

Regulation of Nutritional Composition and Nutrition Labelling – the International Scene

Legislative Proposal Relating to
Formula Products and Foods Intended for
Infants and Young Children under the Age of
36 Months in Hong Kong

Technical Meeting with Trade
15 November 2012

Overview

- Codex requirement
 - a) Relevant standards
 - b) 4 major food entities for infants and young children
 - c) Nutritional composition requirements for different entities
 - d) Nutrition labelling requirements for different entities
 - e) Stance on nutrition claims and health claims

- Overseas requirement

Codex requirement

a). Relevant standards

- On nutritional composition and nutrition labelling for formulae/foods for 36 months or younger
 - Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Codex Stan 72-1981);
 - Codex Standard for Follow-up Formula (Codex Stan 156-1987);
 - Codex Standard for Canned Baby Foods (Codex Stan 73-1981); and
 - Codex Standard for Processed Cereal-Based Foods for Infants and Young Children (Codex Stan 74-1981)

a). Relevant standards (cont'd)

- On labelling and claims for other foods for special dietary uses and special medical purposes
 - General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (Codex Stan 146-1985); and
 - Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (Codex Stan 180-1991)

b) 4 major food entities for infants and young children

- Infant formula:
 - Breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding

- Follow-up formula:
 - Food intended for use as a liquid part of the weaning diet for the infant from the 6th months on and for young children

b) Processed cereal-based food

- Food intended for feeding infants as a complementary food generally from the age of 6 months onwards, taking into account infants' individual nutritional requirements, and for feeding young children as part of a progressively diversified diet
 - Prepared primarily from one or more milled cereals, which should constitute at least 25% of the final mixture on a dry weight basis
 - Specific requirements for each of the 4 categories:
 - Cereal to be prepared with milk/nutritious liquids
 - Cereal with an added high protein food
 - Uncooked pasta
 - Rusk and biscuits

b) Baby food

- Foods intended primarily for use during the normal infant's weaning period and also for the progressive adaptation of infants and children to ordinary food
 - In ready-to-eat form, or
 - In dry form requiring constitution with water only

c) Nutritional composition requirements for different entities

Infant formula and follow-up formula

- Main requirements
 - Infant formula: Energy + 33 nutrients
 - Follow-up formula: Energy + 25 nutrients
 - Minimum permitted level: set for all nutrients
 - Maximum level: only set for some nutrients
- Other requirements, e.g.
 - Proportion of selected nutrients
 - Constituents of selected nutrients

Processed cereal-based food and canned baby food

□ Main requirements

- More heterogeneous than for formula products
- Consistent requirement on sodium content (on a ready-to-eat basis), NOT allowed to exceed
 - Processed cereal-based foods: 100 mg/100kcal
 - Canned baby foods: 200mg/100g

d) Nutrition labelling requirement for different entities

General principle

- If a compositional requirement for the nutrient has been defined in the relevant standard document, the nutrient content in the food will usually be required to be listed on the nutrition label

e) Stance on nutrition claims and health claims

Codex's stance on nutrition claims and health claims

□ Nutrition claims

- Should be consistent with national nutrition policy and only nutrition claims that support national nutrition policy should be allowed

□ Health claims

- Should be consistent with national health policy, including nutrition policy, and support such policies where applicable
- Nutrition claims and health claims shall not be permitted for formula products and foods intended for infants and young children except where specifically provided for in relevant national legislation

Overseas requirement

Reviewing 5 jurisdictions

- Examined the regulatory control in Singapore, the United States (US), Australia and New Zealand (ANZ), Mainland and the European Union (EU)
 - Infant formula: regulated in similar manner
 - Follow-up formula* and other foods intended for under 36 months: Codex requirement on nutritional composition and nutrition labelling adapted to different levels

