In the Name of God Almighty

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The National Food Safety Authority

Decree of the Board of Directors No.1 of the year 2018

On

The Rules Governing the Registration and Handling of Foods for Special Dietary Uses

Board of Directors (BoD)

After reviewing the Constitution;

Law No.48 of the year 1941 on Combating Fraud and Deception;

Decree Law No.95 of the year 1945 on Supply Affairs;

Law No.132 of the year 1950 on Milk and Milk products;

Law No.21 of the year 1958 on Regulation of Industry;

Law No.10 of the year 1966 on Food Control and Regulating Handling thereof;

Law No.1 of the year 2017 on the Enactment of the Law of the National Food Safety Authority (NFSA);

Decree of the Minister of Health No.348 of the year 1976 on Conditions and Procedures for Registering Foods for Special Dietary Uses as amended by Decree No.416 of the year 1994;

Decree of the Minister of Health No.530 of the year 1979 on the Addition of Food Preparations to the Preparations enumerated in law No.30 of the year 1976;

Decree of the Minister of Health and Population No.176 of the year 2003;

Approval of the BoD of NFSA in the session held on March 20, 2018; and

After consulting the State Council;

Decreed the following:

Clause (1)

Foods for special dietary uses (FSDU) shall be governed by the provisions of the attached technical regulation issued by the BoD of NFSA.

Clause (2)

Any other provision contrary to what is stated in the present decree shall hereby be repealed.

Clause (3)

This decree shall be published in the Supplement of the Official Gazette (Al-Waqae Al-Misriyya) and shall enter into force on the day following the date of publication.

Chairman of the Board

Dr. Hussein Mansour

The Rules Governing the Registration and Handling of Foods for Special Dietary Uses

Article (1)

The following terms shall, in the application of the provisions of the present decree, have the meanings set forth next to each:

1- "**Foods for special dietary uses (FSDU)"** means food products that are specially processed, prepared or formulated to satisfy particular dietary requirements, or requirements that exist because of specific diseases - including foods intended for feeding infants and children, diets for use in weight gain or reduction, and stimulant, fortified and appetizing foods – as established by the Codex Alimentarius Commission (CAC).

2- "**Foods for special medical purposes (FSMP)"** means a category of FSDU that are specially processed or 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 foodstuffs or certain nutrients contained therein, or who have other special medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two.

3- "**Infant formula and formulas for special medical purposes intended for infants"** means a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding.

4- **"Follow-up formula"** means a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children. It is prepared from the milk of cows or any other animals or any other constituents of animal or plant origin, which have been proved to be suitable for infants.

5- "**Processed cereal-based foods for infants and young children"** means foods prepared primarily from one or more milled cereals, which should constitute at least 25% of the final mixture on a dry weight basis.

6- **"Canned baby foods"** means foods intended primarily for use during the normal infant's weaning period and also for the progressive adaptation of infants and children to ordinary food. They may be either in ready-to-eat form or in dry form requiring reconstitution with water or milk only. They do not include products covered by items (4) and (5).

7- **"Food supplements"** means food products that are intended to supplement the normal diet, contain concentrated sources of nutrients (vitamins and minerals) or other components with nutritional and physiological effects alone or in combinations, and are marketed in forms such as solutions, capsules, powders, tablets, capsules, ampoules, drops, or in any other similar forms that are designed to be taken in measured small-unit quantities but are not in a conventional food form.

8- **"Container"** means any packaging of food for delivery as a single item and includes wrappers. A container may enclose several units or types of packages when such is offered to the consumer.

9- **"Label"** means tag, brand, mark, pictorial or descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to a container of food or placed in close proximity to foods offered for sale.

10- **"Essential nutrients"** means any substance normally consumed as a constituent of food in order to provide energy and which is needed for growth, development and maintenance of life. Any nutrient deficiency can lead to symptoms, biological or physiological changes.

11- "**Fortification"** means the addition of one or more essential nutrients to a food whether or not it is normally contained in the food, for the purpose of preventing or correcting a deficiency of one or more nutrients in the population or specific population.

12- **"Substitute food"** means a food prepared to resemble a common food in appearance, texture, taste and smell and is intended to be used as a complete or partial replacement for the food it resembles.

13- **Claims:**

(a) **"Nutrition claim"** means any representation, which states, suggests or implies that a food has particular nutritional properties, including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals, to meet the requirements stated in items (1) and (2).

(b) **"Health claim"** means any representation, which states, suggests, or implies that a relationship exists between a food or a constituent of that food and health.

14- "**Expiration date"** means the period during which a product maintains its basic characteristics and remains palatable, acceptable and marketable until the end of this period under any stated packaging, transportation and storage conditions, and after which one of its characteristics begins to deteriorate, in accordance with the standard of the CAC.

15- **"Food additives"** means substances added to a food during manufacture, processing, preparation, treatment, packing, packaging or transport for technological purposes or functions or for producing actual or possible effects on food.

These substances are not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities.

