HEALTH FUNCTIONAL FOODS ACT

	Act No.	6727,	Aug.	26,	2002
Amended by	Act No.	7211,	Mar.	22,	2004
	Act No.	7428,	Mar.	31,	2005
	Act No.	8033,	Oct.	4,	2006
	Act No.	8365,	Apr.	11,	2007
	Act No.	8852,	Feb.	29,	2008
	Act No.	8941,	Mar.	21,	2008
	Act No.	9932,	Jan.	18,	2010
	Act No.	10128,	Mar.	17,	2010
	Act No.	10219,	Mar.	31,	2010

CHAPTER I GENERAL PROVISIONS

Article 1 (Purpose)

The purpose of this Act is to secure the safety of health functional foods, improve the quality thereof and promote the sound distribution and sale thereof, thereby contributing to improving the health of nationals and consumer protection.

Article 2 (Obligations)

(1) The State and local governments shall develop rational policies, and instruct or manage persons who manufacture, process, import and sell health functional foods (hereinafter referred to as "business operators"), to ensure that all nationals can be provided with high-quality health functional foods and accurate information on such foods.

(2) Business operators shall provide high-quality health functional foods in a safe and sound manner under the relevant Acts and subordinate statutes.

Article 3 (Definitions)

The definitions of terms used in this Act shall be as follows: <*Amended by Act No. 8941, Mar. 21, 2008*>

1. The term "health functional foods" means foods manufactured (including processed foods; hereinafter the same shall apply) with functional raw materials or ingredients useful for the human body;
2. The term "functionality" means controlling nutrients for the structure or functions of the human body or providing useful effects for hygienic purposes, such as physiological effects;

3. The term "labels" means characters, figures or diagrams labelled on containers or packages of health functional foods (including supplements and contents; hereinafter the same shall apply);
4. The term "advertisements" means showing information on health functional foods or making such information known to the public by a radio, television, newspaper, magazine, voices, sounds, images, Internet, prints, signboards or other means;
5. The term "business" means manufacturing (including processing; hereinafter the same shall apply) or importing health functional foods for sale, or selling such foods (including providing such foods to many and unspecified persons free of charge);
6. The term "health functional food traceability" means tracking health functional foods showing safety problems and managing such foods to investigate the causes of safety problems and take necessary measures by recording and managing information on foods through the production and distribution chain.

CHAPTER Ⅱ BUSINESS

Article 4 (Business Types and Facility Standards)

(1) Any person who intends to engage in any of the following business shall have facilities which meet standards prescribed by Ordinance of the Ministry of Health and Welfare: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

1. Manufacturing health functional foods;
2. Importing health functional foods;
3. Selling health functional foods.

(2) The detailed types and scope of business under paragraph (1) shall be prescribed by Presidential Decree.

Article 5 (Business License, etc.)

(1) Any person who intends to manufacture health functional foods under Article 4 (1) 1 shall have facilities under Article 4 for each place of business, as prescribed by Ordinance of the Ministry of Health and Welfare, and obtain a license from the Commissioner of the Korea Food and Drug Administration. This shall also apply to the amendment to matters prescribed by Presidential Decree. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(2) When any person who has obtained a license under paragraph (1) intends to close down the relevant business or amend the matters prescribed by Ordinance of the Ministry of Health and Welfare in his/her license, he/she shall notify the

Commissioner of the Korea Food and Drug Administration. <*Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010*>

(3) Necessary matters concerning procedures for business licenses, permission for amended license and amended notification under paragraphs (1) and (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <*Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010*>

Article 6 (Notification, etc. of Business)

(1) Any person who intends to import health functional foods for business purpose under Article 4 (1) 2 shall have facilities under Article 4 for each place of business, as prescribed by Ordinance of the Ministry of Health and Welfare, and file notification with the Governor of a Special Self-Governing Province or the head of a *Si/Gun/Gu* (referring to an autonomous *Gu*; hereinafter the same shall apply) having jurisdiction over the place of business. <*Amended by Act No. 10128, Mar. 17, 2010*>

(2) Any person who intends to sell health functional foods for business purpose under Article 4 (1) 3 shall have facilities under Article 4 for each place of business, as prescribed by Ordinance of the Ministry of Health and Welfare, and file notification with the head of a *Si/Gun/Gu* having jurisdiction over the place of business: *Provided*, That this shall not apply in cases where a drug store which has obtained registration of establishment under Article 20 of the Pharmaceutical Affairs Act, sells health functional foods. <*Amended by Act No. 7211, Mar. 22, 2004; Act No. 8365, Apr. 11, 2007; Act No. 8852, Feb. 29, 2008; Act No. 8941, Mar. 21, 2008; Act No. 9932, Jan. 18, 2010*>

