

THE MINISTRY OF
HEALTH

THE SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No. 43/2014/TT-BYT

Hanoi, November 24, 2014

CIRCULAR

Providing the management of functional foods^(*)

Pursuant to the June 17, 2010 Law on Food Safety;

Pursuant to the Government's Decree No. 38/2012/ND-CP of April 25, 2012, detailing a number of articles of the Law on Food Safety;

Pursuant to the Government's Decree No. 63/2012/ND-CP of August 31, 2012, defining the functions, tasks, powers and organizational structure of the Ministry of Health;

At the proposal of the Director of the Vietnam Food Administration,

The Minister of Health promulgates the Circular providing the management of functional foods.

Chapter I

GENERAL PROVISIONS

Article 1. Scope of regulation and application

1. This Circular provides activities related to the production, trading, announcement and labeling of, and provision of use instructions for, functional foods, including supplemented foods, health supplements/food supplements/dietary supplements and medical foods (foods for special medical purposes), and also foods for special dietary uses.

2. This Circular does not apply to infant formulas. The production, trading, announcement and labeling of, and provision of use instructions for, infant formulas must comply with relevant technical regulations and the provisions on trading and use of infant formulas.

Article 2. Interpretation of terms

In this Circular, the terms below are construed as follows:

1. *Supplemented foods* means ordinary foods added with healthy micro-nutrients and elements, such as vitamins, minerals, amino acids, fatty acids, enzymes, probiotics, prebiotics and substances having other biological activities.

2. *Health supplements/food supplements/dietary supplements* means products processed in the form of capsules, pills, tablets, glue, granules, powder or liquids and otherwise processed, which contain one or a mixture of the following substances:

a/ Vitamins, minerals, amino acids, fatty acids, enzymes, probiotics and substances having other biological activities;

b/ Biological active elements of natural origins from animals, minerals and plants in such forms as extracts, subdivisions, concentrations and metabolisms.

^(*) Công Báo Nos 09-10 (04/1/2015)

3. *Medical foods or foods for special medical purposes* means a type of foods for oral feeding or tube feeding which are intended for the dietary management of patients and may be used only under medical supervision.

4. *Foods for special dietary uses* for dieters, the elderly and other special persons under the provisions of the CODEX Alimentarius Commission means foods processed or mixed by special formulas to meet distinctive dietary requirements depending on the habitus or pathological status and specific disorders of users. The ingredients of these foods must be distinctive from those of ordinary foods of the same essence, if any.

5. *Scientific evidence* means scientific information and documents from scientific researches accepted after test by competent state management agencies in charge of scientific research or published by domestic or foreign science journals, or documents on traditional medicine, medicinal plants or remedies published in science publications.

6. *Recommended nutrition intakes (RNI) for Vietnamese* means nutritional needs recommended for Vietnamese which are announced by the National Institute of Nutrition (the Ministry of Health).

Chapter II

GENERAL REQUIREMENTS FOR FUNCTIONAL FOODS

Article 3. Announcement of regulation conformity or conformity with food safety regulations

1. Imported and domestically produced functional foods for which technical regulations are available shall be subject to regulation conformity announcement, and written announcements of regulation conformity shall be registered with the Ministry of Health (the Vietnam Food Administration) before such foods are marketed.

2. Imported and domestically produced functional foods for which no technical regulations are available shall be subject to announcement of conformity with food safety regulations, and written announcements of conformity with food safety regulations shall be registered with the Ministry of Health (the Vietnam Food Administration) before such foods are marketed.

3. The order and dossier for registration of written announcements of regulation conformity or conformity with food safety regulations for imported and domestically produced functional foods must comply with Articles 6 and 7 of the Government's Decree No. 38/2012/ND-CP of April 25, 2012, detailing a number of articles of the Law on Food Safety, and Articles 4, 5, 7 and 9 of the Minister of Health's Circular No. 19/2012/TT-BYT of November 9, 2012, guiding the announcement of regulation conformity or conformity with food safety regulations.

Article 4. Requirements on reports on testing of utility effects

1. Products subject to testing of their utility effects on human health include:

a/ Products with announced recommendations about their disease treatment support effects;

b/ Products with announced new utilities not yet recognized in other countries in the world;

c/ Products containing new active elements not yet permitted for use;

d/ Health supplements which have formulas different from those of products accompanied by scientific evidences and which are marketed for the first time;

dd/ Products of animal or plant origin which are marketed for the first time and have

ingredients different from those of traditional medicine products or traditional medicine products with increased or decreased ingredients or doses, and which have been published in science journals;

e/ Medical foods and foods for special dietary uses which have not yet been permitted by competent agencies or authorized agencies or laws of countries of origin, or of which utilities, users and use instructions permitted to be included in labels have not yet been certified by exporting countries.

