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## **China - Peoples Republic of**

**Post:** Beijing

### **China Notifies Measure on Infant Formula for Young Infants (as SPS 1082)**

**Report Categories:**

FAIRS Subject Report

**Approved By:**

Michael Ward

**Prepared By:**

Abraham Inouye

**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/1082 specifically concerning the technical requirements for infant formula intended for infants aged 0-6 months old. This revision will replace existing GB 10765-2010 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/1082, specifically concerning the technical requirements for infant formula intended for infants aged 0 – 6 months. This revision will replace existing GB 10765-2010 once it enters into force.

This notified measure contains a number of revisions to the existing standard, including an adjustment to the scope, modifications to the terms and definitions, adjustments and additions to the maximum and minimum values for some nutrients, addition of requirements on certain minerals in soy-based formula, revision to the choline requirement, updates to the contents of Appendix A and B, and updates to the testing methods.

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](mailto:sps@aqsiq.gov.cn) by November 11, 2018. There is currently no proposed date of enforcement.

Note, the table on pages 13 and 15 is intended to be printed on Legal size paper (8.5” x 14”).

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

– BEGIN TRANSLATION –



The National Standard of People's Republic of China

GB 10765—201X

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## **National Food Safety Standard**

### **Infant Formula**

(Consultation)

Issued on xx-xx-201x

Implemented on xx-xx-201x

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Issued by the National Health Commission of the People's Republic of China and  
State Administration for Market Regulation

## **Foreword**

The Standard replaces GB 10765-2010 (the National Food Safety Standard Infant Formula). When compared with GB 10765-2010, the Standard mainly has following changes:

- Description of the scope is adjusted.
- Terms and definitions are modified.
- The maximum and minimum values for some nutrients are adjusted or added.
- Requirements on iron, zinc and phosphorus content in soy-based infant formula are added.
- “Optional ingredient” is changed into “essential ingredient” for choline.
- Content in Appendix A and B is adjusted.
- The test methods are updated.

## National Food Safety Standard Infant Formula

### 1 Scope

The Standard applies to infant formulas for infants aged 0 ~ 6 months.

### 2 Terms and Definitions

#### 2.1 Infant Formula

Infant formula refers to formula food fit for normal infants, whose energy and nutrients can meet normal nutrient demands of infants aged 0 ~ 6 months.

2.1.1 Milk-based infant 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.

2.1.2 Soy-based infant 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 demand for nutrient for infants, and materials which will cause harm to nutrition and health for 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 infant formulas 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 infants.

3.3.2 Energy contained in every 100 ml ready-to-eat products shall be within the scope of 250 kJ

(60 kcal)~295 kJ (70 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 infant formula, lactose is the first choice for the source of carbohydrates (the proportion of lactose in total carbohydrates shall be  $\geq 90\%$  ), glucose polymer can be added as appropriate (among which starch may be added 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 <sup>a</sup>					
Milk-based infant formula/(g)	0.43	0.72	1.8	3.0	GB 5009.5
Soy-based infant formula /(g)	0.53	0.72	2.2	3.0	
Fat <sup>b</sup> /(g)	1.05	1.43	4.4	6.0	GB 5009.6
Among which: linoleic acid /(g)	0.07	0.33	0.3	1.4	GB 5009.168
$\alpha$ -linolenic acid /(mg)	12	N.S. <sup>c</sup>	50	N.S. <sup>c</sup>	
Ratio of linoleic acid to $\alpha$ -linolenic acid	5:1	15:1	5:1	15:1	—
Carbohydrate <sup>d</sup> , /(g)	2.2	3.3	9.0	14.0	—

<sup>a</sup> Protein content shall be calculated based on Nitrogen (N)  $\times$  6.25; lactalbumin content in milk-based infant formula shall be  $\geq$ 60% (be calculated on the basis of the quantity of added materials); to improve the quality or nutrient value of protein in infant 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.

