging of all dairy products intended for export must:

i. Be labelled in such a way as to comply with the Food Standards Code[1][2]: or

ii. Be labelled and identified as a dairy product in such a way as to comply with the relevant definition in the Act, interpreted as necessary using the Codex General Standard for the Use of Dairy Terms.

[1] Refer to the Food Standards Code Standard 1.2.2 - Food identification requirements

[2] Or the Supplemented Food Standard

4 Official assurances

For an Official Assurance to be issued for an exported animal product it needs to have been produced in compliance with the Animal Products Act, all regulations and standards made under that Act, and all relevant mandated Export Requirements.

Section 60B provides for some limited exemptions from Food Code requirements (applying where food is manufactured in NZ for export), and from notices issued under s167 of the APA. Section 60B does not permit products to be exempted from the requirements of regulations made under the APA.

NZFSA Policy is to not issue official assurances, or consider the use of Section 60B exemptions, that would have the effect of permitting the export of unsafe product, or product accompanied by representations or statements that are materially false or misleading.

In the case of dairy material or dairy product for export, it is important that the operator is familiar with the relevant requirements around labelling referenced within Overseas Market Access Requirements (OMARs) and/or on official assurances, so that compliance with these can be checked.

Animal Product verifiers are not required to verify against the Dietary Supplement Regulations, they are however required to verify that the operator has met the applicable regulatory standards under the APA. This includes the requirement that the product is safe and suitable. Verifiers will therefore take the compliance of the product with the Food Act into account.

5 Frequently asked questions from colostrum manufacturers

5.1 Is my product a dietary supplement?

The Dietary Supplement Regulations 1985 under clause 2A state the meaning of dietary supplement:

(1) In these regulations, dietary supplement means something to which subclauses (2) to (6) apply.

(2) It is an amino acid, edible substance, herb, mineral, synthetic nutrient, or vitamin.

(3) It is sold by itself or in a mixture.

(4) It is sold in a controlled dosage form as a liquid, powder, or tablet (which might be described on the label as a cachet, capsule, lozenge, or pastille instead of as a tablet).

(5) It is intended to be ingested orally.

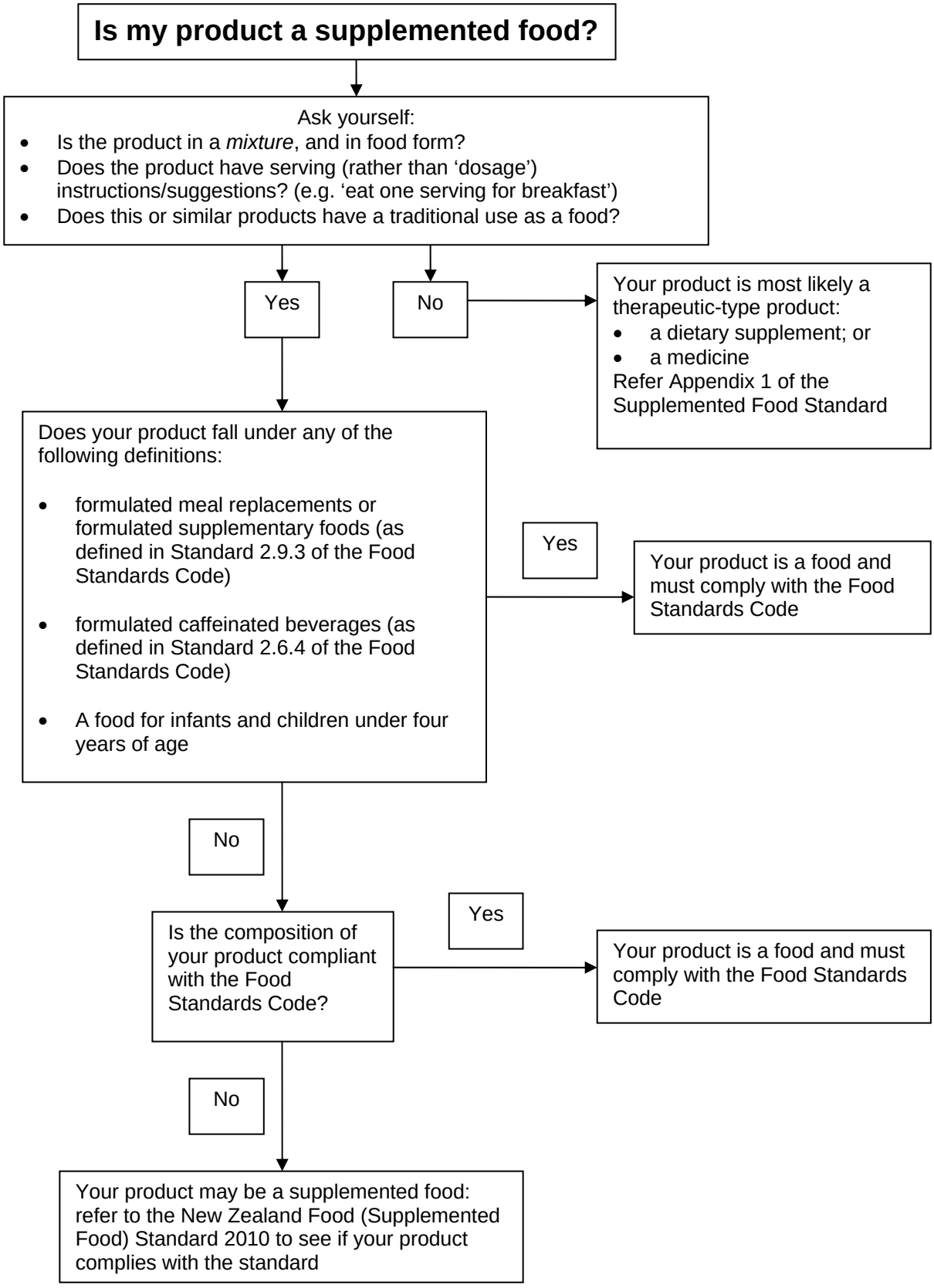
(6) It is intended to supplement the amount of the amino acid, edible substance, herb, mineral, synthetic nutrient, or vitamin normally derived from food.

