

# URUGUAY – REGLAMENTO BROMATOLOGICO

## URUGUAY – FOOD STANDARDS

(NOTE: This is a translation from Spanish, only of those parts of the Food Standards that deal with foods for infants and young children. JPA)

### CHAPTER 29 MODIFIED FOODS

#### Definitions for foods for infants and young children

29.1.25. Infants: persons under 12 months of age.

29.1.26. Young children: persons from 12 to 36 months of age.

29.1.27. Infant formula: a product based on milk from cows or other animals and/or other edible animal components (including fish) or vegetable origin, which are deemed suitable to feed infants and to be used when necessary as a replacement of human milk to satisfy the nutritional needs of infants. It may be liquid or in powder.

29.1.28. Cows' milk based formula: an infant formula in which more than 90% of the animal protein is obtained from cows' milk.

29.1.29. Soya based formula: a food which does not contain cows' milk, prepared with protein from soya beans or soya meal, with various aggregates.

29.1.30. Formula for special indications: a food prepared to satisfy the nutritional or food requirements of some groups of infants who suffer from different troubles or diseases.

29.1.31. Complementary food for infants over six months old and for young children: a food different from human milk and from infant formula, that is used for the gradual transition of such children to the food of older children or of adults.

#### General provisions on foods for infants and young children

29.2.24. These foods shall be nutritionally suitable to promote normal growth and development when used according to the applicable instructions. If they are liquid they can be used as such or diluted in water. If they are in powder, water is needed for their preparation.

29.2.25. Under normal dilution, each 100 ml of the product shall contain not less than 65 kcal and not more than 75 kcal. In formulas for prematures up to 85 kcal shall be admitted, under normal dilution.

#### **29.2.26. Advertising and promotion of these foods shall conform to the WHO/UNICEF International Code of Marketing of Breastmilk Substitutes.**

29.2.27. Infant formula shall contain, for each 100 kcal usable and ingested, the following quantities of vitamins, minerals, choline, proteins, fats and linoleic acid:

##### **Quantities of vitamins per available 100 kcal**

##### **Minimum    Maximum**

Vitamin A 75 ug(\*); 250 U.I.(\*\*) 150 ug; 500 U.I.

Vitamin D 40 U.I. 80 U.I.

Vitamin C 8 mg N.E. (\*\*\*)

Tiarnica 40 ug N.E.

Riboflavine 60 ug N.E.

Nicotinamide 250 ug N.E.

Vitamin B6 (\*\*\*\*) 35 ug N.E.

Folic acid 4 ug N.E.

Pantotenic acid 300 ug N.E.

Vitamin B12 0.15 ug N.E.

Vitamin K1 4 ug N.E.

Biotina 1.5 ug N.E.

Vitamin E 0.7 U.I./g of linoleic acid, but not less than N.E. 0.7 U.I./100 kcal usable

(\*) equivalent of retinol

(\*\*) U. I. = international unit

(\*\*\*) Not specified

(\*\*\*\*) Formulas containing more than 1.8 g. of protein per 100 kcal usable shall contain a minimum of 15 ug of Vitamin B6 per gramme of protein.

29.2.28. If the protein of a formula is soya-based it shall be enriched with Lmentionine to achieve a level of at least 100 of the latter.

29.2.29. Formula may optionally contain other nutrients, when the need for such nutrients is scientifically documented and approved. It may also contain modified starches with the following maximum concentrations:

Aminoacid-based infant formula: 25 g/Kg

Hydrolized protein-based infant formula: 25 g/Kg

Soya-based infant formula: 5 g/Kg.

29.2.30. Vitamins and minerals added to infant formula shall be chosen from the List of vitamins and mineral salts for use in infant foods.

29.2.31. The quantities of sodium and potassium derived from the addition of vitamins and/or minerals shall be within the limits for such nutrients established in the applicable articles.

29.2.32. When prepared according to the instructions provided on the label, the product shall not contain lumps or large parts, so that it can be fed through a rubber or plastic teat.

29.2.33. The food and its components shall not be treated with ionizing radiation.

29.2.34. The food shall not contain residues of hormones nor antibiotics, as measured by conventional analysis methods, and shall be free of any other contaminants, particularly pharmacologically active substances.

29.2.35. The food shall contain only permitted additives for infant formula, as established in Annex II of these Standards.