<sup>b</sup> In the final products, the total quantity of lauric acid and myristic acid (tetradecanoic acid)  $\leq$  20% of total fatty acids; trans fat content  $\leq$  3% of total fatty acids; erucic acid content  $\leq$  1% of total fatty acids; total fatty acids refer to the total of C4~C24 aliphatic acids.

<sup>c</sup> N.S. No special description.

<sup>d</sup> 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<sub>1</sub>——carbohydrate content, g/100g;  
A<sub>2</sub>——protein content, g/100g;  
A<sub>3</sub>——fat content, g/100g;  
A<sub>4</sub>——water content, g/100g;  
A<sub>5</sub>——ash content, g/100g;  
A<sub>6</sub>——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/( $\mu\text{g RE}$ ) <sup>a</sup>	14	36	60	150	GB 5009.82
Vitamin D/( $\mu\text{g}$ ) <sup>b</sup>	0.48	1.20	2.0	5.0	
Vitamin E/(mg $\alpha$ -TE) <sup>c</sup>	0.12	1.20	0.5	5.0	
Vitamin K <sub>1</sub> /( $\mu\text{g}$ )	0.96	6.45	4.0	27.0	GB 5009.158
Vitamin B <sub>1</sub> /( $\mu\text{g}$ )	14	72	60	300	GB 5009.84
Vitamin B <sub>2</sub> /( $\mu\text{g}$ )	19	120	80	500	GB 5009.85
Vitamin B <sub>6</sub> /( $\mu\text{g}$ )	8.4	41.8	35	175	GB 5009.154
Vitamin B <sub>12</sub> /( $\mu\text{g}$ )	0.024	0.359	0.10	1.50	GB 5413.14
Nicotinic acid (nicotinamide) <sup>d</sup> /( $\mu\text{g}$ )	96	359	400	1500	GB 5009.89
folic acid /( $\mu\text{g}$ )	2.9	12.0	12	50	GB 5009.211
pantothenic acid /( $\mu\text{g}$ )	96	478	400	2000	GB 5009.210
Vitamin C/(mg)	2.4	16.7	10	70	GB 5413.18
Biotin /( $\mu\text{g}$ )	0.36	2.39	1.5	10.0	GB 5009.259
Choline /(mg)	4.8	23.9	20	100	GB 5413.20

<sup>a</sup> RE is retinol equivalent. 1 $\mu\text{g RE}$ =1 $\mu\text{g}$  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.

<sup>b</sup> Calciferol, 1 $\mu\text{g}$  vitamin D=40 IU vitamin D.

<sup>c</sup> 1 mg d- $\alpha$ - tocopherol =1 mg $\alpha$ -TE ( $\alpha$ - tocopherol equivalent) ; 1 mg dl- $\alpha$ - tocopherol =0.74 mg $\alpha$ -TE ( $\alpha$ - tocopherol equivalent) .

<sup>d</sup> 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)	7	14	30	59	GB 5009.91
Potassium/(mg)	17	43	70	180	GB5009.268
Copper/( $\mu\text{g}$ )	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) Milk-based	0.10	0.36	0.42	1.50	GB 5009.90



Soy-based	0.15	0.36	0.63	1.50	GB5009.268
Zinc/(mg)					
Milk-based	0.12	0.36	0.50	1.50	GB 5009.14 GB5009.268
Soy-based	0.18	0.36	0.75	1.50	
Manganese /(μg)	0.72	23.90	3.0	100.0	GB 5009.242 GB5009.268
Calcium/(mg)	12	35	50	146	GB 5009.92 GB5009.268
Phosphorus/(mg)					GB 5009.87
Milk-based	6	24	25	100	GB5009.268
Soy-based	7	24	30	100	
Ratio of calcium to phosphorus	1:1	2:1	1:1	2:1	—
Iodine/(μg)	3.6	14.1	15	59	GB 5009.267
Chlorine /(mg)	12	38	50	159	GB 5009.44
Selenium/(μg)	0.72	1.91	3.0	8.0	GB 5009.93 GB5009.268

### 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	1.5	1.3	6.3	GB 29989
Docosahexenoic acid (DHA) <sup>a</sup> /(mg)	3.6	9.6	15	40	GB 5009.168
Eicosatetraenoic acid (AA/ARA) /(mg)	N.S. <sup>b</sup>	19.1	N.S. <sup>b</sup>	80	GB 5009. 168

<sup>a</sup> If docosahexenoic acid (22:6 n-3) is added in infant formulas, at least the same quantity of eicosatetraenoic acid (20:4 n-6) shall be added. The quantity of eicosapentaenoic acid (20:5 n-3) shall not exceed that of docosahexenoic acid.