Note the exclusions highlighted in section 3.3 in relation to infant products.

5.2 If my product is not a dietary supplement what could it be?

5.2.1 New Zealand Food (Supplemented Food) Standard 2010

The flow diagram that follows is intended to assist you to determine if your product is a food or a supplemented food. Please note that it is not intended to be a compliance tool. If you are still unsure, see Section 8 of the Supplemented Food Standard user guide.


Is my product a supplemented food?
Ask yourself:
Is the product in a mixture, and in food form?
Does the product have serving (rather than 'dosage') instructions/suggestions? (e.g. 'eat one serving for breakfast')
Does this or similar products have a traditional use as a food?
Yes
No
Your product is most likely a therapeutic-type product:
a dietary supplement; or
a medicine
Refer Appendix 1 of the Supplemented Food Standard
Does your product fall under any of the following definitions:
formulated meal replacements or formulated supplementary foods (as defined in Standard 2.9.3 of the Food Standards Code)
formulated caffeinated beverages (as defined in Standard 2.6.4 of the Food Standards Code)
A food for infants and children under four years of age
Yes
Your product is a food and must comply with the Food Standards Code
No
Is the composition of your product compliant with the Food Standards Code?
Yes
Your product is a food and must comply with the Food Standards Code
No
Your product may be a supplemented food: refer to the New Zealand Food (Supplemented Food) Standard 2010 to see if your product complies with the standard

5.2.2 Australia-NZ Joint Food Standards Code (ANZFSC) Standard 2.9.2: Foods for Infants

This Standard provides for the compositional (including nutritional) and labelling requirements of foods intended and/or represented for use as food for infants. Foods in this Standard are intended to be fed as a complement to human milk and/or infant formula products. This Standard does not apply to Infant Formula Products, as they are regulated by Standard 2.9.1, nor does it apply to Formulated Meal Replacements and Formulated Supplementary Foods as they are regulated by Standard 2.9.3.

5.2.3 ANZFSC Standard 2.9.3 Formulated Meal Replacements and Formulated Supplementary Foods

This Standard provides compositional and labelling requirements for formulated meal replacements and formulated supplementary foods. In addition, this Standard sets out the compositional and labelling requirements for formulated supplementary foods for young children, aged one to three years.

IF YOUR PRODUCT DOES NOT FIT THE DEFINITION OF 'SUPPLEMENTED FOOD' OR 'DIETARY SUPPLEMENT', IS NOT AN 'INFANT FORMULA' OR 'FOLLOW ON FORMULA', AND IS NOT COVERED BY STANDARDS 2.9.2. OR 2.9.3, IT MAY JUST BE A GENERAL "FOOD" IN WHICH CASE THE GENERAL STANDARDS UNDER THE FOOD CODE APPLY, AS WELL AS THE GENERAL PROVISIONS IN THE FOOD ACT 1981.

6 Consideration of label compliance

6.1 Non-compliant labelling

In situations where the labelling is not compliant with the Food Standards Code, or the Supplemented Food Standard, (whichever applies) the Animal Products (Exemption from Labelling Standards for Dairy Product and Dairy Material Intended for Export) Notice 2006 allows operators to export product, provided that clauses 11 and 12 of the Animal Products (Export Requirements – Dairy Products) Notice 2005 and any other labelling requirements (other than those contained in the Food Standards Code) are adequately addressed.

Dietary Supplements are not covered by the above labelling exemption. NZFSA may in its discretion elect to grant an official assurance if product complies with the APA even though there may be issues of non-compliance with the DSR.

7 Key areas of significance

7.1 Product designation

Does the product description on the label accurately reflect the NZFSA product description assigned to the product specification?

Products that contain less than 100% colostrum (aside from tabletting and encapsulating aids as specified in the Dietary Supplement Regulations 1985) cannot be labelled as “pure colostrum” or any other such statement which implies or suggests the formulation is solely colostrum.

The amount or proportion of colostrum or amount of IgG derived from colostrum should be stated on the label.

Note: The NZFSA website has a list of acceptable product descriptions that are used for certification purposes along with the requirements for selection and verification:

http://foodsafety.govt.nz/registers-lists/product-descriptions/index.htm

7.2 Ingredient listing

All ingredients must be listed, aside from tabletting and encapsulating aids in the case of dietary supplements (as specified in the Dietary Supplement Regulations 1985). See Part 1.2 of the ANZFSC for general ingredient listing requirements for all foods (and there are specific requirements applying to “dietary supplements” in the DSR that must be followed if your product is a dietary supplement – see regulation 9 (Consumer Information Panel)).

7.3 Products that come under the ANZFSC Standard 2.9.2, Foods for Infants

Clause 5 (2) states that the label on a package of food for infants must not include a recommendation, whether express or implied that the food is suitable for infants less than four months old. Refer to section 3.3 above for the requirements for Supplemented Foods.

7.4 Incorrect manufacturer details on the label

It is acceptable to state manufactured for (or “on behalf of”) a company/person who is not the manufacturer however, in such cases the label cannot state “manufactured by”.