Introduction to the Health Functional Foods in Korea

1. Health Functional Food (HFF) is a food (product) derived from functional ingredients that are nutritious and helpful for our body. All of the health functional foods officially distributed in the domestic market are made of ingredients which have passed the meticulous evaluation of the Ministry of Food and Drug Safety for its safety and functionality through the strict review system with human study and animal testing. In addition all of the HFF products shall be manufactured in GMP-certified facilities.

For the distribution of HFF products in the market, each product is strictly controlled by the government with preliminary reviews against its advertising and health claims on the labels and also managed through the record tracking system to enhance the product’s quality and provide consumers with accurate information.

Therefore all the HFF products approved by the government's system are required to have the proper health claims and able to make the official "Health Functional Food" mark.

2. There are two different types of health functional foods in Korea as follows:

1) foods manufactured or processed using functional ingredients notified in the Codes of Health Functional Foods (hereinafter “the Codes”) in accordance with the standards and specifications for health functional foods;
2) foods manufactured or processed using functional ingredients individually recognized by the government pursuant to the regulations.

Therefore (1) a manufacturer can use publicly notified functional ingredient(s) for its health functional food product(s) in accordance with the standards and specifications prescribed in the Code, or (2) a business operator who wants to run the health functional food business can apply for individual recognition of functional ingredients or health functional foods.

In case of individual recognition, a business operator shall submit an application for recognition to the Minister of Food and Drug Safety with the relevant data related to its safety, functionality, and other necessary requirements. It becomes possible for the business operator to use an individually recognized ingredient(s) after he/she receives the letter of recognition from the government (MFDS).

3. Status of Functionality Recognition (approved functionalities by the Ministry of Food and Drug Safety)
VISION & HISTORY

MISSION
Korea Health Supplements Association aims to ensure the sound development of health functional food industry, thereby contributing to improving the health of nationals.

VISION
Health Functional Food Industry: A New High Value-added National Key Growing Industry

Foundation & Development
- Jan. 1990 Establishment of association (Government approved)
- Aug. 2002 Enactment and promulgation of the Health Functional Foods Act
- Oct. 2003 Name change as of Korea Health Supplements Association
- Jan. 2004 Designation as a Deliberation Agency reviewing the health claims and advertisement labeled on product
- Feb. 2004 Designation as a Hygiene Training Institution
- Dec. 2004 Opening of KHSA Affiliated Institution
- Nov. 2007 Creation of Health Functional Foods Future Forum
- Oct. 2012 Executing a MOU with China Health Care Association
- Mar. 2015 Executing a MOU with Bent Creek Institute (USA)
- Jan. 2017 Designation as a GMP Training Institution
- Feb. 2017 The 28th Annual General Meeting of KHSA
- May. 2017 Hosting the 2017 IADSA AGM, Seoul

Scientification & Globalization
- Oct. 2012 Executing a MOU with China Health Care Association
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Korea Health Supplements Association works for achieving 5 main strategic goals focusing on the improvement of supporting service quality for member enterprises as a top priority to lead and promote sound development of the health functional food industry.

**Policy Support**
- Monitoring for changes of regulations at ordinary times
- Collecting members’ opinions, thereby submitting them to the government
- Continuous legislative activities for deregulation of HFFs and system improvement
- Research to develop the system and regulations related to recognition and health claims
- Sponsoring Health Functional Foods Future Forum
- Operating sub-committees (Policy / Technical / Public Relations & Education / Advancement of Distribution / International Exchange)

**Globalization**
- IADSA (International Alliance of Dietary / Food Supplement Associations) activities for globalization of health functional foods system
- Supporting overseas expansion and visits to foreign countries’ exhibitions for members
- Building global networks through executing a MOU with overseas organizations such as
  - China Health Care Association, Bent Creek Institute(USA), etc.
- Holding global seminars such as
  - Global Market Entry Seminars, International Regulatory Symposiums
  - Korea-China Functional Food Information Exchange Conference, etc.
- Providing a variety of information / materials such as

**Industry Activation**
- Holding and supporting exhibitions related to health functional foods
- PR Academy for members to construct PR infra and enhance practical skills
- Support for members’ marketing services
- Workshops / conferences / seminars to activate information exchanges and mutual communications
- Providing a variety of information / materials such as

**Public Relations Campaigns**
- PR campaigns of health functional foods to promote excellence of domestic products, thereby enhancing consumer trust and improving nationals’ awareness such as
  - TV & Radio advertisement, Viral films(internet), Newspapers, Advertisements, etc.
- Regular press release to provide reliable and science-based information about HFF
- Monitoring programs against illegal advertisements
- Countermeasures for managing crisis of main issues through the media(publicity)

**Government Authorized Services**
- Training programs authorized by the government
  - to improve qualifications of those who want to run a health functional foods related business which is described in the Article 15 of the Act
  - Compulsory Training for Manufacturer, Quality Control Manager and Sales of HFF
  - Compulsory Training on the Special Act on Imported Food Safety Management
  - Compulsory Training on Good Manufacturing Practice

**Deliberation on Health Claims and Advertisement**
- to protect the consumer from false and exaggerated advertisement and establish sound advertising culture in the industry
- for the broadcast and the printed media
- against both direct and indirect expressions of health claims and/or advertisement of functionality
Korea Health Supplements Institute (KHSA affiliated) is the Food Inspection Laboratory authorized as inspection laboratory of cosmetic quality control, hygiene inspection laboratory of livestock products, official inspection laboratory related to the foods exported to Japan, and inspection laboratory related to the foods exported to Brazil.