2. The testing of products' utility effects on human health shall be conducted at organizations with the function of scientific research in medicine. Particularly, the testing of products with announced recommendations about their disease treatment support effects shall be conducted at provincial- or higher-level hospitals with the function of scientific research.

3. In case the testing of products' utility effects on human health is conducted overseas, it shall be conducted at units accredited or recognized by competent agencies of host countries, or the testing results shall be published in science journals.

4. The Vietnam Food Administration (the Ministry of Health) shall form a science council composed of experts in relevant fields to appraise reports on testing of utility effects of products and scientific evidences already announced.

The organization and operation of the Science Council must comply with law.

Article 5. Testing requirements

The testing of functional foods for announcement of their conformity with food safety regulations and regular testing must comply with the Minister of Health's Circular No. 19/2012/TT-BYT of November 9, 2012, guiding the announcement of regulation conformity or conformity with food safety regulations, and the following provisions:

1. Main active elements responsible for utilities of a product, which can be tested by domestic testing units, shall be quantified in such product.

2. For main active elements for which domestic testing units have no testing methods or standard samples for testing and quantification, the contents of ingredients containing such main active elements shall be stated in announcement dossiers.

Article 6. Requirements on labeling of functional foods

In addition to the provisions on labeling of packaged foods with respect to product names and ingredients and compulsory details subject to labeling provided in Chapter II on labeling and labeling methods of Joint Circular No. 34/2014/TTLT-BYT-BNNPTNT-BCT of October 27, 2014, of the Ministry of Health, Ministry of Agriculture and Rural Development and Ministry of Industry and Trade, guiding the labeling of foods, food additives and food processing supplements for packaged foods, the labeling of each specific group of functional foods must comply with Articles 9, 11 and 13 of this Circular and the following provisions:

1. Recommendations about risks, if any, shall be announced.

2. Names of products and details on labels must be consistent with the announced contents and enclosed documents in product announcement dossiers.

Article 7. Advertising of functional foods

1. The advertising of functional foods must comply with the law on advertising.

2. When advertising health supplements in audiovisual aids, the phrase "Caution: These products are not medicines and do not substitute curative medicines" shall be shown; the scripts or spoken words must be easy to see or hear under normal conditions.

Chapter III

REQUIREMENTS ON SUPPLEMENTED FOODS

Article 8. Requirements on to-be-announced contents

1. Nutrient content claims:

When adding vitamins, minerals, amino acids, fatty acids, enzymes, probiotics, prebiotics or substances having other biological activities to foods, the announcement of their contents in the foods shall be based on RNI for Vietnamese as provided in Appendix No. 01 to this Circular, specifically as follows:

a/ When the content of a substance is below 10% of RNI, the announcement of such substance is not allowed;

b/ When the content of a substance is 10% or more of RNI, the specific name and content of such substance may be announced for each meal ration or for every 100g of product;

c/ The maximum content of vitamins and minerals in foods calculated based on producers' RNI must not exceed the maximum intake limits of vitamins and minerals provided in Appendix No. 02 to this Circular.

In case Vietnam has no RNI and maximum intake limits, the provisions of CODEX or relevant international organizations shall apply.

2. Health claims:

a/ Health claims for added substances shall be announced only when the contents of such substances in foods reach 10% or more of RNI, which are accompanied by scientific evidences;

b/ For added ingredients for which no RNI are available, health claims for such ingredients shall be announced on product labels only when they are accompanied by scientific evidences or when the contents of such ingredients conform to the recommended intakes in scientific documents already announced;

c/ Health claims must be written clearly and consistently as suitable to users and intakes already announced.

Article 9. Requirements on labeling in Vietnamese

In addition to the requirements provided in Article 6 of this Circular, a supplemented food label must comply with the following provisions:

1. The phrase "Supplemented foods" or the phrase stating the name of the foods as in the national technical regulation must be written in the main part of the label.

2. The specific users suitable to response levels of recommended intakes already announced, or suitable to accompanied scientific evidences on recommended intakes for ingredients for which no response levels are available, must be written.

