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## **China - Peoples Republic of**

**Post:** Beijing

### **National Dairy Standard - Follow-up Formulas**

**Report Categories:**

FAIRS Subject Report

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**Report Highlights:**

On November 20, 2009, China notified the WTO of "National Food Safety Standard of the People's Republic of China for Follow-up Formulas" as SPS/N/CHN/138. This standard relates to the quality specifications of these milk products. The date for submission of final comments to the WTO is January 1, 2010. The proposed date of entry into force has not been specified.

**Executive Summary:**

On November 20, 2009, China notified the WTO of "National Food Safety Standard of the People's Republic of China for Follow-up Formulas" as SPS/N/CHN/138. This standard relates to the quality specifications of these milk products. The date for submission of final comments to the WTO is January 1, 2010. The proposed date of entry into force has not been specified.

According to the WTO notification, "This standard applies to the production, circulation, monitoring

of management of follow-up formulas, and specifies requirements, testing methods, labeling, packaging and storage for follow-up formulas intended for infants and young children aged from six months to 36 months.”

Thanks go to the consortium of industry and 3<sup>rd</sup> country Embassies in Beijing for their assistance in translating and reviewing this standard.

This report contains an UNOFFICIAL translation of National Standard on Follow-up formulas.

### **General Information:**

BEGIN TRANSLATION

ICS 67.040

X 82

GB National Food Safety Standard

GB 10767—xxxx

Replacing GB10767-1997, GB10769-1997, GB10770-1997

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### **Follow-up Formulas**

Issued on xx-xx-xxxx

Implemented on xx-xx-xxxx

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

### **Foreword**

This standard is modified in relation to CODEX Standard 156-1987 (Revision 1989) (Codex Standard for Follow-Up Infant Formulas) formulated by Codex Alimentarius Commission and by reference to Chinese Dietary Reference Intakes compiled by Chinese Nutrition Society in 2000.

This Standard is an integration and amendment to 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). This Standard replaces GB10767-1997, GB 10769-1997 and GB 10770-1997.

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 “Follow-up infant formula and young children formula (for 6 - 36 months old)”

—— 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.

## 1 Scope

This Standard specifies the technical requirements, inspection method, labels and packaging of follow-up formulas of 6-36 months olds.

This Standard applies to production, circulation and, supervision and administration of follow-up formulas.

## 2 Normative References

The following standards contain provisions which, through reference in this text, constitute provisions of this present standard. Note: As for the dated references, all the amendments or revisions after them except the corrigenda are not applicable to this present standard. However, parties to agreements based on this present national standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. As for the references that are not dated, their most recent editions are applicable to this present national standard.

GB 2760 Hygienic Standards for Uses of Food Additives

GB 4789.1 Microbiological Examination of Food Hygiene – General Principles

GB 4789.2 Microbiological examination of food hygiene – Detection of Total Colony Count

GB 4789.3 Microbiological examination of food hygiene – Detection of Coliform Bacteria

GB 4789.4 Microbiological examination of food hygiene – Examination of Salmonella

GB 4789.26 Microbiological examination of food hygiene - Examination of commercial sterilization of canned food

GB 5009.1 Methods of Food Hygienic Analysis – Physical and Chemical Section – General Principles

GB 5009.3 Determination of moisture in Foods

GB 5009.4 Determination of ash in Foods

GB 5009.5 Determination of protein in Foods

GB 5009.12 Determination of Lead in Foods

GB 5009.24 Method for Determination of Aflatoxins M<sub>1</sub> and B<sub>1</sub> in Foods