*Also known as follow-on formula in ANZ and EU

Level of adaption of Codex framework in major countries

	Formula products	Foods for below 36 months
Codex	Age range: 0-36 months -Infant formula (0-complementary feeding) (<12 months) -Follow-up formula (6-36 months)	Age range: 6-36 months -Processed cereal-based foods (6-36 months) -Canned baby foods (weaning-36 months)
Singapore	Age range: 0-12 months -Infant formula (0 or above)	Age range: 6-12 months -Infants foods (6-12 months) [only safety control specified]
US	Age range: 0-12 months -Infant formula (0-12 months)	Not defined (covered as general food)
ANZ	Age range: 0-12 months -Infant formula (0-4 to 6 months) -Follow-on formula (6-12 months)	Age range: 4-12 months -Cereal-based foods (4-12 months) -Non-cereal-based foods (4-12 months)
China	Age range: 0 - 36 months -Infant formula (0-6 months) -Older infants and young children formula (6-36 months)	Age range: 6-36 months -Cereal-based complementary foods for infants and young children (6-36 months) -Canned complementary foods for infants and young children (6-36 months)
EU	Age range: 0-12 months -Infant formula (0-complementary feeding) (<12 months) -Follow-on formula (complementary feeding-12 months)	Age range: 4-36 months -Processed cereal-based foods (4-36 months) -Baby foods (4-36 months)

Thank You!

Codex definitions on infants and young children

- “Infant”
 - A person not more than 12 months of age

- “Young children”
 - Persons from the age of more than 12 months up to the age of three years (36 months)

Codex requirement of nutritional composition in formula products (1)

Macronutrients	Unit	Infant Formula	Follow-up Formula	Remarks
Energy	kcal/100ml	60.0 - 70.0	60.0 - 85.0	
Protein	g/100kcal	1.8 - 3.0	3.0 - 5.5	
Total fat	g/100kcal	4.4 - 6.0	3.0 - 6.0	
Linoleic acid	mg/100kcal	300.0 - NS	300 - NS	For infant formula, ratio of linoleic acid to α -linolenic acid between 5:1 to 15:1; GUL for infant formula: 1400
α -Linolenic acid	mg/100kcal	50.0 - NS	-	
Total carbohydrates	g/100kcal	9.0 - 14.0	-	For follow up formula, available carbohydrate to provide the remaining energy requirement

- ❑ NS = not specified; RE = retinol equivalent
- ❑ GUL = Guidance upper levels (for infant formula);
 - Purpose: To provide guidance to manufacturers (should not be interpreted as goal values)
 - ❑ For nutrients without sufficient information for a scientific-based risk assessment
 - ❑ Derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use
 - ❑ May be adjusted based on relevant scientific or technological progress
 - Nutrient contents should usually not exceed the GUL unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula or due to technological reasons

Codex requirement of nutritional composition in formula products (2)

Vitamins	Unit	Infant Formula	Follow-up Formula	Remarks
Vitamin A	iu/100kcal	200.0 - 600.0 (or 60.0-180.0ug RE/100kcal)	250.0 - 750.0 (or 75.0 - 225.0ug RE/100kcal)	
Vitamin D	ug/100kcal	(Vit D3: 1.0 - 2.5)	1.0 - 3.0 (or 40-120 iu/100kcal)	
Vitamin E	mg alpha-TE/100kcal	0.5 - NS	0.7 - NS(iu/100kcal)	GUL for infant formula: 5
Vitamin K	ug/100kcal	4.0 - NS	(Vit K1: 4.0 - NS)	GUL for infant formula: 27
Thiamin	ug/100kcal	60.0 - NS	40.0 - NS	GUL for infant formula: 300
Riboflavin	ug/100kcal	80.0 - NS	60.0 - NS	GUL for infant formula: 500
Niacin	ug/100kcal	300.0 - NS	(Nicotinamide: 250.0 - NS)	GUL for infant formula: 1500
Vitamin B6	ug/100kcal	35.0 - NS	45.0 - NS	GUL for infant formula: 175
Vitamin B12	ug/100kcal	0.1 - NS	0.15 - NS	GUL for infant formula: 1.5
Pantothenic acid	ug/100kcal	400.0 - NS	300.0 - NS	GUL for infant formula: 2000
Folic acid	ug/100kcal	10.0 - NS	4.0 - NS	GUL for infant formula: 50
Vitamin C	mg/100kcal	10.0 - NS	8.0 - NS	GUL for infant formula: 70
Biotin	ug/100kcal	1.5 - NS	1.5 - NS	GUL for infant formula: 10

