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Prepared By: FAS China Staff

Approved By: Abigail Nguema

Report Highlights:

On September 2, 2025, China published a revised national food safety standard for foods for special medical purposes, which is set to take effect on September 2, 2027. On March 18, 2026, SAMR released a Q&A on product registration under the revised standard to clarify compliance requirements. This report contains a summary of SAMR's clarifications and an unofficial translation of the revised standard. Stakeholders should conduct their own review of the regulations to assess any market or regulatory impacts on their business.

FAS China provides this reporting and analysis as a service to U.S. farmers, ranchers, rural communities, and agribusinesses in support of a worldwide agricultural information system and a level playing field for U.S. agriculture.

Summary:

On September 2, 2025, China published revised National Food Safety Standard General Standard for Foods for Special Medical Purposes (FSMPs) (GB 29922-2025), which is set to take effect on September 2, 2027. The revised standard added new and adjusted existing technical indicators across FSMPs categories.

FSMPs are classified as special dietary foods in China and serve as a means of nutritional supplementation, providing essential nutritional support to target populations who are unable to consume ordinary diets or whose nutritional needs cannot be met through daily meals. Thus, the relevant standards impose strict requirements on various technical parameters, including nutrients, contaminants, and microorganism limits, as specified in the national food safety standards.

This standard applies to FSMPs intended for individuals aged 1 year and older, with definitions, technical indicators, and labeling and packaging requirements. In addition, there are another two mandatory national food safety standards that also regulate FSMPs in China, including:

- National Food Safety Standard Formulas for Special Medical Purposes Intended for Infants (GB25596-2025) that regulates products intended for infants aged 0 to 12 months.

- National Food Safety Standard Good Manufacturing Practice for Foods for Special Medical Purposes (GB29923-2023) (link in Chinese) that applies to the production and sanitation of FSMPs.

Following the release of the revised standard of GB 29922-2025, SAMR released its Announcement of Q&A (link in Chinese) on clarification of several key concerns regarding product registration under the revised standard on March 18, 2026. This Announcement provided guidance on whether products need to submit new application for registration, conditions for on-site verifications, and compliance timelines. The Announcement didn't change the overall regulatory requirements for FSMPs in China.

The key summary of the Q&A section Announcement includes:

- **Compliance Timing for Registration and Production**

  - Applicants may submit product registration or modification applications according to the revised standard immediately after its publication;
  - Manufacturers must produce products according to the revised standard beginning on its implementation date;
  - Products manufactured under the previous standard (GB 29922-2013) may continue to be sold until the end of shelf life.

- Early submission of modification applications is recommended due to review timelines.

- **Registration Modification and New Registration**

  - For registered formula products that only adjust product formulas, label instructions, and product categories, the changes should be handled as modifications;
  - If products adjust formulas together with production processes, resulting in new formulas of the products, applicants should cancel the previous registration and apply for new registration;

- **On-site Inspection and Verification**

  For FSMP products that have already been registered, if the applicant applies under the revised standard (including modifications) and there are no substantive changes to the production processes, on-site production inspections and product sampling tests are typically not required.

- **Registration of Partially Adjusted Nutritionally Complete Formula Foods**

  Since this is a new category under FSMPs in the revised standard, product registration for this category requires applicants to conduct a comprehensive assessment of the product's clinical usage scenarios, target populations, and populations for whom it is unsuitable. Furthermore, applicants must provide the rationale for the adjustments made to the product's energy content and macronutrient profile, the criteria used to define the target and unsuitable populations, and relevant materials regarding clinical use or research. Additionally, appropriate risk warnings must be incorporated into the product's labeling and instructions.

- **Registration for Extensively Hydrolyzed Milk Protein Formulas for Individuals Aged 1 to 10**

  - Extensively hydrolyzed milk protein formulas intended for individuals aged 1 to 10 with food protein allergies require submission of clinical trial data, either for the specific product undergoing registration or for the hydrolyzed protein ingredient utilized;
  - Extensively hydrolyzed milk protein formulas intended for individuals aged 1 to 10 with gastrointestinal dysfunction require submission of clinical evidence based on parameters such as changes in gastrointestinal symptoms.

For more detailed product registration and administrative measures, please refer to Section VII of China's Food and Agricultural Import Regulations and Standards Report. The report also contains an unofficial translation of the revised standard below. Stakeholders should conduct their own review of the regulations to assess any market or regulatory impacts on their business.

BEGIN UNOFFICIAL TRANSLATION

Food Safety National Standard

General Principles for Foods for Special Medical Purposes

Foreword

This Standard replaces GB 29922-2013 Food Safety National Standard General Principles for Foods for Special Medical Purposes.

Compared with GB 29922-2013, the main changes in this Standard are as follows:

- Revision of terms and definitions;
- Revision of descriptions of sensory requirements;
- Revision of raw material requirements;
- Revision of technical requirements for nutrient composition of nutritionally complete formula foods: including addition of product categories, revision of energy calculation requirements, addition of certain optional components, revision of minimum or maximum values of certain nutrients, and updating of test method standard numbers;
- Adjustment of the catalog of specific nutritionally complete formula foods;
- Revision of technical requirements for nutrient composition of nutritionally incomplete formula foods: including addition of product categories and revision of technical indicators of commonly used nutritionally incomplete modules and formula products;
- Reference to general standards for limits of contaminants, mycotoxins, and pathogenic microorganisms;
- Revisions to the appendices: Addition of Appendix A “Partially adjusted nutritionally complete formula foods for population aged 1–10 years” and its technical requirements; revision of Appendix B “Catalog of Common Specific Nutritionally Complete Formula Foods”; and revision of Appendix C “Amino Acids Permitted for Use in Foods for Special Medical Purposes.”

