# Dairy Based Products – Food Standards Exemption

60B exemption No. 2

10 May 2017

#### TITLE

Animal Products Notice: Dairy Based Products – Food Standards Exemption

#### COMMENCEMENT

This Animal Products Notice comes into force on 10 May 2017

#### REVOCATION

This notice revokes and replaces Animal Products (Dairy Based Products – Food Standard Exemption) Notice 2017 issued 10 March 2017.

#### **ISSUING AUTHORITY**

This Animal Products Notice is issued pursuant to sections 60B, 159 (3), 167(1)(jb) and 167(1)(o) of the Animal Products Act 1999 for the purpose of exempting specified animal products that are intended for export from the requirements of food standards issued under the Food Act 2014, and having had regard to the requirements of the relevant overseas markets.

Dated at Wellington this 10th day of May 2017

[signed]

Rachel Harvie
Acting Manager Food Assurance
Ministry for Primary Industries
(acting under delegated authority of the Director-General)

Contact for further information
Ministry for Primary Industries (MPI)
Regulation & Assurance Branch
Systems Audit, Assurance and Monitoring Directorate
PO Box 2526
Wellington 6140
Email: food.assurance@mpi.govt.nz

Ministry for Primary Industries Page 1 of 24

Conte	ents	Page
Introduc	ction	3
Part 1: 1.1 1.2	Preliminary Requirements Application Interpretation	<b>5</b> 5 5
<b>Part 2:</b> 2.1	Specified Exemptions Specified Exemptions from Standards for Export Purposes	<b>6</b> 6
<b>Part 3:</b> 3.1	Other Exemptions for Supplementary Food for Young Children Exemption from Standards for export purposes where formulated supplementary foods for young children meet importing country's product or food standard	<b>7</b> 7
3.2	Exemption from Standards for export purposes where formulated supplementary foods for young children meet importing country's product labelling, registration of approval requirements  Exemption from Standards for export purposes for formulated supplementary foof for young children that meet accepted international standard	r 7
<b>Part 4:</b> 4.1	General Record-keeping requirements	<b>10</b> 10
Schedu	le 1: Countries, Levels, and Requirements to which Specified Exemptions for Dairy Based Formulated Supplementary Foods for Young Children Apply	11
Schedu	le 2: Countries, Products, Levels, and Requirements to which Specified Exemptions for Dairy Based Infant Formula Products Apply	12
Schedu	le 3: Countries, Levels, and Requirements to which Exemptions for Dairy Bas Supplemented Foods Apply	sed 22

Ministry for Primary Industries Page 2 of 24

#### Introduction

This introduction is not part of the Animal Products Notice, but is intended to indicate its general effect.

#### **Purpose**

The purpose of this Notice is to exempt dairy based products from certain requirements in the New Zealand (Australia New Zealand Food Standards Code) Food Standards 2002 (which adopts the Australia New Zealand Food Standards Code) where importing country requirements differ.

#### **Background**

The Director-General is empowered by section 60B of the Animal Products Act 1999 to exempt any 1 or more classes or descriptions of animal material or animal product that is intended for export from New Zealand from the requirements of any food standards issued under the <u>Food Act 2014</u> or any standards specified by notice under <u>section 167</u> of this Act. Before granting an exemption, the Act requires the Director-General to be satisfied that it is appropriate to do so having regard to the requirements of the relevant overseas market.

The Manager Food Assurance, acting under delegated authority of the Director-General, issues this Notice granting the requested exemption.

#### Who should read this Animal Products Notice?

This notice applies to risk management programme operators that process dairy based products for export.

## Why is this important?

The 60B exemption process assists in the facilitation of trade through the provision of a mechanism for businesses which allows them to meet importing country legislative requirements that vary from New Zealand legislative requirements. This notice exempts infant and follow on formula and dairy based supplemented foods from specified NZ standards for export purposes. It also exempts formulated supplementary foods for young children from NZ standards where the specified importing country has acceptable standards provided evidence is maintained of the importing country standards for verification purposes.

