

## Regulatory View of Point on Health Functional Foods in Korea, Japan, and China

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**Abstract** – This is the re-arrangement of the 2004 Asia Nutrition & Dietary Supplement Conference organized by ABF(The Asia Business Forum) in Singapore, especially regulatory view of point of health functional foods for Korea, Japan, and China. Foods that may have health benefits beyond the traditional nutrients that they contain are often called “Functional Foods”. The concept of functional foods has become popular in recent years, first in Japan and later in other countries, including the USA. In USA, The functional foods was controlled by ACSH(the American Council on Science and Health). In Korea, “Functional Foods”. was defined on the “The Law for the Health Functional Foods”(Law No. 6727 : effective as of 26<sup>th</sup>, Aug. 2002). KFDA(Korea Food and Drug Administration) is the only authority body for approval, advertisement and claims for the Health Functional Foods in Korea. In Japan, the Japan Health Food and Nutrition Food Association controls the approval, regulate functional foods’ advertisement and claims under the name of FOSHU(Foods for Specified Health Uses). In China, the State Food and Drug Administration(SFDA) is the only authoritative organization for the application, supervision and administration of health related products. Asia, especially Korea, Japan and China, is one of the leader in the vitamins and dietary supplement(VDS) market. Regulatory issues on restrictions are the most important how to tap into the health functional foods market including Korea.

**Keywords** – Health Functional Foods, Regulatory, Korea, Japan, China

### Introduction

This is the re-arrangement of the Asia Nutrition & Dietary Supplement Conference organized by ABF(The Asia Business Forum), which was held from 18<sup>th</sup> to 19<sup>th</sup>, Nov. 2004 at Raffles The Plaza Hotel, Singapore, especially Regulatory View of Point of Health Functional Foods for Korea, Japan, and China.

The key issues and highlights of this conference were 1) latest information on market performance, outlook and product leaders in Asia, 2) regulatory issues on restrictions, classifications, certification and labeling, 3) opportunities and challenges in the China market, 4) false advertising and legal consequences, 5) best practices for GMP-the USA experience, and 6) winning marketing and branding strategies(case studies).

### Understanding Vitamins & Dietary Supplements Trends in Asia-Pacific area

According to the Ms. Gigi Tan, manager of Euromonitor

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International Asia-Pacific which is one of the leader in global consumer market intelligence, the life-expectancy was tremendously extended in 2003 comparing to 1993, e.g. Korea(68 → 75), Singapore(72 → 77), Indonesia(61 → 65), Vietnam(58 → 66), and Japan(76 → 81). The personal disposable income of major Asia countries in 2003 was also increased 2-3 times as compared with 10 years ago.

The total OTC sales in 2003 was US\$ 95 billion with 9.5% increase over 2002 and the market size of its Asia-Pacific was US\$ 29.8 billion with 8.4% increase over 2002.

The global vitamins and dietary supplement(VDS) sales in 2003 was Western Europe(US\$ 5500 million), North America(US\$ 13000 million), Asia-Pacific(US\$ 16500 million) and Australia(US\$ 500 million).

For the distribution in Asia, the predominant market is chemists and pharmacies, which is quite different from Korea distribution channel for VDS.

Euromonitor forecast that the emerging trends of VDS in the future will be 1) demand for product convenience, 2) growing importance of personal appearance, 3) strong request for new formulations and new ingredient, 4) dietary

supplements targeted for ageing population, 5) child-specified product, 6) gender - specified products, and 7) new packaging.

### The Regulation of Approval and Claims in Korea

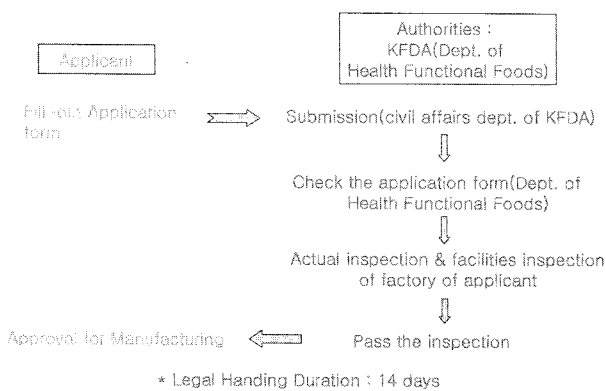
In Korea, “The Law for the Health Functional Foods”(Law No. 6727 : effective as of 26<sup>th</sup>, AUG. 2002) defined “Functional Foods”. has to prepare for approval.

