



中華人民共和國香港特別行政區政府總部食物及衛生局  
Food and Health Bureau, Government Secretariat  
The Government of the Hong Kong Special Administrative Region  
The People's Republic of China

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30 September 2014

Ms Alice LEUNG  
Clerk to LegCo Subcommittee on  
Food and Drug (Composition and Labelling)  
(Amendment) (No. 2) Regulation 2014  
Legislative Council Complex  
1 Legislative Council Road  
Central, Hong Kong  
(Fax: 2509 9055)

Dear Ms Leung,

**Food and Drugs (Composition and Labelling)  
(Amendment) (No. 2) Regulation**

Thank you for your letter of 4 July 2014. In response to Members' request at the meeting on 2 July 2014 for the Government to provide supplementary information, our reply is set out below:

*Members pointed out that it had become increasingly popular for some parents to buy formula products directly from overseas markets via online purchasing agents. Concerns were raised whether and in what ways online purchasing activities and the offering of formula products as gifts by some private clinics and child service organisations were subject to the regulation of the Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014 ("the Amendment Regulation"). There was a view that the moisture content of and the*

*use of additives in formula products should also be regulated. The Administration was requested to respond to Members' concerns and views.*

2. Under the Amendment Regulation, any person who advertises for sale, sells or manufactures for sale any infant formula that does not conform to the nutritional composition requirements in the Amendment Regulation, or any infant formula, follow-up formula or prepackaged food for infants and young children that does not comply with the nutrition labelling requirements in the Amendment Regulation, commits an offence. The provisions are applicable to conducting sales and advertising for sale on the Internet.

3. However, as with legislation in general in Hong Kong, the provisions do not regulate conduct outside the Hong Kong jurisdiction. In other words, such conduct shall be regulated by the Amendment Regulation if it is carried out within the Hong Kong jurisdiction.

4. As for whether the offering of formula product as a gift is subject to regulation, it depends on whether the mode and conduct of the gift-offering falls within the conduct of advertising for sale or selling under the Amendment Regulation. In enforcing the law, the Centre for Food Safety (CFS) will have regard to the actual circumstances of the case and relevant information.

5. On regulation of additives, various legislations govern the use of additives in food at present. Apart from section 54 of the Public Health and Municipal Services Ordinance (the Ordinance) (Cap. 132) which provides that all food (including formula products) for sale must be fit for human consumption, various subsidiary legislations under the Ordinance also regulate the use of additives in food (including formula products). These subsidiary legislations include:

- (a) Preservatives in Food Regulations (Cap.132BD) ;
- (b) Colouring Matter in Food Regulations (Cap.132H) ; and
- (c) Sweeteners in Food Regulations (Cap.132U)

6. As for moisture content, the Codex Alimentarius Commission (Codex) has not introduced requirements on the moisture content of infant formula and follow-up formula. Major jurisdictions (including the European Union, the United States, Australia and New Zealand, and

Singapore) have no such practice either. In view of this, the Government considers that it is not necessary to regulate the moisture content of formula products.

*While Members held different views on the suitable length of grace period, members shared similar view that the Administration should provide the same grace period for infant formula, follow-up formula and prepackaged food for infants and young children under the age of 36 months. The Administration was requested to respond to Members' views.*

7. Before implementing the proposed legislation, we need to provide a suitable grace period to allow sufficient time for the trade to prepare for the changes and for the necessary laboratory equipment and techniques on the testing of the relevant nutrients to be in place in Hong Kong. Having regard to the fact that a two-year grace period had been given to the trade for launching of the existing Nutrition Labelling Scheme (NLS), as well as the views of trade members, we propose, for the purpose of the Amendment Regulation, to also introduce a grace period of two years for follow-up formula and prepackaged food for infants and young children, for the trade to undertake the following work:

- (a) the trade needs to perform calibration of the composition of their products with the new requirements to ensure compliance with the Amendment Regulation;
- (b) calibration results may require their products to be reformulated. Product reformulation involves product development, trial production and stability tests, as well as re-labelling of the products;
- (c) as formula products and most prepackaged food for infants and young children are not manufactured in Hong Kong, the aforesaid reformulated products need to be shipped to Hong Kong upon production; and
- (d) the trade needs sufficient time to phase out old products that do not comply with the new requirements before introducing new ones into the market.

Other considerations should be given to infant formula. This is because where breastfeeding is not feasible, infant formula is the only

processed foodstuff which wholly fulfils the nutritional requirements of infants during the first months of life until the introduction of appropriate complementary feeding<sup>1</sup>. Therefore, we propose a shorter grace period of 18 months for infant formula to protect infants' health. We expect the trade to deploy resources to give priority to the regulatory compliance of their infant formula products.

*The Administration was requested to:*

*(a) advise whether and to what extent the proposed nutritional composition and labelling requirements for infant formula, follow-up formula and prepackaged food for infants and young children under the age of 36 months under the Amendment Regulation were in line with the international standards adopted by other overseas jurisdictions, including such as the United States, Australia, New Zealand, European Union and Singapore*

9. We have compared the nutritional composition and nutrition labelling requirements for infant formula, follow-up formula and prepackaged food for infants and young children under the age of 36 months proposed under the Amendment Regulation with the corresponding requirements of Codex and other major jurisdictions (including the European Union, the United States, Australia and New Zealand, Singapore and Mainland China). The relevant information is at **Annex I and II**.

