Standard 2.9.1 Infant formula products

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

2.9.1—1 Name

This Standard is *Australia New Zealand Food Standards Code* – Standard 2.9.1 – Infant formula products.

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.

2.9.1—2 Outline of Standard

(1) This Standard regulates various types of infant formula products.

(2) Division 1 deals with preliminary matters.

(3) Division 2 sets out general compositional requirements for infant formula products.

(4) Division 3 sets out compositional requirements for infant formula and follow-on formula.

(5) Division 4 sets out compositional requirements for infant formula products for special dietary use.

(6) Division 5 sets out labelling and packaging requirements for infant formula products.

(7) Division 6 sets out guidelines for infant formula products. The guidelines are not legally binding.

2.9.1—3 Definitions

Note In this Code (see sections 1.1.2—2 and 1.1.2—3):

follow-on formula means an infant formula product that:

(a) is represented as either a breast-milk substitute or replacement for infant formula; and

(b) is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.

infant formula means an infant formula product that:

(a) is represented as a breast-milk substitute for infants; and

(b) satisfies by itself the nutritional requirements of infants under the age of 4 to 6 months.

infant formula product means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.

medium chain triglycerides means triacylglycerols that contain predominantly the saturated fatty acids designated by 8:0 and 10:0.

pre-term formula means an infant formula product specifically formulated to satisfy particular needs of infants born prematurely or of low birthweight.

protein substitute means:

(a) L-amino acids; or

(b) the hydrolysate of one or more of the proteins on which infant formula product is normally based; or

(c) a combination of L-amino acids and the hydrolysate of one or more of the proteins on which infant formula product is normally based.

soy-based formula means an infant formula product in which soy protein isolate is the sole source of protein.

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2.9.1—4 Interpretation

Interpretation of compositional requirements

(1) Compositional requirements in this Standard apply to:

(a) a powdered or concentrated form of infant formula product that has been reconstituted with water according to directions; or

(b) an infant formula product in 'ready to drink' form.

Calculation of energy, protein and potential renal solute load

(2) In this Standard:

(a) energy must be calculated in accordance with section S29—2; and

(b) protein content must be calculated in accordance with the equation set out in section S29—3; and

(c) potential renal solute load must be calculated in accordance with section S29—4.

Division 2 General compositional requirements for infant formula products

2.9.1—5 Use of substances as nutritive substances

Use of nutritive substances

(1) A substance listed in Column 1 of the table to section S29—5 may be *used as a nutritive substance in an infant formula product only if:

(a) it is in a permitted form listed in Column 2 of the table; and

(b) the amount of the substance in the product (including any naturally-occurring amount) is no more than the corresponding amount listed in Column 4 of the table.

Labelling of nutritive substances

(2) For the labelling provisions, a label may include words or other indications to the effect that the product contains a substance that is listed in Column 1 or Column 2 of the table to section S29—5 only if the amount of the substance in the product (including any naturally-occurring amount) is at least the corresponding amount listed in Column 3 of that table.

Note The labelling provisions are set out in Standard 1.2.1.

2.9.1—6 Addition of lactic acid producing microorganisms

L(+) lactic acid producing microorganisms may be added to infant formula product.

2.9.1—7 Restriction on addition to infant formula product of inulin-type fructans and galacto-oligosaccharides

(1) If an inulin-type fructan or a galacto-oligosaccharide is added to an infant formula product, the product must contain (taking into account both the naturally-occurring and added substances) no more than:

(a) if only *inulin-type fructans are added—110 mg/100 kJ of inulin-type fructans; or

(b) if only *galacto-oligosaccharides are added—290 mg/100 kJ of galacto-oligosaccharides; or

(c) if both inulin-type fructans and galacto-oligosaccharides are added:

(i) no more than 110 mg/100 kJ of inulin-type fructans; and

(ii) no more than 290 mg/100 kJ of combined inulin-type fructans and galacto-oligosaccharides.

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(2) An infant formula product to which an inulin-type fructan and/or a galacto-oligosaccharides is added must not contain lacto-N-neotetraose as an added substance.

