เครือรัฐออสเตรเลีย

เรื่อง อาหารทางการแพทย์

(Standard 2.9.5 Food for Special Medical Purposes)

รายละเอียด	:	มาตรฐานข้อกำหนดสำหรับอาหารทางการแพทย์
กลุ่มอาหาร	:	อาหารสำหรับวัตถุประสงค์เฉพาะด้านการแพทย์
ลำดับขั้นกฎหมาย	:	มาตรฐาน
หัวข้อสำคัญ	:	-
วันที่ออกประกาศ	:	14 สิงหาคม 2556
วันที่บังคับใช้	:	28 มิถุนายน 2557
วันที่ปรับปรุงล่าสุด	:	21 กุมภาพันธ์ 2556

เครือรัฐออสเตรเลีย
เรื่อง อาหารทางการแพทย์
(Standard 2.9.5 Food for Special Medical Purposes)

บังคับใช้ วันที่ 13 เดือน เมษายน พ.ศ. 2560

รายละเอียดโดยสรุป

หน่วยงานมาตรฐานสินค้าอาหารของออสเตรเลียและนิวซีแลนด์ (Food Standards Australia New Zealand: FSANZ.) ประกาศปรับปรุงมาตรฐาน 2.9.5 เรื่อง อาหารสำหรับวัตถุประสงค์เฉพาะทางการแพทย์ (Standard 2.9.5 Food for Special Medical Purposes) ซึ่งมาตรฐานนี้มีขอบข่ายบังคับอาหารที่มีสูตรหรือส่วนผสมที่เกี่ยวข้องกับสภาวการณ์ทางการแพทย์ เช่น เป็นอาหารสำหรับผู้ป่วยบางโรค หรือ อาหารที่ใช้ตามที่แพทย์สั่ง เป็นต้น โดยครอบคลุมตั้งแต่การผลิต การจัดจำหน่าย และ การนำไปใช้

อาหารที่มีวัตถุประสงค์เฉพาะทางการแพทย์ตามมาตรฐานนี้ หมายรวมถึงอาหารที่ใช้กับบุคคลซึ่ง

1. ต้องได้รับอาหารสูตรเฉพาะที่มีการปรับปรุงสารอาหารบางชนิดสำหรับผู้มีความต้องการเฉพาะด้านการแพทย์ หรือมีข้อจำกัดพิเศษเกี่ยวกับระบบการย่อยหรือการใช้สารอาหารของร่างกาย เช่น การดูดซึม การย่อย เมตาโบลิซึม หรือการทำงานของลำไส้ ซึ่งต้องได้รับอาหารหรือสารอาหารเฉพาะ
2. ผู้ที่ไม่สามารถใช้ประโยชน์จากสารอาหารที่ได้รับแบบปกติได้

ดังนั้น จึงมีการกำหนดมาตรฐานอาหารเฉพาะสำหรับผู้ที่ต้องการสารอาหารพิเศษหรืออยู่ในภาวะที่ต้องการสารอาหารเฉพาะสำหรับร่างกายขณะนั้น

สาระสำคัญของมาตรฐาน ได้แก่

(ก) มาตรฐานนี้ไม่รวมถึง

- Food used as nutritive substances และ Novel food
- อาหารที่ได้รับการยกเว้นในการแสดงฉลากตาม Part 1.2 of Chapter 1 (Labelling and other information requirements และ
- อาหารตามมาตรฐาน Standard 2.9.2, 2.9.3 or 2.9.4 food for infants, formulated meal replacements and formulated supplementary foods, formulated supplementary sports foods

(ข) ส่วนประกอบที่อนุญาตให้ใช้

- สำหรับอาหารทางการแพทย์ สามารถใช้ส่วนประกอบเหล่านี้ได้

(ก) สารที่ระบุไว้ในคอลัมน์ 1 และ 2 ของตาราง Section S29-20 Substances that may be added to food for special medical purposes

(ข) สารที่ระบุไว้ในคอลัมน์ 1 และ 2 ของตาราง Section S29-7 Permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants and food for special medical purposes

(ค) สารอื่น ๆ ที่อนุญาตให้ใช้ตามกฎหมาย

- ส่วนประกอบที่เป็นแหล่งของสารอาหาร (Source of nutrition)

(ก) ปริมาณการใช้ต้องไม่เกินที่กำหนดไว้ในคอลัมน์ 2 ถึง คอลัมน์ 3 ของตาราง Section S29-21 Amounts of nutrients for food for special medical purposes represented as a sole source of nutrition

(ข) กรณีที่อาหารไม่ได้มีข้อกำหนดปริมาณสูงสุดหรือต่ำสุดของสารอาหาร สามารถใช้ได้ตามต้องการ และแสดงข้อมูลบนฉลากตามที่กำหนดในมาตรฐานนี้

(ค) ข้อกำหนดการแสดงฉลาก

- การแสดงฉลากอาหารที่มีวัตถุประสงค์พิเศษทางการแพทย์เฉพาะอาหารที่บรรจุหีบห่อ
- ข้อกำหนดในการแสดงฉลาก ให้แสดงข้อมูลต่อไปนี้

(ก) ชื่อหรือรายละเอียดที่บรรยายลักษณะตามธรรมชาติที่แท้จริงของอาหาร

(ข) หมายเลข Lot

(ค) คำเตือน

(ง) ข้อมูลส่วนประกอบ

(จ) วันหมดอายุ

(ฉ) วิธีการใช้หรือวิธีการเก็บรักษา

(ช) ข้อมูลโภชนาการ

- คำแนะนำและการแสดงคำเตือน เช่น

(ก) ต้องระบุผลกระทบที่อาจเกิดขึ้นเมื่อใช้ภายใต้คำแนะนำของแพทย์

(ข) ต้องระบุคำเตือนที่จำเป็นสำหรับอาหารที่อาจส่งผลต่อสุขภาพของผู้บริโภค หรือความเกี่ยวข้องกับโรคต่าง ๆ