*(b) advise whether the nutrition labels of infant formula products, which were currently on sale in Hong Kong, indicating energy value and the 33 nutrients ("1+33") that were required to be present in infant formula could comply with the nutrition labelling requirement under the Amendment Regulation, and whether or not these labels were required to be re-printed for indicating energy value and 29 nutrients ("1+29") as prescribed under the Amendment Regulation*

10. There is no legislation at present requiring infant formula to indicate its "1+33" nutrition composition. We propose, through the Amendment Regulation, to require infant formula to be labelled with a list of nutrients setting out "1+29", and the composition requirement on the relevant product is "1+33". These requirements are in line with those proposed by the Codex. Besides, subsection 1(7) of Schedule 6A, which is

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<sup>1</sup> Complementary feeding is normally introduced at 6 months of age.

newly added under section 13 of the Amendment Regulation, stipulates that other information may be set out in a list of nutrients if the information is not false, misleading or deceptive in any respect as to the nutritional or dietary value of the infant formula, follow-up formula or prepackaged food for infants and young children. Thus, the labels of the products in question should have conformed to the Amendment Regulation and no re-printing is required.

*(c) in respect of the 33 nutrients required to be present in infant formula under the Amendment Regulation, advise which four nutrients were not covered in the proposed labelling requirements ("1+29"), and provide reasons for that*

11. The four nutrients are linoleic acid,  $\alpha$ -linolenic acid, myo-Inositol and l-carnitine. The nutrition labelling requirements on infant formula we propose are in line with those proposed by the Codex, which does not require infant formula to be labelled with these four nutrients. For major jurisdictions (including the European Union, the United States, Australia and New Zealand, Singapore and Mainland China), there is no standard practice on the labelling of these four nutrients: none of these jurisdictions require the labelling of  $\alpha$ -linolenic acid, while for each of the remaining three nutrients, only one or two jurisdictions require the labelling of the nutrient content. Since infant formula products in the local market are imported from overseas, we are of the view that the proposed nutrition labelling requirements can strike a balance between the protection of the health of infants and young children, informed food choices for parents and the need to maintain stable supply of formula products for infants.

*(d) explain why it was proposed to exempt prepackaged food for infants and young children from the proposed nutrition labelling requirement if it was packed in a container with a total surface area of less than 100 cm<sup>2</sup>; and provide information on the Administration's estimation on the number and types of such products*

12. The Amendment Regulation requires all prepackaged food for infants and young children to provide legible nutrition labels. However, we proposed to exempt products packed in a container with a small surface area from the nutritional labelling requirements because such container is too small to be labelled with all the required nutrition information in a legible font size by the trade. Since the amount of nutrition information required

to be provided on the labels of prepackaged food for infants and young children (i.e. energy value and four nutrients ("1+4"), and vitamin A and vitamin D (if added to the food)) is similar to the requirements of the existing NLS (i.e. 1+7), we propose to model on the requirements under the existing NLS and exempt such food packed in a container with a total surface area of less than 100 cm<sup>2</sup>.

13. CFS has earlier conducted inspections on retail outlets selling food for infants and young children and no prepackaged food for infants and young children with packages of total surface area of less than 100m<sup>2</sup> was found to be on sale in the market. While the Amendment Regulation exempts such products from the nutrition labelling requirements, we consider that the possibility of the exemption creating an incentive for food traders to reduce the package size of their products is not high. This is because food traders may need to redesign the package of the products, thus incurring additional costs. They may also need to consider the impact that the reduction of the package size will have on the effective promotion of their products.

*(e) provide information, in a table format, the tolerance limits adopted by the CFS for each nutrient against the minimum and maximum levels of the 33 nutrients as set out under the Amendment Regulation, with reference to the tolerance limits adopted by other overseas jurisdictions including such as the United States, Australia, New Zealand, European Union and Singapore;*

14. Tolerance limits refer to the discrepancies between "values on nutrition labels" and "values from testing and measurement" which can be tolerated. The tolerance limits will be stipulated in the Technical Guidance Notes to be issued by CFS. As the nutrients in food may degrade during the shelf-life period, the values from testing and measurement may be different from values on nutrition labels. Thus it is necessary to stipulate tolerance limits in the Guidance Notes.

15. Here we have to emphasise that the tolerance limits are applicable to nutrition labelling only but not to the regulation of nutritional composition of infant formula. Where breastfeeding is not feasible, infant formula is the only processed foodstuff which wholly fulfils the nutritional requirements of infants during the first months of life until the introduction of appropriate complementary feeding. We must ensure that infant formula is safe and

nutritionally adequate. Hence, we mandate that the nutrient contents of infant formula must be within the range specified in Division 1 and 2 of Part IV of Schedule 1 to the Amendment Regulation (see Annex II).

16. For the existing NLS, tolerance limits are also in place for labelled nutrient values. In introducing the tolerance limits, we have made reference to the Codex principles for formulation of tolerance limits, namely public health concerns, shelf-life, processing variability, variability of the nutrients, and whether the nutrient is naturally occurring or added etc. We have also made reference to the practice of other jurisdictions (including the United States, Mainland China and Singapore). Since the NLS was formally implemented in 2010, the application of tolerance limits has been effective in operation.