(3) During the exclusive use period, an infant formula product which contains the following added substances may only be sold if the infant formula product is a prescribed infant formula product:

(a) 2′- fucosyllactose; and

(b) an inulin-type fructan, a galacto-oligosaccharides, or both.

(4) For the purposes of subsection (3):

(a) **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1251 – 2′-FL combined with galacto-oligosaccharides and/or inulin-type fructans in infant formula products) Variation* and ending 15 months after that date; and

(b) **prescribed infant formula product** means an infant formula product that:

(i) is manufactured by Nutricia Australia Pty. Ltd.; and

(ii) contains, as a nutritive substance, 2′-fucosyllactose sourced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Escherichia coli* O126.

2.9.1—8 Restriction on levels of other substances in infant formula product

Infant formula product must not contain:

(a) detectable gluten; or

(b) more than 3.8 mg/100 kJ of nucleotide-5′-monophosphates; or

(c) more than the following amounts of aluminium:

(i) for a pre-term formula—0.02 mg/100 mL;

(ii) for a soy-based formula—0.1 mg/100 mL;

(iii) otherwise—0.05 mg/100 mL.

Note Standard 1.4.1 contains the maximum level (ML) of lead contaminant in infant formula products.

Division 3 Infant formula and follow-on formula

2.9.1—9 Infant formula and follow-on formula—composition

(1) Infant formula must have:

(a) an energy content of no less than 2500 kJ/L and no more than 3150 kJ/L; and

(b) a protein content of no less than 0.45 g/100 kJ and no more than 0.7 g/100 kJ; and

(c) a fat content of no less than 1.05 g/100 kJ and no more than 1.5 g/100 kJ.

(2) Follow-on formula must have:

(a) an energy content of no less than 2500 kJ/L and no more than 3550 kJ/L; and

(b) the following protein content:

(i) for a milk-based follow-on formula—a protein content of no less than 0.38 g/100 kJ and no more than 1.3 g/100 kJ; and

(ii) for all other follow-on formulas—a protein content of no less than 0.45 g/100 kJ and no more than 1.3 g/100 kJ;

(c) a fat content of no less than 1.05 g/100 kJ and no more than 1.5 g/100 kJ;

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and

(d) a potential renal solute load value of no more than 8 mOsm/100 kJ.

Note Section 2.9.1—15 sets the protein content for infant formula and follow-on formula that are for special dietary use based on a *protein substitute.

2.9.1—10 Infant formula and follow-on formula—protein—further requirements

(1) The L-amino acids listed in the table to section S29—6 must be present in infant formula and follow-on formula at a level no less than the corresponding minimum level specified in the table.

(2) Despite subsection (1), L-amino acids listed in the table to section S29—6 may be added to infant formula or follow-on formula only in an amount necessary to improve protein quality.

2.9.1—11 Infant formula and follow-on formula—fat—further requirements

(1) The fats in infant formula and follow-on formula:

(a) may contain *medium chain triglycerides only if the medium chain triglyceride is present as the result of its being:

(i) a natural constituent of a milk-based ingredient of that formula; or

(ii) for a fat soluble vitamin that is specified in the table to section S29—9—a substance that was *used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the formula; and

(b) must have a ratio of linoleic acid to α-linolenic acid of no less than 5 to 1 and no more than 15 to 1; and

(c) must have a ratio of total long chain omega 6 series fatty acids (C> = 20) to total long chain omega 3 series fatty acids (C> = 20) that is not less than 1 in an infant formula or follow-on formula which contains those fatty acids; and

(d) for any long chain *polyunsaturated fatty acids that are present—must have an eicosapentaenoic acid (20:5 n-3) content of no more than the docosahexaenoic acid (22:6 n-3) content; and

(e) for a fatty acid that is listed in the table to section S29—8—must comply with the limits (if any) specified in the table.

2.9.1—12 Infant formula and follow-on formula—vitamins, minerals and electrolytes—further requirements

(1) Infant formula and follow-on formula must contain the vitamins, minerals and electrolytes specified in Column 1 of the table to section S29—9 in an amount that is:

(a) no less than the minimum amount specified in Column 2 of the table; and

(b) no more than the maximum amount (if any) specified in Column 3 of the table.