1 Scope

This Standard applies to foods for special medical purposes intended for individuals aged 1 year and older.

2 Terms and Definitions

2.1 Foods for Special Medical Purposes

Formulated foods specially processed and prepared to meet the specific nutritional or dietary needs of individuals with restricted food intake, impaired digestion or absorption, metabolic disorders, or under specific disease conditions. Such products shall be used under the guidance of a physician or clinical nutritionist, either as the sole source of nutrition or in combination with other foods.

2.2 Nutritionally Complete Formula Foods

Foods for Special Medical Purposes (FSMPs) that can serve as a sole source of nutrition for the target population, including nutritionally complete formula foods for individuals aged 1 to 10 years, nutritionally complete formula foods for individuals aged over 10 years, and partially adjusted nutritionally complete formula foods.

2.3 Specific Nutritionally Complete Formula Foods

FSMPs that can serve as the sole source of nutrition to meet the nutritional needs of specific disease or medical conditions.

2.4 Nutritionally Incomplete Formula Foods

FSMP that can meet only part of the nutritional needs of the target population and are not suitable for use as a sole source of nutrition, including non-nutritionally complete components (nutrient modules, thickening modules, dietary fiber modules); non-nutritionally complete formulas (electrolyte formulas, liquid formulas, preoperative carbohydrate formulas, formulas for amino acid metabolism disorders); non-nutritionally complete formulas for specific diseases; and other related categories.

3 Technical Requirements

3.1 General Requirements

3.1.1 Formulations of foods for special medical purposes shall be based on medical and/or nutritional research, and their safety and clinical effectiveness shall be scientifically verified.

3.1.2 Production conditions shall comply with relevant national regulations.

3.2 Raw Material Requirements

3.2.1 Raw materials used shall comply with relevant safety standards and regulations, and substances harmful to human health shall not be used.

3.2.2 Products intended for individuals aged 1 to 10 years shall not use hydrogenated oils.

3.3 Sensory Requirements

Sensory requirements shall comply with Table 1.

Table 1: Sensory Requirements

Item	Requirement	Test Method
Color	Shall conform to product characteristics	Take an appropriate amount of sample in a 50 mL beaker or white porcelain dish, observe color and appearance under natural light, smell the odor, rinse mouth with warm water, and taste it.
Taste and odor	Shall conform to product characteristics	
State	Shall conform to product characteristics and contain no visible foreign object	
Reconstitution	Shall conform to product characteristics	

3.4 Nutritional Components

3.4.1 Nutritionally Complete Formula Foods

3.4.1.1 Nutritionally complete formula foods for individuals aged 1 to 10 years

3.4.1.1.1 For nutritionally complete formula foods intended for individuals aged 1 to 10 years, the energy content per 100 mL (for liquid products or products reconstituted into liquid form, in the ready-to-consume state) or per 100 g (for solid or semi-solid products intended for direct consumption) shall not be less than 250 kJ (60 kcal).

Energy shall be calculated by multiplying the content of protein, fat, carbohydrates, and dietary fiber in each 100 mL or 100 g of product by their respective energy conversion factors such as 17 kJ/g, 37 kJ/g, 17 kJ/g, and 8 kJ/g, and summing the results to obtain the value in kilojoules per 100 mL (kJ/100 mL) or per 100 g (kJ/100 g). This value is then divided by 4.184 to obtain kilocalories per 100 mL (kcal/100 mL) or per 100 g (kcal/100 g).

If other substances contribute 5% or more of the total energy, the substances shall also be included in the total energy calculation.

3.4.1.1.2 For nutritionally complete formula foods intended for individuals aged 1 to 10 years, the protein content shall not be less than 0.5 g/100 kJ (2 g/100 kcal). High-quality protein shall account for no less than 50% of the total protein (not applicable to nutritionally complete formulas based on amino acids). Protein testing methods shall be conducted in accordance with GB 5009.5.

3.4.1.1.3 For nutritionally complete formula foods intended for individuals aged 1 to 10 years, the proportion of energy derived from linoleic acid shall not be less than 2.5%, and the proportion of energy derived from α-linolenic acid shall not be less than 0.4%. Fatty acid testing methods shall be conducted in accordance with GB 5009.168.

3.4.1.1.4 The content of vitamins and minerals in nutritionally complete formula foods intended for individuals aged 1 to 10 years shall comply with the requirements specified in Table 2.

3.4.1.1.5 In addition to the components specified in Table 2, if one or more components listed in Table 3 are optionally added to the product or declared on the label, their contents shall comply with the requirements specified in Table 3.