17. Having regard to the above situation, we propose to adopt the same tolerance limits as the existing NLS for nutrition labelling of infant formula, follow-up formula and prepackaged food for infants and young children. In gist:

- (a) for nutrients which may have a positive effect on the body, the tolerance limits of the nutrition labels are set at no less than 80% of the labelled values;
- (b) for nutrients which may have a negative effect on the body, the tolerance limits of the nutrition labels are set at no more than 120% of the labelled values;
- (c) for added vitamins and minerals, as they are added to the products during the manufacturing process, producers should be able to ensure that the vitamin and mineral contents do not fall beneath the labelled values within the shelf-life period. Thus, the tolerance limits of nutrition labels on added vitamins and minerals will be set at no less than the labelled values; and
- (d) as for vitamin A and vitamin D, since insufficient intake and excessive intake both have negative effect on the body, the tolerance limits of their nutrition labels will be set at 80-180% of the labelled values.

18. A comparison of the tolerance limits in Hong Kong and the practice of various jurisdictions (including the European Union, the United States, Australia and New Zealand, Singapore and Mainland China) is at Annex III.

*(f) provide information on the sampling tests on the nutritional*

*composition of formula products and prepackaged food for infants and young children under the age of 36 months conducted by CFS in the past two years, including the number of samples taken for testing, the number and names of nutrients tested as well as the testing results, and details of the food samples where there were discrepancies between labelled and tested nutrient values;*

19. Between 2012 and 2013, CFS conducted surveys on the nutrient contents of infant formula and follow-up formula available in the market. For infant formula, the CFS has performed tests on the values of energy and 33 nutrients specified in the relevant Codex standard of 56 infant formula products. Tests were also conducted on the iodine content of 8 infant formula products. Test results have shown that the nutritional composition of 20 products did not conform to the Codex standard (details are at Annex IV). Of the 89 follow-up formula products, the nutritional composition of only one product fell short of the standards of Codex and the country of origin (see Annex IV).

20. In the same period, CFS did not research on the discrepancies between the values on the nutrition labels of the products in question and the values from testing and measurement.

*(g) advise whether the term "infants" was defined in the law; and if so, please provide details*

21. At the last meeting, Members were concerned whether the definition of "infant" or "嬰兒" in other ordinances will affect the meaning of "infant" or "嬰兒" in the Amendment Regulation.

22. While "infant" or "嬰兒" is defined in other ordinances<sup>2</sup>, generally speaking, defined terms in a particular ordinance are provided to cater for the purposes of, and are applicable to, that ordinance only. The definitions of "infant" or "嬰兒" in other ordinances do not apply to the Amendment Regulation. In the Amendment Regulation, "infant" or "嬰

<sup>2</sup> For instance:

In section 2 of the Legal Aid Ordinance (Cap. 91), "infant" (幼年人) means an unmarried person who has not attained the age of 18 years.

In paragraph 1 of Schedule 1 to the Immigration Ordinance (Cap. 115), "new born infant" (初生嬰兒) means a child under the age of 12 months or a child who appears to the Director to be under the age of 12 months.

In section 2 of the Adoption Ordinance (Cap. 290), "infant" (幼年人) means a person under 18 years of age, but does not include a person who is or has been married.



兒” does not appear in isolation but constitutes part of the following terms: “infant formula” (嬰兒配方產品), “follow-up formula” (較大嬰兒及幼兒配方產品), “prepackaged food for infants and young children” (預先包裝嬰幼兒食物) and “formula for special medical purposes for infants and young children” (特殊醫用嬰幼兒配方產品). The four terms are clearly defined in the Amendment Regulation, including the target age groups. As such, their meanings will not be affected by the definitions of “infant” or “嬰兒” in other ordinances.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Jeff Leung', with a long horizontal flourish extending to the right.

( Jeff LEUNG )  
for Secretary for Food and Health

**Annex I**

**Comparison between the Nutrition Labelling Requirements proposed under the  
Amendment Regulation and the Corresponding Requirements of  
Codex Alimentarius Commission and Other Major Jurisdictions**

**Table 1. Nutrition labelling requirements of infant formula**

		<b>Amendment Regulation</b>	<b>Codex Alimentarius Commission</b>	<b>European Union</b>	<b>USA</b>	<b>Australia / New Zealand</b>	<b>Singapore</b>	<b>Mainland China</b>
	Energy	o	o	o	o	o	o	o
<b>Macro nutrients</b>	Protein	o	o	o	o	o	o	o
	Total fat	o	o	o	o	o	o	o
	Linoleic acid				o			
	$\alpha$ -Linolenic acid							
	Total carbohydrates	o	o	o	o	o	o	o
<b>Vitamins</b>	Vitamin A	o	o	o	o	o	o	o
	Vitamin D3	o	o	o	o	o	o	o
	Vitamin E	o	o	o	o	o	o	o
	Vitamin K	o	o	o	o	o	o	o
	Thiamine	o	o	o	o	o	o	o
	Riboflavin	o	o	o	o	o	o	o
	Niacin	o	o	o	o	o	o	o
	Vitamin B6	o	o	o	o	o	o	o
	Vitamin B12	o	o	o	o	o	o	o
	Pantothenic acid	o	o	o	o	o	o	o
	Folic acid	o	o	o	o	o	o	o
	Vitamin C	o	o	o	o	o	o	o
Biotin	o	o	o	o	o	o	o	
<b>Minerals</b>	Iron	o	o	o	o	o	o	o
	Calcium	o	o	o	o	o	o	o
	Phosphorus	o	o	o	o	o	o	o
	Magnesium	o	o	o	o	o	o	o
	Sodium	o	o	o	o	o	o	o
	Chloride	o	o	o	o	o	o	o
	Potassium	o	o	o	o	o	o	o
	Manganese	o	o	o	o	o	o	o