The necessary documentation for the health functional foods manufacturer are 1) sale application form for manufacturing of health functional foods, 2) the kinds and manufacturing process of intended manufacturing items, 3) the list of manufacturing facilities and equipments and its lay-out, 4) registration copy of building and land on court, 5) appointment of the Q/C manager, 6) certification of necessary education of representative, and 7) certification of water purification issued by provincial government according to the clause 35 of law of portable water management.

The necessary documentation for the importation of health functional foods are 1) sale application form for Importation of health functional foods, 2) the lay-out of sale department or sales, 3) certification of necessary education of representative, and 4) certification of lease of warehouse if leased.

The necessary documentation for the health functional foods sales are 1) sale application form for sales of health functional foods, 2) the lay-out of sales place, 3) registration copy of building and land on court, 4) certification of necessary education of representative, 5) certification of lease of warehouse if leased, and 6) contract of OEM production with manufacturer, if they have.

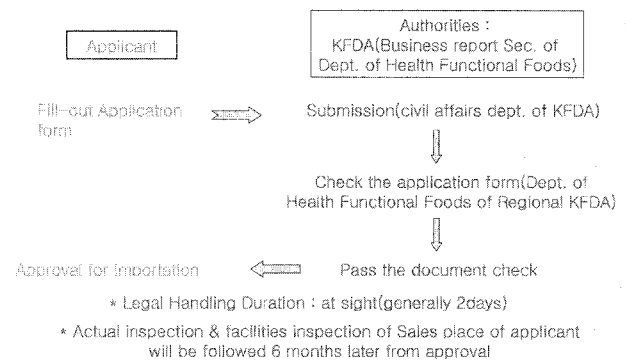
The necessary documents of the application for manufacturing the items are 1) report form of the application



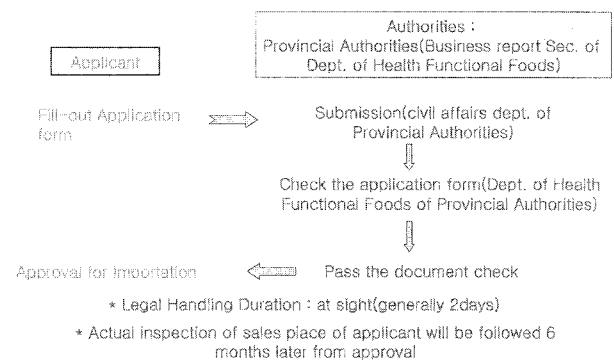
**Scheme 1.** The Approval Procedure for the Health Functional Foods Manufacturer.

of manufacturing item, 2) flow chart and method of manufacturing (inclusive of certification of expiration date), 3) name and contents of main and sub-main ingredients, 4) statement of expiration duration, standard.

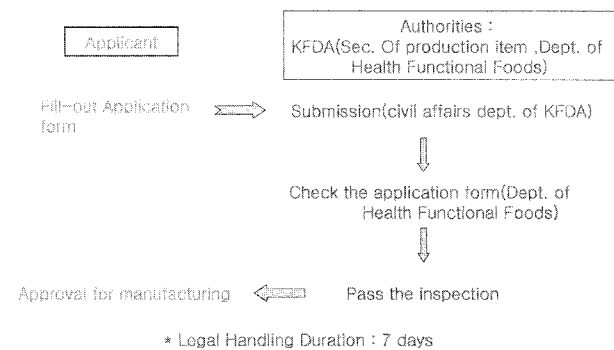
Manufacturing items of health functional foods in Korea are 32 categories ; 1) nutritional supplement foods (protein, vitamins, minerals, amino acids, fatty acids, and dietary fiber), 2) ginseng products, 3) red ginseng products,



**Scheme 2.** The Approval Procedure for the Health Functional Foods Importation.



**Scheme 3.** The Approval Procedure for the Health Functional Foods Sales.



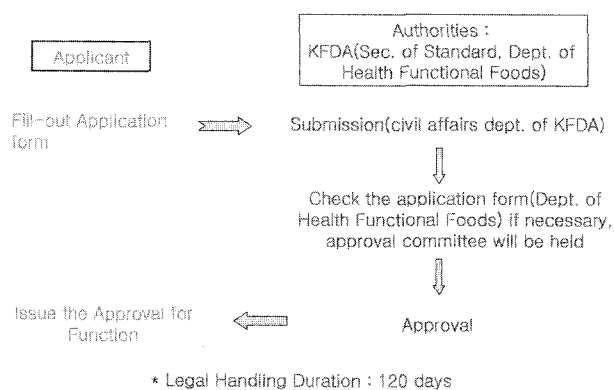
**Scheme 4.** The Process of the Application of Health Functional Foods Manufacturing Item.

