

Research Article

Research of Safety Management and Supervision System of Health Functional Foods in Korea

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Abstract: This study aims to explore the effectiveness of Korean food safety management system. Research on the safety management system of functional food of Korea through the functional food category, laws and regulations, examination and approval system, tag, function declaration, supervision and management and other aspects. In Korea, taking classification management according to the daily health/functional food and special health/functional food. Before the Health/functional food listed and subject to approval of the Korea food and Drug Administration, to evaluate the safety of its active ingredients. Through the approval of functional food in strict accordance with the provisions of the label and the function claims. Illegal sales of functional foods will be punished. After assessment, functional food management system in Korea has validity, it is worth our country learn and reference.

Keywords: Functional food, HFFs management, Korean

INTRODUCTION

In recent years, people's diet from the traditional to the modern, food of animal origin and severe food processing is a large consumer, followed by excess and imbalance nutrients which resulting in a high proportion of obesity, diabetes, coronary heart disease and other diseases (Xinjian, 2012). Therefore, function foods that improving the human health is more and more popular in the world. This kind of food has the regulation of circadian rhythms, preventing diseases and promoting the rehabilitation and other functions (Xiu, 2012), it must meet the following criteria: non-toxic and harmless, conform to the requirements of the proper nutrition; its function must be clearly and specifically; developed for specific populations; not for therapeutic purposes.

Currently the functional food industry in the United States, Japan and Europe has fast-growing, the management of functional foods in these countries is relatively perfect. America has a mature functional food management system, relevant laws and regulations including the "Nutrition Labelling and Education Act," "Dietary Supplement Health and Education Act," "Food and Drug Administration Modernization Act" and under the strict food labeling claims (Weng *et al.*, 2009a); Japanese has a strict approval and management processes of foods for specified health care and the approval of harsh conditions, health food for granted have a specific identity to distinguish (Hongyu *et al.*, 2012). Entering the new century, functional food industry spring up in Korea and quickly became one of the largest markets in Asia functional foods. 2002 Korea enacted The Health/Functional Food Act

(HFFA), for the management of functional food production and distribution in the country.

As the similar culture, market between Korea and China, the article analysis of functional food management system of Korea from the laws and regulations, approval system, safety evaluation, labeling, function claims and supervision of management, in order to provide reference for scientific management and standardize the development of functional food industry in China.

Korean functional food category: In South Korea, functional foods are called "Health/Function Foods (HFFs)". Korean think compared to other countries of functional foods, HFFs are more similar to nutritional supplements. HFFA defined HFFs as "containing nutrient component or other material has nutritional or physiological function, aim to supplement of normal diet (in concentrated form)" and come on stream as measured form of a pill, tablet, capsule, liquid. HFFs have physiological activity-so called refers to a certain nutrients can reduce the incidence of illness or improve human health (Chao *et al.*, 2012). A product of scientific data proved can be labeled "HFFs". This is the main basis of HFFs were isolated from food in general.

HFFs divided into daily HFFs and special HFFs. Daily HFFs design for different physical characteristics and nutritional needs of people with different growth stages, the main function is to promote growth and development, maintaining physical activity, improves immunity. Special HFFs design for specific health consumer groups, emphasizing the prevention of disease and the promotion of rehabilitation (Ting, s

Table 1: Thirty seven kinds of daily HFFS

Dietary supplement	Grape seed oil products
Ginseng products	Fermented vegetable extracts products
Red ginseng products	Mucopolysaccharide products
Eel oil products	Chlorophyll-containing products
EPA/DHA-containing products	Mushroom products
Royal jelly products	Aloevera products
Yeast products	Apricot extract products in Japan
Pollen products	Soft-shell turtle products
Squalene-containing (angle) /squalene product	β-carotene products
Yeast-containing products	Chitosan-containing products
Probiotic products	Shell products containing oligosaccharides
Chlorella products	Glucosamine-containing products
Spirulina products	Propolis extract product
Product containing γ-linolenic acid	Green tea extract products
Germ oil products	Soy protein products
Germ products	Products containing phytosterols
Lecithin products	Containing oligofructose (FOS) products
Products containing octacosanol	Red yeast rice products
Containing alkoxy-glycerol products	

2011). Korea currently has a total of 37 daily HFF (Table 1); these foods can be listed for sale by default. The special HFFs often introduce new active components; need to go through the Korea Food and Drug Administration (KFDA) for approval.

