

CODEX ALIMENTARIUS

INTERNATIONAL FOOD STANDARDS



Food and Agriculture
Organization of
the United Nations



World Health
Organization

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STANDARD FOR FOLLOW-UP FORMULA

CXS 156-1987

Adopted in 1987. Amended in 1989, 2011, 2017.

1. SCOPE

This standard applies to the composition and labelling of follow-up formula.

It does not apply to foods covered by the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981).

2. DESCRIPTION

2.1 Definitions

2.1.1 Follow-up formula means a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children.

2.1.2 The term *infant* means a person of not more than 12 months of age.

2.1.3 The term *young children* means persons from the age of more than 12 months up to the age of three years (36 months).

2.1.4 The term *calorie* means a kilocalorie (kcal). 1 kilojoule (kJ) is equivalent to 0.239 calories (kcal).

2.2 Follow-up formula is a food prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin, which have been proved to be suitable for infants from the 6th month on and for young children.

2.3 Follow-up formula is a food processed by physical means only so as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution.

2.4 Follow-up formula, when in liquid form, is suitable for use either directly or diluted with water before feeding, as appropriate. In powdered form it requires water for preparation. The product shall be nutritionally adequate to contribute to normal growth and development when used in accordance with its directions for use.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Energy Content

When prepared in accordance with the instructions for use, 100 ml of the ready-for-consumption product shall provide not less than 60 kcal (or 250 kJ) and not more than 85 kcal (or 355 kJ).

3.2 Nutrient Content

Follow-up formula shall contain the following nutrients at minimum and maximum levels indicated below:

3.2.1 Protein

3.2.1.1 Not less than 3.0 g per 100 available calories (or 0.7 g per 100 available kilojoules) of protein of nutritional quality equivalent to that of casein or a greater quantity of other protein in inverse proportion to its nutritional quality. The quality¹ of the protein shall not be less than 85% of that of casein. The total quantity of protein shall not be more than 5.5 g per 100 available calories (or 1.3 g per 100 available kilojoules).

3.2.1.2 Essential amino acids may be added to follow-up formula only to improve its nutritional value. Essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L forms of amino acids shall be used.

3.2.2 Fat

3.2.2.1 Not less than 3 g and not more than 6 g per 100 calories (0.7 and 1.4 g per 100 available kilojoules).

3.2.2.2 The level of linoleic acid (in the form of a glyceride) shall not be less than 300 mg per 100 calories (or 71.7 mg per 100 available kilojoules).

3.2.3 Carbohydrates

The product shall contain nutritionally available carbohydrates suitable for the feeding of the older infant and the young child in such quantities as to adjust the product to the energy density in accordance with the requirements set out in Section 3.1.

¹ Protein quality shall be determined provisionally using the PER method as laid down in the section dealing with methods of analysis.

Vitamins and Minerals

	Amounts per 100 available calories		Amounts per 100 available kilojoules	
	Minimum	Maximum	Minimum	Maximum
3.2.4 Vitamins other than Vitamin E				
Vitamin A	250 I.U. or 75 µg expressed as retinol	750 I.U. or 225 µg expressed as retinol	60 I.U. or 18 µg expressed as retinol	180 I.U. or 54 µg expressed as retinol
Vitamin D	40 I.U. or 1 µg	120 I.U. or 3 µg	10 I.U. or 0.25 µg	30 I.U. or 0.75 µg
Ascorbic Acid (Vitamin C)	8 mg	N.S. ²	1.9 mg	N.S. ²
Thiamine (Vitamin B ₁)	40 µg	N.S. ²	10 µg	N.S. ²
Riboflavin (Vitamin B ₂)	60 µg	N.S. ²	14 µg	N.S. ²
Nicotinamide	250 µg	N.S. ²	60 µg	N.S. ²
Vitamin B ₆ ³	45 µg	N.S. ²	11 µg	N.S. ²
Folic acid	4 µg	N.S. ²	1 µg	N.S. ²
Pantothenic acid	300 µg	N.S. ²	70 µg	N.S. ²
Vitamin B ₁₂	0.15 µg	N.S. ²	0.04 µg	N.S. ²
Vitamin K ₁	4 µg	N.S. ²	1 µg	N.S. ²
Biotin (Vitamin H)	1.5 µg	N.S. ²	0.4 µg	N.S. ²
3.2.5 Vitamin E (α-tocopherol compounds)	0.7 I.U./g linoleic acid ³ , but in no case less than 0.7 I.U./100 available calories	N.S. ²	0.7 I.U./g linoleic acid ⁴ , but in no case less than 0.15 I.U./100 available kilojoules	N.S. ²
3.2.6 Minerals				
Sodium (Na)	20 mg	85 mg	5 mg	21 mg
Potassium (K)	80 mg	N.S. ²	20 mg	N.S. ²
Chloride (Cl)	55 mg	N.S. ²	14 mg	N.S. ²
Calcium (Ca) ⁵	90 mg	N.S. ²	22 mg	N.S. ²
Phosphorus (P) ⁶	60 mg	N.S. ²	14 mg	N.S. ²
Magnesium (Mg)	6 mg	N.S. ⁷	1.4 mg	N.S. ²
Iron (Fe)	1 mg	2 mg	0.25 mg	0.50 mg
Iodine (I)	5 µg	N.S. ²	1.2 µg	N.S. ²
Zinc (Zn)	0.5 mg	N.S. ²	0.12 mg	N.S. ²

