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China Notifies Measure on Young Children Formula (as SPS 1084)

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Report Highlights:
On September 19, 2018, China notified the World Trade Organization's Sanitary and Phytosanitary Committee of revisions to several national standards concerning infant and young children formula, including SPS/CHN/1084, specifically concerning the technical requirements for formula intended for young children aged 13 - 36 months. This revision will replace existing GB 10767-2010 once it enters into force. Comments on the notification can be sent to China's WTO/SPS National Notification and Enquiry Center by November 11, 2018. There is currently no proposed date of enforcement. The following report contains an unofficial translation of the notified measure.

Executive Summary:

On September 19, 2018, China notified the World Trade Organization's Sanitary and Phytosanitary Committee of revisions to several national standards concerning infant and young children formula, including SPS/CHN/1084, specifically concerning the technical requirements for young children formula (children aged 13 - 36 months). This revision will replace existing GB 10767-2010 once it enters into force.

This notified measure contains a number of revisions to the existing standard, including changes to the scope, additional requirements on the proportion of lactose, maximum and minimum values for various nutrients are adjusted or added, and the testing methods are updated.

Interested parties can provide comments on the notification by sending them to China's WTO/TBT National Notification and Enquiry Center sps@aqsiq.gov.cn by November 11, 2018. There is currently no proposed date of enforcement.

The following report contains an unofficial translation of the notified measure.

– BEGIN TRANSLATION –

The National Standard of People's Republic of China

GB 10767—201X

National Food Safety Standard

Young Child Formula

(Consultation)

Issued on xx-xx-201x Implemented on xx-xx-201x

Issued by the National Health Commission of the People's Republic of China and

State Administration for Market Regulation

Foreword

The Standard replaces content on formula food for young children aged 13~36 months in GB 10767-2010 (National Food Safety Standard Older Infants And Young Children Formula).

When compared with content on formula food for young children aged 13~36 months in GB 10767-2010, the Standard mainly has following changes:

- The Standard scope is modified.
- Requirements on proportion of lactose are added.
- The maximum and minimum values for a part of nutrients are adjusted or added.
- The test methods are updated.

National Food Safety Standard

Young Child Formula

1 Scope

The Standard applies to young child formulas for young children aged 13 ~ 36 months.

2 Terms and Definitions

2.1 Toddler formula

Toddler formula refers to products which use milk and milk protein products and/or soybeans and soybean protein products as the main source of proteins, are fortified with appropriate amount of vitamins, mineral substances and/or other materials, are produced only with physical methods and are fit for young children, whose energy and nutrients can meet a part of nutrient demands of normal young children.

3 Technical Requirements

3.1 Requirements on Materials

3.1.1 Materials used in products shall comply with corresponding safety standards and or relevant provisions to protect safety and meet demand for nutrient for young children, and materials which will cause harm to nutrition and health for young children shall not be used.

3.1.2 Hydrogenated oil and fat shall not be used.

3.1.3 Materials treated with radiation shall not be used.

3.2 Sensory Requirements

The color, luster, taste, smell, texture and soakage of young child formula shall be consistent with characteristics of corresponding products, and there shall be no visible foreign matters in the case of normal vision.

3.3 Essential Ingredients

3.3.1 All essential ingredients in products shall be necessary for growth and development of young children.

3. 3.2 Energy contained in every 100 ml ready-to-eat products shall be within the scope of 250 kJ (60 kcal)～334 kJ (80 kcal). Protein content, fat content and carbohydrate content per 100 ml product are respectively multiplied by energy coefficient 17 kJ/g, 37 kJ/g and 17 kJ/g (the energy coefficient of dietary fiber is 8 kJ/g), and their sum is the value of KJ/100 ml which can be divided by 4.184 to get the value of kcal/100mL.

3.3.3 The protein content, fat content and carbohydrate content per 100kJ (100 kcal) in products shall be consistent with provisions of Table 1.

