S8 - 3

Regulatory Framework of Health Functional Food in Korea

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INTRODUCTION

Health functional food has been the issue of consideration in the Republic of Korea from the end of 90s. In 1980s, foods with nutrition claim were called as the health supplement foods (hereinafter "the supplements"), which were similar to US dietary supplement-type products. A rapid economic growth and better living condition led Korean people to pay more attention to health, and naturally to the supplements especially because the supplements with nutrition claim were thought to give health benefit with use. Accordingly, the problem of false or exaggerated advertisement was getting worse and became a social issue.

For that reason, there was a clear need to control compositional and labeling aspects of the supplements to protect consumers and ensure public health. Such a need was clearly demanded by consumers as well as industrial sector related to the supplements. Consequently, a draft of the Health Functional Food Act (hereinafter the Act) was developed, reviewed, and finally endorsed by the National Assembly. The Act has been in effect from August 2003 and the supplements are called as health functional foods since then.

In addition to the Act itself, the new regulatory framework for safety, efficacy and labeling/advertisement of health functional foods was prepared. The penalty for false or exaggerated advertisements was far more strengthened for functional foods compared to other foods. And, the evaluation methods and procedures of the functional foods were established to give consumers more chance to purchase quality products at affordable prices.

The health functional food industry has great potential of expansion as the size of global market of functional food reached 140 trillion won ($115 billion) and that of domestic market also reached 1.5 trillion won in 2001. The functional food product industry also will contribute to the growth of the health industry in Korea.

Followings are the outlines of regulatory framework of Health Functional Food in Korea.

The Definition and Types of the Health Functional Food

The Health Functional Food (hereinafter the Functional Food) is a processed food used with intention to enhance and preserve human health physiologically by functional ingredients and/or components in the forms of

Type of health functional foods included in public notice

1) Nutritional supplement products 2) Ginseng products 3) Red ginseng products 4) Eel oil products 5) EPA/DHA fish oil products 6) Royal jelly products 7) Pollen products 8) Squalene product 9) Product of digestive Enzyme 10) Edible Lactic acid forming bacteria products 11) Chlorella products 12) Spirulina products 13) Edible oil containing gama-linolenic acid products 14) Wheat Germ/Rice bran Oil Products 15) Products with wheat germ and/or others 16) Egg and/or Soybean Lecithin products 17) Octacosanol products 18) Alkoxy-glycerol products 19) Grape seed oil products 20) Fermented Vegetable extract products 21) Muco-polysaccharide protein products 22) Chlorophyll containing products 23) Mushroom processed products 24) Aloe products 25) Plum product 26) Turtle products 27) Beta-carotene products 28) Chitosan products 29) Chito-oligo-saccharide 30) Glucosamine 31) Propolis Extract products 32) Yeast products

tablet, capsule, powder, granule, pill, liquid, and so on.

The Commissioner of the Korea Food and Drug Administration (KFDA) has responsibility to prepare and disseminate the Health Functional Food Code containing standards and specifications of the Functional Food. If the standard and specification of a certain functional food is not notified in public, the manufacturer or importer may prepare their own standards and specifications to submit for approval of KFDA.

Permission for Business

Anyone who intends to start business of manufacturing functional foods should get permission from KFDA. Business Permit Application Form should be submitted to KFDA along with following documents:

1. Documents describing the type and processing method of the functional food to be manufactured.
2. Documents describing the layout and the list of major equipments and facilities.
3. Certificate of education (only for those who has taken the education course based on the Act already).
4. Water Quality Certificate issued by a drinking water quality inspection agency according to the Drinking Water Management Act (only when other source(s) of water than tap water was used in manufacturing process).
5. Documents describing the site and building of the factory.
6. Document declaring the appointment of Quality Control Manager.

Anyone who intends to start the importing business of the functional food should submit the business application to the corresponding Regional KFDA office. And, the imported functional food for sale or business use should be reported to the regional KFDA office. The imported functional food would be tested.

Anyone who intends to sell and/or distribute the functional food without manufacturing should file the business application to the local authority i.e., City Office, District Office or County Office.

Good Manufacturing Practice for the Health Functional Food

The commissioner of KFDA has prepared the Notice of Good Manufacturing Practice (GMP) for the functional foods that dealt with how to control their quality and manufacturing process to protect consumer and ensure public health. The notice includes the procedure of the application, good facility criteria, quality assurance team building, self-regulations of manufacturing, sanitation, quality control and preservation. The GMP is expected to enhance manufacturing process as well as the stability and quality of product. Although this practice is not a mandatory program yet, it will be mandated for venture companies and toll manufacturing companies from February 2006.

Prior Appraisal of Advertisement and Health Claim

In order to protect consumers, the commissioner of KFDA entrusted the Association of Health Functional Food Industry with a responsibility to investigate and review the advertisement and labeling of the functional food with health claim. Accordingly, the Association created a review committee with members from consumer association, academia, industrial sector and government. The result of the appraisal on the advertisement and health claim is kept open to public through KFDA homepage that people can get clear and accurate information on functional foods.

Labeling Standards

The Commissioner of KFDA determines and gives notice to public about the standards necessary for labeling

of the functional food for sale. The functional food shall not be sold, displayed or transported for sale or business use without labeling in compliance with such standards. And, with respect to denomination, manufacturing method and quality of the functional foods, no false labeling or exaggerated advertisement that may cause consumers to confuse them with medicine shall be made.

The labeling/advertisement mentioned in the Act pertains to displaying or announcing information on the name, manufacturing method, quality, nutritional content, raw materials, ingredients or use of functional foods through any form of media including container, packaging, radio, TV, newspaper, journal, billboard, oral presentation, internet, etc. And the scope of false labeling and/or exaggerated advertisement encompasses followings:

1. Labeling/advertisement that may mislead consumer to think that the food is effective in treating diseases or the food is a medicinal product
2. Labeling/advertisement with false description of raw materials or ingredients.
3. Labeling/advertisement that includes a letter of appreciation, a certificate of merit, a story of personal experience of the product or expressions such as "a rush of orders", "professional organization recommended" or similar.

If anyone is charged with untruthful and misleading information on the label, he/she will be punished by the act and forced to get maximum 3 years of sentence or pay a fine up to US $40,000.

New Functional Ingredient

In the case of a functional ingredient of the product which was not included in the Notice, the manufacturer or importer who intends to use or sell the ingredient should provide KFDA with evidence(s) of the product's safety and efficacy (in vitro, in vivo and/or clinical trial data) that can be used in supporting the health claims. And, within 120 days, KFDA has to complete the pre-market review of the ingredient/product and give the result.

The Act allows using various types of statements on health claims including nutrient function, other functions and reducing disease risks according to the level of evidence provided. The Act also requires the establishment of a Committee to develop recommendations regarding the regulation on the health claims and statements on functional foods and procedures for the appraisal of health claims.

CONCLUDING REMARKS

The Act gives great attention to consumers and industry sector. Consumers demand truthful information and high quality about products. The food industry has high expectations regarding the market potential for the functional food products. The policies and regulations by which the government made have to give a trust to consumer and a guidance to industry sector. So sharing responsibility is the one of the most important success factors in making healthy community.