(2) Any vitamins, minerals or electrolytes that are used as nutritive substances must be in a permitted form as listed in the table to section S29—7.

(3) Infant formula and follow-on formula must contain no less than 0.5 mg of vitamin E/g of polyunsaturated fatty acids.

(4) The ratio of calcium to phosphorus in infant formula and follow-on formula must be no less than 1.2 to 1 and no more than 2 to 1.

(5) The ratio of zinc to copper must be:

(a) for infant formula—no more than 15 to 1; and

(b) for follow-on formula—no more than 20 to 1.

Division 4 Infant formula products for special dietary use

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2.9.1—13 Products formulated for premature or low birthweight infants

(1) A compositional requirement of this Standard does not apply to the extent that it would prevent the sale of an infant formula product that has been specifically formulated for premature or low birthweight infants.

(2) If an infant formula product would not comply with this Standard apart from this section, then for the labelling provisions:

(a) the following *warning statement is required: 'Suitable only for pre-term infants under specialist medical supervision'; and

(b) the name of food must include the words 'pre-term'.

Note The labelling provisions are set out in Standard 1.2.1.

2.9.1—14 Products for metabolic, immunological, renal, hepatic and malabsorptive conditions

(1) A compositional requirement of this Standard does not apply to the extent that it would prevent the sale of an infant formula product that is specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions.

(2) If:

(a) an infant formula product would not comply with this Standard apart from this section; and

(b) the label contains a statement that the infant formula product is suitable for infants with metabolic, immunological, renal, hepatic or malabsorptive conditions;

then for the labelling provisions, a statement indicating the following is required:

(c) that the product is not suitable for general use and should be used under medical supervision; and

(d) the condition, disease or disorder for which the product has been specially formulated; and

(e) the nutritional modifications, if any, which have been made to the product.

Note The labelling provisions are set out in Standard 1.2.1.

Special requirements for food represented as lactose free and low lactose formulas

(3) A compositional or labelling requirement of this Standard, other than a requirement that relates to lactose content, applies to an infant formula product that is represented as lactose free formula or low lactose formula.

(4) If the formula is represented as lactose free, it must contain no detectable lactose.

(5) If the formula is represented as low lactose, it must contain no more than 0.3 g lactose/100 mL of infant formula product.

(6) For the labelling provisions, if a label contains a claim that the infant formula product is lactose free, low lactose or words of similar import:

(a) the name of food must include the following:

(i) for a formula represented as lactose free—the words 'lactose free'; and

(ii) for a formula represented as low lactose—the words 'low lactose'; and

(b) the following statements are required:

(i) the amount of lactose expressed in g/100 mL; and

(ii) the amount of galactose expressed in g/100 mL.

Note The labelling provisions are set out in Standard 1.2.1.

2.9.1—15 Products for specific dietary use based on a protein substitute

(1) The protein content of an infant formula product based on a *protein substitute may

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be in the form of a protein substitute.

(2) Such infant formula product must:

(a) have an energy content of:

(i) for an infant formula—no less than 2 500 kJ/L and no more than 3 150 kJ/L; and

(ii) for a follow-on formula—no less than 2 500 kJ/L and no more than 3 550 kJ/L; and

(b) have a potential renal solute load of no more than 8 mOsm/100 kJ; and

(c) have a protein content of no less than 0.45 g/100 kJ and no more than 1.4 g/100 kJ; and

(d) have a fat content of no less than 0.93 g/100 kJ and no more than 1.5 g/100 kJ; and

(e) contain:

(i) chromium in an amount of no less than 0.35 µg/100 kJ and no more than 2.0 µg/100 kJ; and

(ii) molybdenum in an amount of no less than 0.36 µg/100 kJ and no more than 3.0 µg/100 kJ.

(3) Section 2.9.1—10 applies to such infant formula product as if it were infant formula.

(4) Such infant formula product may contain added medium chain triglycerides.

Division 5 Labelling and packaging requirements

2.9.1—16 Representations about food as an infant formula product

A food may only be represented as an infant formula product if it complies with this Standard.