² N.S. = Not specified³ Formulas should contain a minimum of 15 µg Vitamin B₆ per gramme of protein. See Section 3.2.1.1.⁴ Or per g polyunsaturated fatty acids, expressed as linoleic acid.⁵ The Ca:P ratio shall be not less than 1.0 and not more than 2.0.⁶ The Ca:P ratio shall be not less than 1.0 and not more than 2.0⁷ N.S. = Not specified

3.3 Ingredients

3.3.1 Essential Ingredients

3.3.1.1 Follow-up formula shall be prepared from the milk of cows or of other animals and/or other protein products of animal and/or plant origin which have been proved suitable for infants from the 6th month on and for young children and from other suitable ingredients necessary to achieve the essential composition of the product as set out in Sections 3.1 and 3.2 above.

3.3.1.2 Follow-up formula based on milk shall be prepared from ingredients as set out in Section 3.3.1.1 above except that a minimum of 3 g per 100 available Calories (or 0.7 g per 100 kilojoules) of protein shall be derived from whole or skimmed milk as such, or with minor modification that does not substantially impair the vitamin or mineral content of the milk and which represents a minimum of 90% of the total protein.

3.3.2 Optional Ingredients

3.3.2.1 In addition to the vitamins and minerals listed under 3.2.4 to 3.2.6, other nutrients may be added when required to ensure that the product is suitable to form part of a mixed feeding scheme intended for use from the 6th month on.

3.3.2.2 The usefulness of these nutrients shall be scientifically shown.

3.3.2.3 When any of these nutrients is added, the food shall contain significant amounts of these nutrients, based on the requirements of infants from the 6th month on and young children.

3.4 Purity Requirements

3.4.1 General

All ingredients shall be clean, of good quality, safe and suitable for ingestion by infants from the 6th month on and young children. They shall conform with their normal quality requirements, such as colour, flavour and odour.

3.4.2 Vitamin Compounds and Mineral Salts

3.4.2.1 Vitamin compounds and mineral salts used in accordance with Sections 3.3.1 and 3.3.2 should be selected from the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Children* (CXG 10-1979).

3.4.2.2 The amounts of sodium derived from vitamin and mineral ingredients shall be within the limit for sodium in Section 3.2.6.

3.5 Consistency and Particle Size

When prepared according to the directions for use, the product shall be free of lumps and of large, coarse particles.

3.6 Specific Prohibition

The product and its components shall not have been treated by ionizing radiation.

4. FOOD ADDITIVES

The following additives are permitted:

	Maximum Level in 100 ml of Product Ready-for-Consumption
4.1 Thickening Agents	
4.1.1 Guar gum	} 0.1 g
4.1.2 Locust bean gum	}
4.1.3 Distarch phosphate	} 0.5 g singly or in
4.1.4 Acetylated distarch phosphate	} combination in soy-based products only
4.1.5 Phosphated distarch phosphate	}
4.1.6 Acetylated distarch adipate	} 2.5 g singly or in } combination in hydrolyzed } protein and/or amino acid- } based products only

4.1.7	Carrageenan	} 0.03 g singly or in } combination in milk and soy- } based products only } } 0.1 g singly or in } combination in hydrolyzed } protein and/or amino acid- } based liquid products only
4.1.8	Pectins	1 g
4.2	Emulsifiers	
4.2.1	Lecithin	0.5 g
4.2.2	Mono- and Diglycerides	0.4 g
4.3	pH-Adjusting Agents	
4.3.1	Sodium hydrogen carbonate	}
4.3.2	Sodium carbonate	}
4.3.3	Sodium citrate	}
4.3.4	Potassium hydrogen carbonate	} }
4.3.5	Potassium carbonate	} Limited by Good
4.3.6	Potassium citrate	} Manufacturing Practice
4.3.7	Sodium hydroxide	} within the limits for sodium in
4.3.8	Potassium hydroxide	} Section 3.2.6
4.3.9	Calcium hydroxide	}
4.3.10	L (+) Lactic acid	}
4.3.11	L (+) Lactic acid producing cultures	} }
4.3.12	Citric acid	}
4.4	Antioxidants	
4.4.1	Mixed tocopherols concentrate	} 3 mg singly or in } combination
4.4.2	α-Tocopherol	}
4.4.3	L-Ascorbyl palmitate	} 5 mg singly or in
4.4.4	L-Ascorbic acid and its Na, Ca salts	} combination, expressed as } ascorbic acid (see Section 3.2.6)
4.5	Flavourings	
4.5.1	Natural Fruit Extracts	GMP
4.5.2	Vanilla extract	GMP
4.5.3	Ethyl vanillin	5 mg
4.5.4	Vanillin	5 mg

4.6 Carry-Over Principle

Section 4.1 of the *General Standard for Food Additives* (CXS 192-1995) shall apply.