Codex requirement of nutritional composition in formula products (3)

Minerals	Unit	Infant Formula	Follow-up Formula	Remarks
Iron	mg/100kcal	0.45 - NS	1.0 - 2.0	
Calcium	mg/100kcal	50 - NS	90.0 - NS	Calcium to phosphorus ratio between 1:1 to 2:1; GUL for infant formula: 140
Phosphorus	mg/100kcal	25 - NS	60.0 - NS	GUL for infant formula: 100
Magnesium	mg/100kcal	5 - NS	6.0 - NS	GUL for infant formula: 15
Sodium	mg/100kcal	20 - 60	20.0 - 85.0	
Chloride	mg/100kcal	50 - 160	55.0 - NS	
Potassium	mg/100kcal	60 - 180	80.0 - NS	
Manganese	ug/100kcal	1 - NS	-	GUL for infant formula: 100
Iodine	ug/100kcal	10 - NS	5.0 - NS	GUL for infant formula: 60
Selenium	ug/100kcal	1 - NS	-	GUL for infant formula: 9
Copper	ug/100kcal	35 - NS	-	GUL for infant formula: 120
Zinc	mg/100kcal	0.5 - NS	0.5 - NS	GUL for infant formula: 1.5

Codex requirement of nutritional composition in formula products (4)

Others	Unit	Infant Formula	Follow-up Formula	Remarks
Choline	mg/100kcal	7 - NS	-	GUL for infant formula: 50
Myo-Inositol	mg/100kcal	4 - NS	-	GUL for infant formula: 40
L-Carnitine	mg/100kcal	1.2 - NS	-	

- For formulas for special medical purposes intended for infants, requirements are also provided in Codex Stan 72-1981:
 - Energy + nutrient composition: shall be based on the requirement for general infant formula as listed in the above table
 - Except for the composition provisions which must be modified to meet the special nutritional requirements arising from the disease(s), disorder(s) or medical condition(s) for whose dietary management the product is specifically formulated, labelled and presented

Codex requirement of nutritional composition in foods for infants and young children (1)

Category	Processed Cereal-based Foods for Infants and Young Children				Canned Baby Foods
Definition	prepared primarily from one or more <u>milled cereals</u> , which should constitute at least 25% of the final mixture on a dry weight basis; [milled cereal products: such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat; may contain legumes (pulses), starchy roots (such as arrow root, yam or cassava) or starchy stems or oil seeds in smaller proportions.]				prepared from any suitable nutritive material that is used, recognized or commonly sold as an article or ingredient of food
Sub-category	Cereals for consumption with milk or other appropriate nutritious liquids	Cereals with added high protein food prepared for consumption with water or other appropriate protein-free liquid	Pasta	Rusks and biscuits	-
Energy	≥0.8kcal/g	≥0.8kcal/g	≥0.8kcal/g	≥0.8kcal/g	Not specified

Codex requirement of nutritional composition in foods for infants and young children (2)

	Cereals for consumption with milk or other appropriate nutritious liquids	Cereals with added high protein food prepared for consumption with water or other appropriate protein-free liquid	Pasta	Rusks and biscuits	Canned Baby Foods
Protein	Not specified	5.5g/100kcal or below (the added protein ≥ 2 g/100kcal)	Not specified	5.5g/100kcal or below (for biscuit made with addition of a high protein food, the added protein ≥ 1.5 g/100kcal)	Not specified
Lipids	3.3g/100kcal or below	4.5g/100kcal or below (if lipid > 3.3 g/100kcal, then linoleic acid 0.3-1.2 and lauric acid and myristic acid each $\leq 15\%$ of lipid content)	Not specified	3.3g/100kcal or below	Not specified
Carbohydrates	Not more than 7.5g/100kcal from added sucrose, fructose, glucose, glucose syrup, honey; added fructose not more than 3.75g/100kcal	Not more than 5g/100kcal from added sucrose, fructose, glucose, glucose syrup, honey; added fructose not more than 2.5g/100kcal	Not specified	not more than 7.5g/100kcal if sucrose, fructose, glucose, glucose syrup, honey added; added fructose not more than 3.75g/100kcal	Not specified

Codex requirement of nutritional composition in foods for infants and young children (3)

