Appendix V

PROPOSED DRAFT REVISED STANDARD FOR INFANT FORMULA

(CODEX STAN 72-1981)

(At Step 3 of the Procedure)

1. SCOPE

1.1 This standard applies to infant formula in liquid or powdered form intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of healthy infants. [The provisions in this standard are intended for infants with special nutritional requirements, except for certain provisions which must be modified to meet those special requirements.]

1.2 The standard contains compositional, quality and safety requirements to ensure a safe and nutritionally adequate product.

1.3 The application of the Standard should take into account the recommendations given to countries under the International Code of Marketing of Breast-milk Substitutes and relevant World Health Assembly Resolutions [to date][25].

2. DESCRIPTION

2.1 PRODUCT DEFINITIONS

2.1.1 Infant formula, when in liquid form, may be used either directly or diluted with safe, potable, and previously boiled water before feeding, as appropriate. In powdered form it requires safe, potable, and previously boiled water for preparation.

2.1.2 Infant formula shall be nutritionally adequate to promote normal growth and development when used in accordance with its directions for use [and to satisfy by itself the nutritional requirements of infants during the first four to six months of life].

2.1.3 Infant formula is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

2.2 OTHER DEFINITIONS

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

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 ESSENTIAL COMPOSITION

3.1.1 Infant formula is a product based on milk of cows or other animals and/or other edible constituents of animal, including fish, or plant origin, which have been proved to be suitable for infant feeding.

3.1.2 Infant formula shall contain per 100 kilocalories (or 100 kilojoules) of intake, the following minimum and maximun levels of vitamins, minerals in an available form, choline, protein, fat and fatty acid, carbohydrates and energy:

[25] [WHA 33.32 1980; WHA 34.22 1981; WHA 35.26 1982; WHA 37.30 1984; WHA 39.28 1986; WHA 41.11 1988; WHA 44.33 1991; WHA 45.34 1992; WHA 47.5 1994; WHA49.15 1996]

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	Amounts per 100 kilocalories		Amounts per 100 kJ	
	Minimum	**Maximum**	**Minimum**	**Maximum**
(a) Vitamins				
Vitamin A*	60 µg	180 µg	14 µg	43 µg
Vitamin D	40 I.U. or 1 µg	100 I.U. or 2,5 µg	10 I.U. or 0.25 µg	25 I.U. or 0.63 µg
Vitamin E (α-tocopherol equivalent TE)	0,5 mg/g linoleic acid[2], but in no case less than 0.5 mg/100 kcal	N.S.[1]	0.5 mg/g linoleic acid[2] but in no case less than 0.1 mg /100 kJ	N.S.[1]
Ascorbic Acid (Vitamin C)	8 mg	N.S.[1]	1,9 mg	N.S.[1]
Thiamine (Vitamin B_1)	40 µg	N.S.[1]	10 µg	N.S.[1]
Riboflavin (Vitamin B_2)	60 µg	N.S.[1]	14 µg	N.S.[1]
Niacin, niacin equivalents	0,8 mg	N.S.[1]	0,2 mg	N.S.[1]
Vitamin B_6	15 µg/g protein but in no case less than 35 µg/100 kcal	N.S.[1]	15 µg/g protein but in no case less than 9 µg/100 kJ	N.S.[1]
Folic acid	4 µg	N.S.[1]	1 µg	N.S.[1]
Pantothenic acid	300 µg	N.S.[1]	70 µg	N.S.[1]
Vitamin B_{12}	0.10 µg	N.S.[1]	0.025 µg	N.S.[1]
Vitamin K_1	4 µg	N.S.[1]	1 µg	N.S.[1]
Biotin (Vitamin H)	1.5 µg	N.S.[1]	0.4 µg	N.S.[1]
(b) Minerals				
Sodium (Na)	20 mg	60 mg	5 mg	15 mg
Potassium (K)	60 mg	145 mg	15 mg	35 mg
Chloride (Cl)	50 mg	125 mg	12 mg	29 mg
Calcium (Ca)[3]	50 mg	N.S.[1]	12 mg	N.S.[1]
Phosphorus (P)[3]	25 mg	90 mg	6 mg	22 mg
Magnesium (Mg)	5 mg	15 mg	1.2 mg	3,6 mg