(3) When any person who has filed notification under paragraph (1) or (2) intends to close down the relevant business or amend matters prescribed by Ordinance of the Ministry of Health and Welfare, he/she shall notify the Commissioner of the Korea Food and Drug Administration or the head of a *Si/Gun/Gu*, respectively. <*Amended by Act No. 8852, Feb. 29, 2008; Act No. 8941, Mar. 21, 2008; Act No. 9932, Jan. 18, 2010*>

(4) Necessary matters concerning the procedures for filing business notification and amended notification under paragraphs (1) through (3) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <*Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010*>

Article 7 (Notification of Manufacturing Products, etc.)

(1) When any person who has obtained a license to manufacture health functional foods under Article 5 (1) intends to manufacture health functional foods, he/she shall notify matters prescribed by Ordinance of the Ministry of Health and Welfare, including manuals for manufacturing the relevant product, to the Commissioner of the Korea Food and Drug Administration. This shall also apply to the amendment

to matters prescribed by Ordinance of the Ministry of Health and Welfare in a notification. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(2) Necessary matters concerning procedures for filing product manufacturing notification and amended notification under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 8 (Declaration of Importing Health Functional Foods, etc.)

(1) Any person who intends to import health functional foods to be used for sale shall file a declaration with the Commissioner of the Korea Food and Drug Administration, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(2) The Commissioner of the Korea Food and Drug Administration shall order the relevant public officials or inspection institutions to conduct the necessary inspection of health functional foods declared under paragraph (1) before the completion of customs procedures, when grounds prescribed by Ordinance of the Ministry of Health and Welfare exist. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(3) Notwithstanding paragraph (2), the Commissioner of the Korea Food and Drug Administration may grant full or partial exemption from inspections to health functional foods declared under paragraph (1) that fall under any of the following subparagraphs: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

1. When it has been confirmed in advance and publicly notified (hereinafter referred to as "preconfirmation based registration of imported health functional foods") by the Commissioner of the Korea Food and Drug Administration that health functional foods meet facility standards and standards and specifications under Articles 4, 14, 15 and 17 and do not fall under grounds for prohibiting advertisements and sales under Articles 18 and 23 through 25;
2. When the importers of health functional foods undergo inspection conducted by a food sanitary inspection institution (hereinafter referred to as "inspection institution") designated by the Commissioner of the Korea Food and Drug Administration or foreign inspection institutions recognized and publicly notified by the Commissioner of the Korea Food and Drug Administration under Article 18 of the Food Sanitation Act, and submit inspection records or inspection certificates;
3. Cases falling under grounds prescribed by Ordinance of the Ministry of Health and Welfare, which are equivalent to matters under subparagraphs 1 and 2.

(4) Necessary matters concerning the procedures for import declaration under paragraph

(1), the types, subject matters or methods of inspection under paragraph (2) and the standards and recognition procedures of preconfirmation based registration of imported health functional foods under paragraph (3) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <*Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010*>

Article 9 (Limitation on Business Licenses, etc.)

(1) The Commissioner of the Korea Food and Drug Administration shall not grant a business license under Article 5 (1), in cases falling under any of the following subparagraphs:

1. When a person, for whom six months have not elapsed since his/her business license was cancelled under the subparagraphs of Article 32 (1) (excluding subparagraph 9; hereafter the same shall apply in this Article, Articles 34 and 35), intends to conduct the same type of business at the same place of business: *Provided*, That this shall not apply in cases where his/her business license has been cancelled due to the removal of all business facilities;
2. When a person (including representatives, in cases of corporations) whose business was cancelled by an order under the subparagraphs of Article 32 (1), intends to conduct the same type of business before the lapse of one year since the order was issued;
3. When a person (including representatives, in cases of corporations) who intends to obtain a business license is incompetent or has been declared bankrupt by the court and has not been reinstated.

(2) No person who intends to import or sell health functional foods may file business notification under Article 6 (1) and (2), in cases falling under any of the following subparagraphs:

1. When a person, for whom six months have not elapsed since he/she was issued an order to close down the place of business under the subparagraphs of Article 32 (1), intends to conduct the same kind of business at the same place of business: *Provided*, That this shall not apply to cases where he/she has been issued an order to close down the place of business due to removal of all business facilities;
2. When a person (including representatives, in cases of corporations) whose place of business was closed down by an order under the subparagraphs of Article 32 (1), intends to conduct the same type of business before the lapse of one year since the order was issued;;
3. When a person (including representatives, in cases of corporations) who intends to file business notification is incompetent or has been declared bankrupt by

the court and has not been reinstated.

