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Evaluation System for Health Functional Food in Korea

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1. Standard and regulations for functional food evaluation cases from overseas

(1) Japan

For food function indication, Food Nutrition Improvement Act was amended in September 1991 and they managed functional food after setting specific health food in one of classification of special functional foods. For manifestation of raw material usage, the classification of health functional foods was performed by their application on: the control of internal organ status, cholesterol, blood pressure, mineral absorption, and prevention of dental caries.

Evaluation tests were performed through in vitro and in vivo tests, and clinical trials.

(2) China

General Hygienic Regulation was enacted for Heal Functional Food Act and use of health food in 1996. Evaluation procedure and test method (e.g. basic requirement, test items, test results etc.), and toxicological test procedure for food safety was established and have been executed.

(3) USA

In 1990, Nutritional Labeling Education Act, NLEA, for health claim and Dietary Supplement Health Education Act, DSHEA, for nutritional support statement was enacted and executed. Until recently, 12 types of nutrition information labeling have been provided.

(4) Canada

In 1998, Health Canada (one of government organizations) established basic policies for functional food and health information labeling. Establishment of the scientific evaluation standard is under consideration.

2. Health functional food classification System provision

(1) Significant facts of health functional food classification

- a. Labeling of effectiveness is important content in Health Functional Food Act
- b. For labeling of effectiveness, evaluation of function of the food is required
- c. Health functional food classification for the evaluation is preceding condition
- d. By the classification, researchers finding new health functional food material is able to be promoted, and false and overstated advertisement can be controled

(2) Classification (10 areas)

Growth, development and differentiation control

Metabolism (endocrine metabolism control)

Protection from noxious material

Cardiovascular function maintenance

Physiological and functional control of gastrointestinal tract

Behavior and mental state control

Immune function control

Dental health maintenance

Aesthetic effect

Neoplasm suppression

Etc.

(3) Health functional food effectiveness labeling

The effectiveness labeling should express level of function, ingredients and function.

3. Standard regulation for function evaluation system

(1) Health functional food evaluation methods (for individual permission): Scientific evaluation methods for health functional food should include in vivo, in vitro and clinical trials

(2) In vivo test management and clinical trial regulation for health functional food evaluation was established

- (3) Presentation of standard evaluation methods by food function: Standard in vitro, in vivo and clinical trials for 10 areas fo health functional food presented
- (4) Toxicity test: Acute and subacute (12 weeks) test and additional toxicity tests should be included for the permission as health functional food

4. Studies on examination standard for food function evaluation

- (1) Examination standard for submitted data
- (2) Board for approving health functional food individual permission is managed in KFDA. The board is organized by expert from various field related with safety and functional studes for the examination
- (3) Regulation for health functional food permission: For the permission as health functional food, regulation for health functional food approval and regulation for health functional food board related with approval procedure, limit of submission data, condition, preparation points and permission standard was established.