#### **Document History**

#### Document history

Animal Products (Dairy Based Products – Food Standards Exemption) Notice 2012 issued 7/11/12

Animal Products (Dairy Based Products – Food Standards Exemption) Notice 2012 No.2 issued 30/11/12

Animal Products (Dairy Based Products – Food Standards Exemption) Notice 2012 No.3 issued 6/12/12

Animal Products (Dairy Based Products – Food Standards Exemption) Notice 2012 No.4 issued 24/12/12

Animal Products (Dairy Based Products – Food Standards Exemption) Notice 2013 issued 8/1/13

Animal Products (Dairy Based Products – Food Standards Exemption) Notice 2013 No.2 issued 22/1/13

Animal Products (Dairy Based Products – Food Standards Exemption) Notice 2013 No.3 issued 18/2/13

Animal Products (Dairy Based Products – Food Standards Exemption) Notice 2013 No.4 issued 20/5/13

Ministry for Primary Industries Page 3 of 24

Animal Products (Dairy Based Products – Food Standards Exemption) Notice 2013 No.5 issued 19/7/13

Animal Products (Dairy Based Products – Food Standards Exemption) Notice 2013 No.6 issued 3/10/13

Animal Products (Dairy Based Products – Food Standards Exemption) Notice 2013 No.7 issued 22/11/13

Animal Products (Dairy Based Products – Food Standards Exemption) Notice 2014 issued 27/5/14

Animal Products (Dairy Based Products - Food Standards Exemption) Notice 2014 No. 2 issued 9/12/14

Animal Products (Dairy Based Products – Food Standards Exemption) Notice 2015 issued 1/4/15

Animal Products (Dairy Based Products – Food Standards Exemption) Notice 2015 No. 2 issued 17/6/15

Animal Products (Dairy Based Products – Food Standards Exemption) Notice 2015 No. 3 issued 26 August 2015.

Animal Products (Dairy Based Products – Food Standards Exemption) Notice 2015 No. 4 issued 4 November 2015.

Animal Products (Dairy Based Products – Food Standards Exemption) Notice 2016 issued 30 September 2016

Animal Products (Dairy Based Products – Food Standards Exemption) Notice 2016 No. 2 issued 9 November 2016

Animal Products (Dairy Based Products – Food Standards Exemption) Notice 2016 No. 3 issued 20 December 2016

Animal Products (Dairy Based Products - Food Standards Exemption) Notice 2017 issued 10 March 2017

Ministry for Primary Industries Page 4 of 24

### Part 1: Preliminary Requirements

### 1.1 Application

- (1) This notice applies to the following dairy based products that are for export from New Zealand to a country specified in this notice:
  - a) formulated supplementary foods for young children;
  - b) infant formula products; and
  - c) supplemented foods.
- (2) Nothing in this notice affects or limits any requirements imposed by or under the Animal Products Act 1999 or the Food Act 2014 (including under the Food Standards Code, Supplemented Food Standard 2016 and any other food standard) relating to the production of any dairy based formulated supplementary foods for young children, infant formula products or supplemented foods that
  - a) are not for export; or
  - b) are for export to a country other than a country specified in this notice.

#### 1.2 Interpretation

(1) In this notice, unless the context otherwise requires –

**Food Standards Code** means the New Zealand (Australia New Zealand Food Standards Code) Food Standards 2002 (which adopts the Australia New Zealand Food Standards Code)

**formulated supplementary food for young children** has the same meaning as in standard 2.9.3 of the Food Standards Code

**infant formula product** has the same meaning as in standard 2.9.1 of the Food Standards Code and includes infant formula and follow-on formula

supplemented food has the same meaning as in the Supplemented Food Standard 2016

**Supplemented Food Standard 2016** means the New Zealand Food (Supplemented Food) Standard 2016

- (2) Any word defined by or under the Animal Products Act 1999 or the Food Act 2014, but not defined in this notice, has the same meaning as in the Act or regulations in which it is defined.
- (3) References to clauses and schedules are references to clauses in and schedules to this notice.

Ministry for Primary Industries Page 5 of 24

### **Part 2: Specified Exemptions**

#### 2.1 Specified Exemptions from Standards for Export Purposes

#### (1) Formulated supplementary foods for young children:

Dairy based formulated supplementary foods for young children are exempt from the requirements in the Food Standards Code relating to the additives, ingredients and substances specified in column 2 of Schedule 1 if -

- a) the dairy based formulated supplementary foods for young children are for export to a country identified in column 1 of Schedule 1; and
- b) the additives, ingredients and substances listed in column 2 of the corresponding country row of schedule 1 do not exceed the maximum level (if any) specified in that column; and
- c) the dairy based supplementary foods for young children comply with the requirements (if any) specified in column 3 of the corresponding country row of Schedule 1.