Article 10 (Matters to be Observed by Business Operators)

(1) Business operators shall observe the following matters, in order to secure the safety of health functional foods, manage the quality, maintain order in distribution and improve public health: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

1. Business operators shall manage manufacturing facilities and products (including materials), to ensure that such facilities and products cause no harm to health and sanitation, and secure the safety thereof;
2. No business operator shall sell expired products, display and keep them for sale, or use them for manufacturing health functional foods;
3. Business operators shall exchange products that are decomposed or decayed, or expired or products to be abandoned, unless any justifiable ground exists to the contrary;
4. No business operator shall incite a speculative spirit in selling products, by providing reward gifts, free gifts, etc.;
5. Other matters corresponding to subparagraphs 1 through 4, which are recognized and determined by Ordinance of the Ministry of Health and Welfare as necessary for securing the safety of health functional foods, managing the quality and improving public health and sanitation.

(2) Manufacturers of health functional foods shall report production records and other matters to the Commissioner of the Korea Food and Drug Administration, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 11 (Succession to Business)

(1) In case of death of a business operator, assignment of business, or merger with a corporate business operator, the heir, assignee of business, corporation that has survived merger or has been newly established as a result of merger shall succeed to the status of the previous business operator.

(2) Any person who has acquired all business facilities and equipment by auctions under the Civil Execution Act, assignment under the Debtor Rehabilitation and Bankruptcy Act, the sales of seized property under the National Tax Collection Act, the Customs Act or the Framework Act on Local Taxes or other procedures corresponding thereto, shall succeed to the status of the previous business operator under this Act. *<Amended by Act No. 7428, Mar. 31, 2005; Act No. 10219, Mar. 31, 2010>*

(3) Any person who has succeeded to the status of the previous business operator

under paragraph (1) or (2) shall file notification with the Commissioner of the Korea Food and Drug Administration or the head of a *Si/Gun/Gu,* within one month after such succession, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 8941, Mar. 21, 2008; Act No. 9932, Jan. 18, 2010>*

(4) Article 9 (1) and (2) shall apply *mutatis mutandis* to the succession under paragraphs (1) and (2): *Provided,* That this shall not apply for three months from the date of succession, when a successor falls under Article 9 (1) 3 or (2) 3.

Article 12 (Quality Control Managers)

(1) Any person who intends to manufacture health functional foods after obtaining a business license under Article 5 (1), shall have quality control managers (hereinafter referred to as "quality control managers"), as prescribed by Ordinance of the Ministry of Health and Welfare: *Provided,* That this shall not apply when a business operator qualified as a quality control manager engages in the business of quality control management. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 8941, Mar. 21, 2008; Act No. 9932, Jan. 18, 2010>*

(2) Any quality control manager shall offer guidance to the manufacturers of health functional foods, to ensure that such manufacturers do not violate this Act or orders or dispositions under this Act, and manage products or facilities in a hygienic manner.

(3) No manufacturer of health functional foods shall obstruct the performance of duties of a quality control manager under paragraph (2) and, upon receiving a request from a quality control manager, shall comply with such request unless any justifiable ground exists to the contrary.

(4) Where a manufacturer of health functional foods appoints or dismisses a quality control manager, he/she shall file notification with the Commissioner of the Korea Food and Drug Administration, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(5) Necessary matters concerning qualification and duties of quality control managers shall be prescribed by Presidential Decree.

Article 13 (Education)

(1) The Minister of Health and Welfare may order business operators or employees to receive education on the safety of health functional foods and quality control management, when it is deemed necessary for preventing harm to public health. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(2) Any person who intends to conduct business under Article 4 shall receive education on the safety of health functional foods and quality control management in advance:

Provided, That when a business operator can not receive education in advance due to grounds prescribed by Ordinance of the Ministry of Health and Welfare, he/she may receive education prescribed by the Minister of Health and Welfare, after commencing business. <*Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010*>

(3) Any person who has been appointed as a quality control manager under Article 12 shall receive education on the safety of health functional foods and quality control management, etc. on a regular basis.