**VISION**
- A World-class Leading Testing and Research Institute

**STRATEGY**
- RELIABILITY: Conducting meticulous quality assurance of its inspection results
- PROFESSIONALISM: Participating in the international comparative proficiency tests such as FAPAS (Food Analysis Performance Assessment Scheme)
- KOLAS (Korea Laboratory Accreditation Scheme)

**2004. 06** Completion of installing inspection facility
**2004. 08** Designation as a Hygiene Inspection Laboratory for Foods (MFDS)
  - Self-Inspection for Quality Control and Inspection for Reporting on Manufacturing Items of Foods and Health Functional Foods
**2004. 12** Opening of Korea Health Supplements Institute (KHSA affiliated)
**2004. 12.** Expended Designation of the Food Hygiene Inspection Laboratory (MFDS)
  - Extension of the inspection range and subject foods (Pesticide and Imported Foods)

**2007. 12.** Designation as an Entrusted Inspection Laboratory of Cosmetic Quality Control (MFDS)
**2009. 10.** Start of Inspecting Imported Marine Products (MFQS)
**2009. 12.** Designation as an Irradiated Foods Inspection Laboratory (MFDS)
**2010. 06.** Designation as a Hygiene Inspection Laboratory of Livestock Products (QIA)
**2010. 07.** Being a Good Laboratory Testing·Inspection Agency selected by the government (MFDS)
**2010. 08.** Designation as an Inspection Laboratory Related to the Foods Exported to Brazil (MFDS)

**2012. 10.** Designation as an Official Inspection Laboratory Related to the Foods Exported to Japan by the Ministry of Health, Labour and Welfare of Japan (MHW)
**2014. 06.** Designation as a Quality Inspection Laboratory of Salt (MOF)
**2015. 01.** Designation as a Livestock Products Testing Inspection Laboratory (MFDS to Gyeongin)
**2015. 06.** Designation as a Radioactivity Testing Inspection Laboratory
**2017. 05.** Designation as a GMO Testing Inspection Laboratory
Inspection of Foods-Livestock Products-Health Functional Foods

- Self-inspection for quality control of foods and livestock products
- Self-inspection for quality control of health functional foods
- Inspection for reporting on manufacturing items of foods and livestock products
- Inspection for reporting on manufacturing items of health functional foods
- Inspection for individual recognition of health functional foods (functional / reference materials, microorganism, heavy metals, pesticide residue, fungal toxin, etc.)
- Other Inspections for Submission of Foods / Health Functional Foods, etc.

For foods exported to
- Brazil
- Japan

Testing Inspection of Foods for Export

- Inspection of imported foods, health functional foods and food additives and their instruments-containers packaging
- Inspection of nutritional ingredients mandatorily labeled
- Inspection of pesticide residue of foods, health functional foods, agricultural products, etc.
- Inspection of various toxic substances (heavy metals, Phthalate, Viagra alike substances, benzopyrene, PCBs, etc.)
- For foods exported to Brazil
- For foods exported to Japan

Inspection of ingredients and specification of food additives

Inspection of instruments-containers to contact with foods and food additives and of packaging

Inspection for quality control of cosmetics

Inspection for checking irradiated foods

Inspection of radioactivity for foods

Inspection of GMO foods

- Research Programs

<table>
<thead>
<tr>
<th>Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual Recognition Consulting</td>
</tr>
<tr>
<td>Private Research on Functional Ingredients</td>
</tr>
<tr>
<td>Government Contracting Research Business</td>
</tr>
<tr>
<td>Industrial R&amp;D</td>
</tr>
<tr>
<td>Food Safety &amp; Sanitation Business</td>
</tr>
<tr>
<td>Training Programs for Industry</td>
</tr>
</tbody>
</table>

- EQUIPMENTS

- High Performance Liquid Chromatography (HPLC)
- Liquid Chromatography Tandem-Mass Spectrometry (LC/MS/MS)
- Gas Chromatograph
- Gas Chromatography Mass Spectrometry (GC/MS), GC/MS/MS
- Inductively Coupled Plasma (ICP)
- Inductively Coupled Plasma Mass Spectrometry (ICP-MS)
- Ion Chromatograph
- Amino acid Analyzer
- Infrared Spectrophotometer (FT-IR)
- Photostimulated Luminescence (PSL)
- Erythrocyte Sedimentation Rate (ESR)
- Thermo Luminescence (TL)
- UV-VIS spectrophotometer
- Mercury Analyzer
- Nitrogen Analyzer
- Karl-Fisher Analyzer
- Polymerase Chain Reaction
- Microbial Identification (Vitek-2)
- High Purity Germanium Radiation Detector