#### (2) Infant formula products:

Dairy based infant formula products are exempt from the requirements in the Food Standards Code relating to the additives, ingredients and substances specified in column 3 of Schedule 2 if -

- a) the infant formula products are for export to a country identified in column 1 of Schedule 2; and
- b) the infant formula products are infant formula products of the kind listed in column 2 of the corresponding country row of Schedule 2; and
- the additives, ingredients and substances in the infant formula products do not exceed the maximum level (if any) specified in column 3 of the corresponding country row of Schedule 2; and
- d) the infant formula products comply with the requirements (if any) specified in column 4 of the corresponding country row of Schedule 2.

#### (3) Supplemented foods:

Dairy based formulated supplemented foods are exempt from the requirements in the Supplemented Food Standard 2016 relating to the additives, ingredients and substances specified in column 2 of Schedule 3 if -

- a) the dairy based supplemented foods are for export to a country identified in column 1 of Schedule 3:
- b) the additives, ingredients and substances listed in column 2 of the corresponding country row of Schedule 3 do not exceed the maximum level (if any) specified in that column; and
- c) the dairy based supplemented foods comply with the requirements (if any) specified in column 3 of the corresponding country row of Schedule 3.

Ministry for Primary Industries Page 6 of 24

# Part 3: Other Exemptions for Supplementary Food for Young Children

# 3.1 Exemption from Standards for export purposes where formulated supplementary foods for young children meet importing country's product or food standard

- (1) Formulated supplementary foods for young children are exempt from the requirements relating to additives, ingredients and substances in the Food Standards Code if and to the extent that the formulated supplementary foods for young children:
  - a) are for export to a country identified in clause 3.1(2);
  - b) are subject to a relevant product or food standard issued by a competent authority or other government authority in the importing country; and
  - c) comply with any additive, ingredient or substance levels specified at the time of export in the relevant product or food standard in the importing country.
- (2) The importing countries to which the exemption for formulated supplementary foods for young children in clause 3.1(1) applies are:
  - a) China:
  - b) European Union
  - c) Malaysia;
  - d) Philippines;
  - e) Republic of Korea
  - f) Saudi Arabia;
  - g) Singapore;
  - h) Taiwan; and
  - i) Vietnam
- (3) If the additive, ingredient or substances levels specified at the time of export in the relevant product or food standard in the importing country do not cover all of the additives, ingredients and substances requirements in the Food Standards Code then the operator is exempt under clause 3.1(1) only for the additives, ingredients and substances specified in the importing country's relevant product or food standard and must, in relation to any additional additives, ingredients and substances specified in the Food Standards Code, comply with the requirements of the Food Standards Code, unless those requirements are exempted under clause 3.2 or 3.3 below.

# 3.2 Exemption from Standards for export purposes where formulated supplementary foods for young children meet importing country's product labelling, registration or approval requirements

- (1) Formulated supplementary foods for young children are exempt from the requirements relating to additives, ingredients and substances in the Food Standards Code if and to the extent that:
  - a) the formulated supplementary food for young children is for export to a country identified in clause 3.2(2):
  - the additives, ingredients and substances are not at the time of export subject to a relevant product or food standard issued by a competent authority or other government authority of the importing country that specifies additive, ingredient or substance levels or any other requirements or conditions applicable to formulated supplementary foods for young children;
  - c) the additives, ingredients and substances are registered or officially approved at the time of export by a competent authority or other government agency in the importing country according

Ministry for Primary Industries Page 7 of 24

- to that country's then applicable product labelling, product registration or product approval requirements; and
- d) the formulated supplementary food for young children complies with any additive, ingredient or substance levels and any other requirements or conditions applicable to formulated supplementary foods for young children that are specified in the then applicable requirements for product labelling, product registration or product approval requirements in the importing country.
- (2) The importing countries to which the exemption for formulated supplementary foods for young children in clause 3.2(1) applies are:
  - a) countries forming part of the Customs Union, namely Russia, Belarus and Kazakhstan;
  - b) Indonesia:
  - c) Philippines;
  - d) Thailand:
  - e) Ukraine;
  - f) Vietnam.

