Standard 2.9.5 – Food for Special Medical Purposes – Food Standards (Proposal P1025 – Code Revision) Variation—Australia New Zealand Food Standards Code – Amendment No. 154

The Board of Food Standards Australia New Zealand gives notice of the making of this standard under section 92 of the *Food Standards Australia New Zealand Act 1991*.

The Standard commences on 1 March 2016.

Dated 25 March 2015

Standards Management Officer, Delegate of the Board of Food Standards Australia New Zealand.

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC 96 on 10 April 2015.

Note 1 This instrument is a standard under the *Food Standards Australia New Zealand Act 1991* (Cth). The standards together make up the *Australia New Zealand Food Standards Code*. See also section 1.1.1—3.

Note 2 The provisions of the Code that apply in New Zealand are incorporated in, or adopted under, the *Food Act 2014* (NZ). See also section 1.1.1—3.

Division 1 Preliminary

2.9.5—1 Name

This Standard is *Australia New Zealand Food Standards Code* – Standard 2.9.5 – Food for special medical purposes.

Note Commencement: This Standard commences on 1 March 2016, being the date specified as the commencement date in notices in the *Gazette* and the *New Zealand Gazette* under section 92 of the *Food Standards Australia New Zealand Act 1991* (Cth). See also section 93 of that Act.

2.9.5—2 Definitions

Note 1 Section 1.1.2—5 (Definition of ***food for special medical purposes***) provides as follows:

(1) In this Code:

food for special medical purposes means a food that is:

(a) specially formulated for the dietary management of individuals:

(i) by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and

(ii) whose dietary management cannot be completely achieved without the use of the food; and

(b) intended to be used under medical supervision; and

(c) represented as being:

(i) a food for special medical purposes; or

(ii) for the dietary management of a disease, disorder or medical condition.

(2) Despite subsection (1), a food is not ***food for special medical purposes*** if it is:

(a) formulated and represented as being for the dietary management of obesity or overweight; or

(b) an infant formula product.

Note 2 In this Code (see section 1.1.2—2):

inner package, in relation to a food for special medical purposes, means an individual package of the food that:

(a) is contained and sold within another package that is labelled in accordance with section 2.9.5—9; and

(b) is not designed for individual sale, other than a sale by a responsible institution to a patient or resident of the responsible institution.

Example An example of an inner package is an individual sachet (or sachets) of a powdered food contained within a box that is fully labelled, being a box available for retail sale.

responsible institution means a hospital, hospice, aged care facility, disability facility, prison, boarding school or similar institution that is responsible for the welfare of its patients or residents and provides food to them.

Note 3 In this Standard (see section 1.1.2—2), a reference to a ***package*** does not include a reference to a plate, cup, tray or other food container in which food for special medical purposes is served by a responsible institution to a patient or resident of the responsible institution.

2.9.5—3 Application of other standards

The following provisions do not apply to food for special medical purposes:

(a) Standard 1.2.7 (nutrition, health and related claims) or Standard 1.1A.2 (transitional standard for health claims);

(b) unless the contrary intention appears, Part 2 of Chapter 1 (labelling and other information requirements);

(c) Standard 1.3.2 or Standard 1.5.1 (vitamins and minerals, novel foods);

(d) Standard 2.9.2, Standard 2.9.3 or Standard 2.9.4 (food for infants, formulated meal replacements and formulated supplementary foods, formulated supplementary sports foods).

2.9.5—4 Claims must not be therapeutic in nature

A claim in relation to food for special medical purposes must not:

(a) refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition; or

(b) compare the food with a good that is:

(i) represented in any way to be for therapeutic use; or

(ii) likely to be taken to be for therapeutic use, whether because of the way in which the good is presented or for any other reason.

Division 2 Sale of food for special medical purposes

2.9.5—5 Restriction on the persons by whom, and the premises at which, food for special medical purposes may be sold

(1) A food for special medical purposes must not be sold to a consumer, other than from or by:

(a) a medical practitioner or dietitian; or

(b) a medical practice, pharmacy or responsible institution; or

(c) a majority seller of that food for special medical purposes.

(2) In this section:

medical practitioner means a person registered or licensed as a medical practitioner under legislation in Australia or New Zealand, as the case requires, for the registration or licensing of medical practitioners.

majority seller: a person is a ***majority seller*** of a food for special medical purposes during any 24 month period if:

(a) during the period, the person sold that food for special medical purposes to medical practitioners, dietitians, medical practices, pharmacies or responsible institutions; and

(b) the sales mentioned in paragraph (a) represent more than one half of the total amount of that food for special medical purposes sold by the person during the period.