- GB 5009.33 Determination of nitrate and nitrite in Foods
- GB 5009.93 Determination of Selenium
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of Fatty Acid
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of Fat
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of Fatty Acid
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of Insoluble Dietary Fiber
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of vitamin A, D, E content
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of vitamin K<sub>1</sub> content
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of vitamin B<sub>1</sub> content
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of vitamin B<sub>2</sub> content
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of vitamin B<sub>6</sub> content
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of vitamin B<sub>12</sub> content
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of niacin and niacinamide
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of folic acid (folate activity)
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of pantothenic acid
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of vitamin C content
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of free biotin content
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of choline content
- GB xxxx Milk Powder and Formula Foods for Infants and young children--Determination of calcium, iron, zinc, sodium, potassium, magnesium, copper and manganese
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of phosphorus
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of

iodine content

GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of chlorine

GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of Inositol

GB xxxx Milk powder and formula foods for infants and young children--Determination of taurine content

GB xxxx Milk Powder and Formula Foods for Infants and young children - Determination of Urease

GB xxxx Milk Powder and Formula Foods for Infants and young children - Determination of L-carnitine

GB 10765 Infant formula

GB 13432 General standard for the Labeling of Prepackaged Foods for Special Dietary Uses.

GB 14880 Hygienic Standard for the Use of Nutritional Fortification Substances in Foods

### **3 Terms and Definitions**

The following terms and definitions are applicable to this Standard.

#### **3.1 Older infants**

Older infants refer to persons 6 to 12 months old.

#### **3.2 Young children**

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

#### **3.3 Follow-up formulas:**

Refers 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 follow-up infants and young children of 6 to 36 months old, where the nutrition can satisfy partial requirements normal follow-up infants and young children.

### **4 Requirements**

#### **4.1 Requirements for Raw Materials**

4.1.1 The raw and supplementary materials for follow-up formulas should comply with the related national or trade standards or regulations. Non-desalted whey powders should NOT be used. Raw materials, supplementary materials and food additives

adopted should NOT contain gluten.

4.1.2 Hydrogenated oil and fat should NOT be used in follow-up formulas.

4.1.3 Raw and supplementary materials treated by irradiation should NOT be used in follow-up formulas.

4.2 Sensory requirement

The color, flavor, smell, structure, and fast dissolvability of the product should meet the requirement on the quality of related products.

4.3 Essential components

4.3.1 All ingredients in follow-up formulas should be fit for feeding of infants, and all essential components should be necessary for growth and development of infants.

4.3.2 Necessary ingredients contained per 100kJ (100kcal) follow-up formulas after being mixed or in ready formulas must comply with this standard.

4.3.3 The energy in the ready-to-eat follow-up formulas per 100ml should be within the range of 250 kJ (60 kcal)~ 335 kJ (85 kcal).

4.3.4 Protein and fat content in follow-up formula should meet the requirement in Table 1.

Table 1 Index of Protein and Fat

Nutrient	Unit	Per 100 kJ		Per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
Protein <sup>2)</sup>	g	0.7	1.2	3.0	5.0
Fat in which: linoleic acid	g	0.7	1.4	3.0	6.0
	g	0.07	NS <sup>1)</sup>	0.3	...NS <sup>1)</sup>

<sup>1)</sup> N.S.: No specification

<sup>2)</sup> For infant formulas based on milk protein and its processed products, the content of protein should be calculated as nitrogen (N) × 6.25; for infant formulas based on beans and their processed products, the content of protein should be calculated as nitrogen (N) × 5.71.

4.3.5 Vitamins

Vitamin content in follow-up formulas should meet the specification in Table 2.