16- **"Food additives carried over into foods"**: food additives not authorized in food ingredients and raw materials may be used in or added to a food if the raw material or ingredient is carried over unintentionally into the food. The food additives in this case are called "food additives carried over into foods" and must be included in the lists of the authorized food additives. In addition, the food additives carried over into foods may not be used in infant formula or complementary foods.

17- "**Warnings"** means the warnings issued by the CAC, the European legislation or the international legislative bodies, for instance (if aspartame is added to a

food product, a phrase indicating that it contains source of phenylalanine should be on the label).

18- **"Allergens"** means the allergens determined and enumerated in the latest publications of the CAC and international legislation.

19- **"Infants"** means a person not more than 12 months of age.

20- **"Young children"** means a person from 12 months up to 36 months of age.

Article (2)

The following food products shall, in the application of the provisions of the present decree, be deemed to be FSDU:

1. infant formula and formulas for special medical purposes intended for infants, (breast-milk substitutes) and formulated complementary foods;
2. processed cereal-based foods for infants and young children;
3. canned baby foods;
4. foods intended for persons with special physiological conditions;
5. FSMP;
6. foods that are marketed with health claims as stated in items 1, 2 and 7 of Article (1) of the present regulation, and as established by the CAC and international legislation;
7. low-energy diets (800 – 1200 kcal) and very low energy diets (400 – 800 kcal) used in weight control or reduction and presented as a total or partial replacement for daily food, with the exception of the prepackaged foods put up for sale as conventional foods;
8. high-energy diets for use in weight gain;
9. low-sodium foods, including salt substitutes that bear health claims;
10. foods to which vitamins or minerals are added by (15%) or more of the reference value per 100 g of solids, or by (7.5%) of the reference value per 100 ml of liquids;
11. foods to which prebiotics, or other fortifying substances, compounds or elements are added in the light of international legislation;
12. foods containing stimulant, fortifying and appetizing substances;
13. food supplements provided that they do not contain any substances with a therapeutic pharmacological effect;

14. food supplements for athletes, and foods intended for intense muscular effort;
15. individual herbs and spices or mixtures thereof bearing health claims; and
16. prepacked artificial sweeteners (table sugar substitutes).

Article (3)

The provisions of the present decree may not apply to the following products; however, they are subject to the rules governing the handling of common foods:

1. individual herbs and spices or mixtures thereof not bearing health claims;
2. low-calorie foods not intended for specific groups of population (such as sugar-free or low-calorie foods and beverages);
3. foods that are by their nature deemed a source of vitamins, minerals, or other elements or nutrients;
4. foods that contain vitamins and minerals less than (15%) of the reference value per 100 g of solids, or (7.5%) of the reference value per 100 ml of liquids and other nutrients, in accordance with international legislation;
5. fiber-reinforced products that contain less than 3 g per100 g (30 g daily) or10 % of the daily intake reference value (DIRV);
6. natural bottled drinking water and mineral bottled drinking water; or
7. low-sodium foods, including salt substitutes not bearing health claims.

Article (4)

The label of the prepackaged FSDU shall bear a label indicating the following information:

1. the name of FSDU;
2. a list of ingredients in descending or ascending order;
3. ingredients, additives, and nutrients that may cause food allergies;
4. authorized food additives, and flavorings except for processing aids;
5. net weight or size;
6. names and addresses:
    a. the name, address and brand of the producer shall, if any, be indicated on the food container,
    b. in case of imported products, the name and address of the importer, as well as the country of origin shall be indicated; furthermore, the name and address of the producer may be written in English or French if writing in Arabic is difficult, and

c. in case of packaging, the name and address of the packer shall be indicated;

7. country of origin (production);
8. batch/lot identification;
9. expiration date;
10. product-specific storage instructions;
11. in case of domestic production, any of the following phrases (Made in Egypt, Made in A.R.E., or equivalent) shall be used; and
12. nutritional data/facts.

Nutritional facts/values shall be declared on the label as follows:

1. the declaration of nutritive value shall be numerical; however, the use of additional means of presentation may also be used;
2. information on energy value shall be expressed in Kilocalories (kcal) or in Kilojoules (KJ) per 100 grams or per 100 ml of the food as sold and per specified quantity of the food as suggested for consumption;
3. information on amounts of protein, carbohydrates and fat present in food shall be expressed in Grams (g) per 100 g or per 100 ml of the food as sold and per specified quantity of the food as suggested for consumption;
4. information on amounts of essential and non-essential amino acids or essential fatty acids may be expressed similarly in metric units as appropriate;
5. information on amounts of vitamins and essential minerals present in the food shall be expressed in metric units per 100 g or per 100 ml of the food as sold and per specified quantity of the food as suggested for consumption;
6. where it is appropriate, the quantities of nutrients may be expressed in terms of percentages of the relevant internationally recognized recommended daily allowances;
7. information on osmolality or osmolarity, or acid-base balance of a product shall be provided when appropriate; and
8. the nature of the animal or plant proteins, or protein hydrolysates shall be declared.