- การแสดงข้อมูลส่วนประกอบ ข้อมูลของส่วนประกอบอาหารให้สอดคล้องตาม Articles 18, 19, 20 ของ EU Regulation 1169/2011 of the European Parliament and of the Council of 25 October 2011 หรือ 21 CFR 101.4
- การแสดงวันหมดอายุ ตามที่กำหนดใน Standard 1.2.5 โดยแสดงวันหมดอายุด้วยคำว่า “Expiry Date” หรือคำอื่นที่ความหมายคล้ายกัน
- การแสดงข้อมูลโภชนาการ ให้ระบุปริมาณต่ำสุดหรือค่าเฉลี่ยของพลังงานและสารอาหารต่อไปนี้

(ก) โปรตีน

(ข) ไขมัน

(ค) คาร์โบไฮเดรต

(ง) วิตามิน, แร่ธาตุ หรือ อีเล็กโตรไลต์ ที่ใช้เป็นสารอาหาร

(จ) สารอื่น ๆ ที่กำหนดให้ใช้ในตาราง Section S29-20 Substances that may be added to food for special medical purposes

- การกล่าวอ้าง ได้แก่

(ก) ไม่อนุญาตให้กล่าวอ้างเกี่ยวกับปริมาณแลกโตสหรือผลกระทบจากแลกโตส เช่น Lactose free แต่สามารถกล่าวอ้างว่า Low lactose ได้ถ้ามีปริมาณน้อยกว่า 2 g of lactose per 100 g of food และต้องแสดงปริมาณ *average quantity of the lactose and galactose in the food ด้วย

(ข) การกล่าวอ้างปริมาณกลูเต็น สามารถระบุว่า Gluten free ได้หากอาหารที่มีวัตถุประสงค์พิเศษทางการแพทย์นั้นตรวจไม่พบกลูเต็น (no detectable) หรือระบุว่า Low gluten ได้ในกรณีที่ตรวจพบปริมาณน้อยกว่า 20 mg gluten per 100 g of food และต้องแสดง average quantity of the gluten in the food ด้วย

- การแสดงฉลากสำหรับบรรจุภายใน หรือ inner packaging สามารถแสดงเฉพาะชื่อและคุณลักษณะอาหาร, หมายเลข Lot, ข้อมูลคำเตือนและคำแนะนำ และ วันหมดอายุ (แต่ต้องสอดคล้องตามมาตรฐานการแสดงข้อมูลใน Standard 1.2.1)
- การแสดงฉลากสำหรับบรรจุภัณฑ์ภายนอก หรือ บรรจุภัณฑ์เพื่อการขนส่ง สามารถแสดงเฉพาะ ชื่อและคุณลักษณะของอาหาร, หมายเลข Lot, และชื่อและที่อยู่ของ supplier ได้

เอกสารอ้างอิง:

มาตรฐานอาหารสำหรับวัตถุประสงค์เฉพาะทางการแพทย์ สามารถดูรายละเอียดได้จากเอกสารแนบหรือเว็บไซต์ https://www.legislation.gov.au/Details/F2017C00337/Download

ข้อมูลเพิ่มเติม:

กฎ ระเบียบ และมาตรฐานสินค้าอาหารไทยและประเทศคู่ค้า สามารถดูรายละเอียดเพิ่มเติมได้จากฐานข้อมูลกฎหมายมาตรฐานอาหาร ภายในเว็บไซต์ศูนย์อัจฉริยะเพื่ออุตสาหกรรมอาหาร เมนู Law & Safety (http://fic.nfi.or.th)

****

Standard 2.9.5 Food for special medical purposes

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) paragraphs 1.1.1—10(6)(b) (foods used as nutritive substances) and 1.1.1—10(6)(f) (novel foods); and

(b) unless the contrary intention appears, Part 1.2 of Chapter 1 (labelling and other information requirements); and

(c) 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 Articles 18, 19, 20 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers; 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).

Amendment History

The Amendment History provides information about each amendment to the Standard. The information includes commencement or cessation information for relevant amendments.

These amendments are made under section 92 of the *Food Standards Australia New Zealand Act 1991* unless otherwise indicated. Amendments do not have a specific date for cessation unless indicated as such.

About this compilation

This is compilation No. 2 of Standard 2.9.5 as in force on **13 April 2017** (up to Amendment No. 168). It includes any commenced amendment affecting the compilation to that date.

Prepared by Food Standards Australia New Zealand on **13 April 2017**.

Uncommenced amendments or provisions ceasing to have effect

To assist stakeholders, the effect of any uncommenced amendments or provisions which will cease to have effect, may be reflected in the Standard as shaded boxed text with the relevant commencement or cessation date. These amendments will be reflected in a compilation registered on the Federal Register of Legislation including or omitting those amendments and provided in the Amendment History once the date is passed.