	Cereals for consumption with milk or other appropriate nutritious liquids	Cereals with added high protein food prepared for consumption with water or other appropriate protein-free liquid	Pasta	Rusks and biscuits	Canned Baby Foods
Vitamin A	60-180ug RE/100 kcal (if added)	60-180ug RE/100 kcal	60-180ug RE/100 kcal (if added)	60-180ug RE/100 kcal (if added)	Not specified
Vitamin D	1-3ug/100kcal (if added)	1-3ug/100kcal	1-3ug/100kcal (if added)	1-3ug/100kcal (if added)	Not specified
Thiamin	Not less than 50ug/100kcal	Not less than 50ug/100kcal	Not less than 50ug/100kcal	Not less than 50ug/100kcal	Not specified
Calcium	Not specified	not less than 80mg/100kcal	Not specified	not less than 50mg/100 kcal if manufactured with the additional of milk and presented as such	Not specified
Sodium	not exceed 100mg/100kcal (on ready-to-eat basis)	not exceed 100mg/100kcal (on ready-to-eat basis)	not exceed 100mg/100kcal (on ready-to-eat basis)	not exceed 100mg/100kcal (on ready-to-eat basis)	not exceed 200mg/100g (on ready-to-eat basis)

Codex requirement of nutrition labelling in formula products

	Expression	Energy	Protein, Fat, Carbohydrates	Vitamins & Minerals
Infant formula#	per 100g or per 100mL as sold <u>as well as</u> per 100mL as consumed [in addition, may also include per 100 kcal/kJ]	in kcal and/or kJ	in g	13 vitamins, 12 minerals and choline (optional ingredient if added)
Follow-up formula	per 100g as sold <u>as well as</u> per serving as consumed [in addition, may also include per 100 kcal/kJ]	in kcal and/or kJ	in g	13 vitamins and 9 minerals (optional ingredient if added)

#Codex only requires labelling of the content of 29 of the 33 nutrients considered to be essential in infant formula. However, we propose in our legislative proposal to require listing of the nutrient content of all 33 nutrients as a means to declare the fulfilment of the nutritional composition requirement

Codex requirement of nutrition labelling in processed cereal-based foods

	Expression	Energy	Protein, Fat, Carbo- hydrates	Vitamins & Minerals
Cereal to be prepared with milk or nutritious liquid	per 100g or per 100ml as sold; <u>where appropriate</u> , also per serving as consumed	in kcal <u>and</u> kJ	in g	1 vitamin (B1) and 1 mineral (sodium) (vitamin A and D if added)
Cereal with an added high protein food	per 100g or per 100ml as sold; <u>where appropriate</u> , also per serving as consumed	in kcal <u>and</u> kJ	in g	3 vitamins (A, B1 and D) and 2 minerals (sodium and calcium)
Pasta	per 100g or per 100ml as sold; <u>where appropriate</u> , also per serving as consumed	in kcal <u>and</u> kJ	in g	1 vitamin (B1) and 1 mineral (sodium) (vitamin A and D if added)
Rusk and biscuit	per 100g or per 100ml as sold; <u>where appropriate</u> , also per serving as consumed	in kcal <u>and</u> kJ	in g	1 vitamin (B1) and 1 mineral (sodium) (calcium if milk is added) (vitamin A and D if added)

Codex requirement of nutrition labelling in other foods for infants and young children

	Expression	Energy	Protein, Fat, Carbohydrates	Vitamins & Minerals
Canned baby foods	per 100g as sold <u>as well as</u> per serving as consumed	in kcal and/or kJ	in g	If added
Prepackaged food for special dietary uses	Per 100g or 100ml as sold; where appropriate, also per serving as consumed	in kcal and kJ	in g	(specific nutrients or other components which provide the characterizing essential feature of the food)

* If the above product is a **food for special medical purposes** which is for the dietary management of patients and to be used only under medical supervision, requirements in Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) should be followed. For these foods, the amounts of vitamins and essential minerals should also be labelled.

Codex definitions on nutrition claims and health claims

- Nutrition claim
 - Any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals

- Health claim
 - Any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health
 - Nutrient function claims,
 - Other function claims , and
 - Reduction of disease risk claims