Chapter IV

REQUIREMENTS ON HEALTH SUPPLEMENTS

Article 10. Requirements on to-be-announced contents

1. Content claims:

a/ The main ingredient responsible for utilities of a product must be listed first together with its full name and content. Other ingredients shall be listed later in the order of their gradually reduced volumes;

b/ The content of vitamins and minerals in foods calculated based on daily intakes recommended by producers must reach at least 15% of RNI as provided in Appendix No. 01 to this Circular;

c/ The maximum content of vitamins and minerals in foods calculated based on daily intakes recommended by producers must not exceed the maximum intake limits of vitamins and minerals provided in Appendix No. 02 to this Circular;

d/ The content of vitamins and minerals in a product must be written on its label in numbers and percentage (%) of RNI, based on such product's daily recommended intakes or based on a serving size.

In case Vietnam has no RNI and maximum intake limits, the provisions of CODEX or relevant international organizations shall apply.

2. Health claims:

a/ Health claims must be announced strictly based on the essence of a product; the utilities of ingredients responsible for main utilities or the component utilities of ingredients shall be announced only when they are accompanied by scientific evidences; not to make announcement by listing the utilities of ingredients;

b/ Health claims, intakes, users and use instructions must be announced in consistency with documents in dossiers;

c/ When the content of vitamins, minerals and biological active elements in a product is smaller than that stated in accompanied scientific documents, such product's utilities may not be announced;

d/ When the content of vitamins, minerals and biological active elements of a product is the same as that recommended in scientific documents, such product's utilities may be announced provided that appropriate users and intakes must be stated;

dd/ When there are no RNI for ingredients, it is necessary to provide scientific documents proving the utilities of such ingredients together with recommended intakes upon announcement.

3. Users:

a/ Users must suit the announced utilities as approved by competent state agencies through the written certifications of announcement of conformity with food safety regulations;

b/ There must be warnings about non-users (if any).

Article 11. Requirements on labeling in Vietnamese

In addition to the requirements provided in Article 6 of this Circular, a label of health supplements must comply with the following provisions:

1. The phrase "Health supplements" must be written in the main part of the label to distinguish them from ordinary foods and medicines.

2. When taking the main ingredient responsible for the utilities of a product as the product's name, the following details must be written beside or below the product's name in the main part of the label and in the ingredients in the label:

a/ The content of active elements in such ingredient if these active elements can be quantified; or,

b/ The content of such ingredient if active elements in such ingredient cannot be quantified.

3. The effect mechanism shall not be written in the product's label.

4. The phrase "Caution: These products are not medicines and do not substitute curative medicines" shall be written right below the label's section for writing utilities of the products or in the same place with other recommendations, if any. This phrase must be in a color in contrast with the background color of the label and the height of letters must be at least 1.2 mm; in case the area of a side of the package for labeling is smaller than 80 cm², the height of letters must be at least 0.9 mm.

Chapter V

REQUIREMENTS ON MEDICAL FOODS AND FOODS FOR SPECIAL DIETARY USES

Article 12. Requirements on to-be-announced contents

1. Nutrient content claims:

a/ The names of ingredients of food products shall be fully listed in the order of their gradually reduced volumes;

b/ The response levels based on RNI for vitamins and minerals in serving sizes or contents per 100g of products shall be announced;

c/ The maximum content of vitamins and minerals in foods calculated based on daily intakes recommended by producers must not exceed the maximum intake limits of vitamins and minerals provided in Appendix No. 02 to this Circular.

In case Vietnam has no RNI and maximum intake limits, the provisions of CODEX or relevant international organizations shall apply.

2. Health claims:

The announcement must clearly state health claims suitable to nutritive response levels for specific users.

3. Users:

The announcement must clearly state users enclosed with warnings about non-users (if any).

4. Intakes:

To announce intakes suitable to users in a given period of time.

Article 13. Requirements on labeling in Vietnamese

In addition to the requirements provided in Article 6 of this Circular, a label of medical foods or foods for special dietary uses must satisfy the following conditions:

1. For medical foods, the phrase "Medical foods" shall be written on the main side of the label to distinguish them from ordinary foods, and the phrase "For use under medical supervision" shall be written.

2. For foods for special dietary uses, the phrase "Nutritious products (for specific users)" shall be written on the main side of the label to distinguish them from ordinary foods.

3. There must be detailed instructions on the instrument cleansing process and preparation method to ensure food hygiene and safety and sufficient nutrition, as suitable to the health status of users.