2.9.1—17 Prescribed names

The following are *prescribed names:

(a) 'Infant formula'; and

(b) 'Follow-on formula'.

2.9.1—18 Requirement for measuring scoop

(1) A package of infant formula product in a powdered form must contain a scoop to enable the use of the infant formula product in accordance with the directions contained in the label on the package.

(2) Subsection (1) does not apply to single serve sachets, or packages containing single serve sachets, of an infant formula product in a powdered form.

2.9.1—19 Requirement for warning statements and directions

(1) For the labelling provisions, the following *warning statements are required:

(a) for infant formula product in powdered form—'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of powder except on medical advice. Incorrect preparation can make your baby very ill';

(b) for concentrated infant formula product—'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of concentrate except on medical advice. Incorrect preparation can make your baby very ill';

(c) for ready-to-drink infant formula product—'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not dilute or add anything to this 'ready to drink' formula except on medical advice. Incorrect

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preparation can make your baby very ill';

(d) subject to subsection (2), a heading that states 'Important Notice' (or words to that effect), with under it the *warning statement—'Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice'.

Note The labelling provisions are set out in Standard 1.2.1.

(2) Paragraph (1)(d) does not apply to infant formula products for metabolic, immunological, renal, hepatic or malabsorptive conditions.

(3) For the labelling provisions, directions (in words and pictures) for the preparation and use of the infant formula product are required, which instruct that:

(a) each bottle should be prepared individually; and

(b) if a bottle of made up formula is to be stored prior to use, it must be refrigerated and used within 24 hours; and

(c) potable, previously boiled water should be used; and

(d) if a package contains a measuring scoop—only the enclosed scoop should be used; and

(e) formula left in the bottle after a feed must be discarded.

Note The labelling provisions are set out in Standard 1.2.1.

(4) For the labelling provisions, the required statements are ones indicating that:

(a) for infant formula—the infant formula product may be used from birth; and

(b) for follow-on formula—the infant formula product should not be used for infants aged under the age of 6 months; and

(c) subject to subsection (5), it is recommended that infants from the age of 6 months should be offered foods in addition to the infant formula product.

Note The labelling provisions are set out in Standard 1.2.1.

(5) Paragraph (4)(c) does not apply to packages of pre-term formula.

2.9.1—20 Print size

The statements required by subsections 2.9.1—19(1) and 2.9.1—13(2) must be in a *size of type of at least:

(a) if the package of infant formula product has a net weight of more than 500 g—3 mm;

(b) if the package of infant formula product has net weight of 500 g or less—1.5 mm.

2.9.1—21 Declaration of nutrition information

(1) For the labelling provisions, a statement of the following nutrition information is required:

(a) for 'ready to drink' infant formula product, and for powdered or concentrated infant formula product:

(i) the *average energy content expressed in kJ/100 mL; and

(ii) the average amount of protein, fat and *carbohydrate expressed in g/100 mL; and

(iii) the average amount of each vitamin or mineral and any other substance *used as a nutritive substance permitted by this Standard expressed in weight/100 mL (including any naturally-occurring amount); and

(iv) if added, the average amount of the following, expressed in weight/100 mL:

(A) inulin-type fructans; or

(B) galacto-oligosaccharides; or

(C) a combination of *inulin-type fructans and galacto-oligosaccharides; and

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(b) for a powdered or concentrated form of infant formula product, additionally, a declaration of:

(i) the proportion of powder or concentrate required to reconstitute the formula according to directions; and

(ii) for powdered infant formula product—the weight of one scoop.

Note The labelling provisions are set out in Standard 1.2.1.

(2) For a powdered or concentrated form of infant formula product, the information mentioned in subsection (1) must be expressed in terms of the product as reconstituted according to directions on the package.

(3) The information required by this section may be expressed in the form of a table.

Note For an example of how the nutrition information may be presented, see the guidelines set out in section S29—10.

2.9.1—22 Storage instructions

For the labelling provisions, the storage instructions must cover the period after the package is opened.

Note The labelling provisions are set out in Standard 1.2.1.

