

APPENDIX IV

REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA

(REMAINING SECTIONS HELD AT STEP 4 FOR ADVANCEMENT TO STEP 5/8 AS PART OF THE ENTIRE STANDARD)

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

3.3 Purity Requirements

3.3.1 General

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

3.3.2 Vitamin Compounds and Mineral Salts

3.3.2.1 Vitamin compounds and mineral salts used in accordance with Sections 3.1.3 (d) and (e) and 3.2.1 should be selected from the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children* (CXG 10-1979).

3.3.2.2 The amounts of sodium derived from vitamin and mineral ingredients shall be within the limit for sodium in Section 3.1.3 (e).

3.4 Consistency and Particle Size

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

3.5 Specific Prohibitions

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

4. Food Additives

The following additives are permitted¹⁾:

INS	Additive	Maximum level in 100 mL of the product ready for consumption
4.1 Thickeners		
412	Guar gum	0.1 g
410	Carob bean gum	0.1 g
1412	Distarch phosphate	0.5 g singly or in combination in soy-based products only; 2.5 g singly or in combination in hydrolyzed protein and/or amino acid-based products only
1414	Acetylated distarch phosphate	
1413	Phosphated distarch phosphate	
1422	Acetylated distarch adipate	
407	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
440	Pectins	1 g
4.2 Emulsifiers		
322(i)	Lecithin	0.5 g
471	Mono- and diglycerides of fatty acids	0.4 g
4.3 Acidity Regulators		

¹⁾ The table of food additive provisions is for information only. Following the completion of the alignment work for CXS 156-1987, the table will be replaced by a general reference to the GSFA as below:

“Acidity regulators, antioxidants, emulsifiers, thickeners, packaging gases used in accordance with Tables 1 and 2 of the *General Standard for Food Additives* (CXS 192-1995) in food category 13.1.2 (Follow-up formulae) are acceptable for use in foods conforming to this Standard.”

500(ii)	Sodium hydrogen carbonate	Limited by GMP Within the limits for sodium in Section 3.1
500(i)	Sodium carbonate	
331(i)	Sodium dihydrogen citrate	
331(iii)	Trisodium citrate	
524	Sodium hydroxide	
501(ii)	Potassium hydrogen carbonate	Limited by GMP
501(i)	Potassium carbonate	
332(i)	Potassium dihydrogen citrate	
332(ii)	Tripotassium citrate	
525	Potassium hydroxide	
526	Calcium hydroxide	Limited by GMP
270	Lactic acid, L-, D-, and DL-	Limited by GMP
330	Citric acid	Limited by GMP
4.4 Antioxidants		
307b	Tocopherols concentrate, mixed	3 mg singly or in combination
307a	Tocopherol, d-alpha	
307c	Tocopherol, dl-alpha	
304	Ascorbyl palmitate	5 mg singly or in combination, expressed as ascorbic acid (INS 300, 301,302,304) Within the limits for sodium in Section 3.1
300	Ascorbic acid, L-	
301	Sodium ascorbate	
302	Calcium ascorbate	
4.5 Packaging Gases		
290	Carbon dioxide	GMP
941	Nitrogen	GMP

4.6 Flavourings

No flavourings are permitted in this product.

4.7 Carry-Over Principle

Only the food additives listed in this Section or in the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children* (CXG 10-1979) may be present in the foods described in Section 2.1 of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

- The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and
- The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the *General Standard for Food Additives* (CXS 192-1995).

5. Contaminants

The products covered by this Standard shall comply with the Maximum levels of the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995).

The products covered by this Standard shall comply with the maximum residue limits for pesticides 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 *General Principles of Food Hygiene* (CXC 1-1969), and other relevant Codex texts such as the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CXC 66-2008), and in the case of liquid formula that has been commercially sterilised should also consider the appropriate sections of the *Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods* (CXC 40-1993) and the *Code of Hygienic Practice for Low and Acidified Low-acid Canned Foods* (CXC 23-1979), as applicable.

6.2 The products should comply with any microbiological criteria established in accordance with the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).

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

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

SECTION B: DRINK FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR DRINK FOR YOUNG CHILDREN OR PRODUCT FOR YOUNG CHILDREN

3.3 Purity Requirements

3.3.1 General

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

3.3.2 Vitamin Compounds and Mineral Salts

Vitamin compounds and mineral salts used in accordance with Sections 3.1.3 (d) and (e) and 3.2.1 should be selected from the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children* (CXG 10-1979).

3.4 Consistency and Particle Size

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

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4.4 Antioxidants		
307b	Tocopherols concentrate, mixed	3 mg singly or in combination
307a	Tocopherol, d-alpha	
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300	Ascorbic acid, L-	
301	Sodium ascorbate	
302	Calcium ascorbate	
4.5 Packaging Gases		
290	Carbon dioxide	GMP
941	Nitrogen	GMP

4.6 Flavourings ²⁾

Natural Fruit Extracts: GMP

Vanilla extract: GMP

Ethyl vanillin (JECFA no. 893): 5 mg/100 ml

Vanillin (JECFA no. 889): 5 mg/ 100 ml

The flavourings used in products covered by this Standard should comply with the *Guidelines for the Use of Flavourings* (CXG 66-2008).

²⁾ National and/or regional authorities may restrict or prohibit the use of the listed flavourings.

4.7 Carry-Over Principle

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