		Amendment Regulation	Codex Alimentarius Commission	European Union	USA	Australia / New Zealand	Singapore	Mainland China
	Iodine	0	0	0	0	0	0	0
	Selenium	0	0	0		0	0	0
	Copper	0	0	0	0	0	0	0
	Zinc	0	0	0	0	0	0	0
Others	Choline	0	0	0	0			
	Myo-Inositol			0	0			
	L-Carnitine			0				
	Fluoride			0				
	Water				0			

**Table 2. Nutrition labelling requirements of follow-up formula**

		Amendment Regulation	Codex Alimentarius Commission	European Union	USA*	Australia / New Zealand	Singapore*	Mainland China
	Energy	0	0	0	-	0	-	0
<b>Macro nutrients</b>	Protein	0	0	0	-	0	-	0
	Total fat	0	0	0	-	0	-	0
	Carbohydrates	0	0	0	-	0	-	0
<b>Vitamins</b>	Vitamin A	0	0	0	-	0	-	0
	Vitamin D	0	0	0	-	0	-	0
	Vitamin E	0	0	0	-	0	-	0
	Vitamin K	0	0	0	-	0	-	0
	Thiamine	0	0	0	-	0	-	0
	Riboflavin	0	0	0	-	0	-	0
	Niacin	0	0	0	-	0	-	0
	Vitamin B6	0	0	0	-	0	-	0
	Vitamin B12	0	0	0	-	0	-	0
	Pantothenic acid	0	0	0	-	0	-	0
	Folic acid	0	0	0	-	0	-	0
	Vitamin C	0	0	0	-	0	-	0
Biotin	0	0	0	-	0	-	0	
<b>Minerals</b>	Iron	0	0	0	-	0	-	0
	Calcium	0	0	0	-	0	-	0
	Phosphorus	0	0	0	-	0	-	0
	Magnesium	0	0	0	-	0	-	0
	Sodium	0	0	0	-	0	-	0
	Chloride	0	0	0	-	0	-	0
	Potassium	0	0	0	-	0	-	0
	Manganese			0	-	0	-	
	Iodine	0	0	0	-	0	-	0
	Selenium			0	-	0	-	
	Copper			0	-	0	-	0
	Zinc	0	0	0	-	0	-	0
<b>Others</b>	Fluoride			0	-		-	

Note: \*No specific nutrition labelling requirement for follow-up formula in USA and Singapore

**Table 3. Nutrition labelling requirements of prepackaged food for infants and young children**

<b>Jurisdiction</b>	<b>Product Category</b>		<b>Nutrition labelling requirements</b>
<b>Amendment Regulations</b>	Prepackaged food for infants and young children		Energy + 3 macronutrients <sup>1</sup> + sodium (+ added vitamin A and vitamin D)
<b>Codex Alimentarius Commission</b>	Canned baby foods		Energy + 3 macronutrients (+ added vitamin A and vitamin D) (+other added vitamins and minerals)
	Processed cereal-based foods for infants and young children	Cereals for consumption with milk or other nutritious liquids	Energy + 3 macronutrients + sodium + vitamin B1 (+ added vitamin A and vitamin D)
		Cereals with added high protein food	Energy + 3 macronutrients + sodium, calcium + vitamin B1, vitamin A, vitamin D
		Pasta	Energy + 3 macronutrients + sodium + vitamin B1 (+ added vitamin A and vitamin D)
		Rusks and biscuits	Energy + 3 macronutrients + sodium + vitamin B1 (+ added vitamin A and vitamin D)(products manufactured with the addition of milk: + calcium)
<b>European Union</b>	Baby food (other than processed cereal-based foods)		Energy + 3 macronutrients + sodium + vitamin A, vitamin C, vitamin D (+ added vitamins/minerals)
	Processed cereal-based foods for infants and young children	Cereals for consumption with milk or other nutritious liquids	Energy + 3 macronutrients + sodium + vitamin B1 (+ added vitamin A and vitamin D)
		Cereals with added high protein food	Energy + 3 macronutrients + sodium, calcium + vitamin B1, vitamin A, vitamin D
		Pasta	Energy + 3 macronutrients + sodium + vitamin B1 (+ added vitamin A and vitamin D)
		Rusks and biscuits	Energy + 3 macronutrients + sodium + vitamin B1 (+ added vitamin A and vitamin D)(products manufactured with the addition of milk: + calcium)

<sup>1</sup> The three macronutrients are protein, carbohydrate, fat

<b>Jurisdiction</b>	<b>Product Category</b>	<b>Nutrition labelling requirements</b>
<b>USA</b>	Foods intended for children under 2 years of age	Energy + 3 macronutrients + sodium + sugars, dietary fibre, trans fat; % daily value of protein, vitamin A, vitamin C, calcium and iron
	Foods intended for children under 4 years of age	Energy + 3 macronutrients + sodium + sugars, dietary fibre, saturated fat, trans fat, cholesterol; % daily value of protein, vitamin A, vitamin C, calcium and iron
<b>Australia / New Zealand</b>	Foods for infants	Energy + 3 macronutrients + sodium +sugars
<b>Singapore</b>	Foods for infants	no specific labelling requirement for infants' food mentioned (nutrition labelling requirement for general food if claim is made: energy + 3 macronutrients + claimed nutrients)
<b>Mainland China</b>	Canned complementary foods for infants and young children	Energy + 3 macronutrients (+vitamins/minerals that reflect the characteristics of the food for special dietary purpose)
	Cereal-based complementary foods for infants and young children	

