

Voluntary Report – Voluntary - Public Distribution

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Report Highlights:

On February 22, 2021, the National Health Commission of the People's Republic of China and the State Administration for Market Regulation issued the Standard GB 10767 - 2021 (the National Food Safety - Formula for Young Children). After a transition period of 2 years, this Standard will be implemented on February 22, 2023. The following report contains an unofficial translation of the Standard along with a PRC provided list of questions and answers regarding the Standard.

Executive Summary:

On February 22, 2021, the National Health Commission of the People's Republic of China and the State Administration for Market Regulation issued the Standard GB 10767 - 2021 (the National Food Safety - Formula for Young Children). This Standard will be implemented on February 22, 2023.

The Formula for Young Children Standard is a mandatory national food safety standard. The transition period is 2 years. Before the implementation date of this Standard (February 22, 2023), food production and business enterprises are allowed and encouraged to implement this Standard. After the implementation date of this Standard, food production and business enterprises, food safety regulatory agencies and inspection agencies shall implement this Standard. Formula for Young Children that has been produced before the implementation date can continue to be sold within the period of its shelf life.

Compared with GB10767-2010, the Standard GB10767 - 2021 mainly has following changes:

- In consideration of the revisions to the Codex Alimentarius Commission, "Older Infants and Young Children Formula" (GB10767-2010) is divided into two standards, namely GB10766 - 2021 and GB10767- 2021;
- The minimum values of vitamins and minerals in the products have been changed to ensure the nutritional effectiveness of formula food;
- The maximum nutrients contents have been changed to ensure the safety of infants;
- The relevant standards are referred to for pollutants, mycotoxins, and pathogens limit to reflect the coordination between the standards.

The following report contains an unofficial translation of the Standard.

NOTE: The State Administration for Market Supervision (SAMR) provided Q&A announcement for infant formula producers, including certain technical guidance for registering facilities under the new standards (GB 10765-2021, GB 10766-2021, and GB 10767-2021). For additional information please find the Chinese version of the Q&A here.

http://www.samr.gov.cn/tssps/tzgg/zjwh/202106/t20210608_330383.html

(Begin Unofficial Translation)



The National Standard of People's Republic of China

GB 10767—2021

National Food Safety Standard

Formula for Young Children

Issued on 02-22-2021

Implemented on 02-22-2023

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

State Administration for Market Regulation

Foreword

The Standard replaces content concerning formula foods for young children aged 12~36 months in GB 10767-2010 (National Food Safety Standard Older Infants and Young Children Formula).

When compared with content concerning formula foods for young children aged 12~36 months in GB 10767-2010, the Standard mainly has following changes:

- Description of the scope is modified.
- Requirements on proportions of lactose are added.
- The maximum and minimum values for some nutrients are adjusted
- The maximum and minimum values for some nutrients are added.
- The test methods are updated.

National Food Safety Standard

Formula for Young Children

1 Scope

The Standard applies to formula food for young children aged 12 ~ 36 months.

2 Terms and Definitions

2.1 Formula for Young Children

Refers to products which use milk and milk protein products 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, and are produced only with physical methods. Formula food 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 formula for young children 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) ~334kJ (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 /g	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, e} /g	1.8	3.6	7.5	15.0	-

^a Protein content shall be calculated based on Nitrogen (N) \times 6.25.

^b Trans fat content \leq 3% 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 formula for young children (except lactose-free and low-lactose products), lactose should account for more than 50% of carbohydrate content. (lactose content in solid lactose-free

formula should be $\leq 0.5\text{g}/100\text{g}$; The lactose content in solid low lactose formula should be $\leq 2\text{g}/100\text{g}$.)

e Carbohydrate content A_1 is calculated according to Expression (1):

$$A_1 = 100 - (A_2 + A_3 + A_4 + A_5 + A_6) \dots \dots \dots (1)$$

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 ^a /μg RE	18	43	75	180	GB 5009.82
Vitamin D ^b /μg	0.48	1.20	2.0	5.0	
Vitamin E ^c /mg a-TE	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

Table 2 (continued)

Nutrient	Index				Test method
	Per 100 kJ		Per 100 kcal		
	Minimum	Maximum	Minimum	Maximum	
Vitamin B ₆ /μg	11.0	41.8	46	175	GB 5009.154
Vitamin B ₁₂ /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	2 000	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 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 mg α- TE (α- tocopherol equivalent);1 mg dl-α- tocopherol =0.74 mg α-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				Test method
	Per 100 kJ		Per 100 kcal		
	Minimum	Maximum	Minimum	Maximum	
Sodium /mg	N.S. ^a	20	N.S. ^a	84	GB 5009.91
Potassium/mg	18	69	75	290	
Copper /μg	6.9	34.9	29	146	GB 5009.13
Magnesium/mg	1.4	4.3	6.0	18.0	GB 5009.241
Iron/mg	0.24	0.60	1.0	2.5	GB 5009.90

Zinc /mg	0.10	0.31	0.40	1.30	GB 5009.14
Calcium/mg	17	50	71	210	GB 5009.92
Phosphorus /mg	8	26	35	110	GB 5009.87
Ratio of calcium to phosphorus	1.2:1	2:1	1.2:1	2:1	-
Iodine /μg	1.4	14.1	6	59	GB 5009.267
Chlorine /mg	N.S. ^a	52	N.S. ^a	218	GB 5009.44
^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	2.06	2.0	8.6	GB 5009.93
Choline /mg	4.8	23.9	20	100	GB 5413.20
Manganese/ μg	0.24	23.90	1.0	100.0	GB 5009.242
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	N.S. ^a	1.3	N.S. ^a	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/ (%)	≤	5.0	GB5009.4
Liquid product(calculated on the basis of total solids)/(%)	≤	5.3	
Impurity degree ^b			
Solid product/(mg/kg)	≤	12	GB5413.30
Liquid product/(mg/8 L)	≤	2	
^a limited to solid product.			
^b Not applicable to products added with 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

3.8.1 Pathogenic bacteria limit for solid products shall be consistent with provisions of GB 29921, and other microbial indexes shall be consistent with provisions of Table 6.

3.8.2 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	Sampling 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	10 000	GB 4789.2
Coli group	5	2	10	100	GB 4789.3 plate counting method
^a Analysis and treatment for samples are conducted according to GB 4789.1 and GB 4789.18.					
^b It is not applicable to products added with active bacteria (aerobic and facultative anaerobic bacteria) [viable count of active probiotics in products should be $\geq 10^6$ 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 and nutrient supplement shall be consistent with corresponding standards and or relevant provisions.

3.10 Urease Activity

Urease activity in products with soybean or soybean products as the source of protein 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 quantity of liquid products shall be converted according to dry matter content.		

4 Others

4.1 Labeling

4.1.1 Content indicated on the label shall be consistent with GB 13432 and/or relevant provisions, and content “per 100 kJ (100 kcal)” for essential ingredients and optional ingredients shall be indicated.

4.1.2 The category, properties (for example, product state) and applicable age shall 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 cm² 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 conforming to national food safety standard may serve as packaging medium.

(End Translation)

Attachments:

No Attachments.