

Regulations on Nutrition Labeling for Prepackaged Infant and Follow-up Formula and Formula for Certain Disease

1. This regulation is established under the provisions of Paragraph 3 of Article 22 of the Act Governing Food Safety and Sanitation (hereinafter the “Act”).
2. Matters that are not provided herein shall be governed by the “Regulations on Nutrition Labeling for Prepackaged Food Products.”
3. The nutrition labeling for a prepackaged infant and follow-up formula and formula for certain disease on the market shall provide the following information refer to Appendices 1.1 and 1.2 shown at a conspicuous place of the outer package or container of the product.
 - 3.1 Infant and follow-up formula :
 - 3.1.1 Title of the “Nutrition Facts,”
 - 3.1.2 Contents of energy,
 - 3.1.3 Contents of protein,
 - 3.1.4 Contents of fat, saturated fat, trans fat, linoleic acid, and α -linolenic acid,
 - 3.1.5 Contents of carbohydrate and sugars,

- 3.1.6 Contents of sodium,
- 3.1.7 Contents of water,
- 3.1.8 Contents of vitamins,
- 3.1.9 Contents of choline,
- 3.1.10 Contents of myo-inositol,
- 3.1.11 Contents of L-carnitine,
- 3.1.12 Contents of ash,
- 3.1.13 Contents of minerals (excluding sodium) and trace elements,
- 3.1.14 Contents of other nutrients labeled voluntarily by the manufacturer.

3.2 Formula for certain disease :

- 3.2.1 Title of the “Nutrition Facts,”
- 3.2.2 Contents of energy,
- 3.2.3 Contents of protein,
- 3.2.4 Contents of fat, saturated fat, and trans fat,
- 3.2.5 Contents of carbohydrate and sugars,
- 3.2.6 Contents of sodium,
- 3.2.7 Contents of other nutrients designated by the central

competent authority in a public announcement,

3.2.8 Contents of other nutrients declared in the nutrition claim,

3.2.9 Contents of other nutrients labeled voluntarily by the manufacturer.

Dietary fiber may be labeled under carbohydrate item, indent and after sugar item. Cholesterol may be labeled under fat item, indent and after trans-fat item.

Content of α -linolenic acid, choline, myo-inositol, and L-carnitine may be labeled voluntarily for prepackaged follow-up infant formula on the market.

4. Caloric and nutritional content labeling for prepackaged infant and follow-up formula and formula for certain disease on the market shall be carried out under the following provisions:

4.1 Infant and follow-up formula :

Use “per 100 g (or Kcal)” and “per 100 mL” for labeling.

4.2 Formula for certain disease :

Use “one serving (or per serving)” and “per 100 g (or mL)” for labeling, and the number of servings contained in each package

of the product shall also be specified. Solid (semi-solid) shall be expressed in grams (g); liquid shall be expressed in milliliters (mL). In the case of a product requiring reconstitution, where a nutrition claim is made about the product after reconstitution, the information on nutrition labeling shall be provided accordingly; where no nutrition claim is made, the information on nutrition labeling may be provided for the product either before or after reconstitution.

5. The quantity (weight or volume) of serving size of prepackaged formula for certain disease on the market shall be determined by considering the product consumption method and general amount consumed each time for prepackaged formula for certain disease.
6. Measure units for nutrition labeling of prepackaged infant and follow-up formula and formula for certain disease on the market shall conform to the following regulations:
 - 6.1 Energy content is expressed in kilocalories (Kcal).
 - 6.2 Contents of protein, fat, saturate fat, trans fat, carbohydrate, sugars, dietary fiber, water, and ash are expressed in grams.
 - 6.3 Contents of fatty acids and amino acids are expressed in grams

or milligrams (mg).

6.4 Contents of sodium, cholesterol, choline, myo-inositol, and L-carnitine are expressed in milligrams.

6.5 Contents of vitamins and minerals shall be expressed in appropriate unit in accordance with the Appendix 2 of the “Regulations on Nutrition Labeling for Prepackaged Food Products.” Contents of vitamin B₁, vitamin B₂, and vitamin B₆ may be expressed in micrograms (µg) and niacin shall be expressed in milligrams for prepackaged infant and follow-up formula on the market.

6.6 Contents of other nutrients are expressed using universal units.

7. Data formatting of nutrition labeling of prepackaged infant and follow-up formula and formula for certain disease on the market shall conform to the following regulations:

7.1 Servings per container and sodium content shall be expressed in whole numbers.

7.2 Serving size, energy, protein, amino acid, fat, saturate fat, trans fat, fatty acid, cholesterol, carbohydrate, sugar, dietary fiber, water, ash, choline, myo-inositol, and L-carnitine contents shall

be expressed in whole numbers or to one decimal place. Energy, protein, fat, saturate fat, trans fat, carbohydrate and sugar contents may be expressed to two decimal places when the serving size is too small to meet the criteria of labeling as “0.”