Table 2: Indicators for Vitamins and Minerals (aged 1 to 10 years)

Nutrient	per 100 kJ		per 100 kcal		Test method
	Minimum value	Maximum value	Minimum value	Maximum value	
Vitamin A (μg RE) [a]	8.4	53.8	35.0	225.0	GB 5009.82
Vitamin D (μg) [b]	0.25	0.75	1.05	3.14	GB 5009.296
Vitamin E/ (mg α-TE) [c]	0.15	N.S.[e]	0.63	N.S.[e]	GB 5009.82
Vitamin K_1 /μg	1	N.S.[e]	4	N.S.[e]	GB 5009.158
Vitamin B_1 /mg	0.01	N.S.[e]	0.05	N.S.[e]	GB 5009.84
Vitamin B_2 /mg	0.01	N.S.[e]	0.05	N.S.[e]	GB 5009.85
Vitamin B_6 /mg	0.01	N.S.[e]	0.05	N.S.[e]	GB 5009.154
Vitamin B_{12} /μg	0.04	N.S.[e]	0.17	N.S.[e]	GB 5009.285
Niacin (Nicotinamide) /mg [d]	0.11	N.S.[e]	0.46	N.S.[e]	GB 5009.89
Folic Acid /μg	1.0	N.S.[e]	4.0	N.S.[e]	GB 5009.211
Pantothenic Acid /mg	0.07	N.S.[e]	0.29	N.S.[e]	GB 5009.210
Vitamin C /mg	1.8	N.S.[e]	7.5	N.S.[e]	GB 5009.86
Biotin /μg	0.4	N.S.[e]	1.7	N.S.[e]	GB 5009.259
Sodium /mg	5	20	21	84	GB 5009.91 / GB 5009.268
Potassium /mg	18	69	75	289	
Copper /μg	7	35	29	146	GB 5009.13 / GB 5009.268
Magnesium /mg	1.4	N.S.[e]	5.9	N.S.[e]	GB 5009.241 / GB 5009.268
Iron /mg	0.25	0.50	1.05	2.09	GB 5009.90

					/ GB 5009.268
Zinc /mg	0.1	0.4	0.4	1.5	GB 5009.14 / GB 5009.268
Manganese /μg	0.3	24.0	1.1	100.4	GB 5009.242 / GB 5009.268
Calcium /mg	17	N.S.[e]	71	N.S.[e]	GB 5009.92 / GB 5009.268
Phosphorus /mg	8.3	46.2	34.7	193.5	GB 5009.87 / GB 5009.268
Iodine /μg	1.4	N.S.[e]	5.9	N.S.[e]	GB 5009.267
Chloride /mg	N.S.[e]	52	N.S.[e]	218	GB 5009.44
Selenium /μg	0.5	2.9	2.0	12.0	GB 5009.93 / GB 5009.268

[a] RE = Retinol Equivalent. 1 μg RE = 3.33 IU Vitamin A = 1 μg all-trans retinol (Vitamin A). Vitamin A only includes preformed retinol, and no carotenoid components are included when calculating or declaring vitamin A activity.
[b] Calciferol, 1 μg Vitamin D = 40 IU Vitamin D.
[c] 1 mg d-α-tocopherol = 1 mg α-TE (alpha-tocopherol equivalent); 1 mg dl-α-tocopherol = 0.74 mg α-TE (alpha-tocopherol equivalent).
[d] Niacin excludes precursor forms.
[e] N.S. means not specified.

Table 3: Optional Components Indicators (Aged 1 to 10 Years)

Optional Component[a]	per 100 kJ		per 100 kcal		Test Method
	Minimum value	Maximum value	Minimum value	Maximum value	
Chromium /μg	0.4	5.7	1.8	24.0	GB 5009.123 / GB 5009.268
Molybdenum /μg	1.2	5.7	5.0	24.0	GB 5009.297 / GB 5009.268
Fluoride /mg	N.S.[b]	0.05	N.S.[b]	0.20	GB 5009.18
Choline /mg	1.7	19.1	7.1	80.0	GB 5413.20
Inositol /mg	1.0	9.5	4.2	39.7	GB 5009.270
Taurine /mg	N.S.[b]	3.1	N.S.[b]	13.0	GB 5009.169
L-Carnitine /mg	0.3	N.S.[b]	1.3	N.S.[b]	GB 5009.300
DHA /mg	N.S.[b]	9.6	N.S.[b]	40.0	GB 5009.168
AA/ARA /mg	N.S.[b]	19.1	N.S.[b]	80.0	
Nucleotides /mg	0.5	N.S.[b]	2.0	N.S.[b]	GB 5413.40
Dietary Fiber /g	N.S.[b]	0.7	N.S.[b]	2.7	GB 5009.88[c]
1,3-dioleoyl-2-palmitoyl glycerol /g	0.12	0.51	0.50	2.14	—
Lutein /μg	8.1	22.5	33.8	94.2	GB 5009.248
Lactoferrin /mg	N.S.[b]	5.3	N.S.[b]	22.3	GB 5009.299
Casein Phosphopeptides /mg	N.S.[b]	16	N.S.[b]	67	—

a. The source of fluoride compounds is sodium fluoride and potassium fluoride.
The sources of nucleotides and dietary fiber shall refer to the permitted sources specified in GB 14880 and relevant national regulations. The addition of other ingredients and the sources of their compounds shall comply with GB 14880 and relevant national regulations.
b. N.S. means not specified.
c. For the addition of soluble dietary fiber, an appropriate test method may be selected.