#### **Explanatory Note**

Clause 4.1 of the notice requires the operator to retain documentary evidence that the variance from the Food Standard Code meets the import requirements for the intended destination country or countries. This evidence may take the form of a registration certificate or other official document issued by the relevant competent authority. The competent authorities for each importing country may change from time to time (for example, due to reorganisations of the importing country's public sector departments) and as a result are not listed in this notice. As at November 2012 the competent authorities are:

Country	Competent Authority
Customs Union	Federal Service on Customer's Rights Protection and Human Well- Being Surveillance, Russian Federation
Indonesia	The National Agency of Drug and Food Control of the Republic of Indonesia
Philippines	Republic of the Philippines, Food and Drug Administration, Department of Health
Thailand	Food and Drug Administration, Ministry of Public Health, Thailand
Ukraine	Ministry of Health of Ukraine
Vietnam	Department of Food Safety and Sanitation, Ministry of Health, Socialist Republic of Vietnam

(3) If the additive, ingredient or substances levels registered or officially approved at the time of export by a competent authority or other government agency in the importing country according to that country's then applicable product labelling, product registration or product approval requirements do not cover all, of the additives, ingredients and substances requirements in the Food Standards Code then the operator can rely on the exemption in clause 3.2 only for the additives, ingredients and substances covered by the importing country's relevant product labelling, product registration or product approval requirements and must, in relation to any additional additives, ingredients and substances specified in the Food Standards Code, comply with the requirements of the Food Standards Code unless those requirements are exempted under clause 3.1 above or clause 3.3 below.

Ministry for Primary Industries Page 8 of 24

# 3.3 Exemption from Standards for export purposes for formulated supplementary foods for young children that meet accepted international standard

- (1) Formulated supplementary foods for young children are exempt from the requirements relating to the additives, ingredients and substances in the Food Standards Code if and to the extent that:
  - a) the formulated supplementary food for young children is for export to a country identified in clause 3.3(2);
  - b) the additives, ingredients and substances are not at the time of export subject to any of the following instruments issued by a competent authority or other government authority in the importing country that are applicable to formulated supplementary foods for young children:
    - a relevant product or food standard that specifies additive, ingredient or substance levels and any other requirements or conditions applicable to formulated supplementary foods for young children; or
    - ii) product labelling, product registration or product approval requirements;
  - c) the additives, ingredients and substances comply with one of the following standards (or, if such standard is amended or replaced, with the relevant amended or replacement standard) as specified for the relevant importing country in clause 3.3(2):
    - Codex any explicit numerical levels or guidance upper limits for additives, ingredients and substances set out in the Codex Standard Follow-up Formula (CODEX STAN 156-1987); or
    - ii) European Union -
      - 1. Commission Directive 2006/141 EC on infant formulae and follow-on formulae; and
      - 2. Commission Regulation (EC) No. 1243/2008 amending Annexes III and VI to Directive 2006/141/EC as regards compositional requirements for certain infant formulae.
- (2) The importing countries to which the exemption for formulated supplementary foods for young children in clause 3.3(1) applies and the standard(s) specified for such countries are:

Hong Kong (Codex)

Ministry for Primary Industries Page 9 of 24

#### Part 4: General

#### 4.1 Record-keeping requirements

- (1) An operator relying on any exemption in this notice must keep records that are readily available and readily verifiable that detail which ingredients, additives and substances were not in compliance with the Food Standards Code or the Supplemented Food Standard 2016 and must:
  - identify product, whether at the product line level or otherwise, that has been processed under an exemption in this notice; and
  - b) include in the specification description for such product or include in documents associated with the product
    - i) an explicit statement that the product is subject to an exemption under section 60B of the Animal Products Act 1999, including identification of the compositional variance from the Food Standards Code or the Supplemented Food Standard 2016:
    - ii) countries for which the product is intended to be eligible and the clause(s) of this notice that apply to the product and, where the exemption is under clause 2.1, the relevant part(s) of a schedule that applied for each identified country; and
    - iii) an explicit statement that the product cannot be sold for human consumption in New Zealand or Australia, including an alert stating that the product cannot be re-specified as product suitable for sale in New Zealand, Australia or a country different to the intended country unless it is subject to re-processing to result in compliance with the Food Standards Code or the Supplemented Food Standard 2016.
- (2) In relation to subclause (1)(b)(i) of this clause, identification of the compositional variance must include documentary evidence that the variance meets the exemption requirements for the intended destination country or countries.