<sup>b</sup> N.S. No special description.

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

**Table 5 Other Indexes**

Item		Inde	Test method
Water/(%) <sup>a</sup>	≤	5.0	GB 5009.3
Ash			
Milk-based solid product/(%)	≤	4.0	GB 5009.4
Milk-based liquid product(calculated on the basis of total	≤	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 infant formula)			
Solid product/(mg/kg)	≤	12	GB 5413.30
Liquid product/(mg/kg)	≤	2	
<sup>a</sup> 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: 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	Sampling plan <sup>a</sup> 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 <sup>b</sup>	5	2	1000	10000	GB 4789.2
Coli group	5	2	10	100	GB 4789.3 plate counting method
Staphylococcus aureus	5	2	10	100	GB 4789.10 plate counting method
Enterobacter sakazakii	3	0	0/100g	—	GB 4789.40 qualitative method
Salmonella	5	0	0/25g	—	GB 4789.4
<sup>a</sup> Analysis and treatment for samples are conducted according to GB 4789.1 and GB 4789.18. <sup>b</sup> It is not applicable to products to which active probiotics are added [viable count of each kind of active probiotics shall 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 shall be consistent with corresponding standards and or relevant provisions.

3.10 **Urease activity:** urease activity in soy-based infant formulas 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 <sup>a</sup>
<sup>a</sup> The sampling quantity 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.

4.1.3 Labels of infant formulas shall bear a statement indicating that: “for infants aged 0 ~ 6 months, the ideal food is breast milk, and this product can be used when breast milk is absent or not enough”.

4.1.4 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<sup>2</sup> 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  $\geq 99.9\%$  may serve as packaging medium.

## Appendix A

### (Informative)

#### Recommended Content of Essential and Semi-Essential Amino Acids in Infant Formula

A.1 By referring to data on protein 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 infant 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 infant 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. For results, please see Table A.1. It is recommended that content of essential and semi-essential amino acids contained in infant 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 Acids in Infant Formulas**

Amino Acid	Index	
	mg/g N	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

Note, this table is intended to be printed on Legal size paper (8.5" x 14")