## Annex II

### Comparison between Nutritional Composition Requirements of Infant Formula proposed under the Amendment Regulation and the Corresponding Requirements of Codex Alimentarius Commission and Major Jurisdictions

Nutritional Composition		Amendment Regulation	Codex Alimentarius Commission	European Union	USA	Australia / New Zealand	Singapore	Mainland China
Energy (kcal [kJ]/100mL)	Min:	60 [250]	60 [250]	60 [250]	--	[250]	64	60 [250]
	Max:	70 [295]	70 [295]	70 [295]	--	[315]	72	70 [295]
Protein (for infant formulae based on cows milk protein) (g/100kcal [kJ])	Min:	1.8 [0.45]	1.8 [0.45]	1.8 [0.45]	1.8	[0.45]	1.8	1.88 [0.45]
	Max:	3.0 [0.7]	3.0 [0.7]	3.0 [0.7]	4.5	[0.7]	4.0	2.93 [0.7]
Protein (for infant formulae based on soy protein isolate) (g/100kcal [kJ])	Min:	2.25 [0.5]	2.25 [0.5]	2.25 [0.56]	1.8	[0.45]	1.8	2.09 [0.5]
	Max:	3.0 [0.7]	3.0 [0.7]	3.0 [0.7]	4.5	[0.7]	4.0	2.93 [0.7]
Total Fat <sup>1</sup> (g/100kcal [kJ])	Min:	4.4[1.05]	4.4[1.05]	4.4 [1.05]	3.3 (or 30% of energy)	[1.05]	3.3	4.39 [1.05]
	Max:	6.0 [1.4]	6.0 [1.4]	6.0 [1.4]	6.0 (or 54% of energy)	[1.5]	6.0	5.86 [1.4]

**Abbreviations:**

%tFA = percentage of total fatty acids;

GUL = Guidance upper levels. (Guidance upper levels are for nutrients without sufficient information for a scientific-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GUL is to provide guidance to manufacturers and they should not be interpreted as goal values. Nutrient contents in infant formula 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.)

**1 The requirements for individual fatty acid contents are as follows:**

Lauric acid and myristic acid

For the Amendment Regulation, Codex, European Union and Mainland China, the content of lauric acid and myristic acid shall not exceed 20% of total fatty acids.

There is no relevant requirement in USA, Australia and New Zealand and Singapore.

Trans fatty acids

For the Amendment Regulation, Codex and Mainland China, the content of trans fatty acids shall not exceed 3% of total fatty acids.

For European Union, the content of trans fatty acids shall not exceed 3% of total fat.

For Australia and New Zealand, the content of trans fatty acids shall not exceed 4% of total fatty acids.

There is no relevant requirement in USA and Singapore.

Erucic acid

For the Amendment Regulation, Codex, Australia and New Zealand and Mainland China, the content of erucic acid shall not exceed 1% of total fatty acids.

For European Union, the content of erucic acid shall not exceed 1% of total fat.

There is no relevant requirement in USA and Singapore.

Nutritional Composition	Amendment Regulation	Codex Alimentarius Commission	European Union	USA	Australia / New Zealand	Singapore	Mainland China	
Linoleic Acid (mg/100kcal [kJ])	Min: Max:	300 [70] 1400 [330] <sup>GUL</sup>	300 [70]* 1200 [285]	300 (or 2.7% of energy) --	9 (%FA) 26 (%FA)	300* --	290 [70] 1380 [330]	
$\alpha$ -Linolenic acid (mg/100kcal [kJ])	Min: Max:	50 [12] --	50 [12] --	-- --	1.1 (%FA) 4 (%FA)	-- --	50 [12] --	
Linoleic Acid: $\alpha$ -Linolenic acid	Min: Max:	5:1 15:1	5:1 15:1	-- --	5:1 15:1	-- --	5:1 15:1	
Carbohydrates (g/100kcal [kJ])	Min: Max:	9.0 [2.2] 14.0 [3.3]	9.0 [2.2] 14 [3.4]	-- --	-- --	-- --	9.2 [2.2] 13.8 [3.3]	
Vitamin A ( $\mu$ g RE/100kcal [kJ])	Min: Max:	60 [14] 180 [43]	60 [14] 180 [43]	60 [14] 180 [43]	250 International Unit 750 International Unit	[14] $\mu$ g [43] $\mu$ g	75 $\mu$ g 150 $\mu$ g	59 [14] 180 [43]
Vitamin D3 ( $\mu$ g/100kcal [kJ])	Min: Max:	1 [0.25] 2.5 [0.6]	1 [0.25] 2.5 [0.6]	1 [0.25] 2.5 [0.65]	40 International Unit 100 International Unit	[0.25] [0.63]	40 International Unit 100 International Unit	1.05 [0.25] 2.51 [0.6]
Vitamin E <sup>2</sup> (mg $\alpha$ -TE/100kcal [kJ])	Min: Max:	0.5 [0.12] --	0.5 [0.12] 5 [1.2] <sup>GUL</sup>	0.5 [0.1] 5 [1.2]	0.7 International Unit --	[0.11] mg [1.1] mg	0.7 International Unit --	0.5 [0.12] 5.02 [1.2]
Vitamin K ( $\mu$ g/100kcal [kJ])	Min: Max:	4 [1] --	4 [1] 27[6.5] <sup>GUL</sup>	4 [1] 25[6]	4 --	[1] --	4 --	4.2 [1] 27.2 [6.5]

<sup>2</sup> For the Amendment Regulation, Codex and Mainland China, the content of vitamin E shall be at least 0.5 mg  $\alpha$ -TE per g polyunsaturated fatty acids.  
For USA and Singapore, the content of vitamin E shall be at least 0.7 International Unit per g polyunsaturated fatty acids.  
For European Union and Australia and New Zealand, the content of vitamin E shall be at least 0.5 mg per g polyunsaturated fatty acids.