4) eel oil products, 5) products containing EPA and/or DHA, 6) royal jelly products, 7) yeast products, 8) pollen products, 9) squalene products, 10) enzyme products, 11) lactic acid bacteria products, 12) chlorella products, 13) spirulina products, 14)  $\gamma$ -linolenic acid products, 15) embryo bud oil foods, 16) embryo bud products, 17) lecithin products, 18) octacosanol products, 19)alkoxy glycerol products, 20) grapeseed oil products, 21) plant extracts fermented products, 22) mucopoly-saccharide proteinous products, 23) chlorophyll products, 24) mushroom products, 25) aloe products, 26) japanese apricot extract products, 27) soft-shelled turtle products, 28)  $\beta$ -carotene products, 29) chitosan products, 30) chito-oligosaccharide products, 31) glucosamine products, and 32) propolis products.

The necessary documents of the application for approval the new function are 1) summary paper, 2) reference of the function for the enhancement of health, 3) origin, history of development and statement of foreign countries use, 4) manufacturing process and its back data, 5) flow chart and method of manufacturing (inclusive of certification of expiration date), 6) characteristics of functional property, 7) Q/C approval paper of specification and standard, 8) safety data, 9) functional data, 10) dosage and its back data, 11) other precaution and its back data, 12) data for the no-pharmaceutical purpose, and 13) samples for test. Toxicity test should be executed in GLP facilities which are approved by KFDA.

Claims for the health functional foods in Korea are obligatory claims and prohibition of claims.

Obligatory claims are 1) the facts of "Health Functional Foods", 2) the name and contents of nutritive elements, 3) the recommendable dose and its ratio, 4) the dosage, method for administration, precaution, 5) expiry date, storage method, and 6) the facts of "It is not a medicine for treatment of illness".



**Scheme 5.** The Process of the Application of New Function Approval.

Prohibition of claims are 1) the facts of "Effectiveness of Specific Disease", 2)the obscure and/or equivocal claims between foods and medicines, and 3) the false claims or exaggeration claims from the approved items, which lead the consumer to deception.

Other prohibition is that all claims on advertisement should be approved by the Judging committee of the advertisement for the health functional foods at the KFDA.

### The Regulation of Approval and Claims in Japan

Definition of foods for specified health uses(FOSHU) is as followings; 1) food that contain functional substances that affect the physiological function and biological activities of the body, 2) foods that, if used in the daily diet, one in need of a specified health benefit can hope for such a benefit, and 3) foods that are evaluated individually according to their substantiation, validity, safety, and quality and finally approved by the government.

FOSHU prerequisites must be foods that can be hoped to improved one's dietary habits and help maintain/promote health. The specified health use of the food or the functional component must be backed up by scientific evidence(through medical and nutritional studies). Adequate amount of intake must be indicated according to medical and nutritional studies. The safety of food/functional ingredient must be clearly understood from the material attached to the application. The functional ingredient must be defined in physical, chemical, and physiological properties and must have its own testing method, including quantitative and qualitative analysis. The nutritional composition of FOSHU should not be fundamentally different from a similar food that is non-FOSHU. FOSHU prerequisites must be foods that is eaten on daily basis, not something that is rarely eaten. The functional ingredient must not be included in the list of mainly medical ingredients of the ministry's notice.

Evidence that must be included in the FOSHU application material is effectiveness, safety of use, and quality. Effectiveness materials are mechanism of the function itself or of several functions(tested in vitro and clinically), amount of intake(tested clinically), and scientific evidence on the specified health use(tested clinically). Materials for safety of use are judged from experience, toxicity, long-term/over intake. Quality materials are physiochemical properties of the functional component and analytical method and stability tests.

FOSHU is approved 454 foods as of Sept. 27, 2004.

**Table 1.** Health Claims and Functional Ingredients in Japan

Health Claims	Functional Ingredients	FOSHU products	Share
Helps maintain good gastro-intestinal condition	Oligosaccharides, Lactobacillus, Bifidobacterium, Dietary Fiber	206	45%
Good for those who have high serum cholesterol/triglycerides	Soy protein, Peptides, Dietary fiber, Diacylglycerol, Plant sterol/stanol(ester)	87	19%
Goods for those who have high blood pressure	Peptides, Glucosides	41	9%
Helps improve absorption of calcium(minerals)	CPP, CCM, Soy isoflavonoids, Oligosaccharides, MBP, Heme iron	30	7%
Goods for those who have high blood glucose	Dietary fiber, Albumin, Polyphenols, L-Arabinose	59	13%
Helps maintain strong and healthy teeth	Xylitol, Polyols, Polyphenols, CPP-ACP	31	7%

Health claims and functional ingredients are as Table 1.