Ministry for Primary Industries Page 10 of 24

# Schedule 1<sup>1</sup>: Countries, Levels, and Requirements to which Specified Exemptions for Dairy Based Formulated Supplementary Foods for Young Children Apply

Country	Constituent and Maximum <sup>2</sup> Permitted Levels	Notes
Chile	Vitamin A – 200 μg /serve	
United States of America	Lactoferrin – maximum not specified	

Ministry for Primary Industries Page 11 of 24

<sup>&</sup>lt;sup>1</sup> for all countries listed under Part 3 (3.1, 3.2 and 3.3) specific exemptions have been removed as these are covered by the general exemption, please refer to the Animal Products (Dairy Based Products – Food Standard Exemption) Notice 2015 No. 3 issued 26 August 2015 for this detail.

<sup>&</sup>lt;sup>2</sup> unless otherwise specified

# Schedule 2: Countries, Products, Levels, and Requirements to which Specified Exemptions for Dairy Based Infant Formula Products Apply

Country	Product Description	Maximum¹ Levels of Additives and Ingredients	Other Requirements
China	Infant formula and follow-on formula	Polyfructose and Galacto- oligosaccharide – 64.5 g/kg (in dry powder form)	Any proportional mixture of galacto-oligosaccharide and polyfructose (Inulin), including fructo-oligosaccharide.
		Copper* minimum – 8.5µg/100kJ maximum – 29µg/100kJ	Levels expressed in units per 100gms or units per kg refer to the levels present in the powder form of the product.
		Casein phosphopeptide – 3g/kg	form of the product.
		Choline – 12mg/100kJ	*This limit only applies to infant formula. Levels for
		lodine – 14 μg/100kJ*	follow-on formula is covered in the below
		Iron minimum – 0.1mg/100kJ maximum – 0.36mg/100kJ	follow-on formula only section.
		L-Carnitine – maximum not specified	
		Lactoferrin – 1g/kg	
		Lactulose – 15g/kg	
		Linoleic acid (18:2) – 31.3 % total fatty acids (Infant formula – minimum 0.07g/100kJ and maximum 0.33g/100kJ. Followon formula – minimum 0.07g/100kJ and maximum not specified.)	
		Lutein - 2000 μg/kg maximum addition rate*	
		Niacin minimum – 70μg/100kJ	

Ministry for Primary Industries Page 12 of 24

Country	Product Description	Maximum¹ Levels of Additives and Ingredients	Other Requirements
		maximum – 360µg/100kJ	
		Nucleotides (total) maximum addition rate – 0.58g/kg	
		Nucleotides (individual) – no specified minimum or maximum	
		Adenosine 5'-monophosphate Cytidine 5'-monophosphate Guanosine 5'monophosphate Inosine 5'-monophosphate Uridine 5'-monophosphate	
		Potassium*	
		minimum – 14mg/100kJ	
		maximum – 43mg/100kJ	
		Selenium – 1.9µg/100kJ	
		Vitamin B6	
		minimum – 8.5µg/100kJ	
		maximum – 45μg/100kJ*	
		Zinc to Copper ratio – no specified ratio	
China	Follow-on formula	Calcium – no specified maximum	Levels expressed in units
	only	Chloride – 52mg/100kJ	per 100gms or per kg refer to the levels present in the powder form of the
		Copper	product.
		minimum – 7μg/100kJ	
		maximum – 35µg/100kJ	*While no maximum level for iodine has been
		Fat	specified in Chinese
		minimum – 0.7g/100kJ	regulation, manufacturers should be
		maximum – 1.4g/100kJ	cognisant of the dietary
		Iron	recommendations and upper intake levels given
		minimum – 0.25mg/100kJ	for iodine in various publications, and be
		maximum – 0.5mg/100kJ	guided by them in formulating products.  RE – Retinol Equivalent
		lodine – maximum not specified*	
		Lutein – 4230µg/kg	

Ministry for Primary Industries Page 13 of 24

Country	Product Description	Maximum¹ Levels of Additives and Ingredients	Other Requirements
		Magnesium – no specified maximum	
		Omega 6:Omega 3 – minimum ratio not specified	
		Phosphorus – no specified maximum	
		Potassium – 69mg/100kJ	
		Renal Solute Load – no specified requirement	
		Sodium – 20mg/100kJ	
		Vitamin A – 54μgRE/100kJ	
		Vitamin B3 (Niacin) – no specified maximum	
		Vitamin B6 – no specified maximum	
		Vitamin B12 – no specified maximum	
		Vitamin C – no specified maximum	
		Vitamin D – 0.75μg/100kJ	
		Vitamin E – no specified maximum	
The Customs Union (CU) of Belarus, Kazakhstan and Russia	Infant formula and follow-on formula	Fructo-oligosaccharide and Galacto-oligosaccharide – 0.8g/100ml (when reconstituted / ready to consume in accordance with label directions)	Proportions of each oligosaccharide making up the 0.8g/100ml maximum have not been specified.
European Union	Infant formula and follow-on formula	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% oligogalactosyllactose and 10% high molecular weight oligofructosylsaccharose.
Hong Kong	Infant formula	Zinc to Copper ratio – no specified ratio	*(for naturally occurring and added L-carnitine in