Nutritional Composition		Amendment Regulation	Codex Alimentarius Commission	European Union	USA	Australia / New Zealand	Singapore	Mainland China
Thiamine (µg/100kcal [kJ])	Min:	60 [14]	60 [14]	60 [14]	40	[10]	40	59 [14]
	Max:	--	300 [72] <sup>GUL</sup>	300 [72]	--	--	--	301 [72]
Riboflavin (µg/100kcal [kJ])	Min:	80 [19]	80 [19]	80 [19]	60	[14]	60	80 [19]
	Max:	--	500 [119] <sup>GUL</sup>	400 [95]	--	--	--	498 [119]
Niacin (µg/100kcal [kJ])	Min:	300 [70]	300 [70]	300 [72]	250	[130]	250	293 [70]
	Max:	--	1500 [360] <sup>GUL</sup>	1500 [375]	--	--	--	1506 [360]
Vitamin B6 (µg/100kcal [kJ])	Min:	35 [8.5]	35 [8.5]	35 [9]	35 <sup>3</sup>	[9]	35 <sup>3</sup>	35.6 [8.5]
	Max:	--	175 [45] <sup>GUL</sup>	175 [42]	--	[36]	--	188.3 [45]
Vitamin B12 (µg/100kcal [kJ])	Min:	0.1 [0.025]	0.1 [0.025]	0.1 [0.025]	0.15	[0.025]	0.15	0.105 [0.025]
	Max:	--	1.5[0.36] <sup>GUL</sup>	0.5[0.12]	--	--	--	1.506 [0.36]
Pantothenic acid (µg/100kcal [kJ])	Min:	400 [96]	400 [96]	400 [95]	300	[70]	300	402 [96]
	Max:	--	2000 [478] <sup>GUL</sup>	2000 [475]	--	--	--	2000 [478]
Folic acid (µg/100kcal [kJ])	Min:	10 [2.5]	10 [2.5]	10 [2.5]	4	[2]	4	10.5 [2.5]
	Max:	--	50 [12] <sup>GUL</sup>	50 [12]	--	--	--	50.2 [12]
Vitamin C (mg/100kcal [kJ])	Min:	10 [2.5]	10 [2.5]	10 [2.5]	8	[1.7]	8	10.5 [2.5]
	Max:	--	70 [17] <sup>GUL</sup>	30 [7.5]	--	--	--	71.1 [17]
Biotin (µg/100kcal [kJ])	Min:	1.5 [0.4]	1.5 [0.4]	1.5 [0.4]	1.5 <sup>4</sup>	[0.36]	1.5	1.5 [0.4]
	Max:	--	10 [2.4] <sup>GUL</sup>	7.5 [1.8]	--	--	--	10 [2.4]
Iron (mg/100kcal [kJ])	Min:	0.45 [0.1]	0.45 [0.1]	0.3 [0.07] <sup>5</sup>	0.15	[0.2]	0.15	0.42 [0.1]
	Max:	--	GUL to be determined by national authorities	1.3 [0.3] <sup>5</sup>	3.0	[0.5]	--	1.51 [0.36]

<sup>3</sup> \* if protein content exceeds certain level, there are specific requirements in the content of vitamin B6 per g protein.

<sup>4</sup> Only for non-milk based infant formula.

<sup>5</sup> The minimum and maximum values for infant formula manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins are 0.45mg/100kcal [0.12mg/100kJ] and 2mg/100kcal [0.5mg/100kJ] respectively.

Nutritional Composition		Amendment Regulation	Codex Alimentarius Commission	European Union	USA	Australia / New Zealand	Singapore	Mainland China
Calcium (mg/100kcal [kJ])	Min:	50 [12]	50 [12]	50 [12]	60	[12]	50	50 [12]
	Max:	--	140 [35] <sup>GUL</sup>	140 [33]	--	--	--	146 [35]
Phosphorus (mg/100kcal [kJ])	Min:	25 [6]	25 [6]	25 [6] <sup>6</sup>	30	[6]	25	25 [6]
	Max:	--	100 [24] <sup>GUL</sup>	90 [22] <sup>6</sup>	--	[25]	--	100 [24] <sup>7</sup>
Calcium : Phosphorus	Min:	1:1	1:1	1:1	1.1:1	1.2:1	1.2:1	1:1
	Max:	2:1	2:1	2:1	2:1	2:1	2:1	2:1
Magnesium (mg/100kcal [kJ])	Min:	5 [1.2]	5 [1.2]	5 [1.2]	6	[1.2]	6	5 [1.2]
	Max:	--	15 [3.6] <sup>GUL</sup>	15 [3.6]	--	[4.0]	--	15.1 [3.6] <sup>7</sup>
Sodium (mg/100kcal [kJ])	Min:	20 [5]	20 [5]	20 [5]	20	[5]	20	21 [5]
	Max:	60 [14]	60 [14]	60 [14]	60	[15]	60	59 [14]
Chloride (mg/100kcal [kJ])	Min:	50 [12]	50 [12]	50 [12]	55	[12]	55	50 [12]
	Max:	160 [38]	160 [38]	160 [38]	150	[35]	150	159 [38]
Potassium (mg/100kcal [kJ])	Min:	60 [14]	60 [14]	60 [15]	80	[20]	80	59 [14]
	Max:	180 [43]	180 [43]	160 [38]	200	[50]	200	180 [43]
Manganese (µg/100kcal [kJ])	Min:	1 [0.25]	1 [0.25]	1 [0.25]	5	[0.24]	5	5 [1.2]
	Max:	--	100 [24] <sup>GUL</sup>	100 [25]	--	[24.0]	--	100.4 [24]
Iodine (µg/100kcal [kJ])	Min:	10 [2.5]	10 [2.5]	10 [2.5]	5	[1.2]	5	10.5 [2.5]
	Max:	--	60 [14] <sup>GUL</sup>	50 [12]	75	[10]	--	58.6 [14]
Selenium (µg/100kcal [kJ])	Min:	1 [0.24]	1 [0.24]	1 [0.25]	1.35	[0.25]	1	2.01 [0.48]
	Max:	--	9 [2.2] <sup>GUL</sup>	9 [2.2]	8	[1.19]	5	7.95 [1.90]