5. CONTAMINANTS

5.1 Pesticide Residues

The product shall be prepared with special care under good manufacturing practices, so that residues of those pesticides which may be required in the production, storage or processing of the raw materials or the finished food ingredient do not remain, or, if technically unavoidable, are reduced to the maximum extent possible.

5.2 Other Contaminants

The product shall be free from residues of hormones and antibiotics, as determined by means of agreed methods of analysis, and practically free from other contaminants, especially pharmacologically active substances.

6. HYGIENE

6.1 To the extent possible in good manufacturing practice, the product shall be free from objectionable matter.

6.2 When tested by appropriate methods of sampling and examination, the product:

- a) shall be free from pathogenic microorganisms;
- b) shall not contain any substances originating from microorganisms in amounts which may represent a hazard to health; and
- c) shall not contain any other poisonous or deleterious substances in amounts which may represent a hazard to health.

6.3 The product shall be prepared, packed and held under sanitary conditions and should comply with the relevant provisions of the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CXC 66-2008).

7. PACKAGING

7.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form, the product shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as packing media.

7.2 The containers, including packaging materials, shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply.

8. FILL OF CONTAINERS

In the case of products in ready-to-eat form, the fill of container shall be:

- (i) not less than 80% v/v for products weighing less than 150 g (5 1/2 oz.);
- (ii) not less than 85% v/v for products in the weight range 150-250 g (5 1/2 - 9 oz.); and
- (iii) not less than 90% v/v for products weighing more than 250 g (9 oz.)

of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.

9. LABELLING

In addition to the requirements of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985), the following specific provisions apply:

9.1 The Name of the Food

9.1.1 The name of the food shall be "Follow-up Formula". In addition thereto, any appropriate designation may be used in accordance with national usage.

9.1.2 Those products which are prepared from whole or skimmed milk in accordance with Section 3.3.1.2 and where 90% or more of the protein is derived from whole or skimmed milk as such, or with minor modification that does not substantially impair the vitamin and mineral content of the milk, may be labelled "Follow-up Formula based on milk".

9.1.3 All sources of protein shall be clearly shown on the label in close proximity to the name of the food in descending order of proportion by weight.

9.1.4 A product which contains neither milk nor any milk derivative may be labelled "contains no milk or milk products" or an equivalent phrase.

9.2 List of Ingredients

The declaration of the list of ingredients shall be in accordance with Sections 4.2.1, 4.2.2 and 4.2.3 of the *General Standard for the Labelling of Prepackaged Foods* except that in the case of added vitamins and added minerals, these ingredients shall be arranged as separate groups for vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.

9.3 Declaration of Nutritive Value

The declaration of nutrition information shall contain the following information in the following order:

- (a) The amount of energy, expressed in Calories (kcal) and/or kilojoules (kJ) per 100 g of the food as sold as well as per specified quantity of the food as suggested for consumption.
- (b) The number of grammes of protein, carbohydrate and fat per 100 g of the food as sold as well as per specified quantity of the food as suggested for consumption. In addition, the declaration per 100 calories (or per 100 kilojoules) is permitted.
- (c) The total quantity of each vitamin, mineral and any optional ingredient, as listed in Section 3.3.2 of this standard per 100 g of the food as sold as well as per specified quantity of the food as suggested for consumption. In addition, the declaration per 100 calories (or per 100 kilojoules) is permitted.

9.4 Date Marking and Storage Instructions

In addition to the declaration of date marking and storage instructions in accordance with Sections 4.7.1 and 4.7.2 of the *General Standard for the Labelling of Prepackaged Foods*, the following provisions apply:

9.4.1 Storage of Opened Food

Storage instructions of opened packages of a food for special dietary uses shall be included on the label if necessary to ensure that the opened product maintains its wholesomeness and nutritive value. A warning should be included on the label if the food is not capable of being stored after opening or is not capable of being stored in the container after opening.

9.5 Information for Utilization

9.5.1 Directions as to the preparation and use of the food, and its storage and keeping after the container has been opened shall appear on the label.

9.5.2 The labelling of a Follow-up Formula shall include a statement that Follow-up Formula shall not be introduced before the 6th month of life.

9.5.3 Information that infants and children fed Follow-up Formula shall receive other foods in addition to the food shall appear on the label.

9.6 Additional Requirements

The products covered by this standard are not breast-milk substitutes and shall not be presented as such.

10. METHODS OF ANALYSIS AND SAMPLING

For checking the compliance with this standard, the methods of analysis and sampling contained in the *Recommended methods of analysis and sampling* (CXS 234-1999) relevant to the provisions in this standard, shall be used.