Ministry for Primary Industries Page 14 of 24

Country	Product Description	Maximum¹ Levels of Additives and Ingredients	Other Requirements
		L-carntine – maximum not specified*	products where L- carnitine has been added)
	Follow-on formula only	Omega 6:Omega 3 – minimum ratio not specified	
	Infant formula and follow-on formula	Choline – 12mg/100kJ	
Indonesia	Infant formula and follow-on formula	Fructo-oligosaccharide and Galacto-oligosaccharide – maximum levels not specified	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.
		Choline – 11.95mg/100kJ (50mg/100kcal)	
	Infant formula	L-carnitine – maximum not specified	
Iraq	Infant formula	Iron – minimum 0.04mg/100kJ	
		L-carnitine – maximum not specified	
		Niacin (Vitamin B3) – minimum 60µg/100kJ	
		Selenium – maximum not specified	
	Follow-on formula	Vitamin A - 54μg/100kJ*	* Expressed as retinol
		Chloride – maximum not specified	** Choline Guidance Upper Level of 12 mg/100kJ
		Choline – maximum not specified**	*** Selenium Guidance Upper Level of 2.2 µg/100kJ
		lodine – maximum not specified	μg/100λο
		L-carnitine – maximum not specified	

Ministry for Primary Industries Page 15 of 24

Country	Product Description	Maximum¹ Levels of Additives and Ingredients	Other Requirements
		Niacin (Vitamin B3) – minimum 60µg/100kJ	
		Phosphorus – maximum not specified	
		Renal Solute Load – maximum not specified	
		Selenium – maximum not specified***	
Malaysia	Infant formula and follow-on formula	Fructo-oligosaccharide and Galacto-oligosaccharide – maximum levels not specified	Authorities may specify minimum levels and proportionalities for specific label claim requests.
		Choline – 12mg/100kJ	
	Infant formula only	L-carnitine – maximum level not specified	
	Follow-on formula only	Calcium – maximum level not specified*	*The Malaysia regulations specify minimum amounts of these ingredients in follow-on formula but does not prescribe maximums
		Chloride – maximum level not specified*	
		Phosphorus – maximum level not specified*	
		Potassium – maximum level not specified*	
		Renal Solute Load – no specified requirement	
		Vitamin B12 – maximum level not specified*	
		Vitamin C – maximum level not specified*	
Philippines	Follow-on formula only	Vitamin A – 48.7μg/100kJ	
		Vitamin B6 – 73.8µg/100kJ	
		Vitamin C – maximum level not specified	

Ministry for Primary Industries Page 16 of 24

Country	Product Description	Maximum¹ Levels of Additives and Ingredients	Other Requirements
		Vitamin B12 – maximum level not specified	
		Vitamin E – maximum level not specified	
		Calcium – maximum level not specified	
		Chloride – maximum not specified	
		Choline – 12mg/100kJ	
		lodine – 14μg/100kJ	
		Lutein – 8.1µg/100kJ	
		Phosphorous – maximum not specified	
		Potassium – maximum not specified	
		Guanosine 5 monophosphate – 0.73mg/100kJ	
		Cytidine 5 monophosphate – 1.54mg/100kJ	
		Uridine 5 monophosphate – 0.67mg/100kJ	
		Adenosine 5 monophosphate – 0.49mg/100kJ	
		Selenium	
		– minimum level not specified	
		– maximum 1.529µg/100kJ	
		Sodium – 21mg/100kJ	
Republic of Korea	Infant formula and follow-on formula	Alpha-lactalbumin – maximum level not specified	
		Fructo-oligosaccharide and Galacto-oligosaccharide – maximum levels not specified	

