National Standards of People's Republic of China

GB 10767—2010

National food safety standard

Older infants and young children formula

Issued on: 2010-03-26 Implemented on: 2011-04-01

Issued by Ministry of Health of the People's Republic of China

Foreword

This standard corresponds to the Codex Stan 156-1987 (Amendment 1989) (Codex Standard for Follow-up Infant Formulas) issued by Codex Alimentarius Commission (CAC). The consistency level between this standard and Codex Stan 156-1987 is non-equivalent. This standard is in reference to Chinese Dietary Reference Intakes compiled by Chinese Nutrition Society in 2000.

This Standard replaces GB10767-1997 *General Technical Regulations for Infant Blended Milk Powder and Infant Completed Grain Flour*, GB 10769-1997 *Formulated Weaning Foods for Infants and Young Children* and GB 10770-1997 *Supplementary Weaning Foods for Infants and Young Children*, as well as their amendments.

Comparing with GB10767-1997, GB 10769-1997 and GB 10770-1997, the following main changes have been made to the Standard:

—— Integrate the above three standards to one, titled as “Older infants and young children formula”

—— Provisions therein are modified.

The original editions replaced by this present National Standard include:

——GB 10767-1997;

——GB 10769-1989, GB 10769-1997;

——GB 10770- 1989, GB 10770-1997.

National food safety standard

Older infants and young children formula

1 Scope

This Standard applies to older infants and young children formula.

2 Normative References

The normative documents referenced in the text are indispensable to the application of this standard. For dated references, only the edition bearing such date applies to this standard. For undated references, the latest edition of the normative document referred to (including all the amendments) applies.

3 Terms and Definitions

3.1 Older infants

Older infants refer to persons of 6 ~ 12 months old.

3.2 Young children

Young children refer to young children of 12 - 36 months old.

3.3 Older infants and young children formula

Refer to liquid or powder products made only through physical methods, of which the main material is milk and its product, and/ or beans and their products, supplemented with a proper amount of vitamins, minerals and other supplementary materials, which are applicable to older infants and young children, where the nutrition can satisfy partial requirements normal older infants and young children.

4 Requirements

4.1 Requirements for Raw Materials

The raw materials used in products should comply with appropriate safety standards and/or relevant regulations, ensure the safety of older infants and young children, and meet the nutrition requirement. The substance that detrimental to the health and nutrition of older infants and young children should not be used.

Hydrogenated oil and fat should NOT be used in older infants and young children formula.

Raw and supplementary materials treated by irradiation should NOT be used in older infants and young children formula.

4.2 Sensory requirement

Table 1 Sensory requirement

Items	Requirements

color	conform to the identity of related product
taste and flavor	conform to the identity of related product
structural	conform to the identity of related product, no visible foreign matter
dissolvability	conform to the identity of related product

4.3 Essential components

4.3.1 All essential components used in products should be necessary for growth and development of older infants and young children.

4.3.2 The energy in the ready-to-eat older infants and young children formula per 100ml should be within the range of 250 kJ (60 kcal)~ 335 kJ (85 kcal). For calculation of energy, the content of protein, fat, carbohydrate per 100mL of product multiplied by the energy coefficient of 17 kJ / g, 37 kJ / g, 17 kJ / g (the energy coefficient of dietary fiber is calculated as 50% of carbohydrate energy coefficient) respectively, the obtained sum (kJ/100mL) divided by 4.184 to obtain the kcal / 100 ml value.

4.3.3 Protein and fat contained per 100kJ (100kcal) ready-to-eat older infants and young children formula should meet the specification in Table 2. The content of trans fatty acid should not be more than 3% total fatty acid.

Table 2 Indices of Protein and Fat

Nutrient	Per 100 kJ		Per 100 kcal		Test method
	Minimum	Maximum	Minimum	Maximum	
Protein[a]/(g)	0.7	1.2	2.9	5.0	GB 5009.5
Fat/(g)	0.7	1.4	2.9	5.9	GB 5413.3
in which: linoleic acid/(g)	0.07	N.S.[b]	0.29	N.S.[b]	GB 5413.27
[a] the content of protein should be calculated as nitrogen (N) × 6.25; [b] N.S.: No specification					