The following abbreviations may be used in the table below:

ad = added or inserted
am = amended
exp = expired or ceased to have effect
rep = repealed
rs = repealed and substituted

Standard 2.9.5 was published in the Food Standards Gazette No. FSC96 on 10 April 2015 as part of Amendment 154 (F2015L00472 –- 1 April 2015) and has since been amended as follows:

Section affected	A'ment No.	FRL registration Gazette	Commencement (Cessation)	How affected	Description of amendment
2.9.5—3	157	F2015L01374 1 Sept 2015 FSC99 3 Sept 2015	1 March 2016	am	Removal of reference to Standard 1.1A.2 in paragraph (a).
2.9.5—3	161	F2016L00120 18 Feb 2016 FSC103 22 Feb 2016	1 March 2016	am	Correction of reference to Part 1.2.
2.9.5—3	168	F2017L00414 11 April 2017 FSC110 13 April 2017	13 April 2017	rs	Section to correct cross-references.
2.9.5—11	168	F2017L00414 11 April 2017 FSC110 13 April 2017	13 April 2017	am	Paragraph (b) replaced to update reference.

Schedule 29 Special purpose foods

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.

Special purpose foods are regulated by Part 9 of Chapter 2, which contains Standard 2.9.1, Standard 2.9.2, Standard 2.9.3, Standard 2.9.4, Standard 2.9.5 and Standard 2.9.6. This Standard prescribes information for these standards.

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.

S29—1 Name

This Standard is *Australia New Zealand Food Standards Code* – Schedule 29 – Special purpose foods.

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.

S29—2 Infant formula product—calculation of energy

(1) For paragraph 2.9.1—4(2)(a), the energy content of infant formula product must be calculated using:

(a) the energy contributions of the following *components only:

(i) fat; and

(ii) protein; and

(iii) carbohydrate; and

(b) the relevant energy factors set out in section S11—2.

(2) The energy content of infant formula product must be expressed in kilojoules.

S29—3 Infant formula product—calculation of protein content

For paragraph 2.9.1—4(2)(b), the protein content (***PC***) of infant formula product must be calculated in accordance with the following equation:

$$PC = NC \times F$$

where:

NC is the nitrogen content of the infant formula product.

F is:

(a) for milk proteins and their partial protein hydrolysates—6.38; or

(b) otherwise—6.25.

S29—4 Infant formula product—calculation of potential renal solute load

(1) For paragraph 2.9.1—4(2)(c), the potential renal solute load (***PRSL***), in mOsm/100 kJ, must be calculated in accordance with the following equation:

$$PRSL = \frac{Na}{23} + \frac{Cl}{35} + \frac{K}{39} + \frac{P_{avail}}{31} + \frac{N}{28}$$

where:

Na is the amount of sodium in the infant formula product in mg/100 kJ.

Cl is the amount of chloride in the infant formula product in mg/100 kJ.

K is the amount of potassium in the infant formula product in mg/100 kJ.

P_{avail} is given by the formula set out in subsection (2).

N is the amount of nitrogen in the infant formula product in mg/100 kJ.

(2) In subsection (1), P_{avail} is calculated in accordance with the following equation:

$$P_{avail} = P_{mbf} + \left(\frac{2}{3} \times P_{sbf} \right)$$

where:

P_{mbf} is the amount of phosphorus in the milk-based formula.

P_{sbf} is the amount of phosphorus in the soy-based formula.

S29—5 Infant formula products—substances permitted as nutritive substances

For section 2.9.1—5, the table is:

Infant formula products—substances permitted for use as nutritive substances

Column 1	***Column 2***	***Column 3***	***Column 4***
Substance	*Permitted forms*	*Minimum amount per 100 kJ*	*Maximum amount per 100 kJ*
Adenosine-5′-monophosphate	Adenosine-5′- monophosphate	0.14 mg	0.38 mg
L-carnitine	L-carnitine	0.21 mg	0.8 mg
Choline	Choline chloride	1.7 mg	7.1 mg
	Choline bitartrate		
Cytidine-5′-monophosphate	Cytidine-5′-monophosphate	0.22 mg	0.6 mg
Guanosine-5′-monophosphate	Guanosine-5′-monophosphate	0.04 mg	0.12 mg
	Guanosine-5′-monophosphate sodium salt		
Inosine-5′-monophosphate	Inosine-5′-monophosphate	0.08 mg	0.24 mg
	Inosine-5′-monophosphate sodium salt		
Lutein	Lutein from *Tagetes erecta L.*	1.5 µg	5 µg
Inositol	Inositol	1.0 mg	9.5 mg
Taurine	Taurine	0.8 mg	3 mg
Uridine-5′-monophosphate	Uridine-5′-monophosphate sodium salt	0.13 mg	0.42 mg

S29—6 Infant formula products—L-amino acids that must be present in infant formula and follow-on formula

For section 2.9.1—10, the table is:

L-amino acids that must be present in infant formula and follow-on formula

L-amino acid	***Minimum amount per 100 kJ***
Histidine	10 mg
Isoleucine	21 mg
Leucine	42 mg
Lysine	30 mg
Cysteine & cysteine total	6 mg
Cysteine, cystine & methionine total	19 mg
Phenylalanine	17 mg

L-amino acid	*Minimum amount per 100 kJ*
Phenylalanine & tyrosine total	32 mg
Threonine	19 mg
Tryptophan	7 mg
Valine	25 mg

S29—7 Permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants and food for special medical purposes

For sections 2.9.1—12, 2.9.2—4, 2.9.2—5, 2.9.2—6 and 2.9.5—6, the table is:

Permitted forms of vitamins, minerals and electrolytes in infant formula products, etc