3.4.1.2 Complete nutritional formula foods for individuals aged 10 years and older

3.4.1.2.1 For complete nutritional formula foods intended for individuals aged 10 years and above, the energy content per 100 mL (for liquid products or products that can be reconstituted into liquid in ready-to-consume form) or per 100 g (for directly consumed solid or semi-solid

products) shall be not less than 295 kJ (70 kcal). The energy shall be calculated as follows: The contents of protein, fat, carbohydrates, and dietary fiber per 100 mL or 100 g of product are multiplied by their respective energy conversion factors of 17 kJ/g, 37 kJ/g, 17 kJ/g, and 8 kJ/g.

The sum of these values is expressed as kJ/100 mL (kJ/100 g) and then divided by 4.184 to obtain the value in kcal/100 mL (kcal/100 g). If other energy-contributing substances account for 5% or more of the total energy, they shall be included in the total energy calculation.

3.4.1.2.2 For complete nutritional formula foods intended for individuals aged 10 years and above, the protein content shall be not less than 0.7 g/100 kJ (3 g/100 kcal). The proportion of high-quality protein shall be not less than 50% (this requirement does not apply to complete nutritional formula foods with amino acids as the protein source). The testing method for protein refers to GB 5009.5.

3.4.1.2.3 For complete nutritional formula foods intended for individuals aged 10 years and above, the energy contribution ratio of α-linolenic acid shall be not less than 0.5% and the energy contribution ratio of linolenic acid shall be not less than 2.0%. The testing method for fatty acid refers to GB 5009.168.

3.4.1.2.4 The content of vitamins and minerals in complete nutritional formula foods intended for individuals aged 10 years and above shall comply with the requirements specified in Table 4.

3.4.1.2.5 In addition to the components specified in Table 4, if one or more components listed in Table 5 are added or declared on the product label, their content shall comply with the requirements specified in Table 5.

Table 4: Vitamins and Minerals Indicators (10 years and older)

Nutrient	per 100 kJ		per 100 kcal		Testing Method
	Minimum	Maximum	Minimum	Maximum	
Vitamin A/ (μg RE) [a]	9.3	53.8	39.0	225.0	GB 5009.82
Vitamin D/ μg [b]	0.19	0.75	0.80	3.14	GB 5009.296
Vitamin E / (mg α-TE) [c]	0.19	N.S. [e]	0.80	N.S. [e]	GB 5009.82
Vitamin K_1 /μg	1.05	N.S. [e]	4.40	N.S. [e]	GB 5009.158
Vitamin B_1 /mg	0.02	N.S. [e]	0.07	N.S. [e]	GB 5009.84
Vitamin B_2 /mg	0.02	N.S. [e]	0.07	N.S. [e]	GB 5009.85
Vitamin B_6 /mg	0.02	N.S. [e]	0.07	N.S. [e]	GB 5009.154
Vitamin B_{12} /μg	0.03	N.S. [e]	0.13	N.S. [e]	GB 5009.285
Niacin /mg [d]	0.05	N.S. [e]	0.20	N.S. [e]	GB 5009.89
Folic Acid /μg	5.3	N.S. [e]	22.2	N.S. [e]	GB 5009.211
Pantothenic Acid /mg	0.07	N.S. [e]	0.29	N.S. [e]	GB 5009.210
Vitamin C /mg	1.3	N.S. [e]	5.6	N.S. [e]	GB 5009.86
Biotin /μg	0.5	N.S. [e]	2.2	N.S. [e]	GB 5009.259
Sodium /mg	14	N.S. [e]	58	N.S. [e]	GB 5009.91 or

Potassium /mg	27	N.S. [e]	111	N.S. [e]	GB 5009.268
Copper /μg	11	120	44	500	GB 5009.13 or GB 5009.268
Magnesium /mg	4.4	N.S. [e]	18.3	N.S. [e]	GB 5009.241 or GB 5009.268
Iron /mg	0.20	0.55	0.83	2.30	GB 5009.90 or GB 5009.268
Zinc /mg	0.1	0.5	0.4	2.2	GB 5009.14 or GB 5009.268
Manganese /μg	6.0	146.0	25.0	611.0	GB 5009.242 or GB 5009.268
Calcium /mg	13	N.S. [e]	56	N.S. [e]	GB 5009.92 or GB 5009.268
Phosphorus /mg	9.6	N.S. [e]	40.0	N.S. [e]	GB 5009.87 or GB 5009.268
Iodine /μg	1.6	N.S. [e]	6.7	N.S. [e]	GB 5009.267
Chlorine /mg	N.S. [e]	52	N.S. [e]	218	GB 5009.44
Selenium /μg	0.8	5.3	3.3	22.2	GB 5009.93 or GB 5009.268

[a] RE stands for Retinol Equivalents. 1 μg RE = 3.33 IU Vitamin A = 1 μg all-trans-retinol (Vitamin A). Vitamin A refers exclusively to preformed retinol; when calculating and making claims regarding Vitamin A activity, no carotenoid components are included.
[b] Calciferol; 1 μg Vitamin D = 40 IU Vitamin D.
[c] 1 mg d-α-tocopherol = 1 mg α-TE (α-Tocopherol Equivalents); 1 mg dl-α-tocopherol = 0.74 mg α-TE (α-Tocopherol Equivalents).
[d] Niacin does not include precursor forms.
[e] N.S. stands for "Not Specified."

