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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 10766 - 2021 (the National Food Safety - Older Infants Formula). 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 link to PRC provided 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 10766 - 2021 (the National Food Safety - Older Infants Formula). This Standard will be implemented on February 22, 2023.

The Older Infants Formula standard is a mandatory national food safety standard. The transition period for this standard 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. Older Infants Formula 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 GB10766 - 2021 mainly has the following changes:

- In consideration of the revisions of the Codex Alimentarius Commission, the "Older Infants and Young Children Formula" (GB10767-2010) has been 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 content has been changed to ensure the safety of infants;
- The relevant standards are referred to for pollutants, mycotoxins, and pathogen limits 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 TRANSLATION** -

The National Standard of People's Republic of China

GB 10766—2021

National Food Safety Standard

Older Infants Formula

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 older infants aged 6~12 months in GB 10767-2010 (National Food Safety Standard Older Infants And Young Children Formula).

When compared with content concerning formula foods for older infants aged 6~12 months in GB 10767-2010, the Standard mainly has following changes:

- Description of the scope is modified.
- Terms and definitions are modified.
- Requirements on proportions of lactalbumin and lactose are added.
- The maximum and minimum levels for most nutrients are adjusted or added.
- Requirements on proteins, iron, zinc and phosphorus content in soy-based older infants formula are added.
- Manganese, selenium and choline are changed into necessary ingredients from optional ingredients.
- A part of labeling requirements are modified.
- Appendices A and B are added.
- The test methods are updated.

National Food Safety Standard

Older Infants Formula

1 Scope

The Standard applies to formula for older infants aged 6~12 months.

2 Terms and Definitions

2.1 Older Infants Formula

Formula food fit for normal older infants, whose energy and nutrients can meet normal nutrient demands of older infants aged 6 ~ 12 months.

2.2 Milk-based Older Infants formula

Refers to products which use milk and milk 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.

2.3 Soy-based older infants formula

Refers to products which use soybeans and soybean protein products as the main source of proteins, are fortified with appropriate amount of processed vitamins, minerals and/or other materials, and are produced only with physical methods.

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 the nutrients demand for older infants, and materials which will cause harm to nutrition and health for older infants shall not be used.

3.1.2 Materials and food additives shall not contain glutelin.

3.1.3 Hydrogenated oil and fat shall not be used.

3.1.4 Materials treated with radiation shall not be used.

3.2 Sensory Requirements

The color, luster, taste, smell, texture and soakage of older infants 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 older infants.

3.3.2 Energy contained in every 100 ml ready-to-eat products shall be within the scope of 250 kJ(60 kcal)~314 kJ (75 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.

3.3.4 For milk-based older infants formula, lactose is the first choice for source of carbohydrates (the portion of lactose in total carbohydrates shall be ≥ 90%), glucose polymer can be added as appropriate (among which starch may be added after only after being pre-gelatinized), and no levulose or saccharose shall be used.

Table 1 Indexes of Proteins, Fats and Carbohydrates

Nutrient	Index				Test method
	Per 100 kJ		Per 100 kcal		
	Minimum	Maximum	Minimum	Maximum	
Protein [a]					GB 5009.5
Milk-based older infants formula/g	0.43	0.84	1.8	3.5	
Soy-based older infants formula /g	0.53	0.84	2.2	3.5	
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	2.2	3.3	9.0	14.0	-

[a] Protein content shall be calculated based on Nitrogen (N) × 6.25; lactalbumin content in milk-based older infants formula shall be ≥ 40% (be calculated on the basis of the quantity of added materials); to improve the quality or nutrient value of protein in older infants formula, L mono-amino acids can be added according to provisions on content of essential and semi-essential amino acids in Appendix A, whose source shall be consistent with provisions of Appendix B.

[b] In the final products, the total quantity of lauric acid and myristic acid (tetradecanoic acid) ≤ 20% of total fatty acids; trans fat content ≤ 3% of total fatty acids; erucic acid content ≤ 1% of total fatty acids; total fatty acids refer to the total of C4~C24 aliphatic acids.

c N.S. No special description.

d 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.

3.3.5 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 a-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	120	80	500	GB 5009.85
Vitamin B_6/μg	11.0	41.8	46	175	GB 5009.154
Vitamin B_{12}/μg	0.041	0.359	0.17	1.50	GB5413.14
Nicotinic acid(nicotinamide)[d]/μg	110	359	460	1 500	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
Choline /mg	4.8	23.9	20	100	GB 5413.20

[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 mgα-TE (α- tocopherol equivalent)；1 mg dl-α- tocopherol =0.74 mgα-TE (α- tocopherol equivalent). [d] Nicotinic acid doesn't include precursor forms.