4.3.4 Vitamins: should meet the specification in Table 3.

Table 3 Indices of Vitamins

Nutrient	Per 100 kJ		Per 100 kcal		Test method
	Minimum	Maximum	Minimum	Maximum	
Vitamin A/(μg RE)[a]	18	54	75	225	GB 5413.9
Vitamin D[b]/(μg)	0.25	0.75	1.05	3.14	
Vitamin E/ (mg α-TE[c])	0.15	N.S.[e]	0.63	N.S.[e]	
Vitamin K_1/(μg)	1	N.S.[e]	4	N.S.[e]	GB 5413.10
Vitamin B_1/(μg)	11	N.S.[e]	46	N.S.[e]	GB 5413.11
Vitamin B_2/(μg)	11	N.S.[e]	46	N.S.[e]	GB 5413.12

Vitamin B_6/(μg)	11	N.S.[e]	46	N.S.[e]	GB 5413.13
Vitamin B_{12}/(μg)	0.04	N.S.[e]	0.17	N.S.[e]	GB 5413.14
Niacin (Niacinamide)[d]/(μg)	110	N.S.[e]	460	N.S.[e]	GB 5413.15
Folic acid/(μg)	1	N.S.[e]	4	N.S.[e]	GB 5413.16
Pantothenic acid/(μg)	70	N.S.[e]	293	N.S.[e]	GB 5413.17
Vitamin C/(mg)	1.8	N.S.[e]	7.5	N.S.[e]	GB 5413.18
Biotin/(μg)	0.4	N.S.[e]	1.7	N.S.[e]	GB 5413.19

[a)] RE is retinol equivalent. 1 μg RE=1μg All trans retinol (Vitamin A)= 3.33 IU Vitamin A. Ingredients of Vitamin A shall only include preformed retinol. When calculating or claiming activities of Vitamin A, no carotenoids ingredient shall be included.

[b)] Calciferol, 1μg Vitamin D = 40 IU Vitamin D.

[c)] 1 mg α-TE (α-tocopherol equivalent)=1 mg d-α-tocopherol. There should be at least 0.5 mg of α-TE per gram of polyunsaturated fatty acid. The minimum of Vitamin E content should be regulated according to the number of double bonds in polyunsaturated fatty acids in the formula as follows: 0.5 mg of α-TE per gram of linoleic acid (18:2 n-6); 0.75 mg of α-TE per gram of α-linolenic acid (18:3 n-3); 1.0 mg of α-TE per gram of arachidonic acid (20:4 n-6); 1.25mg of α-TE per gram of Eicosapentaenoic Acid (20:5 n-3); 1.5mg of α-TE per gram of docosahexenoic acid (22:6 n-3).

[d)] Niacin: excludes precursor form.

[e] NS: No specification

4.3.5 Minerals: should meet the specification of Table 4.

Table 4 Indices of Minerals

Nutrient	Per 100 kJ		Per 100 kcal		Test method
	Minimum	Maximum	Minimum	Maximum	
Sodium/(mg)	N.S.[a]	20	N.S.[a]	84	GB 5413.21
Potassium/(mg)	18	69	75	289	
Copper/(μg)	7	35	29	146	
Magnesium/(mg)	1.4	N.S.[a]	5.9	N.S.[a]	
Iron/(mg)	0.25	0.50	1.05	2.09	
Zinc/(mg)	0.1	0.3	0.4	1.3	
Calcium/(mg)	17	N.S.[a]	71	N.S.[a]	
Phosphorus/(mg)	8.3	N.S.[a]	34.7	N.S.[a]	GB 5413.22
Calcium / phosphorus	1.2:1	2:1	1.2:1	2:1	—
Iodine/(μg)	1.4	N.S.[a]	5.9	N.S.[a]	GB 5413.23
Chloride/(mg)	N.S.[a]	52	N.S.[a]	218	GB 5413.24

[a)] NS: No specification

4.4 Optional components

4.4.1 Besides the essential components specified in 4.3, one or more optional components as shown in Table 5 can be added to or claimed in the label of older infants and young children formula, whereas the content should meet the specification of Table 5.