Table 1 Indexes of Proteins, Fats and Carbohydrates

Nutrient	Index				Test method
	Per 100 kJ		Per 100 kcal		
	Minimum	Maximum	Minimum	Maximum	
Protein [a]	0.43	0.96	1.8	4.0	GB 5009.5
Fat [b]/(g)	0.84	1.43	3.5	6.0	GB 5009.6
Among which: linoleic acid /(g)	0.07	0.33	0.3	1.4	GB 5009.168
α-linolenic acid /(mg)	12	N.S.[c]	50	N.S.[c]	
Ratio of linoleic acid to α-linolenic acid	5:1	15:1	5:1	15:1	—
carbohydrate [d], /(g)	1.8	3.6	7.5	15.0	—

[a] Protein content shall be calculated based on Nitrogen (N) × 6.25.
[b] Trans fat ≤ 3% of total fatty acids; erucic acid ≤ 1% of total fatty acids; total fatty acids refer to the total of C4～C24 aliphatic acids.
[c] N.S. No special description.
[d] For milk-based young child formulas (except products without lactose or products with low lactose content), the proportion of lactose in the total carbohydrates shall be ≥50%. (For solid lactose-free formula: lactose content in food shall ≤0.5 g/100 g; for solid formula with low lactose content: lactose content in food shall ≤2 g/100 g)
[e] Carbohydrate content A1 is calculated according to Expression (1):

$A_1 = 100 - (A_2 + A_3 + A_4 + A_5 + A_6)$…….. (1)

among the Expression:
A_1——carbohydrate content, g/100g;
A_2——protein content, g/100g;
A_3——fat content, g/100g;
A_4——water content, g/100g;
A_5——ash content, g/100g;
A_6——dietary fiber content (on the basis of the quantity added oligosaccharide and polysaccharide, g/100g。

3.3.4 Vitamins: shall be consistent with provisions of Table 2.

Table 2 Vitamin Indexes

Nutrient	Index				Test method
	Per 100 kJ		Per 100 kcal		
	Minimum	Maximum	Minimum	Maximum	
Vitamin A/(μg RE)[a]	18	43	75	180	GB 5009.82
Vitamin D/(μg)[b]	0.48	1.20	2.0	5.0	
Vitamin E/(mg$_{\alpha}$-TE)[c]	0.14	1.20	0.6	5.0	
Vitamin K_1/(μg)	0.96	6.45	4.0	27.0	GB 5009.158
Vitamin B_1/(μg)	14	72	60	300	GB 5009.84
Vitamin B_2/(μg)	19	155	80	650	GB 5009.85

Vitamin B_6/(μg)	11.0	41.8	46	175	GB 5009.154
Vitamin B12/(μg)	0.041	0.478	0.17	2.00	GB 5413.14
Nicotinic acid (nicotinamide)[d]/(μg)	110	359	460	1500	GB 5009.89
Folic acid /(μg)	2.4	12.0	10	50	GB 5009.211
Pantothenic acid /(μg)	96	478	400	2000	GB 5009.210
Vitamin C/(mg)	2.4	16.7	10	70	GB 5413.18
Biotin /(μg)	0.41	2.39	1.7	10.0	GB 5009.259

[a]RE RE is retinol equivalent. 1μg RE=1μg alltrans retinol (vitamin A) =3.33 IU vitamin A. Vitamin A only includes preformed retinol, and doesn't include any carotene components when Vitamin A activity is calculated and claimed.
[b] Calciferol, 1μg vitamin D=40 IU vitamin D。
[c] 1 mg d-α- tocopherol =1 m vitamin gα-TEα- tocopherol equivalent) ; 1 mg dl-α- tocopherol =0.74 mg a-TE (α- tocopherol equivalent) 。
[d] Nicotinic acid doesn't include precursor forms.

3.3.5 Mineral substances: shall be consistent with provisions of Table 3.

Table 3 Indexes for Mineral Substances

Nutrient	Index				
	Per 100 kJ		Per 100 kcal		Test method
	Minimum	Maximum	Minimum	Maximum	
Sodium /(mg)	7	14	30	59	GB 5009.91 GB5009.268
Potassium /(mg)	17	43	70	180	
Copper /(μg)	14.3	28.7	60	120	GB 5009.13 GB5009.268
Magnesium /(mg)	1.2	3.6	5.0	15.0	GB 5009.241 GB5009.268
Iron /(mg)	N.S. [a]	20	N.S. [a]	84	GB 5009.91 GB 5009.268
Zinc /(mg)	18	69	75	290	GB 5009.91 GB 5009.268
Calcium /(mg)	6.9	34.9	29	146	GB 5009.13 GB 5009.268
Phosphorus /(mg)	1.4	4.3	6.0	18.0	GB 5009.241 GB 5009.268
Ratio of calcium to phosphorus	0.24	0.60	1.0	2.5	GB 5009.90 GB 5009.268
Iodine /(μg)	0.10	0.31	0.40	1.30	GB 5009.14 GB 5009.268
Chlorine /(mg)	17	50	71	210	GB 5009.92 GB 5009.268

[a] N.S. No special description.

