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GCC STANDARDIZATION ORGANIZATION (GSO)

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اشتراطات عامة لتداول الأغذية المستعملة لأغراض طبية خاصة

General Requirements for Handling of Foods for Special Medical Purposes

Prepared by:
GSO Technical Subcommittee for Organic, Functional and Genetically-modified Food

This document is a draft Gulf Standard circulated for comments. It is, therefore, subject to Alteration and modification, and may not be referred it as a Gulf Standard, until approved by the Board of Directors

ICS :67.250

Foreword

GCC Standardization Organization (GSO) is a regional Organization which consists of the National Standards Bodies of GCC member States. One of GSO main functions is to issue Gulf Standards / Technical regulations through specialized technical committees (TCs).

GSO through the technical program of committee TC No. 05-SC3 'GSO Technical Subcommittee for Organic, Functional and Genetically-modified Food' has updated the GSO standard No. : 1366 / 2002 “General Requirements for Handling of Foods for Special Medical Purposes”. The draft standard has been prepared by Saudi Arabia.

This standard has been approved as a Gulf (Technical Regulation) by GSO Board of Directors in its meeting No. ( ), held on / / H, / / G. The approved standard will replace and supersede the GSO standard No. (1366/2002).

GENERAL REQUIREMENTS FOR HANDLING OF FOODS FOR SPECIAL MEDICAL PURPOSES

1. SCOPE

This GSO Standard applies to the general requirements for handling of foods for special purposes in patients over 12 months of age, including the following products:

1.1 Nutritionally complete formulas.

1.2 Nutritionally incomplete formulas.

1.3 Formulas for metabolic "genetic" disorders in patients over 12 months.

1.4 Oral rehydration solutions.

2. COMPLEMENTARY REFERENCES

2.1 GSO 9 "Labeling and prepackage of Foods".

2.2 GSO 150-1 "Expiration periods for Food products- Part 1: Mandatory expiration dates".

2.3 GSO 150-2 "Expiration periods for Food products- Part 2: Voluntary expiration dates".

2.4 GSO 654 "General Requirements for Handling of prepackage Foods for Special Dietary uses".

2.5 GSO 2333 "Requirements for nutrition and health claim in the food".

2.6 GSO 2233 "Requirements of nutritional labeling".

3. DEFINITIONS

3.1 Foods for special medical purposes: are categories of foods for uses that are specially processed for formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary food stuffs or certain nutrients contained therein, or who have other special medically - determined nutrient requirements, whose dietary uses, or by a combination of the two.

4. REQUIREMENT

Without prejudice to what is given in GSO Standard item (2.4), the following shall be met in handling of foods for special medical purposes.

4.1 The formulation shall be based on medical and nutritional purposes.

4.2 Their use shall be demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended.

4.3 The labels, accompanying leaflets and / or other labeling and advertising of all types of foods for special medical purposes shall provide sufficient information on the nature and purpose of the food as well as detailed instructions and precautions for their use. The format of the information given should be appropriate for the person for whom it is intended.

4.4 Foods for special medical purposes shall be dispensed and marketed only by pharmacies, hospitals, medical centers and children care centers, (or as per appropriate way that are taken by national authorities).

4.5 Products that are mentioned in item 1.1 shall provide the following:

Nutrient	Minimum amount per MJ	Maximum amount per MJ
Vitamins: Vitamin A	84 µg retinol equivalents	430 µg retinol equivalents
Thiamin	0.15 mg	No maximum set
Riboflavin	0.2 mg	No maximum set
Niacin	2.2 mg niacin equivalents	No maximum set
Vitamin B 6	0.2 mg	No maximum set
Folate	25 µg	No maximum set
Vitamin B12	0.17 µg	No maximum set
Vitamin C	5.4 mg	No maximum set
Vitamin D	1.2 µg	6.5 µg or (7.5 µg)*
Vitamin E	1 mg alpha-tocopherol equivalents	No maximum set
Biotin	1.8 µg	No maximum set
Pantothenic Acid	0.35 mg	No maximum set
Vitamin K	8.5 µg	No maximum set
Minerals: Calcium	84 mg or (120 mg)*	420 mg or (600 mg)*
Magnesium	18 mg	No maximum set
Iron	1.2 mg	No maximum set
Phosphorus	72 mg	No maximum set
Zinc	1.2 mg	3.6 mg
Manganese	0.12 mg	1.2 mg
Copper	0.15 mg	1.25 mg