Table 2 Index of Vitamins

Nutrient	Unit	Per 100 kJ		Per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
Vitamin A	µg RE <sup>1)</sup> )	18	54	75	225
Vitamin D <sup>2)</sup> )	µg	0.25	0.75	1	3
Vitamin E	mg α-TE <sup>3)</sup> )	0.15	NS <sup>7)</sup>	0.7	NS <sup>7)</sup>
Vitamin K	µg	1	NS <sup>7)</sup>	4	NS <sup>7)</sup>
Vitamin B <sub>1</sub>	µg	11	NS <sup>7)</sup>	46	NS <sup>7)</sup>
Vitamin B <sub>2</sub>	µg	11	NS <sup>7)</sup>	46	NS <sup>7)</sup>
Niacin or niacinamide <sup>4)</sup> )	µg	110	NS <sup>7)</sup>	460	NS <sup>7)</sup>
Vitamin B <sub>6</sub>	µg	11	NS <sup>7)</sup>	46	NS <sup>7)</sup>
Vitamin B <sub>12</sub>	µg	0.04	NS <sup>7)</sup>	0.15	NS <sup>7)</sup>
Pantothenic acid	µg	70	NS <sup>7)</sup>	300	NS <sup>7)</sup>
Folic acid	µg	1	NS <sup>7)</sup>	4	NS <sup>7)</sup>
Vitamin C <sup>5)</sup> )	mg	1.8	NS <sup>7)</sup>	8	NS <sup>7)</sup>
Biotin	µg	0.4	NS <sup>7)</sup>	1.5	NS <sup>7)</sup>

<sup>1</sup>) RE is retinol equivalent. 1 µg RE=3.33 IU A=1µg All trans retinol (Vitamin A).

Ingredients of Vitamin A shall come from preformed retinol. When calculating or claiming activities of Vitamin A, no carotenoids ingredient shall be included.

<sup>2</sup>) Calciferol, 1µg Calciferol = 40 IU Vitamin D.

<sup>3</sup>) 1 mg α-TE (α-tocopherol equivalent)=1 mg d-α-tocopherol.

<sup>4</sup>) The content of Vitamin E 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).

<sup>5</sup>) Niacin: excludes precursor form.

<sup>6</sup>) Expressed as ascorbic acid.

<sup>7</sup>) NS: No specification

#### 4.3.6 Minerals

The indices of minerals in follow-up formula should meet the specification of Table 3.

Table 3 Index of Minerals

Nutrient	Unit	Per 100 kJ		Per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
Sodium	mg	NS <sup>1</sup> )	20	NS <sup>1</sup> )	85
Potassium	mg	18	69	77	288
Chloride	mg	NS <sup>1</sup> )	52	NS <sup>1</sup> )	<sup>215</sup>
Calcium	mg	17	NS <sup>1</sup> )	70	NS <sup>1</sup> )
Phosphorus	mg	8.3	NS <sup>1</sup> )	35	NS <sup>1</sup> )
Calcium / phosphorus ratio		1.2:1	2:1	1.2:1	2:1
Magnesium	mg	1.4	NS <sup>1</sup> )	6	NS <sup>1</sup> )
Iron	mg	0.25	0.50	1	2
Zinc	mg	0.1	0.3	0.6	1.4
Iodine	µg	1.4	NS <sup>1</sup> )	6	NS <sup>1</sup> )
Copper <sup>1</sup> )	µg	7	35	31	144



<sup>1)</sup> NS: No specification

#### 4.4 Optional components

4.4.1 One or more optional components as shown in Table 4 can be added to follow-up formulas, whereas the content should meet the specification of Table 4.

Table 4 Index of Optional Components

Optional Components	Unit	Per 100 kJ		Per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
Selenium	µg	0.48	1.9	2	8
Manganese	µg	0.25	24	1	100
Taurine	mg	NS <sup>1)</sup>	3	NS <sup>1)</sup>	12
Choline	mg	1.7	12	7.0	50
Inositol	mg	1.0	9.5	4.0	40
L-Carnitine	mg	0.3	NS <sup>1)</sup>	1.2	NS <sup>1)</sup>
Docosahexaenoic acid	% total fatty acid <sup>2)</sup>		0.5		0.5
Arachidonic acid	% total fatty acid <sup>2)</sup>		1		1

1) NS: No specification.  
2) During calculation of total fatty acid, C4 ~ C24 fatty acid should be involved.