Korean functional food approval:

Management agency: HFFA endow the right of reviewing the safety and efficacy for Korea Food and Drug Administration before HFFs listing. KFDA formerly known as the Korea Food and Drug Safety Department (Korea Food and Drug Safety Headquarter, KFDS), upgraded to national level administration in 1998, changed its name to the Korea Food and Drug Administration (KFDA). Headquartered in Seoul, regulatory Seoul, Busan, Incheon, Daegu, Gwangju, Daejeon six divisions. KFDA and division implementation of food, drug supervision work within their respective jurisdictions.

KFDA is a consultative committee consisted of 80 experts, the members have the following expertise or represent the interests of a particular aspect: food science, pharmacy or consumer representatives. The committee consists of six chapters, each providing advice for KFDA on legislation, GMP, import and export, new active ingredient, standards, specifications and labeling and advertising.

Approval procedure: HFFs need to put on the market by passing the test of safety and efficacy. If the functional component of products of Manufacturers to be listed which didn't contain effective ingredients of daily HFFs, must declare special HFFs by the following two steps: the evaluation of safety and efficacy of new active ingredients; specifications and analytical testing of the final product.

First, manufacturers provide proof about the product's safety, efficacy. KFDA in the acceptance of the application for review within 120 days prior to the listing. The new active ingredients to provide the source

and nature of the composition, the content of active ingredients, processing methods, HFFs security, scientific evidence for the efficacy of other information.

After reviewing the safety, efficacy of the active ingredient, KFDA assess the active ingredients through the final product reviews within 90 days. The process requires information of the active ingredient analysis methods and validation, stability data and purity.

METHODOLOGY

Safety evaluation of functional foods in Korea: Safety evaluation of the active ingredient to be reviewed for the following: history of use, processing, consumption, toxicology results, the results of human trials, bioavailability evaluation (Weng *et al.*, 2009b).

Although HFFs has a variety of materials, but most have a clinical history of use, safety of inferences based on clinical information. In addition, you can also establish appropriate product standards to control whether a material can be used for HFFs. HFFs safety evaluation framework in Fig. 1.

Evaluate the effectiveness of functional foods in Korea: HFFs target population is healthy or in the initial stage of disease in an individual, effect of the patient under certain conditions taking the drug is more obvious than such groups when taking HFFs, because the effectiveness of the evaluation should be distinguished from HFFs to drugs (Jing *et al.*, 2014). KFDA take flexible standard as "appropriate and reliable scientific evidence" for HFFs. This allows manufacturers have a variety of options in what quantity, what type of evidence that provision. KFDA make the individual and overall review on evidence provided by manufacturers.

Review of individual research evidence: Firstly, determine the type of each study design. Information obtained from human experiments can fully