Vitamin, mineral or electrolyte	Permitted forms
Vitamin A	
Retinol forms	vitamin A (retinol)
	vitamin A acetate (retinyl acetate)
	vitamin A palmitate (retinyl palmitate)
	retinyl propionate
Provitamin A forms	beta-carotene
Vitamin C	L-ascorbic acid
	L-ascorbyl palmitate
	calcium ascorbate
	potassium ascorbate
	sodium ascorbate
Vitamin D	vitamin D_2 (ergocalciferol)
	vitamin D_3 (cholecalciferol)
	vitamin D (cholecalciferol-cholesterol)
Thiamin	thiamin hydrochloride
	thiamin mononitrate
Riboflavin	riboflavin
	riboflavin-5′-phosphate, sodium
Niacin	niacinamide (nicotinamide)
Vitamin B_6	pyridoxine hydrochloride
	pyridoxine-5′-phosphate
Folate	folic acid
Pantothenic acid	calcium pantothenate
	dexpanthenol
Vitamin B_{12}	cyanocobalamin
	hydroxocobalamin
Biotin	d-biotin
Vitamin E	dl-α-tocopherol
	d-α-tocopherol concentrate
	tocopherols concentrate, mixed

Vitamin, mineral or electrolyte	Permitted forms
	d-α-tocopheryl acetate
	dl-α-tocopheryl acetate
	d-α-tocopheryl acid succinate
	dl-α-tocopheryl succinate
Vitamin K	Vitamin K_1 as phylloquinone (phytonadione)
	phytylmenoquinone
Calcium	calcium carbonate
	calcium chloride
	calcium citrate
	calcium gluconate
	calcium glycerophosphate
	calcium hydroxide
	calcium lactate
	calcium oxide
	calcium phosphate, dibasic
	calcium phosphate, monobasic
	calcium phosphate, tribasic
	calcium sulphate
Chloride	calcium chloride
	magnesium chloride
	potassium chloride
	sodium chloride
Chromium	chromium sulphate
Copper	copper gluconate
	cupric sulphate
	cupric citrate
Iodine	potassium iodate
	potassium iodide
	sodium iodide
Iron	ferric ammonium citrate
	ferric pyrophosphate
	ferrous citrate
	ferrous fumarate
	ferrous gluconate
	ferrous lactate
	ferrous succinate
	ferrous sulphate
Magnesium	magnesium carbonate
	magnesium chloride
	magnesium gluconate
	magnesium oxide

Vitamin, mineral or electrolyte	Permitted forms
	magnesium phosphate, dibasic
	magnesium phosphate, tribasic
	magnesium sulphate
Manganese	manganese chloride
	manganese gluconate
	manganese sulphate
	manganese carbonate
	manganese citrate
Molybdenum	sodium molybdate VI
Phosphorus	calcium glycerophosphate
	calcium phosphate, dibasic
	calcium phosphate, monobasic
	calcium phosphate, tribasic
	magnesium phosphate, dibasic
	potassium phosphate, dibasic
	potassium phosphate, monobasic
	potassium phosphate, tribasic
	sodium phosphate, dibasic
	sodium phosphate, monobasic
	sodium phosphate, tribasic
Potassium	potassium bicarbonate
	potassium carbonate
	potassium chloride
	potassium citrate
	potassium glycerophosphate
	potassium gluconate
	potassium hydroxide
	potassium phosphate, dibasic
	potassium phosphate, monobasic
	potassium phosphate, tribasic
Selenium	seleno methionine
	sodium selenate
	sodium selenite
Sodium	sodium bicarbonate
	sodium carbonate
	sodium chloride
	sodium chloride iodised
	sodium citrate
	sodium gluconate
	sodium hydroxide
	sodium iodide

Vitamin, mineral or electrolyte	Permitted forms
	sodium lactate
	sodium phosphate, dibasic
	sodium phosphate, monobasic
	sodium phosphate, tribasic
	sodium sulphate
	sodium tartrate
Zinc	zinc acetate
	zinc chloride
	zinc gluconate
	zinc oxide
	zinc sulphate

S29—8 Infant formula products—limits on fatty acids that may be present in infant formula and follow-on formula

For section 2.9.1—11, the table is:

Limits on fatty acids that may be present in infant formula and follow-on formula

Fatty acid	***Limits***
Essential fatty acids	
Linoleic acid (18:2)	no less than 9% of the total fatty acids
	no more than 26% of the total fatty acids
α-Linolenic acid (18:3)	no less than 1.1% of the total fatty acids
	no more than 4% of the total fatty acids
Long chain polyunsaturated fatty acids	
Long chain omega 6 series fatty acids (C> = 20)	no more than 2% of the total fatty acids
Arachidonic acid (20:4)	no more than 1% of the total fatty acids
Long chain omega 3 series fatty acids (C> = 20)	no more than 1% of the total fatty acids
Total *trans* fatty acids	no more than 4% of the total fatty acids
Erucic acid (22:1)	no more than 1% of the total fatty acids

S29—9 Required vitamins, minerals and electrolytes in infant formula and follow-on formula

For section 2.9.1—12, the table is:

Required vitamins, minerals and electrolytes in infant formula and follow-on formula

Column 1	***Column 2***	***Column 3***
Vitamin, mineral or electrolyte	*Minimum amount per 100 kJ*	*Maximum amount per 100 kJ*
Vitamins		
Vitamin A	14 µg	43 µg
Vitamin D	0.25 µg	0.63 µg

Column 1	*Column 2*	*Column 3*
Vitamin, mineral or electrolyte	*Minimum amount per 100 kJ*	*Maximum amount per 100 kJ*
Vitamin C	1.7 mg	
Thiamin	10 µg	
Riboflavin	14 µg	
Preformed Niacin	130 µg	
Vitamin B_6	9 µg	36 µg
Folate	2 µg	
Pantothenic acid	70 µg	
Vitamin B_{12}	0.025 µg	
Biotin	0.36 µg	
Vitamin E	0.11 mg	1.1 mg
Vitamin K	1 µg	
Minerals		
Calcium	12 mg	
Phosphorus	6 mg	25 mg
Magnesium	1.2 mg	4.0 mg
Iron	0.2 mg	0.5 mg
Iodine	1.2 µg	10 µg
Copper	14 µg	43 µg
Zinc	0.12 mg	0.43 mg
Manganese	0.24 µg	24.0 µg
Selenium	0.25 µg	1.19 µg
Electrolytes		
Chloride	12 mg	35 mg
Sodium	5 mg	15 mg
Potassium	20 mg	50 mg

S29—10 Guidelines for infant formula products

Guideline for maximum amount of vitamins and minerals in infant formula products

(1) It is recommended that the quantities specified in the table to this section be observed as the maximum levels of vitamins and minerals in infant formula product.