4.4.2 If the added components don't included in 4.3 and 4.4.1, it should follow national related regulations.

Table 5 Indices of Optional Components

Optional Components	Per 100 kJ		Per 100 kcal		Test method
	Minimum	Maximum	Minimum	Maximum	
Selenium/(μg)	0.48	1.90	2.01	7.95	GB 5009.93
Choline/(mg)	1.7	12.0	7.1	50.2	GB/T 5413.20
Manganese/(μg)	0.25	24.0	1.05	100.4	GB 5413.21
Inositol/(mg)	1.0	9.5	4.2	39.7	GB 5413.25
Taurine/(mg)	N.S. [a]	3	N.S. [a]	13	GB 5413.26
L-Carnitine/(mg)	0.3	N.S. [a]	1.3	N.S. [a]	—
Docosahexaenoic acid/ (% total fatty acid [b])	N.S. [a]	0.5	N.S. [a]	0.5	GB 5413.27
Arachidonic acid/ (% total fatty acid [b])	N.S. [a]	1	N.S. [a]	1	

[a] NS: No specification

[b] total fatty acid is the sum of C4 ~ C24 fatty acid.

4.5 Other indices: should meet the specification of Table 6.

Table 6 Other Indices

Item		Index	Test method
Water content/(%)[a]	≤	5.0	GB 5009.3
Ash			GB 5009.4
Powder product/ (%)	≤	5.0	
Liquid product (calculated based on dry matter) / (%)	≤	5.3	
Impurities [b]			GB 5413.30
Powder product/ (mg/kg)	≤	12	
Liquid product / (mg/kg)	≤	2	

[a] Only for powder products.

[b] NOT applicable to products supplemented with fruits and vegetables.

4.6 Limits of Contaminants: should meet the specification of Table 7.

Table 7 Limits of Contaminants (calculated based on Powder product)

Item		Index	Test method
Lead/(mg/kg)	≤	0.15	GB 5009.12
Nitrate (based on $NaNO_3$)[a]/(mg/kg)	≤	100	GB 5009.23
Nitrite (based on $NaNO_2$)[b]/(mg/kg)	≤	2	
[a] NOT applicable to products supplemented with fruits and vegetables. [b] Noly applicable to milk-based product.			

4.7 Limits of Mycotoxins: should meet the specification of Table 8.

Table 8 Limits of Mycotoxins (calculated based on powder product)

Item		Index	Test method
Aflatoxin M_1 or Aflatoxin B_1[a]/ (μg/kg)	≤	0.5	GB 5009.24
[a] The limit of Aflatoxin M_1 is applicalbe to products of which the main materials are milk and its products; the limit of Aflatoxin B_1 is applicalbe to products of which the main materials are beans and their products.			

4.8 Limits of Microorganisms: Indices of Microorganism in powder product should meet the specification of Table 9; Indices of Microorganism in liquid product should meet the requirement of commercial sterilization, and should be tested according to the method specified in GB/T 4789.26.

Table 9 Limits of Microorganisms

Items	Sampling plan [a] and limit (If not specified, it should be expressed in cfu/g or cfu/mL)				Test method
	n	c	m	M	
Total plate count [b]	5	2	1000	10000	GB 4789.2
Coliform bacteria	5	2	10	100	GB 4789.3 plate count
Salmonella	5	0	0/25g	—	GB 4789.4
a. the sample is analysed and processed according to GB 4789.1 and GB 4789.18. b. Not applicable to products supplemented with active bacteria (aerobic and combined-anaerobic probiotics) [viable count of active probiotic bacteria $\geqslant 10^6$ CFU/ g (mL)].					

4.9 Food additives and Nutrition enhancers

4.9.1 The quality of food additives and nutrition enhancers should comply with appropriate safety standards and/or relevant regulations.

4.9.2 The use of food additives and nutrition enhancers should comply with the requirements of GB 2760 and GB 14880.

4.10 Activity of Urease: The activity of urease in the products containing soybean component should meet the specification of Table 10.

Table 10 Indices of Urease Activity

Item		Index	Test method
Urease Activity Qualitative detection	≤	Negative	GB/T 5413.31 [a]

[a] The sample volume of liquid products should be calculated based on the content of dry matter.

5 Others

5.1 Labels

5.1.1 The label of older infants and young children formula should be subject to specifications of GB 13432. In addition, nutrients and optional components content per 100kJ should be also claimed.

5.1.2 On the label, product category and type of the older infants formula and older infants and young children formula (eg. Milk-based and/or Soy-based product and its state), as well as applicable infant age should be indicated. Label of the older infants formula should be indicated with “supplementary foods should also be used”.

5.2 Direction for use

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

5.2.2 The directions indicated should cover warning on the hazard to health resulting from incorrect preparation or application.

5.3 Packaging

Food grade or ⩾99.9%carbon dioxide and/or nitrogen may be used as packaging medium.