<sup>6</sup> The minimum and maximum values for infant formula manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins are 30mg/100kcal [7.5mg/100kJ] and 100mg/100kcal [25mg/100kJ] respectively.

<sup>7</sup> The maximum value is only applicable to milk based infant formula.

Nutritional Composition		Amendment Regulation	Codex Alimentarius Commission	European Union	USA	Australia / New Zealand	Singapore	Mainland China
Copper (µg/100kcal [kJ])	Min:	35 [8.5]	35 [8.5]	35 [8.4]	60	[14]	60	35.6 [8.5]
	Max:	--	120 [29] <sup>GUL</sup>	100 [25]	--	[43]	--	121.3 [29]
Zinc (mg/100kcal [kJ])	Min:	0.5 [0.12]	0.5 [0.12]	0.5 [0.12]	0.5	[0.12]	0.5	0.5 [0.12]
	Max:	--	1.5 [0.36] <sup>GUL</sup>	1.5 [0.36]	--	[0.43]	--	1.51 [0.36]
Choline (mg/100kcal [kJ])	Min:	7 [1.7]	7 [1.7]	7 [1.7]	7 <sup>8</sup>	[1.7]	--	7.1 [1.7]
	Max:	--	50 [12] <sup>GUL</sup>	50 [12]	--	[7.1]	--	50.2 [12]
Myo-inositol (mg/100kcal [kJ])	Min:	4 [1]	4 [1]	4 [1]	4 <sup>8</sup>	[1.0]	--	4.2 [1]
	Max:	--	40 [9.5] <sup>GUL</sup>	40 [10]	--	[9.5]	--	39.7 [9.5]
L-carnitine (mg/100kcal [kJ])	Min:	1.2 [0.3]	1.2 [0.3]	1.2 [0.3] <sup>9</sup>	--	[0.21]	--	1.3 [0.3]
	Max:	--	--	--	--	[0.8]	--	--

<sup>8</sup> Only applicable for non-milk based infant formula.

<sup>9</sup> Only applicable for infant formula based on protein hydrolysates, and infant formula manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins.

Nutritional Composition	Requirements
Taurine	<p>According to the <b>Amendment Regulation</b>, which has the same requirements as Codex, if taurine is added, its content should not exceed 12mg/100kcal [3mg/100kJ].</p> <p>For <b>Codex</b>, taurine should be added in conformity with national legislation, but its content should not exceed 12mg/100kcal [3mg/100kJ].</p> <p>For <b>European Union</b>, if taurine is added, its content should not exceed 12mg/100kcal [2.9mg/100kJ].</p> <p>For <b>Australia and New Zealand</b>, the minimum and maximum content are 0.8mg/100kJ and 3mg/100kJ respectively.</p> <p>For <b>Mainland China</b>, the maximum content is 13mg/100kcal [3mg/100kJ].</p> <p>There are no relevant requirements in <b>USA and Singapore</b>.</p>
Docosahexaenoic acid (DHA)	<p>In accordance with the Codex Standard, the <b>Amendment Regulation</b> requires that if DHA is added, the content of arachidonic acid must not be less than that of DHA and the content of eicosapentaenoic acid must not exceed the content of DHA. For <b>Codex</b>, if DHA is added, the content of arachidonic acid should not be less than that of DHA and the content of eicosapentaenoic acid should not exceed the content of DHA. Meanwhile, GUL is established for DHA (i.e. should not exceed 0.5% of total fatty acids).</p> <p>For <b>European Union</b>, the content of DHA should be less than that of omega-6 poly-unsaturated fatty acids, the content of arachidonic acid should not exceed 1% of total fat and the content of eicosapentaenoic acid should not exceed the content of DHA.</p> <p>For <b>Australia and New Zealand</b>, the content of arachidonic acid should not exceed 1% of total fatty acids and the content of eicosapentaenoic acid should not exceed the content of DHA.</p> <p>For <b>Singapore</b>, the content of arachidonic acid should not exceed 1% of total fat and the content of eicosapentaenoic acid should not exceed the content of DHA.</p> <p>For <b>Mainland China</b>, the content of DHA should not exceed 0.5% of total fatty acids, the content of arachidonic acid should not exceed 1% of total fatty acid. Moreover, if DHA is added, the content of arachidonic acid should not be less than that of DHA and content of eicosapentaenoic acid should not exceed the content of DHA.</p> <p>There are no relevant requirements in <b>USA</b>.</p>