3.3.6 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	54	75	225	
Copper/Mg	8.4	28.7	35	120	GB 5009.13
Magnesium/mg	1.2	3.6	5.0	15.0	GB 5009.241
Iron/mg					
Milk-based	0.24	0.48	1.0	2.0	GB 5009.90
Soy-based	0.36	0.48	1.5	2.0	
Zinc /mg					
Milk-based	0.12	0.36	0.50	1.50	GB 5009.14
Soy-based	0.18	0.36	0.75	1.50	
Manganese/μg	0.24	23.90	1.0	100.0	GB 5009.242
Calcium /mg	17	43	71	180	GB 5009.92
Phosphorus/mg					
Milk-based	8	26	35	110	GB 5009.87
Soy-based	10	26	42	110	
Ratio of calcium to phosphorus	1.2:1	2:1	1.2:1	2:1	-
Iodine/μg	3.6	14.1	15	59	GB 5009.267
Chlorine/mg	N.S. [a]	52	N.S. [a]	218	GB 5009.44
Selenium/μg	0.48	2.06	2.0	8.6	GB 5009.93
[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	
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. [b]	1.3	N.S. [b]	GB 29989
Docosahexenoic acid(DHA)[a]/mg	3.6	9.6	15	40	GB 5009.168
Eicosatetraenoic acid(AA/ARA) /mg	N.S. [b]	19.1	N.S. [b]	80	GB 5009.168

[a] If docosahexenoic acid (22:6n-3) is added in older infants formulas, at least the same quantity of eicosatetraenoic acid (20:4n-6) shall be added. The quantity of eicosapentaenoic acid (20:5n-3) shall not exceed that of docosahexenoic acid.

[b] 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			
Milk-based solid product/%	≤	4.0	GB5009.4
Milk-based liquid product (calculated on the basis of total solids)/%	≤	4.2	
Soy-based solid product/%	≤	5.0	
Soy-based liquid product (calculated on the basis of total solids)/%	≤	5.3	
Impurity degree (limited to milk-based older infants formula)			
Solid product/(mg/kg)	≤	12	GB5413.30
Liquid product/(mg/8 L)	≤	2	
[a] limited to solid product.			

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 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	1 000	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 to which active probiotics (aerobic and facultative anaerobic bacteria) are added [viable count of active probiotics shall be $\geq 10^6$ CFU/g (mL) or $\geq 10^6$CFU/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 supplements shall be consistent with corresponding standards and or relevant provisions.

3.10 Urease Activity

Urease activity in soy-based older infants formula 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. In addition, content “per 100 kJ (100 kcal)” for essential ingredients and optional ingredients shall be indicated.

4.1.2 The category, properties (for example, milk-based or soy-based products and product state) and applicable age shall be indicated on the labels. Meanwhile, the labels shall bear a statement indicating that “corresponding complementary feeding shall be introduced”.

4.1.3 Images of infants or women cannot appear on the labels, and it is not allowed to use the expressions such as “humanized”, “materuized” or similar terms.

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 conforming to national food safety standard may serve as packaging medium.

Appendix A: Recommended Content of Essential And Semi-Essential Amino Acids in Older Infants Formula

A.1 By referring to published and representative data on content of essential and semi-essential amino acids in human milk and data on relevant nitrogen content and/or protein content and taking a certain range of variation into consideration, the minimum limit of content of essential and semi-essential amino acids in older infants formula can be calculated (mg/gN).

A.2 According to the lower limit level of each amino acid in human milk (mg/g N), corresponding amino acid content per 100 kcal in older infants formula with a minimum protein content (1.8g/100 kcal) can be calculated: the amino acid level (in milligram) per gram of nitrogen in human milk is divided by the nitrogen conversion factor, 6.25, and then multiplied by 1.8, at the same time, refer to the provisions in the corresponding standards of Codex Alimentarius Commission. For results, please see Table A.1. It is recommended that content of essential and semi-essential amino acids contained in older infants formula is not lower than the recommended value in Table A.1.

A.3 During calculation, concentration of tyrosine and concentration of phenylalanine may be added together; when the ratio of methionine to cysteine is less than 2:1, the two may be also added together.