4. Requirements on use instructions:

a/ Use instructions must be clear and detailed in product announcement dossiers;

b/ There must be warnings about non-users, if any.

Chapter VI

CONDITIONS FOR PRODUCTION AND TRADING OF, AND USE INSTRUCTIONS FOR, FUNCTIONAL FOODS

Article 14. Conditions for production of functional foods

1. Physical foundations, equipment, instruments, production materials, containers and employees directly engaged in production must comply with Article 3 of the Minister of Health's Circular No. 16/2012/TT-BYT of October 22, 2012, on food safety conditions for establishments engaged in production and trading of foods, instruments, and food packaging and containing materials under the Ministry of Health's management.

2. Pharmaceuticals production establishments already granted good manufacture practice (GMP) certificates when producing functional foods shall be exempted from food safety eligibility certificates.

3. To comply with the Ministry of Health's regulations on a roadmap for compulsory application of GMP and hazard analysis and critical control points (HACCP) systems.

Article 15. Conditions for trading, preservation and transportation of functional foods

1. Physical foundations, equipment, instruments and traders shall comply with Articles 4, 5 and 6 of the Minister of Health's Circular No. 16/2012/TT-BYT of October 22, 2012, on food safety conditions for establishments engaged in production and trading of food, instruments, and food packaging and containing materials under the Ministry of Health's management.

2. Health supplements must be displayed for sale separately from places for display and sale of other foods. Pharmacies must have separate places for display and sale of functional foods.

Chapter VII

RECALL AND DISPOSAL OF UNSAFE FUNCTIONAL FOODS

Article 16. Recall of functional foods

1. Functional foods shall be recalled in the following cases:

a/ They expire;

b/ They fail to conform to technical regulations or the Ministry of Health's food safety regulations;

c/ Information on marketed products is inconsistent with the contents certified by the agency that has issued receipts of the written announcements of regulation conformity or with the contents of the written announcements of conformity with food safety regulations, or violates other regulations;

d/ They are marketed without regulation conformity certificates or written certifications of conformity with food safety regulations;

dd/ There are warnings of competent agencies of related countries or international organizations that the products are unsafe and such is confirmed by the Vietnam Food Administration of the Ministry of Health.

2. Producers and traders of functional foods shall recall unsafe functional foods and report such to the Vietnam Food Administration of the Ministry of Health.

Article 17. Disposal of unsafe functional foods

Producers and traders of unsafe functional foods shall dispose of such foods and bear all expenses for the recall and disposal of such foods in accordance with law.

Article 18. Tracking of origin of unsafe products

1. The tracking of the origin of a product shall be conducted at the last place of packaging of such product. Producers and traders of functional foods shall provide sufficient information on the origin, quality, materials and production, processing and preservation processes to competent state management agencies upon inspection or examination.

2. The tracking of the origin of materials that make foods unsafe shall be inspected at establishments where unsafe products are made, and through inspection and examination operations, material suppliers or material production zones shall be thoroughly tracked.

Chapter VIII

IMPLEMENTATION PROVISIONS

Article 19. Implementation provisions

This Circular takes effect on February 1, 2015.

To annul the Minister of Health's Circular No. 08/2004/TT-BYT of August 23, 2004, guiding the management of functional food products, from the effective date of this Circular.

Article 20. Transitional provision

Functional food products for which receipts of written announcements of regulation conformity or written certifications of conformity with food safety regulations are issued before the effective date of this Circular may be used till their expiry date stated in such receipts or certifications.

Article 21. Organization of implementation

1. The Vietnam Food Administration of the Ministry of Health shall assume the prime responsibility for, and coordinate with functional agencies of the Ministry of Industry and Trade and the Ministry of Public Security in, organizing, directing, examining and supervising the implementation of this Circular within the ambit of their vested powers.

2. Provincial-level Health Departments shall examine and supervise, and direct provincial-level Food Administrations and related units in examining and supervising, producers and traders of functional foods in their localities.

3. Agencies, organizations and persons that have products subject to testing of their utility effects for human health shall bear testing expenses under current regulations.

4. Producers and traders of functional foods shall implement this Circular.

Any problems or difficulties arising in the course of implementation of this Circular should be reported to the Ministry of Health (the Vietnam Food Administration) for consideration and settlement.

For the Minister of Health
Deputy Minister
NGUYEN THANH LONG

** All appendices to this Circular are not translated.-*