Iron (Fe)	0.5 mg	1.5 mg	0.12 mg	0.36 mg
Iron (Fe)[4]	1 mg	2 mg	0.25 mg	0.5 mg
Iodine (I)	5 µg	N.S.[1]	1.2 µg	N.S.[1]
Copper (Cu)	20 µg	80 µg	4.8 µg	19 µg
Zinc (Zn)	0.5 mg	N.S.[1]	0.12 mg	N.S.[1]
Zinc (Zn)[4]	0.75 mg	2.4 mg	0.18 mg	0.6 mg
Manganese (Mn)	5 µg	N.S.[1]	1,2 µg	N.S.[1]
Selenium (Se)	7 µg	3 µg	N.S.[1]	0,7 µg
(c) Choline	N.S.[1]	N.S.[1]	1.7 mg	N.S.[1]

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* expressed as retinol equivalent

[1] N.S. = Not specified

[2] Or per g polyunsaturated fatty acids, expressed as linoleic acid.

[3] The Ca: P ratio shall be not less than 1.2 and not more than [2.0].

4 In formula manufactured from soya proteins, alone or in a mixture with cow's milk protein.]

(d) Protein

(i) Protein content = nitrogen content x 6.38 for cow's milk proteins and protein partial hydrolysates.

Protein content = nitrogen content x 6.25 for soya protein isolates and protein partial hydrolysates.

The "chemical index" shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein (breast milk, as defined in Annex 1).

(ii) The product shall contain protein at a level of not less than 1.8 g/100 kcal (0.45 g/100 kJ) and not more than 3 g/100 kcal (0.7 g/100 kJ).

For an equal energy value, the formula must contain an available quantity each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex 1); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together.

[The minimum value set for quality and the maximum for quantity of the protein may be modified by national authorities according to their own regulations and/or local conditions.]

(iii) Isolated amino acids may be added to Infant Formula only to improve its nutritional value for infants. Essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only natural L forms of amino acids shall be used.

(e) Fat and Fatty Acid

The product shall contain:

- linoleic acid (in the form of glycerides) at a level of not less than 300 mg/100 kcal (or 70 mg/100 kJ) and not more than 1200 mg/100 kcal (285 mg/100 kJ);
- fat at a level not less than 4.4 g/100 kcal (1.05 g/100 kJ) and not more than 6.5 g/100 kcal (1.5 g/100 kJ);
- the alpha-linolenic acid content shall not be less than 50 mg/100 kcal (12 mg/100 kJ);
- the linoleic/alpha-linolenic acid ratio shall not be less than 5 nor greater than 15;
- the trans fatty acid content shall not exceed 4% of the total fat content;
- the erucic acid content shall not exceed 1% of the total fat content;

(f) Carbohydrates

The product shall contain carbohydrates at a level of not less than 7 g/100kcal (1.7 g/100 kJ) and not more than 14 g/100kcal (3.4 g/100 kJ).

(g) Energy content

The energy content of the product shall not be less than 60 kcal/100 ml (250 kJ/100 ml) and not more than 75 kcal/ 100 ml (315 kJ/100 ml).

3.2 OPTIONAL INGREDIENTS

3.2.1 In addition to the vitamins and minerals listed under 3.1.2(a), (b) and (c), other nutrients may be added when required in order to provide nutrients ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrients of the infant.

3.2.2 The usefulness and safety of these nutrients shall be scientifically shown.

3.2.3 When any of these nutrients is added, the formula shall contain sufficient amounts of these nutrients to achieve the intended effect, based on levels in human milk.