What must be labeled on a FOSHU package are 1) "foods with health claims(FOSHU)", 2) approved function claim, 3) nutrition facts, 4) list of ingredients, 5) total content, 6) standard daily intake, 7) methods of intake and warning concerning those methods, 8) percentage of the active substance included in the daily amount of intake to the substance's set RDA, 9) warnings concerning cooking method or preservation, and 10) FOSHU mark of approval.

### The Regulation of Approval in China

Although china has a rather long history in health care, it has a latter start in standard management on health related products in 1996. The method on health product management is issued by the ministry of health on march 15th, 1996. Since june 2003, the state food and drug administration(SFDA) is the only authoritative organization for the application, supervision and administration of health related products. Up to 2004, more than 6000 health functional foods have gained the certificate from the China government. Health functional foods is widely use natural raw materials on the basis of traditional health theory. Focus on health function, about 60% is improving immunity, anti-fatigue, and adjusting blood fat.

The definition about health food in China is special service-health functions, which can be eaten by the given people and adjust body's function, but it's aim is not the cure. Special service-health functions are 27 categories ; 1) enhance immunity, 2) adjust blood fat, 3) adjust blood sugar, 4) anti-oxidation, 5) improve memory, 6) anti-eye fatigue, 7) accelerate excreting plum bum, 8) clean the throat, 9) adjust blood pressure, 10) improve sleep, 11) accelerate lactation, 12) anti-body fatigue, 13) resist anoxia, 14) anti-radiation, 15) slimming, 16) accelerated growth, 17) improve osteoporosis, 18) improve anemia, 19) protect chemical injured liver, 20) beauty care(removing

acne), 21) protecting stomach, 22) beauty care(removing yellow spot), 23) beauty care(keeping skin wet), 24) beauty care(keeping skin's oil), 25) improve intestinal microbial colony, 26) improving digester, and 27) wet intestinal and defecation.

In China, all finished functional foods should be test progress. The test must be held in the institute of food safety and nutrition, china center of disease control and prevention(CDC) and ministry of health(MOH). Preparing documents for test are formulation, active ingredients contained, test method of active ingredients, processing, quality control, explanation and 5-10Kg samples. The tests are including hygienic test, stability test, active ingredients test, functional test, and toxicological test. The most important tests for applying the certificate are functional test. If the product has no health care function, it will not got the certificate. Most of the test must take mouse as object, except anti-eye fatigue, beauty care function. Most of the function must do the clinical test, except improving immunity, anti-body fatigue, protect chemical-injured liver, improving osteoporosis, improving sleep.

When test are finished and the materials are prepared, functional food application will be submit. But, the application is accepted below 1%. Most application need re-judgment and re-submit. In conclusion, registration progress of functional foods in China is very complex and will take a long time. A new regulation of registration is under discussing and will be carried out soon. But, for import health food, the basic program will not be changed largely.

### Conclusion

Asia, especially Korea, Japan and China, is one of the leader in the health functional foods market.

The key challenges of VDS in asia including Korea will be 1) drive to increase self-medication, 2) consumer health

education campaigns, 3) VDS-from cradle to grave, 4) ageing population posing problems for government, and 5) rising tide of consumer skepticism.

In Korea, from 2004, the health functional foods market has been faced “the great change”. Medical doctors, oriental medical doctors and other organizations as well as pharmacists can handle the health functional foods if they report their business license to the district government. In these days, shop-in-shop of health functional foods in clinics and pharmacy is popular. This change will be guided by the tremendous increase of the health functional foods market. Multi-level sales organization of foreign countries, large distributors and large enterprises group will join and focus the health functional foods market.

But, doctors’ and pharmacists’ associations have established the department of assessment of the quality of the health functional foods in their organization. Most likely survivor in the health functional foods market will be the quality and there is endorsement of quality from these associations.

In conclusion, good quality and scientifically approach to the items of health functional foods will be opportunities for the global manufacturer and importer of health functional foods. But, strictly regulatory issues of the quality control, labeling, claims, and so on by government will be threats for the global company. Therefore Regulatory issues on restrictions are the most important how to tap into the health functional foods market including Korea.

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