Table 5: Optional Components Indicators (10 years and older)

Optional [a] Component	per 100 kJ		per 100 kcal		Testing Method
	Min Value	Max Value	Min Value	Max Value	
Chromium /μg	0.4	13.3	1.8	55.6	GB 5009.123 or GB 5009.268
Molybdenum/μg	1.3	12.0	5.6	50.0	GB 5009.297 or GB 5009.268
Fluoride /mg	N.S. [b]	0.05	N.S. [b]	0.20	GB 5009.18
Choline /mg	5.3	39.8	22.2	166.7	GB 5413.20
Inositol /mg	1.0	33.5	4.2	140.0	GB 5009.270
Taurine /mg	N.S. [b]	4.8	N.S. [b]	20.0	GB 5009.169
L-carnitine /mg	0.3	N.S. [b]	1.3	N.S. [b]	GB 5009.300
Nucleotides /mg	0.5	N.S. [b]	2.0	N.S. [b]	GB 5413.40
EPA/mg + DHA/mg	3.3	26.5	13.9	111.1	GB 5009.168

CaHMB /mg	20	80	83	333	—
Dietary Fiber /g	N.S. [b]	0.7	N.S. [b]	2.7	GB 5009.88 [c]
Lutein /μg	120	526	500	2 200	GB 5009.248

[a] The sources of fluorine compounds shall be sodium fluoride and potassium fluoride. The sources of nucleotides and dietary fiber shall refer to the permitted sources listed in GB 14880, as well as relevant national regulations; the addition of other ingredients and the sources of their compounds shall comply with GB 14880 and relevant national regulations.
[b] N.S. stands for "Not Specified."
[c] For the addition of soluble dietary fiber, appropriate testing methods may be selected.

3.4.1.3 Partially Adjusted Nutritionally Complete Formula Foods

This category of products comprises complete nutritional formula foods in which the energy density and macronutrient composition for the age groups of 1 to 10 years and over 10 years have undergone partial adjustment. Examples include high-fat and low-carbohydrate complete nutritional formula foods; high-protein complete nutritional formula foods; and high-energy-density complete nutritional formula foods. High-fat and low-carbohydrate complete nutritional formula foods are suitable for individuals requiring a high-fat and low-carbohydrate diet, wherein fat contributes ≥40% of the total energy and carbohydrates contribute ≤40%; High-protein complete nutritional formula foods are suitable for individuals requiring a high-protein diet, wherein protein contributes ≥20% of the total energy; High-energy-density complete nutritional formula foods are suitable for individuals requiring a high-energy-density diet: for liquid products or products intended to be reconstituted into liquid form, when in a ready-to-consume state, the energy density must be ≥5.0 kJ/mL (1.2 kcal/mL) for the 1 to 10 years age group, and must be ≥6.28 kJ/mL (1.5 kcal/mL) for the over 10 years age group.

For certain categories of partially adjusted nutritionally complete nutritional formula foods intended for individuals aged 1 to 10, the classification and primary technical requirements shall comply with the provisions set forth in Appendix A of this Standard. For other partially adjusted nutritionally complete nutritional formula foods intended for individuals aged 1 to 10, the indicators for essential fatty acids (linoleic acid and α-linolenic acid), vitamins, minerals, and optional components shall comply with the corresponding technical requirements for complete nutritional formula foods intended for individuals aged 1 to 10.

For partially adjusted nutritionally complete nutritional formula foods intended for individuals aged 10 and above, the indicators for essential fatty acids (linoleic acid and α-linolenic acid), vitamins, minerals, and optional components shall comply with the corresponding technical requirements for complete nutritional formula foods intended for individuals aged 10 and above.

3.4.2 Specific Nutritionally Complete Formula Foods

The energy and nutrient content of specific nutritionally complete formula foods shall be based on the nutritionally complete formula foods defined in 3.4.1.1 or 3.4.1.2; however, appropriate adjustments may be made based on the specific requirements for energy and nutrients necessitated by a particular disease or medical condition, in order to meet the nutritional needs of

the target population. Common specific nutritionally complete formula foods are listed in Appendix B.

3.4.2.1 For nutritional formulas that comply with the requirements of the corresponding standards for specific nutritionally complete formula foods, both their safety and their clinical application (efficacy) for populations with specific diseases or medical conditions shall be scientifically verified.

3.4.2.2 For nutritional formulas for which no standards for specific nutritionally complete formula foods currently exist, the formulation shall be based on the findings of medical and/or nutritional research; furthermore, both its safety and its clinical application (efficacy) for populations with specific diseases or medical conditions shall be scientifically substantiated.

3.4.3 Non-complete Nutritional Formula Foods

3.4.3.1 Common non-complete nutritional formula foods primarily include nutrient modules, thickening modules, dietary fiber modules, electrolyte formulas, liquid formulas, pre-operative carbohydrate formulas, formulas for amino acid metabolic disorders, non-complete nutritional formulas for specific diseases, and others. Products in this category cannot serve as the sole source of nutrition to meet the nutritional requirements of the target population; they must be used in conjunction with other foods.