Iodine	15.5 µg	84 µg
Chromium	3 µg	No maximum set
Molybdenum	7 µg	No maximum set
Selenium	6 µg	25 µg
Electrolytes: Sodium	72 mg	No maximum set
Potassium	190 mg	No maximum set
Chloride	72 mg	No maximum set

* This amount applies only to products intended for children aged one to ten years.

5. LABELING

Without prejudice to what is given in GSO standards mentioned in items (2.1 and 2.6), the following shall be declared on the label:

5.1 Name of the product followed by a statement indicating the medical purposes that it is intended for.

5.2 compositional changes in the product that make it appropriate for this medical condition.

5.3 Phrase describes the nature and type of the product according to item (1).

5.4 Information on energy value shall be expressed in kj and kcal per 100 g or 100 ml as sold as well as per scientific quantity of the food as suggested for consumption.

5.5 The amounts of protein, carbohydrate and fat in the food shall be expressed in g per 100 g or per 100 ml as sold, as well as per specific quantify of the food suggested for consumption.

5.6 The amounts of vitamins and essential minerals shall be expressed in metric units per 100 g or per 100 ml as sold, as well as per specific quantity of the food suggested for consumption.

5.7 The quantity of nutrients shall be expressed in terms of percentages of the relevant international recognized recommended daily allowances.

5.8 Information on osmolality or osmolarity and / or in acid -base balance shall be given when appropriate.

5.9 When serving sizes are normally used, information described in sections 5/2 to 5/5 shall be given only per serving as quantified on the label or per portion provided that the number of servings or portions contained in the package is stated.

5.10 The nature of the animal and plant proteins or protein hydrolyses.

5.11 Foods for special medial purposes in which the essential charesterstic involves a specific modification of the content or the nature of proteins, fats or carbohydrates

shall bear a description of this modification and information on the amino acid fatty acid or carbohydrate profile, when necessary.

5.12 A prominent statement "USE UNDER MEDICAL SUPERVISION" shall appear on the label in bold letters in an area separated from other written, printed, or graphic information.

5.13 Adequate directions for the preparation including the requirement to add other ingredients, for the use of the food and its strong and keeping after the container has been opened, shall be included on the label.

5.14 An additional prominent warning statement consisting of an explanatory statement shall appear on the label in bold letters in area separated from other writing, printed or graphic information if the food for special medical purposes a health hazard when consumed by individuals who do not have the diseases, disorders or medical condition for which the food is intended.

5.15 A statement that product is not be used for parenteral administration.

5.16 A prominent statement indicating whether the product is or is not intended as the sole source of nutrition.

5.17 A complete statement concerning adequate precautions, known side effects, contraindications, and product drug interactions, as applicable.

5.18 A statement specifying the nutrient(s) which have been reduced, deleted increased or otherwise modified, relative to normal requirement, and the rational for the reduction, deletion, increase or other indication.

5.19 If the product has been formulated for specific age group, it shall carry a prominent statement to this effect.

5.20 Lactose claims in relation to food for special medical purposes:

5.20.1 A claim to the effect that a food for special medical purposes is lactose free may be made if the food contains no detectable lactose.

5.20.2 A claim to the effect that a food for special medical purposes is low lactose may be made if the food contains not more than 2 g of lactose per 100 g of the food.

5.20.3 If a claim in relation to the lactose content of a food for special medical purposes is made the label on the package of food must include the average quantity of the lactose and galactose in the food, expressed per given quantity of the food.

References:

- Codex Standard for The Labelling of and Claims for Foods for Special Medical Purposes Codex Stan 180-1991
- FSANZ Standard 2.9.5 Food for Special Medical Purposes.
- FDA Medical Foods Program – Import And Domestic: http://www.fda.gov/downloads/Food/ComplianceEnforcement/UCM073339.pdf