4.4.2 Besides the essential components specified in 4.3 and optional components specified in 4.4.1, other nutrients can also be added to follow-up formulas, whereas such nutrients should comply with related regulations of China.

#### 4.5 Nutrient compounds

Source of the nutrient compounds that can be used in follow-up formulas should comply with GB14880.

#### 4.6 Food Additives

Food additives that can be used in follow-up formulas should comply with GB 2760.

#### 4.7 Other indices

Other indices for follow-up formulas should comply with Table 5

Table 5 Other Index (calculated based on dry matter)

Item	Index
Ash, <sup>1)</sup>	
Milk based products, % ≤	3.5
Bean based products, milk and bean based products, % ≤	5.0
Water content <sup>5)</sup> , % ≤	5
Impurities <sup>2)</sup>	
Powder product, mg/kg ≤	12
Liquid product, mg/kg ≤	2
1 ) Only for powder products.	
2 ) NOT applicable to products supplemented with fruits and vegetables.	

#### 4.8 Hygienic requirements

##### 4.8.1 Indices of contaminants

Index of contaminants in follow-up formula should meet the specification of Table 6.

Table 6 Index of contaminants (calculated based on dry matter)

Item	Index
Lead, mg/kg ≤	0.15
Nitrate (based on NaNO <sub>3</sub> ) <sup>①</sup> , mg/kg ≤	100
Nitrite (based on NaNO <sub>2</sub> ) <sup>②</sup> , mg/kg ≤	2
Aflatoxin M <sub>1</sub> or Aflatoxin B <sub>1</sub> <sup>③</sup> , µg/kg ≤	0.5
① NOT applicable to products supplemented with fruits and vegetables. ② Determination of nitrite is not necessary for bean-based products. ③ The index of Aflatoxin M <sub>1</sub> is applicable to products of which the main materials are cow's (or other animals') milk and its products; the index of Aflatoxin B <sub>1</sub> is applicable to products of which the main materials are beans and their products; the indices of Aflatoxin M <sub>1</sub> and Aflatoxin B <sub>1</sub> are applicable to products of which the main materials are cow's (or other animals') milk and its products, and beans and their products.	

##### 4.8.2 Indices of Microorganisms

Indices of Microorganism in follow-up formulas should meet the specification of Table 7; the liquid follow-up formulas should meet the requirement of commercial sterilization.

Table 7 Index of Microorganisms

Microorganism	Sampling plan <sup>a</sup> and limit (If not specified, it should be expressed in cfu/g)			
	n	c	m	M
Total colony count	5	2	1000	10000

<sup>b</sup>				
Coliform bacteria	5	2	10	100
Salmonella	5	0	0/25g	-
a. Subject to 4.2.1 of GB 4789.1				
b. Not applicable to follow-up formulas supplemented with probiotic bacteria.				

#### 4.8.3 Urease

The activity of urease is ONLY for bean-based product. The result of qualitative detection should be negative, and that of the quantitative detection should be less than 0.02 U/g.

### 5 Inspection method

#### 5.1 Energy density

The determined values of protein and fat and the calculated value of carbohydrate multiply the energy factor, 17 kJ/g, 37 kJ/g, and 17 kJ/g respectively, and the sum is the value in kilo Joule per 100 g (kJ/100g); or the determined values of protein and fat and the calculated value of carbohydrate multiply the energy factor, 4 kcal/g, 9 kcal/g, and 4 kcal/g respectively, and the sum is the value in kilo calorie per 100 g (kcal/100g).

#### 5.2 Protein

Determine according to the method specified in GB 5009.5.

#### 5.3 Fat

Determine according to the method specified in GB xxxx.

#### 5.4 Linoleic acid, Docosahexaenoic acid, and Arachidonic acid

Determine according to the method specified in GB xxxx.