7.3 Contents of vitamins and minerals shall be expressed with no more than three significant figures.

7.4 Contents of other nutrients shall be expressed in whole numbers or to one decimal place.

7.5 Data formatting shall refer to the Chinese National Standard CNS 2925 “Practices for Designating Significant Places in Specific Limiting Values.”

8. The values on the nutritional labels of prepackaged infant and follow-up formula and formula for certain disease on the market must be derived from actual test analysis or calculations, and the range of allowable error shall meet the criteria in Appendices 2.1 and 2.2.

Appendix 1.1 Nutrition labeling format for prepackaged infant and follow-up formula^a

Nutrition Facts		
	Per 100 g (or per 100 Kcal)	per 100 mL
Energy	Kcal	Kcal
Protein	g	g
Fat	g	g
Saturated fat	g	g
Trans fat	g	g
Linoleic acid	g or mg	g or mg
α -Linolenic acid ^b	g or mg	g or mg
Carbohydrate	g	g
Sugars	g	g
Sodium	mg	mg
Water	g	g
Vitamins	mg or μg^c	mg or μg^c
Choline ^b	mg	mg
Myo-Inositol ^b	mg	mg
L-Carnitine ^b	mg	mg
Ash	g	g

Minerals (excluding sodium) and Trace Elements	mg or µg	mg or µg
Other nutritional contents labeled voluntarily by the manufacturer	g, mg, or µg	g, mg, or µg

^aNutrition labeling on surface areas smaller than 100 cm² may conform to the following horizontal format, placing labels at a prominent place on the package container:

Nutrition Facts
Per 100 g or 100 Kcal (100 mL): Energy○Kcal (○Kcal), Protein○g (○g), Fat○g (○g), Saturated fat○g (○g), Trans fat○g (○g), Linoleic acid○g or mg (○g or mg), α-Linolenic acid ^b ○g or mg (○g or mg), Carbohydrate○g (○g), Sugars○g (○g), Sodium○mg (○mg), Water○g (○g), Vitamins○mg or µg ^c (○mg or µg ^c), Choline ^b ○mg (○mg), Myo-Inositol ^b ○mg (○mg), L-Carnitine ^b ○mg (○mg), Ash○g (○g), Minerals (excluding sodium) and Trace Elements○mg or µg (○mg or µg), other nutritional content labeled voluntarily by the manufacturer○g, mg, or µg (○g, mg, or µg).

^bContents of α-linolenic acid, choline, myo-inositol, and L-carnitine may be labeled voluntarily for prepackaged follow-up infant formula on the market.

^cContents of vitamin A and vitamin E are expressed in µg RE (retinol equivalents) and mg α-TE (α-tocopherol equivalents), respectively.

Appendix 1.2 Nutrition labeling format for prepackaged formula for certain disease^a

Nutrition Facts		
Serving Size g (or mL)		
Servings Per Container		
	Per serving	Per 100 g (or per 100 mL)
Energy	Kcal	Kcal
Protein	g	g
Fat	g	g
Saturated fat	g	g
Trans fat	g	g
Carbohydrate	g	g
Sugars	g	g
Sodium	mg	mg
Other nutrients designated by the central competent authority in a public announcement	g, mg, or µg ^b	g, mg, or µg ^b
Claims nutritional content	g, mg, or µg ^b	g, mg, or µg ^b
Other nutritional contents labeled voluntarily by the manufacturer	g, mg, or µg ^b	g, mg, or µg ^b

^aNutrition labeling on surface areas smaller than 100 cm² may conform to the following horizontal format, placing labels at a prominent place on the package container:

Nutrition Facts	
Serving size	○g (or mL), Servings per container○. Per serving (per 100 g or 100 mL):
Energy	○Kcal (○Kcal), Protein○g (○g), Fat○g (○g),
Saturated fat	○g (○g), Trans fat○g (○g), Carbohydrate○g (○g),
Sugars	○g (○g), Sodium○mg (○mg), Other nutrients designated by
the central competent authority in a public announcement ○g, mg, or	
μg ^b (○g, mg, or μg ^b), Claims nutritional content ○g, mg, or μg ^b (○g,	
mg, or μg ^b), Other nutritional content labeled voluntarily by the	
manufacturer ○g, mg, or μg ^b (○g, mg, or μg ^b).	