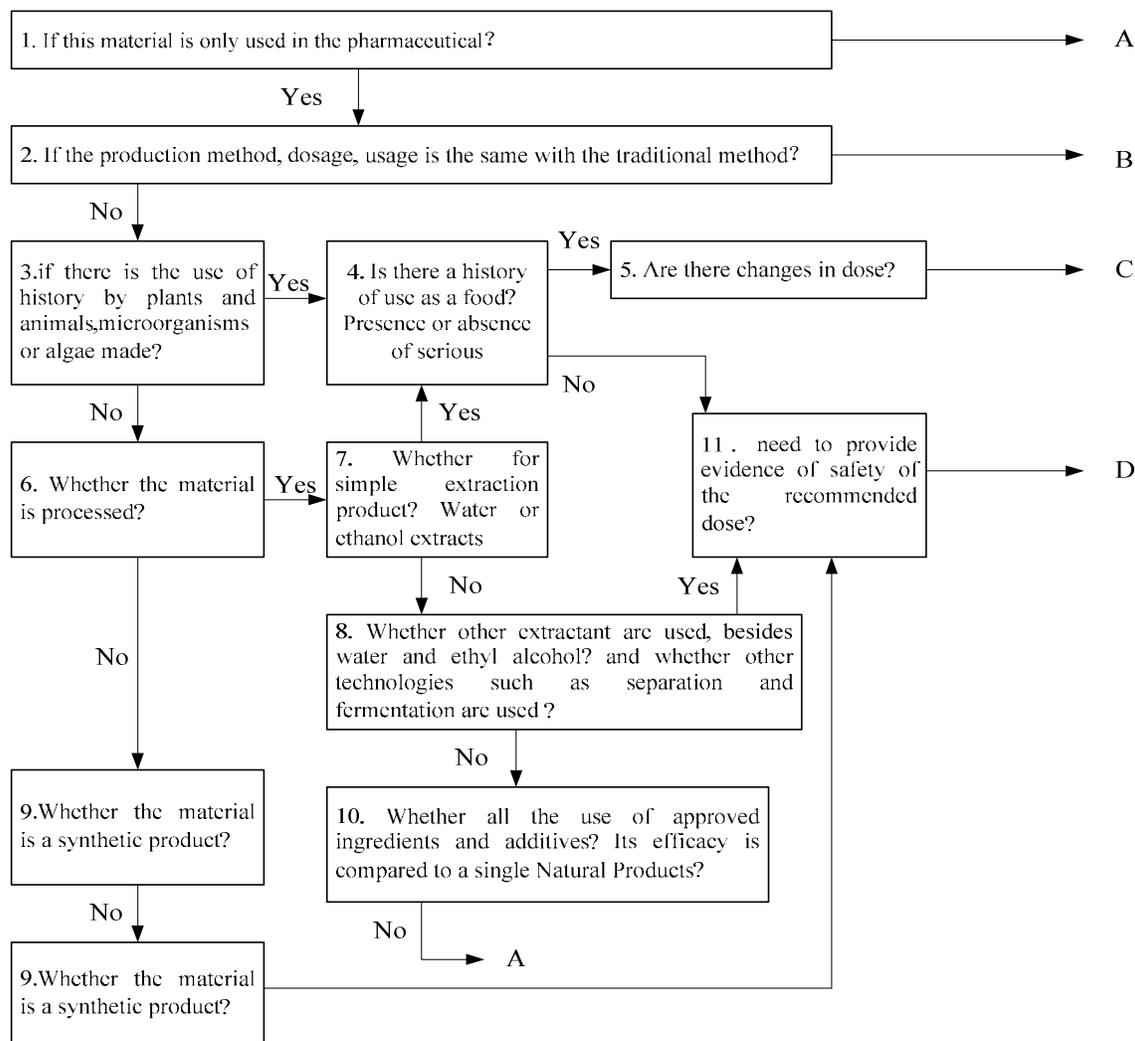


Fig. 1: A safety evaluation system diagram of Korea HFFs

support/prove that a function claims. The results of animal experiments, the results of *in vitro* experiments, observational evidence and overview of the literature can be used as supporting evidence, but cannot prove a single function claims. Secondly, scientific review of each study from the experimental design and implementation condition, the study population, data acquisition, terms of observed indicators, statistical analysis. As with the study of multiple factors, its conclusions should be more objective and reliable.

Review of the evidence as a whole: The overall strength of the scientific evidence was decided by the quality, consistency and relevance. It is meaningful while the results of individual studies to be combined with the overall results of the review. Individual and overall results of the review if consistent, the function claims should be more convincing; if conflicting, this function claims will be questioned.