3.4 Optional Ingredients

3.4.1 In addition to essential ingredients in 3.3, when one or multiple ingredients in Table 4 are selected to be added in products or to be indicated on labels, their content shall be consistent with provisions of Table 4.

3.4.2 When other substances except those in Table 4 are added to products, relevant provisions of the state shall be met.

Table 4 Indexes for Optional Ingredients

Optional ingredient	Index				Test method
	Per 100 kJ		Per 100 kcal		
	Minimum	Maximum	Minimum	Maximum	
Selenium (/μg)	0.48	1.91	2.0	8.0	GB 5009.93 GB 5009.268
Bilineurine /(mg)	4.8	23.9	20	100	GB 5413.20
Manganese/(μg)	0.24	23.90	1.0	100.0	GB 5009.242 GB 5009.268
Inositol (/mg)	1.0	9.6	4	40	GB 5009.270
Taurine /(mg)	0.8	4.0	3.5	16.7	GB 5009.169
L-carnitine /(mg)	0.3	1.5	1.3	6.3	GB 29989
Docosahexenoic acid (DHA)[a] /(mg)	N.S. [a]	9.6	N.S. [a]	40	GB 5009.168
Eicosatetraenoic acid (AA/ARA) /(mg)	N.S. [a]	19.1	N.S. [a]	80	GB 5009.168
[a] N.S. No special description.					

3.5 **Other indexes:** shall be consistent with provisions of Table 5.

Table 5 Other Indexes

Item		Index	Test method
Water/(%)[a]	≤	5.0	GB 5009.3
Ash Solid product/(%) Liquid product(calculated on the basis of total solids)/(%)	≤ ≤	5.0 5.3	GB 5009.4
Impurity degree [b] Solid product/(mg/kg) Liquid product/(mg/kg)	≤ ≤	12 2	GB 5413.30

[a] limited to solid product.
[b] not applicable to products to which vegetables and fruits are added.

3.6 **Contaminant limit:** shall be consistent with provisions of GB 2762.

3.7 **Mycotoxin limit:** shall be consistent with provisions of GB 2761.

3.8 **Microbial limit:** microbial indexes for solid products shall be consistent with provisions of Table 6, and microbial indexes for liquid products shall meet commercial sterility requirements and be tested with the methods specified in GB 4789.26.

Table 6 Indexes of Microbial Limit

Item	Sample plan [a] and limit (it is expressed as CFU/g or CFU/mL except that it is specified otherwise.)				Test method
	n	c	m	M	
Total bacterial count [b]	5	2	1000	10000	GB 4789.2
Coli group	5	2	10	100	GB 4789.3 plate counting method
Salmonella	5	0	0/25g	—	GB 4789.4

[a] Analysis and treatment for samples are conducted according to GB 4789.1 and GB 4789.18.
[b] It is not applicable to products to which active probiotics are added [viable count of each kind of active probiotics shall $\geq 10^6$CFU/g (mL)]

3.9 Food Additives and Nutrient Supplements

3.9.1 Use of food additives and nutrient supplements shall be consistent with provisions of GB 2760 and GB 14880.

3.9.2 Quality of food additives shall be consistent with corresponding standards and or relevant provisions.

3.10 Urease activity: urease activity in young child formulas with soybeans or soy products as the source of proteins shall be consistent with provisions of Table 7.

Table 7 Urease Activity Index

Item	Index	Test method

Determination of urease activity index	Negative	GB 5413.31 [a]
[a] The sampling quality shall be converted according to dry matter content.		

4 Others

4.1 Labeling

4.1.1Content indicated on the label shall be consistent with GB 13432 and/or relevant provisions. In addition, nutrient ingredients should be indicated as content “per 100 kJ (100 kcal)”.
4.1.2 The category, properties (for example, milk-based or soy-based products and product state) and applicable age should be indicated on the labels.

4.2 Directions for Use

4.2.1 The directions for use, proper preparation and illustration as well as storage condition of the product shall be clearly indicated on the labels. If maximum surface area of the package is less than 100 cm^2 or if the weight of product is less than 100 g, illustration is not necessary.

4.2.2 The directions for use shall cover warnings on the hazard to health resulting from improper preparation or use.

4.3 Packaging

Carbon dioxide and/or nitrogen which is at food grade or whose purity is ≥ 99.9% may serve as packaging medium.