



Animal Products (Dairy Based Infant Formula Products – Food Standards Exemption) Notice 2009 No. 3

Pursuant to section 60B and 167(1)(jb) of the Animal Products Act 1999 and having had regard to the requirements of the relevant overseas market, I, Carol Barnao, Director (Standards) issue the following notice for the purpose of exempting specified animal products that are intended for export from the requirements of food standards issued under Part 2A of the Food Act 1981.

Signed at Wellington this 21st day of August 2009

[Signed]

Carol Barnao
Director (Standards)
New Zealand Food Safety Authority
(Acting under delegated authority)

Certified in order for signature

[Signed]

Solicitor

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Notice

1 Title

This notice is the Animal Products (Dairy Based Infant Formula Products – Food Standards Exemption) Notice 2009 No. 3

2 Commencement

This notice comes into force on 24 August 2009.

Part 1

Preliminary Provisions

3 Application

- (1) This notice applies to any dairy based infant formula product that is for export to a country specified in the schedule.
- (2) Nothing in this notice affects or limits any requirements imposed by or under the Act or the Food Act 1981 (including under any food standard) relating to the production of any dairy based infant formula products that—
 - (a) is not for export; or
 - (b) is for export to a country other than a country specified in the schedule.

4 Interpretation

- (1) In the notice, unless the context otherwise requires—

Act means the Animal Products Act 1999

Infant Formula Products has the same meaning as in the Australia New Zealand Food Standards Code and includes infant formula and follow-on formula.

- (2) Any word defined by or under the Act or the Food Act 1981, but not defined in this notice, has the same meaning as in the Act or regulations in which it is defined.

Part 2 Exemption

5 Exemption from Standards for Export Purposes

Dairy based infant formula products are exempt from the requirements in the New Zealand (Australia New Zealand Food Standards Code) Food Standards 2002 (which adopts the Australia New Zealand Food Standards Code) relating to additives and ingredients in infant formula products if—

- (a) the infant formula product is for export to a country identified in column 1 of the schedule; and
- (b) the infant formula product is an infant formula product of the kind listed in column 2 of the corresponding country row of the schedule; and
- (c) the additives and ingredients in the infant formula product do not exceed the maximum level (if any) specified in column 3 of the corresponding country row of the schedule; and
- (d) the infant formula product complies with the requirements (if any) specified in column 4 of the corresponding country row of the schedule.

Part 3 Revocation

6 Revocation

This notice revokes the Animal Products (Dairy Based Infant Formula Products – Food Standards Exemption) Notice 2009 No. 2 dated 5 June 2009.

Schedule

Countries, Products, Levels, and Requirements to which Exemption Applies

Country	Product Description	Permitted Levels of Additives and Ingredients	Other Requirements
China	infant formula and follow-on formula	Maximum Polyfructose and Galacto-oligosaccharide - 64.5 g/kg (in dry powder form).	Any proportional mixture of galacto-oligosaccharide and polyfructose (Inulin), including fructo-oligosaccharide.
		Minimum Copper – 9µg/100kJ.	
		Maximum Nucleotides – total per 100grams (5CMP/5UMP/5AMP/5GMP/5IMP) 58mg.	
China	follow-on formula only	Vitamin A (as retinol) maximum 3900IU/100grams	
		Vitamin E – no specified maximum	
		Phosphorus – no specified maximum.	
		Maximum Potassium – 69mg/100kJ.	
		Lutein – maximum 4230mcg/kg	
		Fat – min 0.7g/100kJ max 1.2g/100kJ	
		Vitamin D – maximum 28IU/100kJ	
		Vitamin B3 (Niacin) – no	

		specified maximum	
		Vitamin B6 – No specified maximum	
		Sodium – maximum 21mg/100kJ	
		Magnesium – maximum 30mg/100g	
European Union	infant formula and follow-on formula	Maximum Fructo-oligosaccharide and Galacto-oligosaccharide -0.8g/100ml (when reconstituted / ready to consume in accordance with label directions).	Must be in a combination of 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl-saccharose. Despite clause 2 exports to individual EU member states may occur prior to 1 January 2008, provided the exporter supplies evidence to the certifier showing transposition of Commission Directive 2006/141/EC into member state legislation.
Indonesia	infant formula and follow-on formula	Maximum Fructo-oligosaccharide and Galacto-oligosaccharide. levels not known.	Product registrations are normally issued, specifically acknowledging the presence of oligosaccharides, on the basis of submission of product formulations including the amount of oligosaccharide in the product as exported.
Malaysia	infant formula and follow-on formula	Maximum Fructo-oligosaccharide and Galacto-oligosaccharide. levels not known.	Authorities may specify minimum levels and proportionalities for specific label claim requests.
Philippines	follow-on formula only	Maximum Vitamin A – 48.7µg/100kJ.	
		Maximum Vitamin B6 – 53.1µg/100kJ.	
		Maximum Phosphorous – 25.9mg/100kJ.	

		Maximum Guanosine 5 monophosphate – 0.32mg/100kJ.	
Republic of Korea	infant formula and follow-on formula	Maximum Fructo-oligosaccharide and Galacto-oligosaccharide. levels not known.	
Russia	infant formula and follow-on formula	Maximum Fructo-oligosaccharide and Galacto-oligosaccharide. levels (total) must not exceed 0.8% of the product weight when reconstituted according to the label instructions.	
Vietnam	follow-on formula only	Maximum Vitamin A – 48.7µg/100kJ.	
		Maximum Vitamin B6 – 53.1µg/100kJ.	
		Maximum Phosphorous – 25.9mg/100kJ.	
		Maximum Guanosine 5 monophosphate – 0.32mg/100kJ.	

Explanatory Note

This note is not part of the notice, but is intended to indicate its general effect.

A number of countries referred to in the Schedule of this notice permit a range of oligosaccharides to be used in infant formula products. This notice accommodates the varied requirements of those countries so as not to artificially restrict the requirements contained in their regulations.

In this notice, specific upper limits have been given for oligosaccharides where these are known. Verification of compliance with these upper limits will contribute to the overall determination of a product’s eligibility for the country concerned.

For the other countries referred to in this notice, permission is given for oligosaccharides in infant formula products, but upper limits were not included. NZFSA strongly recommends that the limits notified for certain countries in this notice form the basis of a best practice guide in the formulation of infant formula products for those countries where NZFSA lacks sufficient information to prescribe upper limits. Eligibility for export to countries with no notified upper limits will not be based on compliance with any particular limit, however where the amount of

oligosaccharide is significantly greater than any upper limits contained in this notice then the operator and exporter should keep documentary evidence on file to show the importing country accepts those levels. Often this evidence takes the form of a product registration application, including formulation information, from the operator or manufacturer, and a registration document issued by the importing health authorities. Exports to countries covered by this paragraph are on the basis of commercial risk and NZFSA will not be in a position intervene on behalf of exporters should they suffer a border rejection as a result of unacceptable oligosaccharide content.

New Zealand food law has not established a safe or recommended level of oligosaccharide in infant formula products at this time.

Issued under section 167(1)(jb) of the Animal Products Act 1999.

Date of notification in Gazette: []

This notice is administered in the New Zealand Food Safety Authority.