3.2.4 Only L(+) producing lactic acid cultures may be used**.**

3.3 VITAMIN COMPOUNDS AND MINERAL SALTS

3.3.1 Vitamins and minerals added in accordance with Section 3.1.2 (a,b,c,d) and 3.2.1 should be selected from the Advisory Lists of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979).

3.4 CONSISTENCY AND PARTICLE SIZE

When prepared according to the label directions for use, the product shall be free of lumps and of large coarse particles and suitable for adequate feeding of young infants.

3.5 PURITY REQUIREMENTS

All ingredients shall be clean, of good quality, safe and suitable for ingestion by infants. They shall conform with their normal quality requirements, such as colour, flavour and odour.

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 in the preparation of Infant Formula, as described in Section 1 of this Standard, and with the restrictions stated below:

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			Maximum level in 100 ml of the ready-to-drink product
4.1	**THICKENING AGENTS**		
4.1.1	Guar gum		0.1 g in all types of infant formula
4.1.2	Locust bean gum[26]		0.1 g in all types of infant formula
4.1.3	Distarch phosphate	}	0.5 g singly or in combination in soy-
4.1.4	Acetylated distarch phosphate	}	based infant formulae only
4.1.5	Phosphated distarch phosphate	}	
4.1.6	Hydroxypropyl starch	}	2.5 g singly or in combination in
		}	hydrolyzed protein and/or amino acid
		}	acid-based infant formulae only
4.1.7	Carrageenan	}	0.03 g in regular, milk- and soy-
		}	based liquid infant formulae only
		}	
		}	0.1 g in hydrolyzed protein and/or amino acid-based liquid infant formulae only
4.2	**EMULSIFIERS**		
4.2.1	Lecithin		0.5 g in all types of infant formulae
4.2.3	Mono- and diglycerides		0.4 g in all types of infant formulae
4.3	**pH-ADJUSTING AGENTS**		
4.3.1	Sodium hydroxide	}	
4.3.2	Sodium hydrogen carbonate	}	
4.3.3	Sodium carbonate	}	Limited by good manufacturing practice
4.3.4	Potassium hydroxide	}	and within the limits for sodium and
4.3.5	Potassium hydrogen carbonate	}	potassium in Section 3.1.2 (c) in all
4.3.6	Potassium carbonate	}	types of infant formulae
4.3.7	Calcium hydroxide	}	
4.3.8	Sodium citrate	}	
4.3.9	Potassium citrate	}	
4.3.10	L(+) Lactic acid	}	Limited by good manufacturing practice
4.3.12	Citric acid		in all types of infant formulae
4.4	**ANTIOXIDANTS**		
4.4.1	Mixed tocopherols concentrate	}	1 mg in all types of infant formulae
4.4.2	L-Ascorbyl palmitate	}	

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[26] Temporarily endorsed.

4.5 CARRY-OVER OF FOOD ADDITIVES

No food additives shall be present as a result of carry-over from raw materials and other ingredients with the exception:

(a) of the food additives listed under Sections 4.1 to 4.4 of this standard within the limits of the maximum levels stipulated in this standard; and

(b) of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children within the limits of the maximum levels stipulated in that List.

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

Infant formula shall not contain contaminants or undesirable substances (e.g. biologically active substances) in amounts which may represent a hazard to the health of the infant

The product covered by the provisions of the Standard shall comply with those maximum residue limits and maximum levels established by the Codex Alimentarius Commission

6. HYGIENE

6.1 It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1 1969, Rev. 3- 1997), and other relevant Codex texts such as the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979).

6.2 The products should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997)

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 CONTAINER

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 oz.);

(ii) not less than 85% v/v for products in the weight range 150-250 g (5-8 oz.); and

(iii) not less than 90% v/v for products weighing more than 250 g (8 oz.)

of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20^{o} C which the sealed container will hold completely filled.