29.2.36. The food shall be packaged in containers that preserve its hygienic and other qualities. Containers and packaging material shall be made only of safe materials suitable for their purpose.

29.2.37. Labels shall provide the following information:

a) The energy provided in kcal and the detailed composition of all nutrients, in units of the metric decimal system per 100 g of food, as well as for any suggested volume of food to be consumed; in addition, quantities may be expressed per 100 kcal usable.

b) The protein origin of the food.

c) Instructions for preparation and conservation, before and after opening the container.

d) If the food does not contain cows' milk, the words "Does not contain cows' milk" may be added.

29.2.38. The label shall contain, in a clearly visible part and in letter of not less than 2 mm height, the following warning: ***"Breastmilk is the ideal food for infants and is of a superior quality to this product. This product must be given only on medical prescription."***

29.2.39. The use of words such as "maternalized", "human milk substitute" or "humanized" shall not be permitted to refer to these foods.

29.2.40. Neither the label nor the container shall have any pictures of infants or others, nor any text that may idealize the use of infant formula.

29.2.41. Complementary foods defined in article 29.1.31. shall comply with the following requirements:

a) They shall contain only components suitable for the age of the children they are intended for;

b) The ingredients must comply with maximum quality conditions.

**Quantities of minerals per 100 kcal available**

**Minimum Maximum**

Sodium (Na) 20 mg 60 mg

Potassium (K) 80 mg 200 mg

Chloride (Cl) 55 mg 150 mg

Calcium (Ca) (\*) 50 mg N.E. (\*\*)

Phosphore (P) 25 mg N.E.

Magnesium (Mg) 6 mg N.E.

Iron (Fe) 1 mg N.E.

Iodine (I) 5 ug N.E.

Copper (Cu) 60 ug N.E.

Zinc (Zn) 0.5 mg N.E.

Manganese (Mn) 5 ug N.E.

Choline 7 mg N.E.

Proteines 1.8 g (\*\*\*) 4 g

Fats 3.3 g 6 g

Linoleic acid 300 mg N.E.

(\*) The Ca:P ratio shall be no less than 1.2 nor more than 2.0

(\*\*) Not specified

(\*\*\*) By virtue of its composition in essential aminoacids and its digestibility, the nutritional quality of the protein must be suitable for the nutritional needs of infants, so as to ensure the recommended level of protein intake.

c) Prepared foods shall be free of any hormones, antibiotics and the content in residual biological substances shall be lower than the maximum tolerable level.

d) Neither the final food nor its ingredients shall be treated with ionizing radiation.

e) Foods may contain only additives permitted under the present Standards.

f) Their content in vitamins and minerals shall satisfy the quantities required to comply with the terms of article 29.2.27 of these Standards.

g) The minimum calorie density of these foods shall be 2 kcal per g;

h) The protein content of these foods shall supply between 10 and 15 % of the total caloric intake based on the dry extract, and said protein shall be of adequate nutritional value, as assessed according to Annex I of these Standards.

i) The fat content of these foods shall supply 20 to 40% of the total energy intake.

j) The content in linoleic acid shall be no less than 300 mg per 100 kcal usable.

k) The content in edible fibre shall not be more than 5 g per 100 g of food.

29.2.42. Complementary foods for infants over 6 months and for young children may be:

a) cereal based;

b) based on leguminosae with the exception of broad beans (*Vicia faba* L.), the inclusion of which shall not be permitted because of the danger of "favism", since thermic treatment does not inactivate the toxic principles of vicina and covicina.

c) based on vegetables, meats, eggs, fruits, etc. and be presented as a paste, powder, puree, etc.

29.2.43. The labels of these foods shall contain in a clearly visible manner, in letters of not less than 2 mm height, the following warning: "To be used on medical prescription".

29.2.44. The labels of these foods shall describe the ingredients used, the energy value of the food expressed in kcal per 100 grammes of ready to eat food, or per portion advised, as well as the mineral and vitamin intake of such portions.

29.2.45. In the case of solid foods which need to be dissolved in water or some other appropriate means, the labels shall include instructions for preparation.

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**Note:** The text above is only that dealing with infant foods as contained the Uruguay Food Standards which are far more extensive and cover all foods.

Translation by J-P. Allain  
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