Ministry for Primary Industries Page 17 of 24

Country	Product Description	Maximum¹ Levels of Additives and Ingredients	Other Requirements
		Lactulose – 15g/kg maximum addition rate	
		Phospholipids – maximum level not specified	
	Follow-on formula only	Chloride – maximum not specified	
		Phosphorus – maximum not specified	
		Potassium – maximum not specified	
Saudi Arabia	Follow-on formula only	Vitamin A (as retinol) – 180IU/100kJ	
		Vitamin E – 1.36mg/100kJ	
		Phosphorus – 32.39mg/100kJ	
		Potassium – 62.21mg/100kJ	
		Lutein – 7.9µg/100kJ	
		lodine – 14.86µg/100kJ	
		Vitamin B6 – 77.77μg/100kJ	
		Choline – 9.1mg/100kJ	
		Chloride – 41.19mg/100kJ	
		Sodium – 21mg/100kJ	
		Magnesium – 4.23mg/100kJ	
Singapore	Infant formula and follow-on formula	Calcium – maximum not specified	
		Chloride – 36mg/100kJ (150mg/100kcal)	
		Phosphorus – maximum not specified	
		Vitamin B12 – maximum not specified	

Ministry for Primary Industries Page 18 of 24

Country	Product Description	Maximum¹ Levels of Additives and Ingredients	Other Requirements
		Vitamin C – maximum not specified	
Syria	Infant formula	Iron – minimum 0.1µg/100kJ	
		L-carnitine – maximum not specified	
		Selenium – 2.2µg/100kJ	
		Vitamin B3 (Niacin) – minimum 19µg/100kJ	
	Follow-on formula	Chloride – maximum not specified	* Choline Guidance Upper Level of 12
		Choline – maximum not specified*	mg/100kJ  ** Selenium Guidance Upper Level of 2.2
		lodine – maximum not specified	mcg/100kJ
		L-carnitine – maximum not specified	
		Phosphorus – maximum not specified	
		Renal Solute Load – maximum not specified	
		Selenium – maximum not specified**	
		Vitamin A - 54μg/100kJ	
		Vitamin B3 (Niacin) – minimum 60µg/100kJ	
Thailand	Follow-on formula only	Calcium – maximum not specified	The Thailand regulations specify minimum amounts of these
		Chloride – maximum not specified	ingredients in follow-on formula but does not
		Phosphorus – maximum not specified	prescribe maximums
		Potassium – maximum not specified	

Ministry for Primary Industries Page 19 of 24

Country	Product Description	Maximum¹ Levels of Additives and Ingredients	Other Requirements
		Vitamin B12 – maximum not specified	
		Vitamin C – maximum not specified	
Ukraine	Infant formula and follow-on formula	Fructo-oligosaccharide and Galacto-oligosaccharide – 0.8g/100ml (when reconstituted / ready to consume in accordance with label directions)	The content of prebiotics in the combination inulin and oligofructose shall not exceed 0.8 g/100ml.
United States of America	Infant formula and follow-on formula	Lactoferrin – no maximum specified	
Vietnam	Infant formula and follow-on formula	Inulin-derived substances – maximum 190mg/100kJ	
		Choline – maximum not specified*	* Choline Guidance Upper Level of 12 mg/100kJ
	Infant formula only	L-carnitine – maximum not specified	
	Follow-on formula	Vitamin A – 48.7μg/100kJ	
	only	Vitamin B6 – 53.1µg/100kJ	
		Vitamin B12 – 0.36μg/100kJ (1.5μg/100kcal)	
		Vitamin C – 9.6mg/100kJ (40mg/100kcal)	
		Calcium – 59.8mg/100kJ (250mg/100kcal)	
		Chloride – maximum not specified	
		Guanosine 5 monophosphate – 0.32mg/100kJ	
		Phosphorous – maximum not specified	
		Potassium – maximum not specified	

Ministry for Primary Industries Page 20 of 24

Country	Product Description	Maximum¹ Levels of Additives and Ingredients	Other Requirements
		Renal Solute Load – no specified requirement	
		Zinc to Copper ratio – no specified ratio	

<sup>&</sup>lt;sup>1</sup>unless otherwise specified

Ministry for Primary Industries Page 21 of 24

## Schedule 3: Countries, Levels, and Requirements to which Exemptions for Dairy Based Supplemented Foods Apply

Country	Constituent and Maximum¹ Permitted Levels	Notes	
China	Folic Acid – 8200μg per kg*^ maximum addition rate	*Applies to drinking powders only.	
		^addition rate levels above 5000μg per kg are restricted to products for "pregnant women and the parturient". Serving recommendations on product labelling must be correspondingly restricted.	
Hong Kong	Calcium – 1990mg/100g**	*Applies to drinking powders for	
	Folic Acid – 857µg/100g*	** Applies to drinking powders for lactating women only	
	Folic Acid – 833µg/100g**		
	Magnesium – 260mg/100g**		

