

Technical Guidelines on Administrative Regulation No. 28/2016 *Nutritional Requirements for Infant Formula*

Introduction:

Where breastfeeding is not feasible, infant formula is the only foodstuff which fulfils the nutritional requirements of infants from birth until the introduction of complementary feeding. Therefore, the SAR government has established the Administrative Regulation No. 28/2016 *Nutritional Requirements for Infant Formula*, as a specific measure to implement the Law No. 5/2013, which regulates nutrients in infant formula. The Regulation sets out the requirements on energy value, nutrient content and ratio of certain nutrients to ensure the healthy growth of infants.

These technical guidelines are prepared in particular to assist the trade to comply with the Administrative Regulation No. 28/2016 *Nutritional Requirements for Infant Formula*. These guidelines provide technical information, which offer guidance to the trade to comply with such requirements.

Scope:

The Administrative Regulation No. 28/2016 *Nutritional Requirements for Infant Formula* applies to infant formula, except formulas for special medical purposes intended for infants.

Definition:

1. Infant: a person not more than 12 months of age;
2. Infant formula: a breast-milk substitute specially manufactured in liquid or powdered form to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding;
3. Formulas for special medical purposes intended for infants: infant formula

that is specially manufactured for infants with specific disorders, diseases or medical conditions.

Implementation Time Frame:

The trade will be given a grace period of ninety days before the Administrative Regulation takes effect. That is, the Regulation will come into force ninety days after the date of its publication (Feb. 27th, 2017).

Nutritional Requirements for Infant Formula:

1. The nutritional requirements for infant formula specified in the Administrative Regulation include the following:
 - (1) Energy value of infant formula;
 - (2) Content of nutrients in infant formula;
 - (3) Ratio of nutrients in infant formula.
2. Under the Administrative Regulation, infant formula, in a form that is reconstituted or served according to any instructions for use provided, must fulfil the following nutritional requirements:
 - (1) Energy value of the infant formula is no less than the minimum level specified and no more than the maximum level specified in Table 1;
 - (2) It contains the nutrients specified in Table 2 and the content of each nutrient is no less than the minimum level, if any, and no more than the maximum level, if any, specified for that nutrient;
 - (3) It meets the nutrient ratio specified in Table 3.

Additional Recommendations:

1. In relation to nutrients without maximum levels specified, it is recommended to follow the guidance upper levels, if any, set out in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72- 1981)* as shown in Table 2;

2. It is also recommended that infant formula to follow other nutritional requirements set out in *CODEX STAN 72- 1981* as below:
- (1) For equal energy value, the infant formula contains an available quantity of each essential and semi-essential amino acid at least equal to that contain in the reference protein (that is, the essential and semi essential amino acids contents in breast milk as defined in Annex I of *CODEX STAN 72-1981*);
 - (2) The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ);
 - (3) If docosahexaenoic acid (DHA) is added, its content should not exceed 0.5% of total fatty acids;
 - (4) Fluoride should not be added to infant formula.

Table 1 Energy Value of Infant Formula

| Energy | Minimum level | | Maximum level | |
|--------|---------------|-----------|---------------|-----------|
| | kcal/100 mL | kJ/100 mL | kcal/100 mL | kJ/100 mL |
| | 60 | 250 | 70 | 295 |

Table 2 Content of Nutrients in Infant Formula

| Nutrients | | Minimum level | | Maximum level | | Guidance upper levels ^(a) | |
|------------------------------------|---|------------------------|-------------------------|----------------|---------------|--------------------------------------|------------------------|
| | | Per100 kcal | Per 100 kJ | Per 100 kcal | Per 100 kJ | Per 100 kcal | Per 100 kJ |
| Protein | Infant formula based on cows' milk protein | 1.8 g | 0.45 g | 3.0 g | 0.7 g | - | |
| | Infant formula based on soy protein isolate | 2.25 g | 0.5 g | | | | |
| Total carbohydrates | | 9.0 g | 2.2 g | 14.0 g | 3.3 g | - | |
| Total fat | | 4.4 g | 1.05 g | 6.0 g | 1.4 g | - | |
| Linoleic acid | | 300 mg | 70 mg | - | | 1400 mg | 330 mg |
| α -Linolenic acid | | 50 mg | 12 mg | - | | - | |
| Vitamin A ^(b) | | 60 μ g RE | 14 μ g RE | 180 μ g RE | 43 μ g RE | - | |
| Vitamin D ₃ | | 1 μ g | 0.25 μ g | 2.5 μ g | 0.6 μ g | - | |
| Vitamin E ^(c) | | 0.5 mg α -TE | 0.12 mg α -TE | - | | 5 mg α -TE | 1.2 mg α -TE |
| Vitamin K | | 4 μ g | 1 μ g | - | | 27 μ g | 6.5 μ g |
| Vitamin B ₁ /Thiamine | | 60 μ g | 14 μ g | - | | 300 μ g | 72 μ g |
| Vitamin B ₂ /Riboflavin | | 80 μ g | 19 μ g | - | | 500 μ g | 119 μ g |
| Vitamin B ₃ /Niacin | | 300 μ g | 70 μ g | - | | 1500 μ g | 360 μ g |