In case of FSMP, all the aforementioned information in addition to a prominent statement **"USE UNDER MEDICAL SUPERVISION"** shall be made in Arabic besides any other languages, and shall be marked in a conspicuous place in such a way as to be easily visible and clearly legible. Furthermore, food preparation

directions (including other ingredients required to be added for the use of the food) shall be declared on the label.

The label of any food that has been treated with ionizing radiation shall bear a written statement indicating that treatment and shall appear in close proximity to the name of the food.

Article (5)

Nutrition and health claims may not be used if they:

a) are false, ambiguous or misleading;
b) give rise to doubt about the safety of food or the nutritional adequacy of other foods;
c) encourage to or condone excess consumption of a food;
d) state or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general; or
e) refer to changes in bodily functions, which could give rise to doubt in the consumer, either textually or through pictorial, graphic, or symbolic representations.

The following may not constitute nutrition claims:

- substances in the list of ingredients,
- nutrients as a mandatory part of nutrition labelling, or
- quantitative or qualitative declaration of certain nutrients on the label if required by the relevant standards and technical rules.

Article (6)

FSDU, whether domestically manufactured or imported, may not be handled nor advertised unless registered and licensed for handling by NFSA.

Article (7)

No FSDU may be manufactured, processed or prepared except in licensed factories that meet hygienic requirements of food factories provided that hygienic requirements for producing foods intended for infants and young children are fulfilled.

Article (8)

No FSDU may be advertised by word of mouth, by picture, or in writing in any kind of mass media unless NFSA is notified of the advertisement text a week prior to advertising.

No FSMP may be advertised to the public.

Breast-milk substitutes may not be advertised by any means.

Article (9)

FSDU shall be registered as follows:

The registration, follow-up and submission of the scientific file shall be paper-based or via the NFSA website and e-mail.

The documents required for registration shall be determined by virtue of a decree of the NFSA chairman.

Registration process may not exceed a 60-day term as of date of receipt of the required documents in full, and a 30-day term in case of registration by notification.

FSDU license shall be valid for a five-year term as of date of registration and obtaining a license for handling provided that the requirements and specifications of the registered product are met.

Registration by notification shall be made for the FSDU handled in the country of origin provided that said country has food safety management systems (FSMS) consistent with the FSMS applied in Egypt, has a Certificate of Free Sale, and submits all the documents required for registration.

Upon dully fulfilling the terms and specifications of the product registered, the re-registration shall be made by notification.

NFSA shall issue a list of FSDU, FSMP, and dietary supplements that are subject to registration under the present regulation.

A database of all registered FSDU companies and factories shall be created.

Article (10)

Registration and licensing for handling of FSDU enumerated hereinbefore shall be made subsequent to paying the following fees:

- EGP 10.000 (ten thousand Egyptian pounds) for FSDU, and

- EGP 15.000 (fifteen thousand Egyptian pounds) for formulas intended for children, and foods for athletes.

FSDU shall be handled in markets in accordance with the product-specific storage and handling conditions approved by NFSA.

No FSMP may be handled outside pharmacies, or hospitals.

Article (11)

NFSA may, for the purpose of controlling FSDU, take the following procedures:

- taking samples in the light of risk analysis rules, and
- taking samples randomly from the FSDU display areas to ensure that such samples are consistent with the data and information recorded in the registration file.

For the purpose of analyzing samples, NFSA may take the following procedures:

a) sending samples taken from raw materials and products to be analyzed in the accredited laboratories to ensure that the registration requirements are fulfilled in compliance with the mandatory technical regulations and the applicable standards;
b) the permissible microbiological limits for FSDU shall be in compliance with the applicable legislation and standards and shall be within the following limits, whichever is less:
    - free of *Salmonella*/25g,
    - free of *Staphylococcus aureus*/25g,
    - free of *Enterobacteriaceae*/g (for infant formulas as well as dried and canned baby foods),
    - free of *Bacillus cereus*/g (for infant formulas and dried and canned baby foods),
    - free of *Enterobacter sakazakii*/25g, and
    - free of *Listeria monocytogenes*/25g;

c) the maximum residue limits (MRL) for pesticides shall be in compliance with international legislation;

d) the veterinary drug residues shall be in compliance with international legislation; and

e) the maximum pollutant limits shall be in compliance with international legislation.

Article (12)

FSDU producers and importers shall submit an application for registration to NFSA as follows:

a) applicant companies that have currently registered products shall submit an application for registration to NFSA and shall bring the original valid license issued by the Ministry of Health (MOH) in order for NFSA to grant a new license for the validity period remaining on the MOH license under the rules provided for in the present regulation;
b) applicant companies that have unregistered products (new products/ re-registration) shall submit an application for registration to NFSA in the light of the rules provided for in the present regulation;
c) applicant companies that have products under registration by MOH shall submit a request to NFSA for completing the registration procedures. These cases shall be examined separately and in accordance with the rules provided for in the present regulation; and
d) in respect of imported FSDU, the MOH license shall remain valid for a three-month term as of date of publication of the present decree pending adjustment.

Article (13)

FSDU production inputs subject to the present rules shall be released from customs by virtue of a valid license issued by NFSA.

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Chairman of Board of Directors

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