

**THE MINISTRY OF HEALTH**

**CIRCULAR No. 08/2004/TT-BYT OF  
AUGUST 23, 2004 GUIDING THE  
MANAGEMENT OF FUNCTIONAL  
FOODSTUFF PRODUCTS**

In order to uniformly manage the trading of functional foodstuff products on the market, ensure safety for consumers' health and create favorable conditions for enterprises in their business activities, the Ministry of Health hereby guides the management of functional foodstuff products (hereinafter called functional foodstuffs for short) as follows:

**I. DEFINITION AND APPELLATIONS OF  
FUNCTIONAL FOODSTUFFS**

1. Functional foodstuffs mean those used to support human organs' functions, have nutrient effects, put human body at ease, increase resistance and reduce pathogenic dangers.

2. Functional foodstuffs, depending on their effects, contents of micro-substances and use instructions, also have other appellations below:

- a/ Foodstuffs complemented with micro-nutrients;
- b/ Complementary foodstuffs;
- c/ Health protection foodstuffs;
- d/ Medical nutritious products.

**II. CONDITIONS FOR DETERMINATION  
OF FUNCTIONAL FOODSTUFFS**

Foodstuff products complemented with such nutrients as vitamins, mineral salts and biological active agent-containing substances, which are announced as functional foodstuffs by producers or are certified by competent State bodies of the producing countries or the circulation-permitting countries that they comply with the foodstuff legislation, and fully meet the following conditions, shall be regarded as functional foodstuffs:

**1. For foodstuffs complemented with micro-nutrients:** If the daily volume of micro-nutrient intakes under the use instructions inscribed in the products' labels consists of at least one vitamin or mineral salt with its content being 3 times higher than that in the Recommended Nutrient Intakes (RNI 2002) issued together with this Circular (not printed herein), the certificates of products' safety issued by the competent State bodies of the producing countries or the circulation-permitting countries are required, and the RNI levels of added micro-nutrients must be clearly inscribed in the products' labels or auxiliary labels (for import products);

**2. For biological active agent-containing functional foodstuffs:** If the products are

announced to have effects of supporting human organs' functions, increasing the resistance or reducing pathogenic dangers, the clinical testing reports on the products' effects or documents proving the effects of the products' components with such functions or the certificates of the products' effects inscribed on the labels, issued by competent State bodies of the producing countries or the circulation-permitting countries, are required.

**3. The contents inscribed in functional foodstuffs' labels must meet the conditions according to law provisions on labels and the following conditions:**

a/ The contents of use instructions for special-purpose products must include appellations of product groups (complementary foodstuffs, health protection foodstuffs, functional foodstuffs, diet foodstuffs, medical nutritious foodstuffs); users, products' effects, dosages, contraindications, special notes, or side-effects of products (if any);

b/ For biological active agent-containing foodstuffs, the following words "These products are not medicines, having no effects of substituting curative medicines" must be inscribed on their labels or auxiliary labels;

c/ Functional foodstuff products' labels must not be inscribed with treatment indications for any specific diseases or with their effect of substituting curative medicines.

4. For vitamin- and mineral salt-containing products which are not listed in the RNI mentioned in Clause 1 of this Section, products which are produced at home but not yet identified as foodstuffs or medicines, or products containing biologically active substances, without adequate documents to prove the safety and effects of such active substances, the Foodstuff Safety and

Hygiene Department shall have to assume the prime responsibility for, and coordinate with Vietnam Pharmacy Management Department and the Traditional Medicine Department of the Health Ministry in, considering for classification and uniform management.

### III. MANAGEMENT OF FUNCTIONAL FOODSTUFFS

1. Functional foodstuffs which fully meet the conditions prescribed in Section II of this Circular shall be managed and compliant with law provisions on foodstuffs. These products are subject to the announcement of foodstuff hygiene and safety standards at the Foodstuff Safety and Hygiene Department, the Health Ministry, strictly according to law provisions on foodstuffs before they are put into circulation on the market.

2. The information on, advertisement for and labeling of products which are regarded as functional foodstuffs shall comply with law provisions on information, advertisement and labeling, and must ensure the truthfulness, accuracy and clarity, and must not cause damage to producers, traders or consumers.

### IV. IMPLEMENTATION ORGANIZATION

1. The Foodstuff Safety and Hygiene Department of the Health Ministry shall have to organize, direct, examine, inspect and supervise the implementation of this Circular.

2. The provincial/municipal Health Services and Health Sections of the branches shall have to organize, direct, inspect, examine and supervise the implementation of this Circular by the functional foodstuff-producing and -trading units.

3. The functional foodstuff-producing and

trading units shall have to implement the provisions of this Circular.

#### V. IMPLEMENTATION PROVISIONS

1. This Circular takes effect 15 days after its publication in the Official Gazette. To annul the Health Ministry's Circular No. 20/2001/TT-BYT of September 11, 2001 guiding the management of medicinal foodstuff products.

2. In the course of implementation of this Circular, if any difficulties or problems arise, the units should report them to the Ministry of Health (the Foodstuff Safety and Hygiene Department) for consideration and settlement.

*For the Health Minister*

*Vice Minister*

**TRAN CHI LIEM**