#### 5.5 Carbohydrates

The mass fraction  $A_1$  of carbohydrate is calculated as per formula (1):

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

Where,

$A_1$ — Mass fraction of carbohydrate, %;

$A_2$ — Mass fraction of Protein, %;

$A_3$ — Mass fraction of Fat, %;

$A_4$ — Mass fraction of Moisture, %;

$A_5$ — Mass fraction of Ash, %;

$A_6$ — Mass fraction of insoluble dietary fiber, %.

- 5.6 Insoluble dietary fiber
  - Determine according to the method specified in GB xxxx.
- 5.7 Vitamin A, D, and E
  - Determine according to the method specified in GB xxxx.
- 5.8 Vitamin K
  - Determine according to the method specified in GB xxxx.
- 5.9 Vitamin B<sub>1</sub>
  - Determine according to the method specified in GB xxxx.
- 5.10 Vitamin B<sub>2</sub>
  - Determine according to the method specified in GB xxxx.
- 5.11 Niacin and niacinamide
  - Determine according to the method specified in GB xxxx.
- 5.12 Vitamin B<sub>6</sub>
  - Determine according to the method specified in GB xxxx.
- 5.13 Vitamin B<sub>12</sub>
  - Determine according to the method specified in GB xxxx.
- 5.14 Pantothenic acid
  - Determine according to the method specified in GB xxxx.
- 5.15 Folic acid
  - Determine according to the method specified in GB xxxx.
- 5.16 Vitamin C
  - Determine according to the method specified in GB xxxx.
- 5.17 Biotin
  - Determine according to the method specified in GB xxxx.
- 5.18 Calcium, magnesium, sodium, potassium, iron, zinc, manganese and copper
  - Determine according to the method specified in GB xxxx.
- 5.19 Phosphorus
  - Determine according to the method specified in GB xxxx.
- 5.20 Chlorine
  - Determine according to the method specified in GB xxxx.
- 5.21 Iodine
  - Determine according to the method specified in GB xxxx.

5.22 Selenium

Determine according to the method specified in GB xxxx.

5.23 Choline

Determine according to the method specified in GB xxxx.

5.24 Inositol

Determine according to the method specified in GB xxxx.

5.25 L-Carnitine

Determine according to the method specified in GB 17787.

5.26 Taurine

Determine according to the method specified in GB xxxx.

5.27 Moisture

Determine according to the method specified in GB 5009.3.

5.28 Ash

Determine according to the method specified in GB 5009.4.

5.29 Impurities

Determine according to the method specified in GB xxxx.

5.30 Lead

Determine according to the method specified in GB 5009.11.

5.31 Nitrate/nitrite

Determine according to the method specified in GB 5009.33.

5.32 Urease activity

Determine according to the method specified in GB xxxx.

5.33 Aflatoxins M<sub>1</sub> and B<sub>1</sub>

Determine according to the method specified in GB 5009.24.

5.34 Commercial sterilization

Determine according to the method specified in GB 4789.26.

5.35 Colony count

Determine according to the method specified in GB 4789.2.

5.36 Coliform Bacteria

Determine according to the method specified in GB 4789.3.

5.37 Salmonella

Determine according to the method specified in GB 4789.4

## **6 Labeling, packaging, transportation and storage**

### **6.1 Labels**

6.1.1 Contents indicated on the label should be subject to specifications of GB 13432. In addition, nutrients and optional components should be labeled as “content per 100 kJ or 100 kcal”.

6.1.2 On the label, product category and applicable infant age should be indicated. Label of the formula for follow-up infants should be indicated with “supplementary foods should also be used”.

#### **6.1.3 Direction for use**

6.1.1.1 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<sup>2</sup> or if the quality of product is less than 100 g, illustration is not necessary.

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

### **6.2 Packaging**

6.2.1 Containers and packaging materials of the products should meet the requirement of the related national standards.

6.2.2 Packages should be completely sealed; Carbon dioxide and/or nitrogen may serve as packaging medium.

6.2.3 Under normal conditions, packages used should not break or be contaminated.