Table A.1 Recommended Content of Essential and Semi-essential Amino Acids in Older Infants formula

Amino Acid	Index	
	mg/gN	mg/100 kcal
Cysteine	131	38
Histidine	141	41
Isoleucine	319	92
Leucine	586	169
Lysine	395	114
Methionine	85	24
Phenylalanine	282	81
Threonine	268	77
Tryptophan	114	33
Tyrosine	259	75
Valine	315	90

Appendix B: Monomeric Amino Acids Which Can Be Added to Older Infants Formula

Table B.1 Monomeric Amino Acids Which Can Be Added to Older Infants Formula [a]

No.	Amino Acid	Source of Chemical Compound	Chemical Name	Molecular Formula	Molecular weight	Specific rotary power [a]D, 20 °C	pH	Purity % ≥	Water% ≤	Ash% ≤	Lead mg/kg ≤	Arsenic mg/kg ≤
1	Cysteine	L-Cysteine	L-α-Amino-β-mercaptopropionic acid	$C_3H_7NO_2S$	121.16	+ 8.3~+ 9.5	4.5 ~5.5	98.5	0.5	0.1	0.3	0.2
		L-Cysteine hydrochloride - monohydrate	L-2-Amino-3 Mercaptopropionic acid hydrochloride monohydrate	$C_3H_7NO_2S•HCl•H_2O$	175.64	+ 5.5 ~+ 7.0	1.5 ~2.0	98.5	8.0~12	0.1	0.3	0.2
		L- cysteine hydrochloride	L-2-Amino-3-mercaptopropionic acid hydrochloride	C_3 $H_7NO_2S•HCl$	157.62	+ 5.6 ~+ 8.9	1.5 ~2.0	98.5	2.0	0.1	0.3	0.2
		L- cystine	L-3,3'-dithiobis (2- aminopropionic acid)	$C_6H_{12}N_2O_4S_2$	240.3	- 215 ~ -230	5.0 ~6.5	98.5	0.2	0.1	0.3	0.2
2	Histidine	L- histidine	α-Amino β- imidazolyl propionic acid	$C_6H_9N_3O_2$	155.15	+ 12.0 ~+ 12.8	7.0~8.5	98.5	0.2	0.2	0.3	0.2
		L- histidine hydrochloride - monohydrate	L-2-Amino-3-propynylpropionic acid hydrochloride imidazolyl	$C_6H_9N_3O_2•HC1•H_2O$	209.63	+ 8.5 ~+ 10.5	3.5 ~4.5	98.5	0.2	0.1	0.3	0.2
3	Isoleucine	L- Isoleucine	L-2-Amino-3-methylpentanoic acid	$C_6H_{13}NO_2$	131.17	+ 38.9 ~+ 41.8	5.5 ~6.5	98.5	0.2	0.2	0.3	0.2
4	Leucine	L- Leucine	L-2-Amino-4-methylpentanoic acid	$C_6H_{13}NO_2$	131.17	+ 14.9 ~+ 16.0	5.5 ~6.5	98.5	0.2	0.2	0.3	0.2
5	Lysine	L-lysinehydrochloride	L-2,6-diaminocaproic acid hydrochloride	$C_6H_{14}N_2O_2•HCl$	182.65	+ 20.4 ~+ 21.5	5.0 ~6.0	98.5	0.4	0.1	0.3	0.2
		L-Lysine monoacetate	L-2,6-diaminocaproic acid acetate	$C_6H_{14}N_2O_2•C_2H_4O_2$	206.24	+ 8.5 -+ 10.0	6.5 ~7.5	98.5	0.3	0.2	0.3	0.2
6	Methionine	L- Methionine	2-Amino-4-methylmercaptobutyric acid	$C_5H_{11}NO_2S$	149.21	+ 21.0 ~+ 25.0	5.6 ~6.1	98.5	0.2	0.2	0.3	0.2
		N- acetyl methionine	N-acetyl-2-amino-4-methylmercaptobutyric acid	$C_7H_{13}NO_3S$	191.25	- 18.0 ~- 22.0	-	98.5	0.5	0.1	0.3	0.2
7	Phenylalanine	L- Phenylalanin	L-2-amino-3 phenylpropionic acid	$C_9H_{11}NO_2$	165.19	-33.0~-35.0	5.4~6.0	98.5	0.2	0.1	0.3	0.2
8	Threonine	L- Threonine	L-2-Amino-3- hydroxybutyric acid	$C_4H_9NO_3$	119.12	- 26.0 ~-29.0	5.0 ~6.5	98.5	0.2	0.2	0.3	0.2
9	Tryptophan	L- Tryptophan	L-2-Amino-3 -indoly-1- propionic acid	$C_{11}H_{12}N_2O_2$	204.23	- 30.0 ~-32.5	5.4 ~6.4	98.5	0.2	0.1	0.3	0.2

10	Tyrosine	L-Tyrosine	S-Amino-3(4-hydroxy-phenyl)-propionic acid	$C_9H_{11}NO_3$	181.19	- 11.3 ~-12.1	5.0 ~6.5	98.5	0.2	0.2	0.3	0.2
11	Valine	L-Valine	L-2-Amino-3-methylbutyric acid	$C_5H_{11}NO_2$	117.15	+ 26.6 ~+ 28.8	5.5 ~6.5	98.5	0.2	0.1	0.3	0.2
[a] Non-edible animal and plant raw materials shall not be used as the source of monomer amino acids.												

Attachments:

No Attachments.