US

#### **Explanatory Note**

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

This notice exempts certain dairy based products from specified requirements of the Food Standards Code and the Supplemented Food Standard 2016. Exemptions have been granted under sections 60B and 167 of the Animal Products Act 1999 for exports of infant formula products, formulated supplementary foods for young children and supplemented foods to specific countries.

This notice exempts certain exported product from the requirements of New Zealand's domestic food regulations where the product will comply with the importing country's requirements and the importing country requirements are sufficiently prescribed. It is important to note that the exemption (and any official assurance) does not guarantee access into the importing market. Product will need to comply with the importing country's requirements to be eligible for import.

Where an exporter is relying on an exemption under this notice, the exporter must retain documents which detail which ingredients, additives and substances were not in compliance with the Food

Ministry for Primary Industries Page 22 of 24

Standard Code or the Supplemented Food Standard 2016 and documents to evidence that those ingredients, additives and substances were exempted from the Food Standard Code under this notice.

The exemptions granted prior to the issue of this notice are now summarised in Schedules 1, 2 and 3. These specified exemptions relate to particular additives, ingredients or substances in the formulated supplementary foods for young children, infant formula products and supplemented foods. MPI considered removing from the Schedules the specified exemptions that are also covered by a general exemption under Part 2 of this notice, but has decided to retain the specified exemptions at this time as there may be some industry benefits in their retention.

If the importing country's requirements change, then it is possible that there may be a mismatch between the specified exemption in the Schedules and the importing country's requirements. Industry should advise MPI if this occurs as alignment between the exemption and the importing country's requirements is preferable, and an amendment to the specified exemption may be appropriate. Regardless of any mismatch, the product will need to meet the importing country's requirements to be eligible for import.

This notice also establishes classes of exemptions in respect of formulated supplementary foods for young children. These exemptions are additional (i.e. mutually exclusive from) the specified exemptions in Part 2. Where the requirements overlap, an operator can either rely on the exemption in Part 2 or rely on an exemption in Part 3. The operator should retain documentary evidence of the exemption relied upon (see clause (4.1(2)).

The Part 3 exemptions aim to deliver a more streamlined process for exporters seeking to export to countries whose requirements in respect of formulated supplementary foods for young children differ from those under the Food Standards Code. These general exemptions are consistent with the criteria that MPI apply when considering requests for specified exemptions, and in each case have had regard to the requirements of each relevant overseas market. The Part 3 exemptions will help to avoid the need for amendments to the specified exemptions.

The classes of general exemptions in Part 3 apply to exports of formulated supplementary food for young children to specified markets on the basis that the:

- (1) Product meets an importing country's product or food standard;
- (2) Product meets an importing country's product labelling, product registration or product approval requirements; or
- (3) Product meets other accepted international standards.

Ministry for Primary Industries Page 23 of 24

The classes of exemptions apply sequentially, such that a product can only be exempted on the basis of meeting other accepted international standards, if (or to the extent that) none of the prior classes are applicable.

The exemptions are drafted to allow the hierarchy to operate at an additive by additive or ingredient by ingredient level. For example, provided all the exemption requirements are met a product could in theory have some additives exempted from the Food Standard Code on the basis that the additives meet the importing country's food standard, other additives exempted on the basis that the additives meet the importing country's registration requirements and the remaining additives may not be exempted from the Food Standards Code (and thus are required to comply with the Code requirements).

If a particular formulated supplementary food for young children, infant formula product or supplemented food is not exempted from the Food Standard Code or the Supplemented Food Standard 2016 under this notice, but an exporter considers an exemption is appropriate, the Director-General may consider amending this notice in respect of that infant formula product or formulated supplementary food for young children.

The official assurance and verification processes that apply to the export of formulated supplementary foods for young children, infant formula products and supplemented foods that meet all the requirements under the Food Standards Code or the Supplemented Food Standard 2016, other than the exempted requirements, continue to apply to products exempted under this notice.

Amendments to the notice and schedule are highlighted in yellow.

Ministry for Primary Industries Page 24 of 24