Guideline for maximum amount of vitamins and minerals in infant formula products

Vitamin or mineral	*Recommended maximum amount per 100 kJ*
Vitamins	
Vitamin C	5.4 mg
Thiamin	48 µg
Riboflavin	86 µg
Preformed Niacin	480 µg
Folate	8.0 µg
Pantothenic acid	360 µg

Vitamin or mineral	*Recommended maximum amount per 100 kJ*
Vitamin B_{12}	0.17 µg
Vitamin K	5.0 µg
Biotin	2.7 µg
Minerals	
Calcium	33 mg
Phosphorus	22 mg
Manganese	7.2 µg, for infant formula products specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions
Chromium	2.0 µg
Molybdenum	3 µg

Guideline on advice regarding additional vitamin and mineral supplementation

(2) Manufacturers are recommended to provide an advice in the label on a package of infant formula product to the effect that consumption of vitamin or mineral preparations is not necessary.

Nutrition information table

(3) It is recommended that the nutrition information table be set out in the format specified in the table to this section.

NUTRITION INFORMATION		
	Average amount per 100 mL made up formula (see Note 1)	Average amount per 100 g of powder (or per 100 mL for liquid concentrate) (see Note 2)
Energy	kJ	kJ
Protein	g	g
Fat	g	g
Carbohydrate	g	g
Vitamin A	µg	µg
Vitamin B_6	µg	µg
Vitamin B_{12}	µg	µg
Vitamin C	mg	mg
Vitamin D	µg	µg
Vitamin E	µg	µg
Vitamin K	µg	µg
Biotin	µg	µg
Niacin	mg	mg
Folate	µg	µg
Pantothenic acid	µg	µg
Riboflavin	µg	µg
Thiamin	µg	µg
Calcium	mg	mg
Copper	µg	µg

Iodine	µg	µg
Iron	mg	mg
Magnesium	mg	mg
Manganese	µg	µg
Phosphorus	mg	mg
Selenium	µg	µg
Zinc	mg	mg
Chloride	mg	mg
Potassium	mg	mg
Sodium	mg	mg
(insert any other substance used as a nutritive substance or inulin-type fructans and galacto-oligosaccharides to be declared)	g, mg, µg	g, mg, µg

Note 1 Delete the words 'made up formula' in the case of formulas sold in 'ready to drink' form.

Note 2 Delete this column in the case of formulas sold in 'ready to drink' form.

S29—11 Food for infants—claims that can be made about vitamins and minerals added to cereal-based food for infants

For section 2.9.2—10, the table is:

Claims that can be made about vitamins and minerals added to cereal-based food for infants

Vitamin or mineral	***Maximum claim per serve***
Thiamin (mg)	15% RDI
Niacin (mg)	15% RDI
Folate (µg)	10% RDI
Vitamin B_6 (mg)	10% RDI
Vitamin C (mg)	10% RDI
Magnesium (mg)	15% RDI

S29—12 Formulated meal replacements—vitamins and minerals that must be present in formulated meal replacements

(1) For sections 2.9.3—3, 2.9.3—4 and 2.9.6—4, the table is set out below.

(2) In the table, the amounts set out in columns 2 and 3 are for a 1-meal serving, and are expressed as a proportion of the RDI.

Vitamins and minerals that must be present in formulated meal replacements

Column 1	*Column 2*	*Column 3*
Vitamin or mineral	*Maximum amount*	*Maximum claim*
Vitamin A	300 µg (40%)	300 µg (40%)
Thiamin	No amount set	0.55 mg (50%)
Riboflavin	No amount set	0.85 mg (50%)
Niacin	No amount set	5 mg (50%)
Folate	No amount set	100 µg (50%)
Vitamin B_6	No amount set	0.8 mg (50%)
Vitamin B_{12}	No amount set	1 µg (50%)
Vitamin C	No amount set	20 mg (50%)
Vitamin D	5.0 µg (50%)	5 µg (50%)
Vitamin E	No amount set	5 mg (50%)
Calcium	No amount set	400 mg (50%)
Iodine	75 µg (50%)	75 µg (50%)
Iron	No amount set	4.8 mg (40%)
Magnesium	No amount set	160 mg (50%)
Phosphorus	No amount set	500 mg (50%)
Zinc	No amount set	4.8 mg (40%)

S29—13 Vitamins and minerals that may be added to formulated meal replacements

(1) For sections 2.9.3—3, 2.9.3—4 and 2.9.6—4, the table is set out below.

(2) In the table, the amounts set out in columns 2 and 3 are for a 1-meal serving, and are expressed as a proportion of the *ESADDI unless stated otherwise.