Division 3 Composition

2.9.5—6 Permitted forms of particular substances

(1) The following substances may be added to food for special medical purposes:

(a) a substance that is listed in Column 1 of the table to section S29—20 and that is in a corresponding form listed in Column 2 of that table;

(b) a substance that is listed in Column 1 of the table to section S29—7 and that is in a corresponding form listed in Column 2 of that table;

(c) any other substance, regardless of its form, that is permitted under this Code to be added to a food, if that substance is added in accordance with any applicable requirement of this Code.

(2) If a provision of this Code limits the amount of a substance referred to in paragraph (1)(a) or (b) that may be added to a food, that limit does not apply in relation to food for special medical purposes.

2.9.5—7 Compositional requirements for food represented as being suitable for use as sole source of nutrition

(1) If food for special medical purposes is represented as being suitable for use as a sole source of nutrition, the food must contain:

(a) not less than the minimum amount, as specified in column 2 of the table to section S29—21, of each vitamin, mineral and electrolyte listed in Column 1 of that table; and

(b) if applicable, not more than the maximum amount, as specified in Column 3 of that table, of each vitamin and mineral listed in Column 1.

(2) However, the food is not required to comply with subsection (1) to the extent that:

(a) a variation from a maximum or minimum amount is required for a particular medical purpose; and

(b) the labelling complies with subparagraph 2.9.5—10(1)(g)(ii).

Division 4 Labelling

2.9.5—8 Labelling and related requirements

(1) If a food for sale consisting of food for special medical purposes is not in a package:

(a) the food for sale must either *bear a label, or have labelling that is displayed in connection with its sale, with the information relating to irradiated foods (see section 1.5.3—9); and

(b) there is no other labelling requirement under this Code.

(2) If the food for sale is in a package, it is required to *bear a label that complies with section 2.9.5—9.

(3) If the food for sale is in an *inner package:

(a) the inner package is required to *bear a label that complies with section 2.9.5—16; and

(b) there is no labelling requirement under this Code for any other packaging associated with the food for sale.

(4) If the food for sale is in a *transportation outer:

(a) the transportation outer or package containing the food for sale is required to *bear a label that complies with section 2.9.5—17; and

(b) there is no labelling requirement under this Code for any other packaging associated with the food for sale.

2.9.5—9 Mandatory labelling information

(1) Subject to this section, the label that is required for food for special medical purposes must state the following information in accordance with the provision indicated:

(a) a name or description sufficient to indicate the true nature of the food (see section 1.2.2—2);

(b) lot identification (see section 1.2.2—3);

(c) if the sale of the food for sale is one to which Division 2 or Division 3 of Standard 1.2.1 applies—information relating to irradiated food (see section 1.5.3—9);

(d) any required advisory statements, *warning statements and other statements (see section 2.9.5—10);

(e) information relating to ingredients (see section 2.9.5—11);

(f) date marking information (see section 2.9.5—12);

(g) directions for the use or the storage of the food, if the food is of such a nature to require such directions for health or safety reasons;

(h) nutrition information (see section 2.9.5—13);

(i) if appropriate, the information required by subsection 2.9.5—14(4) or 2.9.5—15(5).

(2) The label must comply with Division 6 of Standard 1.2.1.

2.9.5—10 Advisory and warning statements—food for special medical purposes

(1) For paragraph 2.9.5—9(1)(d), the following statements are required:

(a) a statement to the effect that the food must be used under medical supervision;

(b) a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food;

(c) a statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated;

(d) a statement describing the properties or characteristics which make the food appropriate for the medical purpose indicated in paragraph (c);

(e) if the food has been formulated for a specific age group—a statement to the effect that the food is intended for persons within the specified age group;

(f) a statement indicating whether or not the food is suitable for use as a sole source of nutrition;

(g) if the food is represented as being suitable for use as a sole source of nutrition:

(i) a statement to the effect that the food is not for parenteral use; and

(ii) if the food has been modified to vary from the compositional requirements of section 2.9.5—7 such that the content of one or more nutrients falls short of the prescribed minimum, or exceeds the prescribed maximum (if applicable):

(A) a statement indicating the nutrient or nutrients which have been modified; and

(B) unless provided in other documentation about the food—a statement indicating whether each modified nutrient has been increased, decreased, or eliminated from the food, as appropriate.