Nutritional Composition	Requirements
<p><b>Fluoride</b></p>	<p>For the <b>Amendment Regulation</b>, if the content of fluoride in infant formula in the form ready for consumption exceed 100µg /100kcal [24µg/100 kJ], the infant formula should bear a specific statement on dental fluorosis.</p> <p>For <b>Codex</b>, the content of fluoride should not be added to infant formula and the content of fluoride in the form ready for consumption should not exceed 100µg /100kcal [24µg/100 kJ].</p> <p>For <b>European Union</b>, the content of fluoride in infant formula in the form ready for consumption should not exceed 100µg /100kcal [25µg/100 kJ].</p> <p>For <b>Australia and New Zealand</b>, if the content of fluoride in powder infant formula exceeds 17µg/100 kJ, or the content of fluoride in infant formula in the form ready for consumption exceeds 0.15mg/100mL, the infant formula should bear a specific statement on dental fluorosis.</p> <p>There are no relevant requirements in <b>USA, Singapore and Mainland China</b>.</p>

Tolerance Limits for Nutrition Labelling in Formula Products  
and Prepackaged Food for Infants and Young Children in  
Different Jurisdictions

Jurisdiction	Tolerance Limits
Hong Kong	<ul style="list-style-type: none"><li>● Energy, total fat, saturated fat, trans fat, cholesterol, sugars, sodium: <math>\leq 120\%</math> declared value</li><li>● Protein, carbohydrates, dietary fibre: <math>\geq 80\%</math> of declared value</li><li>● Vitamins and minerals (other than vitamin A, vitamin D and added vitamins and minerals): <math>\geq 80\%</math> of declared value</li><li>● Vitamin A and vitamin D (including added ones) : 80%-180% of declared value</li><li>● Added vitamins and minerals (other than vitamin A and vitamin D): <math>\geq</math> declared value</li></ul>
USA	<p><u>Infant formula</u></p> <ul style="list-style-type: none"><li>● Energy, fat and sodium: <math>\leq 120\%</math> of declared value</li><li>● Naturally occurring protein, carbohydrate: <math>\geq 80\%</math> of declared value</li><li>● Naturally occurring vitamins and minerals: <math>\geq 80\%</math> of declared value</li><li>● Added vitamins, minerals, protein, linoleic acid: <math>\geq</math> declared value</li></ul>

	<p><u>Other foods</u></p> <ul style="list-style-type: none"> <li>● Energy, sugars, total fat, saturated fat, trans fat, cholesterol, sodium: <math>\leq 120\%</math> declared value</li> <li>● Naturally occurring protein, total carbohydrate, dietary fibre, other carbohydrate, polyunsaturated fat, monounsaturated fat: <math>\geq 80\%</math> of declared value</li> <li>● Naturally occurring vitamins and minerals: <math>\geq 80\%</math> declared value</li> <li>● Added vitamins, minerals, protein, dietary fibre, potassium: <math>\geq</math> declared value</li> </ul>
<p><b>Mainland China</b></p>	<ul style="list-style-type: none"> <li>● Energy/fat/saturated fat /cholesterol/sodium which is claimed to be “low”: <math>\leq 120\%</math> of declared value</li> <li>● Fortified and naturally occurring nutrients: <math>\geq 80\%</math> of declared value</li> </ul>
<p><b>Australia and New Zealand</b></p>	<ul style="list-style-type: none"> <li>● The Australia New Zealand Food Standard Code does not set tolerance limits for nutrition labelling, but requires the declaration of “average quantity” which best represents the values of the nutrient content that the food contains and is to be determined from one or more of the following: <ul style="list-style-type: none"> <li>(i) the manufacturer’s analysis of the nutrient content;</li> <li>(ii) calculation based on the actual or average quantity of nutrients in the ingredients used; or</li> <li>(iii) calculation from generally accepted data.</li> </ul> </li> </ul>

	<p>The above “average quantity” allows for seasonal variability and other known factors that could cause actual nutritional values to vary.</p>
<b>Singapore</b>	<ul style="list-style-type: none"> <li>● Energy, fat, cholesterol, carbohydrates and sodium: : <math>\leq</math> 120% of declared value</li> <li>● Other nutrient : <math>\geq</math> 80% of declared value</li> </ul>
<b>European Union</b>	<ul style="list-style-type: none"> <li>● No guidance on tolerance limits is set for nutrition labelling in formula products and prepackaged food for infants and young children</li> </ul>



**Infant Formula Failing to Conform to the Codex Standard**

<b>Nutrient Failing to Conform to the Codex Standard</b>	<b>Number of Product<sup>1</sup></b>
Iodine	15
Biotin	5
Vitamin K	2
Vitamin C	1
Pantothenic acid	1
Protein	1
Potassium	1
<b>Total:</b>	<b>20</b>

**Follow-up Formula Failing to Conform to the Standards of the Codex and Countries of Origin**

<b>Nutrient Failing to Conform to the Standards</b>	<b>Number of Product</b>
Total fat, vitamin A, vitamin D, vitamin E, vitamin K1, riboflavin, nicotinamide, vitamin B6, pantothenic acid, vitamin C, biotin, iron, chloride, iodine	1
<b>Total:</b>	<b>1</b>

<sup>1</sup> Four products had more than one nutrient that did not conform to the Codex standard.