Vitamins and minerals that may be added to formulated meal replacements

Column 1	*Column 2*	*Column 3*
Vitamin or mineral	*Maximum amount*	*Maximum claim*
Biotin	No amount set	5 µg (17%)
Pantothenic acid	No amount set	0.8 mg (17%)
Vitamin K	No amount set	40 µg (50%)
Chromium:		
inorganic	34 µg (17%)	34 µg (17%)
organic	16 µg (8%)	no claim permitted
Copper:		
inorganic	0.50 mg (17%)	0.50 mg (17%)
organic	0.24 mg (8%)	no claim permitted
Manganese:		
inorganic	0.85 mg (17%)	0.85 mg (17%)
organic	0.4 mg (8%)	no claim permitted

Column 1	*Column 2*	*Column 3*
Vitamin or mineral	*Maximum amount*	*Maximum claim*
Molybdenum:		
inorganic	42.5 µg (17%)	42.5 µg (17%)
organic	20 µg (8%)	no claim permitted
Selenium:		
inorganic	17.5 µg (25% RDI)	17.5 µg (25% RDI)
organic	9 µg (13% RDI)	9 µg (13% RDI)

S29—14 Vitamins and minerals that may be added to formulated supplementary foods

(1) For section 2.9.3—5, the table is set out below.

(2) In the table, the amounts set out in Columns 2 and 3 are for a serving, and are expressed as a proportion of the RDI.

Vitamins and minerals that may be added to formulated supplementary foods

Column 1	*Column 2*	*Column 3*
Vitamin or mineral	*Maximum amount*	*Maximum claim*
Vitamins		
Vitamin A	340 µg (45%)	265 µg (35%)
Thiamin	No amount set	0.55 mg (50%)
Riboflavin	No amount set	0.85 mg (50%)
Niacin	No amount set	5 mg (50%)
Folate	No amount set	100 µg (50%)
Vitamin B_6	No amount set	0.8 mg (50%)
Vitamin B_{12}	No amount set	1 µg (50%)
Vitamin C	No amount set	20 mg (50%)
Vitamin D	5 µg (50%)	5 µg (50%)
Vitamin E	No amount set	5 mg (50%)
Minerals		
Calcium	No amount set	400 mg (50%)
Iodine	75 µg (50%)	75 µg (50%)
Iron	No amount set	6 mg (50%)
Magnesium	No amount set	130 mg (40%)
Phosphorus	No amount set	500 mg (50%)
Zinc	No amount set	3 mg (25%)

S29—15 Vitamins and minerals that may be added to formulated supplementary food for young children

(1) For sections 2.9.3—7 and 2.9.3—8, the table is set out below.

(2) In the table, the amounts set out in Columns 2 and 3 are for a serving, and are expressed as a proportion of the RDI.

Vitamins and minerals that may be added to formulated supplementary food for young children

Column 1	*Column 2*	*Column 3*
Vitamin or mineral	*Maximum amount (as percentage of RDI)*	*Maximum claim (as percentage of RDI)*
Vitamins		
Vitamin A	135 µg (45%)	105 µg (35%)
Thiamin	No amount set	0.25 mg (50%)
Riboflavin	No amount set	0.4 mg (50%)
Niacin	No amount set	2.5 mg (50%)
Folate	No amount set	50 µg (50%)
Vitamin B_6	No amount set	0.35 mg (50%)
Vitamin B_{12}	No amount set	0.5 µg (50%)
Vitamin C	No amount set	15 mg (50%)
Vitamin D	2.5 µg (50%)	2.5 µg (50%)
Vitamin E	No amount set	2.5 mg (50%)
Minerals		
Calcium	No amount set	350 mg (50%)
Iodine	70 µg (100%)	35 µg (50%)
Iron	No amount set	3.0 mg (50%)
Magnesium	No amount set	32 mg (40%)
Phosphorus	No amount set	250 mg (50%)
Zinc	No amount set	1.1 mg (25%)

S29—16 Vitamins and minerals that may be added to formulated supplementary sports foods

(1) For section 2.9.4—3, the table is set out below.

(2) In the table, the amounts set out in Columns 2 and 3 are for a *one-day quantity.

Vitamins and minerals that may be added to formulated supplementary sports foods

Column 1	*Column 2*	*Column 3*
Vitamin or mineral	*Maximum amount*	*Maximum claim*
Vitamins		
Vitamin A	375 µg	375 µg
Thiamin		2.2 mg
Riboflavin		3.4 mg
Niacin		20 mg
Folate		400 µg
Vitamin B_6		3.2 mg
Vitamin B_{12}		4 µg
Vitamin C		80 mg
Vitamin D	2.5 µg	2.5 µg
Vitamin E		20 mg
Biotin		50 µg

Column 1	*Column 2*	*Column 3*
Vitamin or mineral	*Maximum amount*	*Maximum claim*
Pantothenic acid		3.5 mg
Minerals		
Calcium		1 600 mg
Chromium:		
inorganic forms	100 µg	100 µg
organic forms	50 µg	50 µg
Copper:		
inorganic forms	1.5 mg	1.5 mg
organic forms	750 µg	750 µg
Iodine	75 µg	75 µg
Iron		12 mg
Magnesium		640 mg
Manganese:		
inorganic forms		2.5 mg
organic forms		1.25 mg
Molybdenum:		
inorganic forms		125 µg
organic forms		62.5 µg
Phosphorus		1 000 mg
Selenium:		
inorganic forms	52 µg	52 µg
organic forms	26 µg	26 µg
Zinc		12 mg

S29—17 Additional permitted forms for vitamins and minerals in formulated supplementary sports foods and in formulated meal replacements

For sections 2.9.3—3 and 2.9.4—3, the table is:

Additional permitted forms

Column 1	*Column 2*
Vitamin or mineral	*Permitted forms*
Biotin	d-biotin
Pantothenic acid	d-sodium pantothenate
Calcium	Calcium hydroxide
Chromium:	
inorganic forms	Chromic chloride
organic forms	High chromium yeast
	Chromium picolinate
	Chromium nicotinate
	Chromium aspartate

Column 1	***Column 2***
Vitamin or mineral	*Permitted forms*
Copper:	
inorganic forms	Cupric carbonate
	Cupric sulphate
organic forms	Copper gluconate
	Copper-lysine complex
	Cupric citrate
Magnesium	Magnesium citrate
	Magnesium hydroxide
Manganese:	
inorganic forms	Manganese carbonate
	Manganese chloride
	Manganese sulphate
organic forms	Manganese citrate
Molybdenum:	
inorganic forms	Sodium molybdate
organic forms	High molybdenum yeast
Phosphorus	Magnesium phosphate, monobasic
	Potassium phosphate, tribasic
	Sodium phosphate, monobasic
	Sodium phosphate, tribasic
	Phosphoric acid

S29—18 Amino acids that may be added to formulated supplementary sports food

For paragraph 2.9.4—3(1)(b), the table is.

Amino acids that may be added to formulated supplementary sports food

Column 1	***Column 2***
Amino acid	*Maximum amount that may be added to a one-day quantity*
L-Alanine	1 200 mg
L-Arginine	1 100 mg
L-Aspartic acid	600 mg
L-Cysteine	440 mg
L-Glutamine	1 900 mg
L-Glutamic acid	1 600 mg
Glycine	1 500 mg
L-Histidine	420 mg
L-Isoleucine	350 mg
L-Leucine	490 mg
L-Lysine	420 mg

Column 1	*Column 2*
Amino acid	*Maximum amount that may be added to a one-day quantity*
L-Methionine	180 mg
L-Ornithine	360 mg
L-Phenylalanine	490 mg
L-Proline	1 100 mg
L-Serine	1 400 mg
L-Taurine	60 mg
L-Threonine	245 mg
L-Tyrosine	400 mg
L-Tryptophan	100 mg
L-Valine	350 mg

S29—19 Substances that may be used as nutritive substances in formulated supplementary sports food

For paragraph 2.9.4—3(1)(c), the table is:

Substances that may be used as nutritive substances in formulated supplementary sports food

Column 1	*Column 2*
Substance	*Maximum amount that may be added to a one-day quantity*
L-carnitine	100 mg
Choline	10 mg
Inosine	10 mg
Ubiquinones	15 mg
Creatine	3 g
Gamma-oryzinol	25 mg

S29—20 Substances that may be added to food for special medical purposes

For section 2.9.5—6, the table is.

Substances that may be added to food for special medical purposes

Column 1	*Column 2*
Substance	*Permitted forms*
Vitamins	
Niacin	Nicotinic acid
Vitamin B_6	Pyridoxine dipalmitate
Folate	Calcium L-methylfolate
Vitamin E	D-alpha-tocopherol
	D-alpha-tocopheryl polyethylene glycol-1000 succinate (TPGS)

Column 1	***Column 2***
Substance	*Permitted forms*
Pantothenic acid	Sodium pantothenate
	D-panthenol
	DL-panthenol
Minerals and electrolytes	
Boron	Sodium borate
	Boric acid
Calcium	Calcium bisglycinate
	Calcium citrate malate
	Calcium malate
	Calcium L-pidolate
Chloride	Choline chloride
	Sodium chloride, iodised
	Hydrochloric acid
Chromium	Chromium chloride
	Chromium picolinate
	Chromium potassium sulphate
Copper	Copper-lysine complex
	Cupric carbonate
Fluoride	Potassium fluoride
	Sodium fluoride
Iodine	Sodium iodate
Iron	Carbonyl iron
	Electrolytic iron
	Ferric citrate
	Ferric gluconate
	Ferric orthophosphate
	Ferric pyrophosphate, sodium
	Ferric saccharate
	Ferric sodium diphosphate
	Ferrous bisglycinate
	Ferrous carbonate
	Ferrous carbonate, stabilised
	Ferrous L-pidolate
	Iron, reduced (ferrum reductum)
Magnesium	Magnesium acetate
	Magnesium L-aspartate
	Magnesium bisglycinate
	Magnesium citrate
	Magnesium glycerophosphate
	Magnesium hydroxide

Column 1	*Column 2*
Substance	*Permitted forms*
	Magnesium hydroxide carbonate
	Magnesium lactate
	Magnesium phosphate, monobasic
	Magnesium L-pidolate
	Magnesium potassium citrate
Manganese	Manganese glycerophosphate
Molybdenum	Ammonium molybdate
Potassium	Potassium glycerophosphate
	Potassium lactate
	Potassium L-pidolate
Selenium	Selenium enriched yeast
	Sodium hydrogen selenite
	Sodium selenate
Zinc	Zinc bisglycinate
	Zinc carbonate
	Zinc citrate
	Zinc lactate
Other substances	
Amino acids	Sodium, potassium, calcium, magnesium salts of single amino acids listed in this section
	Hydrochlorides of single amino acids listed in this section
	L-alanine
	L-arginine
	L-asparagine
	L-aspartic acid
	L-citrulline
	L-cysteine
	L-cystine
	L-glutamic acid
	L-glutamine
	Glycine
	L-histidine
	L-isoleucine
	L-leucine
	L-lysine
	L-lysine acetate
	L-methionine
	L-ornithine
	L-phenylalanine