(2) For paragraph 2.9.5—9(1)(d), the required advisory and other statements are any that are required by:

(a) items 1, 4, 6 or 9 of the table in Schedule 9; or

(b) subsection 1.2.3—2(2); or

(c) section 1.2.3—4.

(3) For paragraph 2.9.5—9(1)(d), the *warning statement referred to in section 1.2.3—3, if applicable, is required.

2.9.5—11 Information relating to ingredients—food for special medical purposes

For paragraph 2.9.5—9(1)(e), the information relating to ingredients is:

(a) a statement of ingredients; or

(b) information that complies with Article 6, Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs; or

(c) information that complies with 21 CFR § 101.4.

2.9.5—12 Date marking information—food for special medical purposes

(1) For paragraph 2.9.5—9(1)(f), the required date marking information is date marking information in accordance with Standard 1.2.5.

(2) Despite subsection (1), for subparagraph 1.2.5—5(2)(a)(ii), the words 'Expiry Date', or similar words, may be used on the label.

2.9.5—13 Nutrition information—food for special medical purposes

For paragraph 2.9.5—9(1)(h), the nutrition information is the following, expressed per given amount of the food:

(a) the minimum or average energy content; and

(b) the minimum amount or *average quantity of:

(i) protein, fat and carbohydrate; and

(ii) any vitamin, mineral or electrolyte that has been *used as a nutritive substance in the food; and

(iii) any substance listed in the table to section S29—20 that has been *used as a nutritive substance in the food; and

(iv) subject to paragraph 2.9.5—9(1)(i), any other substance in respect of which a nutrition content claim has been made.

2.9.5—14 Claims in relation to lactose content

(1) A claim in relation to the lactose content of a food for special medical purposes must not be made unless expressly permitted by this section.

(2) A claim to the effect that a food for special medical purposes is lactose free may be made if the food for sale contains no detectable lactose.

(3) A claim to the effect that a food for special medical purposes is low lactose may be made if the food for sale contains not more than 2 g of lactose per 100 g of the food.

(4) If a claim in relation to the lactose content of a food for special medical purposes is made, the information required is the *average quantity of the lactose and galactose in the food, expressed per given quantity of the food.

Note See paragraph 2.9.5—9(1)(i).

2.9.5—15 Claims in relation to gluten content

(1) A claim in relation to the *gluten content of a food for special medical purposes is prohibited unless expressly permitted by this section.

(2) A claim to the effect that a food for special medical purposes is gluten free may be made if the food contains:

(a) no detectable gluten; and

(b) no oats or oat products; and

(c) no cereals containing *gluten that have been malted, or products of such cereals.

(3) A claim to the effect that a food for special medical purposes has a low gluten content may be made if the food contains no more than 20 mg *gluten per 100 g of the food.

(4) A claim to the effect that a food for special medical purposes contains *gluten or is high in gluten may be made.

(5) If a claim is made in relation to the *gluten content of a food for special medical purposes, the information required is the *average quantity of the gluten in the food, expressed per given amount of the food.

Note See paragraph 2.9.5—9(1)(i).

2.9.5—16 Labelling requirement—food for special medical purposes in inner package

(1) The label on an *inner package that contains food for special medical purposes must state the following information in accordance with the provision indicated:

(a) a name or description sufficient to indicate the true nature of the food (see section 1.2.2—2);

(b) lot identification (see section 1.2.2—3);

(c) any declaration that is required by section 1.2.3—4;

(d) date marking information (see section 2.9.5—12).

(2) The label must comply with Division 6 of Standard 1.2.1.

(3) To avoid doubt, this section continues to apply to the label on the *inner package if a *responsible institution subsequently supplies the inner package to a patient or resident of the responsible institution.

2.9.5—17 Labelling requirement—food for special medical purposes in transportation outer

(1) If packages of food for special medical purposes are contained in a transportation outer, the information specified in subsection (2) must be:

(a) contained in a label on the transportation outer; or

(b) contained in a label on a package of the food for sale, and clearly discernible through the transportation outer.

(2) For subsection (1), the information is:

(a) a name or description sufficient to indicate the true nature of the food (see section 1.2.2—2); and

(b) lot identification (see section 1.2.2—3); and

(c) unless it is provided in accompanying documentation—the name and address of the *supplier (see section 1.2.2—4).

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