**Annex B  
(Informative)**

**Table B.1 Monomeric Amino Acids Which Can Be Added to Infant Formula<sup>a</sup>**

No.	Amino Acid	Source of Chemical Compound	Chemical Name	Molecular Formula	Molecular Weight	Specific Rotatory Power [α] <sub>D,20°C</sub>	pH	Purity (%) ≥	Water (%) ≤	Ash (%) ≤	Lead (mg/kg) ≤	Arsenic (mg/kg) ≤
1	Cysteine	L- Cystine	L-3,3'- dithiobis(2-aminopropanoic acid)	C <sub>6</sub> H <sub>12</sub> N <sub>2</sub> O <sub>4</sub> S <sub>2</sub>	240.3	-215~-225	5.0~6.5	98.5	0.2	0.1	0.3	0.2
		L-Cysteine	L-α-Amino-β-mercaptopropionic acid	C <sub>3</sub> H <sub>7</sub> NO <sub>2</sub> S	121.16	+8.3~+9.5	4.5~5.5	98.5	0.2	0.1	0.3	0.2
		L-Cysteine hydrochloride monohydrate	L-2-Amino-3-mercaptopropionic acid hydrochloride	C <sub>3</sub> H <sub>7</sub> NO <sub>2</sub> S·HCl·H <sub>2</sub> O	175.63	+5.0~+8.0	-	98.5	0.2	0.1	0.3	0.2
2	Histidine	L- Histidine	α-Aminoβ- propynyl propionic acid	C <sub>6</sub> H <sub>9</sub> N <sub>3</sub> O <sub>2</sub>	155.15	+11.5~+13.5	7.0~8.5	98.5	0.2	0.1	0.3	0.2
		L-Histidine hydrochloride	L-2-Amino-3-propynylpropionic acid hydrochloride imidazolyl	C <sub>6</sub> H <sub>9</sub> N <sub>3</sub> O <sub>2</sub> ·HCl·H <sub>2</sub> O	209.63	+8.5~+10.5	-	98.5	0.2	0.1	0.3	0.2
3	Isoleucine	L- Isoleucine	L-2- Amino -3-methylpentanoic acid	C <sub>6</sub> H <sub>13</sub> NO <sub>2</sub>	131.17	+38.6~+41.5	5.5~7.0	98.5	0.2	0.1	0.3	0.2
4	Leucine	L- Leucine	L-2-Amino-4-methylpentanoic acid	C <sub>6</sub> H <sub>13</sub> NO <sub>2</sub>	131.17	+14.5 ~+16.5	5.5~6.5	98.5	0.2	0.1	0.3	0.2
5	Lysine	L-lysinehydrochloride	L-2,6-Diaminocaproic acid monohydrochloride	C <sub>6</sub> H <sub>14</sub> N <sub>2</sub> O <sub>2</sub> ·HCl	182.65	+20.3~+21.5	5.0~6.0	98.5	0.2	0.1	0.3	0.2
		L-Lysine monoacetate	L-2,6-L-2,6-Diaminocaproic acid monoacetate	C <sub>6</sub> H <sub>14</sub> N <sub>2</sub> O <sub>2</sub> ·C <sub>2</sub> H <sub>4</sub> O <sub>2</sub>	206.24	+8.5~+10.0	6.5~7.5	98.5	0.2	0.1	0.3	0.2

6	Methionine	L- Methionine	2- Amino -4- methionine	C <sub>5</sub> H <sub>11</sub> NO <sub>2</sub> S	149.21	+21.0~+25.0	5.6~6.1	98.5	0.2	0.1	0.3	0.2
		N-Acetyl-L-methionine	N- acetyl -2- Amino -4- methionine	C <sub>7</sub> H <sub>13</sub> NO <sub>3</sub> S	191.25	-18.0~-22.0	-	98.5	0.2	0.1	0.3	0.2
7	Phenylalanine	L- Phenylalanine	L-2- Amino -3- phenylpropionic acid	C <sub>9</sub> H <sub>11</sub> NO <sub>2</sub>	165.19	-33.2~-35.2	5.4~6.0	98.5	0.2	0.1	0.3	0.2
8	Threonine	L- Threonine	2-Amino-3- hydroxybutyric acid	C <sub>4</sub> H <sub>9</sub> NO <sub>3</sub>	119.12	-26.5~-29.0	5.0~6.5	98.5	0.2	0.1	0.3	0.2
9	Tryptophan	L- Tryptophan	L-2-Amino-3-indoly-1- propionic acid	C <sub>11</sub> H <sub>12</sub> N <sub>2</sub> O <sub>2</sub>	204.23	-30.0~-33.0	5.5~7.0	98.5	0.2	0.1	0.3	0.2
10	Tyrosine	L-Tyrosine	(R)-3-Amino-3-(4- hydroxy-phenyl)- propionic acid	C <sub>9</sub> H <sub>11</sub> NO <sub>3</sub>	181.19	-11.0~-12.3	-	98.5	0.2	0.1	0.3	0.2
11	Valine	L-Valine	L-2-Amino--3- methylbutyric acid	C <sub>5</sub> H <sub>11</sub> NO <sub>2</sub>	117.15	+26.7~+29.0	5.5~7.0	98.5	0.2	0.1	0.3	0.2

a Non-edible animal and vegetable materials shall not be used as the source of monomer amino acids. Aqua compounds of above amino acid and their salts may be used as source of the monomer amino acids.