^bContents of vitamin A, vitamin E, and niacin are expressed in μg RE (retinol equivalents), mg α-TE (α-tocopherol equivalents), and mg NE (niacin equivalent), respectively.

Appendix 2.1 Range of allowable error for nutrition labeling values of prepackaged infant and follow-up formula

Items		Range of allowable error	Note ^a	
			Infant formula, Infant formula for special medical purposes	Follow-up infant formula
Protein, Carbohydrate, Energy, Fat, Water ^b , and Ash		80%-120% of the labeled value	1. For nutrients with the minimum amount regulated by the Chinese National Standards (CNS) 6849, the test value shall equal at least 80% of the labeled value and not be below the minimum amount.	1. For nutrients with the minimum amount regulated by the CNS 13235, the test value shall equal at least 80% of the labeled value and not be below the minimum amount.
Saturated fat, Trans fat, Cholesterol, and Sugars		≤ 120% of the labeled value		
Vitamins	Vitamin A, Vitamin D, Vitamin E, and Vitamin K	80%-180% of the labeled value		
	Vitamin B ₁ , Vitamin B ₂ , Niacin, and Vitamin B ₆	80%-250% of the labeled value		
	Vitamin C, VitaminB ₁₂ , Folic acid, Pantothenic acid, and Biotin	80%-300% of the labeled value		
Minerals and Trace Elements	Sodium, Potassium, Chlorine, Calcium, Phosphorus, and Magnesium	80%-150% of the labeled value	2. The range of allowable error presented in the left table applies to the nutrients	2. The range of allowable error presented in the left table applies to
	Iron, Zinc,	80%-200%		

	Copper, Manganese, Selenium, and Iodine	of the labeled value	when the minimum amount is not regulated by the CNS 6849.	the nutrients when the minimum amount is not regulated by the CNS 13235
Amino acids, Poly/Mono unsaturated fat, Dietary fiber, Choline, Myo-Inositol, and L-Carnitine		80%-300% of the labeled value	<p>3. For nutrients with the maximum amount or guidance upper level (GUL) regulated by the CNS 6849, the test value shall be below the maximum amount or GUL.</p> <p>4. The range of allowable error presented in the left table applies to the nutrients when the maximum amount or GUL is not regulated by the CNS</p>	<p>3. .For nutrients with the maximum amount or GUL regulated by the CNS 13235, the test value shall be below the maximum amount or GUL.</p> <p>4. For nutrients without the maximum amount or GUL regulated by the CNS 13235, the maximum</p>

		<p>6849.</p> <p>5. For nutrients in infant formula for special medical purposes, the test value shall be within the range of allowable error presented in the left table. Additionally, the test values of chromium and molybdenum shall meet the following requirements:</p> <p>(a) $\geq 80\%$ of the labeled value,</p> <p>(b) not be below the minimum amount regulated by the CNS 15224,</p> <p>(c) below the</p>	<p>of test value may be determined according to either that for infant formula or the range of allowable error presented in the left table.</p>
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		GUL regulated by the CNS 15224.	
Other nutrients	≥ 80% of the labeled value	The upper level of the range of allowable error shall not exceed the maximum level in manufacturer's specifications.	

^aInfant and follow-up formula shall include infant formula, follow-up infant formula, and infant formula for special medical purposes in accordance with Article 2 of “Enforcement Rules of the Act Governing Food Safety and Sanitation.”

^bFor prepackaged powdered infant and follow-up formula on the market, the range of allowable error of water content shall be $\leq 120\%$ of the labeled value.

Appendix 2.2 Range of allowable error for nutrition labeling values of prepackaged formula for certain disease

Items	Range of allowable error	Note
Protein, Carbohydrate, Energy, and Fat	80%-120% of the labeled value	
Saturated fat, Trans fat, Cholesterol, Sodium, and Sugars	≤ 120% of the labeled value	
Amino acids, Poly/Mono unsaturated fat, Vitamins (excluding Vitamins A and D), Minerals (excluding sodium), and Dietary fiber	≥ 80% of the labeled value	1. The test values are based on a daily caloric intake of 1500 kcal, and shall not exceed the tolerable upper intake level (UL) of dietary reference intake (DRIs) for people aged over 51 years. However, if the nutrient content of a product exceeds the UL of DRIs for people aged over 51 years for target users with special dietary needs, additional relevant literatures are
Vitamins A and D	80%-180% of the labeled value	
Other nutrients	≥ 80% of the labeled value	

		<p>required for product registration.</p> <p>2. For nutrients without the UL for people aged over 51 years, the upper level of the range of allowable error shall not exceed the maximum level in manufacturer's specifications.</p>
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