KFDA establish a rating system based on the above two evidence. Reduce the risk of disease function claims require the highest level of evidence that well-designed human interference. And the evaluation experts with high level of knowledge and rich experience were unanimous. The scientific evidence of other features claimed is more extensive, human intervention is the best choice of experiments, animal experiments, *in vitro* experiments can prove/support HFFs' other functions claimed (Jing *et al.*, 2014). According to credible, probable, insufficient scientific evidence to define additional features three levels of claims Table 2.

Evidence-based rating system would rank the scientific level of evidence with the language describe of the function claims, different levels of evidence with the appropriate language to describe the function claims. In order to increase consumer understanding of function claims that KFDA intends to conduct

Table 2: Function of HFFs claims with appropriate description language

Claiming type	Scientifically proven level	Corresponding language description
Reduce the risk of disease	Clear scientific consensus	Can help reduce the risk of...
Other features (I)	Credible	Be beneficial to...
Other features (II)	Probable	Probable increase/decrease...
Other features (III)	Insufficient	May contribute... but need to prove...

Table 3: Function claims on special health functional products

Claiming category	Function claims
Reduce the risk of disease	Reduce the risk of dental caries
Other functions	Hypotensive
	Lower cholesterol
	Reduce body fat
	Keep healthy
	Regulate blood sugar
	Regulate postprandial glucose
	Maintaining good gastrointestinal function
	Improve memory
	Improve cognitive function

consumer surveys to create a new system of language describe.

KOREA FUNCTIONAL FOOD LABELS AND FUNCTION CLAIMS

Label: HFFs labels generally include the following: "Health/functional foods" word, product name, content, nutrient function information, ingredients, shelf life, storage conditions, manufacturer name and address, taking methods, precautions, warnings, etc., (Hao *et al.*, 2014).

Function claims: Unlike traditional food, HFFs as a special category have special requirements in terms of dosage, safety, efficacy and labeling, etc., (Le, 2011). HFFA rule on function claims such as the main nutrient function claims, other function claims and the claims to reduce the risk of disease. Nutrient-function claims that describe the role played by the nutrients in the body's growth, development and normal physiological functions, applicable to nutrients of RDAs (Recommended Daily Allowance) (Xiu, 2012). Other-function claims means on the basis of a normal diet, HFFs beneficial effects on the body's normal physiological function.

Reduction-of-disease claims is a food or nutrients and reduce the risk or the description of the relationship between health status, but does not mean contain the claim that the prevention and treatment of certain diseases.

The vitamin and mineral supplements in daily HFFs have RDAs, can have nutrient function claims. For special HFFs, KFDA reviewed by the 23 kinds of active ingredients and 27 kinds of special HFFs in 2005, most of them is the other function claims; reduce disease risk claims only for xylitol to reduce caries risk claims (Table 3).

ODS in Korea supervision and management of functional food: HFFs produced in Korea are required to apply for and obtain permission from KFDA. Submit an application to local KFDA to apply for import HFFs, only sales does not produce HFFs should be submitted to the city/district/village. The production of each HFFs site should be according to the GMP standards and to ensure the sanitary conditions, control of quality and safety of the product.

Korea established the Food Safety Policy Committee for health and safety regulation. The Committee consists of the Prime Minister, department chief, experts and other components. Clear division of labor, mutual cooperation, responsibilities clear, work together to ensure the health and safety of HFFs.

In punishment, the unlicensed production of HFFs or sell inferior products will be sentenced to 5 years imprisonment or a fine of 100 million; if the manufacturer is accused of hype or improper identification HFFs, will be sentenced to 5 years imprisonment or a fine of 50 million.

CONCLUSION

South Korea is one of the few Asian countries to develop a functional food regulation. HFFs divide into daily and special categories, Korea take different approach to management them. KFDA take as responsible authority for safety and efficacy before HFFs listing in Korea. Safety evaluation within a certain evaluation framework, the efficacy evaluation adopts the method combine the overall evidence with the single method review. Food safety policy committee responsible for health supervision, chairman of the Prime Minister of any unified command supervision. As production management, HFFs production enforces GMP. With the similar cultural background of Asian countries, Korea has complete set of strict management system of functional foods which deserves China to study.

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