| Nutrients | Minimum level | | Maximum level | | Guidance upper levels ^(a) | |
|------------------------------------|---------------|------------|---------------|------------|--------------------------------------|------------|
| | Per100 kcal | Per 100 kJ | Per 100 kcal | Per 100 kJ | Per 100 kcal | Per 100 kJ |
| Vitamin B ₆ /Pyridoxine | 35 µg | 8.5 µg | - | | 175 µg | 45 µg |
| Vitamin B ₁₂ | 0.1 µg | 0.025 µg | - | | 1.5 µg | 0.36 µg |
| Folic acid | 10 µg | 2.5 µg | - | | 50 µg | 12 µg |
| Pantothenic acid | 400 µg | 96 µg | - | | 2000 µg | 478 µg |
| Vitamin C | 10 mg | 2.5 mg | - | | 70 mg | 17 mg |
| Biotin | 1.5 µg | 0.4 µg | - | | 10 µg | 2.4 µg |
| Sodium | 20 mg | 5 mg | 60 mg | 14 mg | - | |
| Potassium | 60 mg | 14 mg | 180 mg | 43 mg | - | |
| Copper | 35 µg | 8.5 µg | - | | 120 µg | 29 µg |
| Magnesium | 5 mg | 1.2 mg | - | | 15 mg | 3.6 mg |
| Iron | 0.45 mg | 0.1 mg | - | | - | |
| Zinc | 0.5 mg | 0.12 mg | - | | 1.5 mg | 0.36 mg |
| Manganese | 1 µg | 0.25 µg | - | | 100 µg | 24µg |
| Calcium | 50 mg | 12 mg | - | | 140 mg | 35 mg |

| Nutrients | Minimum level | | Maximum level | | Guidance upper levels ^(a) | |
|------------------------|---------------|------------|---------------|------------|--------------------------------------|------------|
| | Per100 kcal | Per 100 kJ | Per 100 kcal | Per 100 kJ | Per 100 kcal | Per 100 kJ |
| Phosphorus | 25 mg | 6 mg | - | | 100 mg | 24 mg |
| Iodine | 10µg | 2.5 µg | - | | 60 µg | 14 µg |
| Chloride | 50 mg | 12 mg | 160 mg | 38 mg | - | |
| Selenium | 1 µg | 0.24 µg | - | | 9 µg | 2.2 µg |
| Choline | 7 mg | 1.7 mg | - | | 50 mg | 12 mg |
| Myo-Inositol | 4 mg | 1 mg | - | | 40 mg | 9.5 mg |
| L-Carnitine | 1.2 mg | 0.3 mg | - | | - | |
| Taurine ^(d) | - | | 12 mg | 3 mg | - | |

Table 3 Ratio of Nutrients in Infant Formula

| Nutrients | Minimum level | Maximum level |
|--|----------------------------------|----------------------------------|
| Ratio of linoleic acid to α -linolenic acid | 5:1 | 15:1 |
| Lauric acid and myristic acid combined | - | 20% of total fatty acids |
| Trans fatty acids | - | 3% of total fatty acids |
| Erucic acid | - | 1% of total fatty acids |
| Ratio of calcium to phosphorus | 1:1 | 2:1 |
| Arachidonic acid ^(e) | Equivalent to the content of DHA | - |
| Eicosapentaenoic acid ^(e) | - | Equivalent to the content of DHA |

Note: a) Guidance upper levels (GUL) are values for nutrients without sufficient information for a scientific-based risk assessment. They are derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The GUL provides guidance values to manufacturers and they should not be interpreted as goal values. Nutrient contents in infant formula should usually not exceed the GUL unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula or due to technological reasons. When a product type or form has ordinarily contained lower levels than the GUL, manufacturers should not increase levels of nutrients to approach the GUL.

b) RE: Retinol Equivalent.

c) α -TE: α -Tocopherol Equivalent.

The content of Vitamin E shall not be less than 0.5 mg α -TE per gram polyunsaturated fatty acids (PUFA). The minimum content of vitamin E is adapted to the number of fatty acid double bonds in the formula using the following factors of equivalence: 0.5 mg α -TE/g linoleic acid (18:2 n-6); 0.75 mg α -TE/g α -linolenic acid (18:3 n-3); 1.0 mg α -TE/g arachidonic acid (20:4 n-6); 1.25 mg α -TE/g eicosapentaenoic acid (20:5 n-3); 1.5 mg α -TE/g docosahexaenoic acid (22:6 n-3).

d) If taurine is added.

e) If docosahexaenoic acid (DHA) is added.

Disclaimer:

The Technical Guidelines do not have the force of law and are intended for reference only. It should be read in conjunction with the relevant legislation including but not limited to the Administrative Regulation No. 28/2016 *Nutritional Requirements for Infant Formula*. Information contained in the Technical Guidelines may not be exhaustive or complete.