9. LABELLING

In addition to the requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev. 1-1991), the following specific provisions apply:

9.1 THE NAME OF THE FOOD

The text of the label and all other information accompanying the product shall be written in the appropriate language**.**

9.1.1 The name of the product shall be either "Infant Formula" or any appropriate designation indicating the true nature of the product, in accordance with national usage.

9.1.2 The sources of protein in the product shall be clearly shown on the label.

9.1.3 If cow's milk is the only source of protein, the product may be labelled "Infant Formula Based on Cow's Milk".

[9.1.4 A product which contains neither milk or any milk derivative [may] be labelled "contains no milk or milk products" or an equivalent phrase.]

[9.1.5 A product intended for infants with special nutritional requirements shall be labelled to show clearly the special requirement for which the formula is to be used and the dietary property or properties on which this is based. [No health claims shall be made regarding the dietary properties of the product.]]

9.1.6 [Products containing not less than 0.5 mg Iron (Fe)/ 100 kilocalories shall be labelled "Infant Forumula with added Iron"].

or

[Products containing less than 0.5 mg Iron (Fe)/ 100 kcal shall be labelled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources.]

9.2 LIST OF INGREDIENTS

9.2.1 A complete list of ingredients shall be declared on the label in descending order of proportion 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.

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate class names for these ingredients and additives may be included on the label.

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 kilocalories (kcal) and/or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes of the food as sold as well as per 100 milliliter of the food ready for use, when prepared according to the instructions on the label.

(b) the total quantity of each vitamin, mineral, choline and any optional ingredient as listed in pragraphs 3.1.2 an 3.2 of this Standard per 100 grammes of the food as sold as well as per 100 milliliter of the food ready for use, when prepared according to the instructions on the label. In addition, the declaration per 100 kilocalories (or per 100 kilojoules) is permitted.

9.4 DATE MARKING AND STORAGE INSTRUCTIONS

9.4.1 The date of minimum durability (preceded by the words "best before") shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer.

In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

9.4.2 In addition to the date, any special conditions for the storage of the food shall be indicated if the validity of the date depends thereon.

Where practicable, storage instructions shall be in close proximity to the date marking.

9.5 INFORMATION FOR USE

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 or on the accompanying leaflet.

9.6 ADDITIONAL LABELLING REQUIREMENTS

9.6.1 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points: a) the words "important notice" or their equivalent; b) a statement of the superiority of breastfeeding or breastmilk [or: the statement: Breastmilk is the best food for your baby, it protects against diarrhea and other illnesses]; c) a statement that the product should only be used on advice of a independent health worker as to the need for its use and the proper method of use; d) instructions for appropriate preparation; e) a warning against the health hazards of inappropriate preparation; and a warning that formula remaining after each feeding should be discarded.

9.6.2 The label shall have no pictures of infants nor any other picture or text which idealizes the use of infant formula. The label may have graphics illustrating the method of preparation of the product.

9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.

9.6.4 Information that infants [over six months of age] should receive supplemental foods in addition to the formula shall appear on the label.

9.6.5 [The products shall be labelled in such a way as to avoid any risk of confusion between infant formula and follow-up formula.]

10. METHODS OF ANALYSIS AND SAMPLING

See Codex Alimentarius Volume 13 and add:

Determination of choline

AOAC 999.14 (Enzymatic method)

Determination of Vitamin K

AOAC 999.15 (LC method)

ANNEX 1

Essential and Semi-Essential Amino Acids in Breast Milk

For the purpose of this Standard the essential and semi-essential amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

	per 100 kJ	**per 100 kcal**
Arginine	25	107
Cystine	11	44
Histidine	12	47
Isoleucine	20	83
Leucine	40	167
Lysine	28	119
Methionine	6	23
Phenylalanine	18	75
Threonine	18	77
Tryptophan	7	31
Tyrosine	20	85
Valine	24	99