2.9.1—23 Statements of protein source and dental fluorosis

(1) For the labelling provisions, the required statements are:

(a) a statement of the specific source, or sources, of protein in the product, immediately adjacent to the name of the product; and

(b) if the infant formula product is one to which subsection (2) applies:

(i) a statement to the effect that consumption of the formula has the potential to cause dental fluorosis; and

(ii) a statement recommending that the risk of dental fluorosis should be discussed with a medical practitioner or other health professional.

Note The labelling provisions are set out in Standard 1.2.1.

(2) This subsection applies to an infant formula product that contains:

(a) for a powdered or concentrated infant formula product—more than 17 µg of fluoride/100 kJ prior to reconstitution; or

(b) for a ready-to-drink formula—more than 0.15 mg of fluoride/100 mL.

2.9.1—24 Prohibited representations

(1) The label on a package of infant formula product must not contain:

(a) a picture of an infant; or

(b) a picture that idealises the use of infant formula product; or

(c) the word ‘humanised’ or ‘maternalised’ or any word or words having the same or similar effect; or

(ca) the words ‘human milk oligosaccharide’, ‘human milk identical oligosaccharide’ or any word or words having the same or similar effect; or

(cb) the abbreviations ‘HMO’ or HiMO’ or any abbreviation having the same or similar effect; or

(d) words claiming that the formula is suitable for all infants; or

(e) information relating to the nutritional content of human milk; or

(f) subject to subsection 2.9.1—14(2), a reference to the presence of any nutrient or substance that may be used as a nutritive substance, except for a reference in:

(i) a statement relating to lactose under subsection 2.9.1—14(6); or

(ii) a statement of ingredients; or

(iii) a declaration of nutrition information under section 2.9.1—21; or

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(g) subject to Division 4, a representation that the food is suitable for a particular condition, disease or disorder.

(2) Subject to subsection 2.9.1—14(2), the label on a package of infant formula product must not contain a reference to *inulin-type fructans or *galacto-oligosaccharides except for a reference in:

(a) a statement of ingredients; or

(b) a declaration of nutrition information under section 2.9.1—21.

Division 6 Guidelines

2.9.1—25 Guidelines for infant formula product

Guidelines for infant formula product are set out in section S29—10.

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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. 5 of Standard 2.9.1 as in force on **2 March 2023** (up to Amendment No. 216). It includes any commenced amendment affecting the compilation to that date.

Prepared by Food Standards Australia New Zealand on **2 March 2023**.

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 2.9.1 was published in the Food Standards Gazette No. FSC96 on 10 April 2015 as part of Amendment 154 (F2015L00409 –- 31 March 2015) and has since been amended as follows:

Section affected	A'ment No.	FRL registration Gazette	Commencement (Cessation)	How affected	Description of amendment
2.9.1— 11(1)	168	F2017L00414 11 April 2017 FSC110 13 April 2017	13 April 2017	am	Cross-reference.
2.9.1— 22	168	F2017L00414 11 April 2017 FSC110 13 April 2017	13 April 2017	rs	Section to clarify provision.
2.9.1— 9(2)(b)	188	F2019L01576 5 Dec 2019 FSC129 5 Dec 2019	5 December 2019	am	Omitting and substituting paragraph 2.9.1—9(2)(b)
2.9.1— 9(2)	188	F2019L01576 5 Dec 2019 FSC129 5 Dec 2019	5 December 2019	ad	Inserting note section 2.9.1—15
2.9.1— 7	198	F2021L00332 25 March 2021 FSC139 26 March 2021	26 March 2021	am	Omitting and substituting section 2.9.1— 7 'Restriction on addition to infant formula product of inulin-type fructans and galacto-oligosaccharides.'

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Section affected	A'ment No.	FRL registration Gazette	Commencement (Cessation)	How affected	Description of amendment
2.9.1—7(2)	205	F2022L00038 18 Jan 2022 FSC 146 20 Jan 2022	20 January 2022	am	Omitting 2′-O-fucosyllactose and substituting 2′-fucosyllactose
2.9.1—7(2)	216	F2023L00145 24 Feb 2023 FSC156 2 March 2023	2 March 2023	am	Omitting and substituting subsection 2.9.1—7(2)

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