3.4.3.2 The technical specifications for nutrient modules, thickening modules, and dietary fiber modules shall comply with the requirements in Table 6.

Table 6: Technical Requirements for Common Non-Complete Nutritional Modules

Product Category		Applicable Population with Special Medical Conditions	Main Technical Requirements for Formulas
Nutrient Modules	Protein module	People who need to supplement with protein	1. Composed of protein; 2. Protein source may be one or more high-quality proteins or their full hydrolysates; 3. Protein count for ≥70% of total product (protein content of liquid product should be ≥65% of its total dry matter); amino acid evaluation score must meet high-quality protein requirements.
	Essential amino acid module	People who need to supplement with essential amino acids	Content of essential amino acids should be ≥70% of total product (dry basis); amino acid evaluation score must meet high-quality protein requirements.
	Branched-chain amino acid module	People who need to supplement with BCAAs	Content of BCAAs should be ≥70% of total product (dry basis).

	Arginine module	People who need to supplement with arginine	Content of arginine should be ≥70% of total product (dry basis).
	Glutamine module	People who need to supplement with glutamine	Content of glutamine should be ≥70% of total product (dry basis).
	Amino acid (or peptide) module for metabolic disorders	Individuals with amino acid metabolism disorders require amino acid supplementation.	Except restricted amino acids, composition of other amino acids (especially essential amino acids) must meet high-quality protein requirements; content of amino acids should be ≥70% of total product (dry basis); content of restricted amino acids (refers to single amino acid content) should be ≤1.5 mg/g protein equivalent.
	Fat (fatty acid) module	Individuals requiring supplementation of specific fats (or fatty acids), or those needing to supplement energy through fats (or fatty acids).	1. Composed of fats and/or fatty acids; 2. Medium-chain triglycerides (MCTs), long-chain triglycerides (LCTs), or other sources of fats (fatty acids) approved by relevant laws and regulations may be selected; the fat sources within the fat component shall not include lipids.; 3. Solid-form lipid (fatty acid) components should possess good solubility to facilitate their incorporation with other food products; 4. For fat components intended to meet specific clinical requirements or those designed to address clinical needs for energy supplementation, the composition of the constituent fat (fatty acids) must be appropriate; 5. The composition, proportions, and content of all ingredients must be controlled, for example, the fatty acid profile of medium-chain triglycerides (MCTs) and omega-3 polyunsaturated fatty acids; 6. While the primary constituents of fat modules are fat (fatty acids), other food ingredients or food additives be incorporated to meet processing requirements, the nature of these additional ingredients and any potential impact they may have on the

			application of the fat component must be thoroughly evaluated and stated.
	Carbohydrate module	People needing carbohydrate supplementation	1. Composed of carbohydrates; 2. Sources of carbohydrates may include monosaccharides, disaccharides, oligosaccharides, polysaccharides, maltodextrin, glucose polymers, or other ingredients approved by relevant laws and regulations; 3. Must not contain insoluble dietary fiber.
Thickening module		People with swallowing difficulties	1. Carbohydrates added only for thickening, not for the purposes of nutrition and energy supplements; 2. One or more thickeners may be added; 3. No additional nutrients are allowed in the formula.
Dietary fiber module		People needing dietary fiber	1. Content of dietary fiber should be ≥78% of the product (dry basis); 2. Soluble fiber should be >50% of total fiber.

3.4.3.3 The technical specifications for electrolyte formulas, liquid formulas, pre-operative carbohydrate formulas, and formulas for amino acid metabolic disorders shall comply with the requirements in Table 7.

Table 7: Technical Requirements for Common Non-Complete Nutritional Formula Products

Product Category	Applicable Population with Special Medical Conditions	Main Technical Requirements of Formulas
Electrolyte formula	People needing electrolyte supplementation	1. Based on carbohydrates; 2. Contains appropriate electrolytes.
Liquid formula	People requiring liquid diets and restricted fat intake	1. Based on carbohydrates and protein, fat should not be added for energy and (or) nutritional purposes. 2. Protein sources may include intact protein, protein hydrolysates, amino acids, and peptides; high-quality protein should be no less than 50%. Protein energy ratio should be controlled within 8% to 25%; 3. May add multiple vitamins and minerals; 4. May add dietary fibers.
Preoperative	Pre-surgery patients	1. Based on carbohydrates, the energy scope is

carbohydrate formula		40 kcal/100 mL to 60 kcal/100 mL; 2. May add electrolytes such as sodium, potassium, chloride, calcium, phosphorus, and magnesium; 3. Should not contain dietary fiber; 4. Osmolality of the product in its ready-to-eat state should not exceed 320 mosm/kg.
Amino acid metabolism disorder formula	People with amino acid metabolism disorders	1. Utilizing amino acids and/or peptides as main raw materials, contains none or minimal amount of those amino acids associated with metabolic disorders. Table 8 outlines the specific types and content limits for amino acids that must be restricted in formula foods designed for common amino acid metabolic disorders; 2. With the exception of amino acids subject to restriction, the composition of all other amino acids, particularly essential amino acids must meet standards for high-quality protein; 3. Adding appropriate amounts of fats, carbohydrates, vitamins, minerals, and (or) other components; 4. While satisfying a portion of the patient's protein (amino acid) requirements, it simultaneously meets or partially meets the patient's requirements for vitamins and minerals.