Column 1	*Column 2*
Substance	*Permitted forms*
	L-proline
	L-serine
	L-threonine
	L-tyrosine
	L-tryptophan
	L-valine
	L-arginine-L-aspartate
	L-lysine-L-aspartate
	L-lysine-L-glutamate
	N-acetyl-L-methionine
Carnitine	L-carnitine
	L-carnitine hydrochloride
	L-carnitine L-tartrate
Choline	Choline
	Choline bitartrate
	Choline chloride
	Choline citrate
	Choline hydrogen tartrate
Inositol	Inositol
Nucleotides	Adenosine-5′-monophosphate
	Adenosine-5′-monophosphate sodium salt
	Cytidine-5′-monophosphate
	Cytidine-5′-monophosphate sodium salt
	Guanosine-5′-monophosphate
	Guanosine-5′-monophosphate sodium salt
	Inosine-5′-monophosphate
	Inosine-5′-monophosphate sodium salt
	Uridine-5′-monophosphate
	Uridine-5′-monophosphate sodium salt
Taurine	Taurine

S29—21 Amounts of nutrients for food for special medical purposes represented as a sole source of nutrition

For section, 2.9.5—7, the table is:

Amounts of nutrients for food for special medical purposes represented as a sole source of nutrition

Column 1	*Column 2*	*Column 3*
Nutrient	*Minimum amount per MJ*	*Maximum amount per MJ*
Vitamins		
Vitamin A	84 µg retinol equivalents[1]	430 µg retinol equivalents[1]

Column 1	***Column 2***	***Column 3***
Nutrient	*Minimum amount per MJ*	*Maximum amount per MJ*
Thiamin	0.15 mg	No maximum set
Riboflavin	0.2 mg	No maximum set
Niacin	2.2 mg niacin equivalents[2]	No maximum set
Vitamin B_6	0.2 mg	1.2 mg
Folate	25 µg	No maximum set
Vitamin B_{12}	0.17 µg	No maximum set
Vitamin C	5.4 mg	No maximum set
Vitamin D		
(a) for products intended for children aged 1–10 years—	1.2 µg	7.5 µg
(b) otherwise—	1.2 µg	6.5 µg
Vitamin E	1 mg alpha-tocopherol equivalents[3]	No maximum set
Biotin	1.8 µg	No maximum set
Pantothenic Acid	0.35 mg	No maximum set
Vitamin K	8.5 µg	No maximum set
Minerals		
Calcium		
(a) for products intended for children aged 1–10 years—	120 mg	600 mg
(b) otherwise—	84 mg	420 mg
Magnesium	18 mg	No maximum set
Iron	1.2 mg	No maximum set
Phosphorus	72 mg	No maximum set
Zinc	1.2 mg	3.6 mg
Manganese	0.12 mg	1.2 mg
Copper	0.15 mg	1.25 mg
Iodine	15.5 µg	84 µg
Chromium	3 µg	No maximum set
Molybdenum	7 µg	No maximum set
Selenium	6 µg	25 µg
Electrolytes		
Sodium	72 mg	No maximum set
Potassium	190 mg	No maximum set
Chloride	72 mg	No maximum set

Note 1 See paragraph 1.1.2—14(3)(a).

Note 2 For niacin, add niacin and any niacin provided from the conversion of the amino acid tryptophan, using the conversion factor 1:60.

Note 3 See paragraph 1.1.2—14(3)(c).

Amendment History

The Amendment History provides information about each amendment to the Schedule. The information includes commencement or cessation information for relevant amendments.

These amendments are made under section 92 of the *Food Standards Australia New Zealand Act 1991* unless otherwise indicated. Amendments do not have a specific date for cessation unless indicated as such.

About this compilation

This is compilation No. 2 of Schedule 29 as in force on **13 April 2017** (up to Amendment No. 168). It includes any commenced amendment affecting the compilation to that date.

Prepared by Food Standards Australia New Zealand on **13 April 2017.**

Uncommenced amendments or provisions ceasing to have effect

To assist stakeholders, the effect of any uncommenced amendments or provisions which will cease to have effect, may be reflected in the Schedule as shaded boxed text with the relevant commencement or cessation date. These amendments will be reflected in a compilation registered on the Federal Register of Legislation including or omitting those amendments and provided in the Amendment History once the date is passed.

The following abbreviations may be used in the table below:

ad = added or inserted
am = amended
exp = expired or ceased to have effect
rep = repealed
rs = repealed and substituted

Schedule 29 was published in the Food Standards Gazette No. FSC96 on 10 April 2015 as part of Amendment 154 (F2015L00463 –- 1 April 2015) and has since been amended as follows:

Section affected	A'ment No.	FRL registration Gazette	Commencement (Cessation)	How affected	Description of amendment
S29—10(3)	157	F2015L01374 1 Sept 2015 FSC99 3 Sept 2015	1 March 2016	rs	Subsection and related table.
table to S29—17	161	F2016L00120 18 Feb 2016 FSC103 22 Feb 2016	1 March 2016	am	Correction of typographical error in table heading.
table to S29—20	168	F2017L00414 11 April 2017 FSC110 13 April 2017	13 April 2017	am	Insertion of a sodium fluoride as a permitted form of fluoride which was inadvertently omitted in FSC96.
S29—21	161	F2016L00120 18 Feb 2016 FSC103 22 Feb 2016	1 March 2016	rs	Notes 1, 2 and 3 to correct incorrect cross-reference and missing full stops.
table to S29—21	168	F2017L00414 11 April 2017 FSC110 13 April 2017	13 April 2017	am	Correction to abbreviation of megajoule in the heading, Correction to formatting error for entry for vitamin E.