Table 8: Restricted Amino Acids in Common Amino Acid Metabolism Disorder Formulas

Common Amino Acid Metabolism Disorder	Types of Amino Acids to be Restricted in Formula Foods	Amino Acid Content to be Limited in Formula Foods mg/g Protein Equivalent
Phenylketonuria	Phenylalanine	≤ 1.5
Maple Syrup Urine Disease	Leucine, Isoleucine, Valine	≤ 1.5[a]
Propionic acidemia / Methylmalonic acidemia	Methionine, Threonine, Valine	≤ 1.5[a]
	Isoleucine	≤ 5
Tyrosinemia	Phenylalanine, Tyrosine	≤ 1.5[a]
Homocystinuria	Methionine	≤ 1.5
Glutaric acidemia Type I	Lysine	≤ 1.5
	Tryptophan	≤ 8
Isovaleric acidemia	Leucine	≤ 1.5
Urea cycle disorders	Non-essential amino acids (Alanine, Arginine, Aspartic acid, Asparagine, Glutamic acid, Glutamine, Glycine,	≤ 1.5[a]

	Proline, Serine)	
[a] indicates limit applies to each individual amino acid.		

3.4.3.4 Non-complete Nutritional Formula Foods for Specific Diseases

Non-complete nutritional formula foods for specific diseases are designed based on findings from medical and nutritional research and formulated to meet the specific nutritional requirements associated with particular diseases or medical conditions; both their safety and clinical application (efficacy) require scientific validation.

3.4.3.5 Others

This category includes, for example, non-complete nutritional formula foods not intended for specific diseases; the nutritional formulations must be based on findings from clinical medical and nutritional research, and both their safety and clinical application (efficacy) require scientific validation.

3.5 Limits for Contaminants

They shall comply with the provisions of GB 2762.

3.6 Limits for Mycotoxins

They shall comply with the provisions of GB 2761.

3.7 Microbiological Limits

3.7.1 The limits for pathogenic bacteria in solid-form foods for special medical purposes shall comply with the provisions of GB 29921, while other microbiological indicators shall comply with the provisions of Table 9.

3.7.2 Liquid and semi-solid foods for special medical purposes shall meet the requirements for commercial sterilization and shall be tested using the methods specified in GB 4789.26.

Table 9: Microbiological Limits

Item	Sampling Plan [a] and Limits (Unless otherwise specified, all values are expressed in CFU/g or CFU/mL)				Test Method
	n	*c*	*m*	*M*	
Total Plate Count [bcd]	5	2	1 000	10 000	GB 4789.2
Coliforms [d]	5	2	10	100	GB 4789.3 plate count method
[a] Sample analysis and preparation shall be conducted in accordance with GB 4789.1 and GB 4789.18. [b] Not applicable to products containing added active bacterial strains (aerobic and facultative anaerobic bacteria) [where the viable bacterial count in the product should be ≥ 10^6 CFU/g					

(mL)].
[c] Applicable only to products intended for individuals aged 1 to 10 years.
[d] For special matrix foods that cannot meet testing requirements (e.g., thickening components), the reconstituted sample may be used as the original sample for testing.

3.8 Food Additives and Nutritional Fortifiers

3.8.1 For products intended for consumers aged 1 to 3 years, the use of food additives must comply with the requirements of GB 2760 regarding the types and maximum levels of additives permitted in formula foods for young children. For products intended for other target populations, the use of food additives shall comply to the types and maximum levels permitted in identical or similar product categories as specified in GB 2760.

3.8.2 The use of nutritional fortification substances shall comply with the provisions of GB 14880.

3.8.3 The quality specifications of food additives and nutritional fortification substances shall comply with the relevant standards and applicable regulations.

3.8.4 Based on the specific nutritional requirements of the target population, one or more amino acids may be selected for addition to various types of foods for special medical purposes; the sources of such amino acids comply with Appendix C, GB 14880, and relevant regulations.

3.8.5 If active microbial strains and (or) other substances are added to formula foods for special medical purposes, such additions shall comply with relevant national regulations.

4 Others

4.1 Labeling

4.1.1 Product labels shall comply with the provisions of GB 13432. The labeling of nutrient and optional ingredient content shall include an additional indication of the content “per 100 kJ (/100 kJ).”

4.1.2 The label shall describe the product’s formulation characteristics or nutritional profile; if dietary fiber is added to the formula, its type (soluble/insoluble) shall be indicated. Furthermore, the product category and the applicable target population shall be specified, along with a statement indicating that the product “is not intended for use by non-target populations.”

4.1.3 The label shall bear the statement: “Please use under the guidance of a physician or clinical nutritionist.”

4.1.4 The label shall bear the statement: “This product is prohibited for use in parenteral nutrition support or intravenous injection.”

4.1.5 Thickening module product shall indicate the corresponding food classification for swallowing disorders after reconstitution with water, as well as parameters such as the preparation temperature and standing time.

4.1.6 Liquid formulas, electrolyte formulas, pre-operative carbohydrate formulas, and formulas for amino acid metabolism disorders shall indicate the product's osmolality in its ready-to-consume state; other products may optionally indicate this information as appropriate, to facilitate guidance on product usage by physicians or clinical nutritionist.

4.2 Instructions for Use

4.2.1 Instructions regarding product usage, preparation guidance, and storage conditions shall be clearly stated on the label.

4.2.2 The instructions shall include warning statements regarding potential health hazards that may result from improper preparation or improper use.

4.3 Packaging

Carbon dioxide and (or) nitrogen gas that comply with national food safety standards may be used as the packaging medium.

Appendix A

Partially Adjusted Nutritionally Complete Formula Foods for Children Aged 1 to 10 Years

Please see Table A.1 for partially adjusted nutritionally complete formula foods for children aged 1–10 years.

Table A.1: Partially Adjusted Nutritionally Complete Formula Foods for Children Aged 1 to 10 Years

Product Category	Applicable Population with Special Medical Conditions	Main Technical Requirements for the Formula
Extensively Hydrolyzed Milk Protein Formula	Children aged 1 to 10 with food protein allergy or gastrointestinal dysfunction	1. The energy content of the product, in its ready-to-consume state, shall range from 250 kJ (60 kcal) to 502 kJ (120 kcal) per 100 mL; 2. The protein in the formula shall be derived from milk protein; 3. All milk proteins in the formula shall undergo extensive hydrolysis, resulting primarily in their breakdown into short peptides and amino acids; 4. Lactose in the formula may be completely or partially replaced by other utilizable carbohydrates; 5. The specifications for protein, fat, carbohydrates, vitamins and minerals, and optional ingredients shall comply with the technical requirements applicable to nutritionally complete formula foods intended for individuals aged 1 to 10 years.
Amino Acid Formula	Children aged 1 to 10 with food protein allergy or gastrointestinal dysfunction	1. The energy content of the product, in its ready-to-consume state, shall range from 250 kJ (60 kcal) to 502 kJ (120 kcal) per 100 mL; 2. The protein in the formula shall be provided by amino acids; 3. The sources of amino acids used shall comply with the provisions of Appendix C; 4. In the formula, lactose may be completely or partially replaced by other utilizable carbohydrates; 5. The specifications for protein, fat, carbohydrates, vitamins and minerals, and optional ingredients shall comply with the technical requirements applicable to nutritionally complete formula foods intended for individuals aged 1 to 10 years.

Appendix B

Common Specific Nutritionally Complete Formula Foods [1]

B.1 Nutritionally complete formula foods for diabetes.
B.2 Nutritionally complete formula foods for respiratory diseases.
B.3 Nutritionally complete formula foods for renal diseases.
B.4 Nutritionally complete formula foods for oncological diseases.
B.5 Nutritionally complete formula foods for liver diseases.
B.6 Nutritionally complete formula foods for sarcopenia.
B.7 Nutritionally complete formula foods for patients in hypermetabolic stress states (e.g., trauma, surgery).
B.8 Nutritionally complete formula foods for inflammatory bowel disease.
B.9 Nutritionally complete formula foods for gastrointestinal malabsorption and pancreatitis.
B.10 Nutritionally complete formula foods for refractory epilepsy.
B.11 Nutritionally complete formula foods for fatty acid metabolism disorders.
B.12 Nutritionally complete formula foods for obesity and bariatric surgery.
B.13 Others.

[1] The names of specific complete nutritional formula foods shall be in accordance with the names specified in the published National Food Safety Standards.

Appendix C

Amino Acids Permitted for Use in FSMP

Please see Table C.1 for amino acids permitted to be used in FSMP.

Table C.1: Amino Acids Permitted for FSMP [a]

No.	Amino Acid	Permitted Compound Sources
1	Aspartic acid	L-aspartic acid
		L-aspartic acid magnesium
2	Threonine	L-threonine
3	Serine	L-serine
4	Glutamic acid	L-glutamic acid
		L-glutamate potassium monohydrate
		L-glutamate calcium tetrahydrate
5	Glutamine	L-glutamine
6	Proline	L-proline
7	Glycine	Glycine
8	Alanine	L-alanine
9	Cystine	L-cystine
		L-cysteine
		L-cysteine hydrochloride monohydrate
		N-acetyl-L-cysteine
10	Valine	L-valine
11	Methionine	L-methionine
		N-acetyl-L-methionine
12	Leucine	L-leucine
13	Isoleucine	L-isoleucine
14	Tyrosine	L-tyrosine
15	Phenylalanine	L-phenylalanine
16	Lysine	L-lysine hydrochloride
		L-lysine acetate
		L-lysine
		L-lysine-L-glutamate dihydrate
		L-lysine-L-aspartate
17	Arginine	L-arginine
		L-arginine hydrochloride
		L-arginine aspartate
18	Histidine	L-histidine
		L-histidine hydrochloride monohydrate
19	Tryptophan	L-tryptophan
20	Citrulline	L-citrulline
21	Ornithine	L-ornithine hydrochloride

[a] The sources and quality specifications of the amino acid compounds covered by this Standard shall comply with the corresponding standards and relevant regulations.

END UNOFFICIAL TRANSLATION

Attachments:

GB 29922-2025.pdf