(4) When any person who shall receive education under paragraphs (1) and (2), intends to conduct business at two or more places or can not receive education due to grounds prescribed by Ordinance of the Ministry of Health and Welfare, he/she may designate persons in charge of food sanitation, from among his/her employees, and have them receive education. <*Amended by Act No. 8852, Feb. 29, 2008; Act No. 8941, Mar. 21, 2008; Act No. 9932, Jan. 18, 2010*>

(5) Necessary matters concerning education institutions, the curriculum of education and the collection of expenses incurred in providing education under paragraphs (1) through (3) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <*Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010*>

CHAPTER Ⅲ STANDARDS, SPECIFICATIONS, LABELING AND ADVERTISEMENTS

Article 14 (Standards and Specifications)

(1) The Commissioner of the Korea Food and Drug Administration shall determine and publicly notify standards and specifications for manufacturing, using and preserving health functional foods for sale.

(2) With respect to foods, the standards and specifications for which are not publicly notified pursuant to paragraph (1), the Commissioner of the Korea Food and Drug Administration may recognize the standards and specifications for such foods as the standards and specifications of health functional foods, after ordering a business operator under Article 5 (1) or 6 (1) to submit data on the standards, specifications, safety and functions of the relevant foods and having the relevant foods inspected by an inspection institution.

(3) The standards and specifications of health functional foods for exports may follow standards and specifications demanded by importers, notwithstanding the provisions

of paragraphs (1) and (2).

(4) Necessary matters concerning the standards, methods and procedures for recognition under paragraph (2) shall be prescribed by the Commissioner of the Korea Food and Drug Administration.

Article 15 (Recognition of Raw Materials, etc.)

(1) The Commissioner of the Korea Food and Drug Administration shall determine and publicly notify raw materials or ingredients of health functional foods for sale.

(2) With respect to health functional foods, the materials or ingredients of which are not publicly notified under paragraph (1), the Commissioner of the Korea Food and Drug Administration may recognize the materials or ingredients of such health functional foods as materials or ingredients that can be used for health functional foods, after receiving data on the safety, functions, etc. of the relevant raw materials or ingredients from a business operator under Article 5 (1) or 6 (1) and examining them.

(3) Necessary matters concerning the standards, methods and procedures for recognition under paragraph (2) shall be prescribed by the Commissioner of the Korea Food and Drug Administration.

Article 16 (Deliberation on Labels or Advertisements regarding Functionality)

(1) Any person who intends to label or advertise the functionality of health functional foods shall undergo deliberation, in accordance with standards, methods and procedures for deliberating on the labeling or advertisements of health functional foods, which are determined by the Commissioner of the Korea Food and Drug Administration.

(2) The Commissioner of the Korea Food and Drug Administration may entrust work concerning deliberation on the labeling or advertisements of the functionality of health functional foods under paragraph (1) to organizations established under Article 28.

Article 16-2 (Application for Objections to Advertisement Deliberations)

(1) Any person who is dissatisfied with the outcomes of deliberation under Article 16 (1) may raise an objection to the Commissioner of the Korea Food and Drug Administration within one month after the date on which he/she is notified of the outcomes of such deliberation.

(2) Upon receipt of an objection under paragraph (1), the Commissioner of the Korea Food and Drug Administration shall examine such objection, acting on the advice of the Health Functional Foods Deliberation Committee under Article 27 (1) and notify the applicant of the outcomes of examination.

(3) Necessary matters concerning the methods, procedures and management of

applications for objections, etc. under paragraphs (1) and (2) shall be prescribed by the Commissioner of the Korea Food and Drug Administration.

[This Article Newly Inserted by Act No. 8941, Mar. 21, 2008]

Article 17 (Standards of Labeling)

(1) The following matters shall be labelled on the containers or packages of health functional foods: *<Amended by Act No. 8033, Oct. 4, 2006>*

1. Word describing health functional foods or diagrams showing health functional foods;
2. Functional ingredients or nutrients and their proportions to dietary reference intake (limited to cases where dietary reference intake has been determined);
3. Amounts and directions of intake or precautions in taking health functional foods;
4. Expiration date and methods of preserving health functional foods;
5. Expressions showing that health functional foods are not medicines for preventing or treating a disease;
6. Other matters prescribed by the Commissioner of the Korea Food and Drug Administration.

(2) Necessary matters concerning the methods of labeling, etc. under paragraph (1) shall be prescribed and publicly notified by the Commissioner of the Korea Food and Drug Administration.

Article 18 (Prohibiting False Labeling or Exaggerated Advertisements)

(1) No business operator shall falsely label or exaggeratedly advertise the names, raw materials, manufacturing methods, nutrients, ingredients, usage methods or qualities of health functional foods and the traceability of health functional foods, as follows: *<Amended by Act No. 8941, Mar. 21, 2008>*

1. Labeling or advertising any indication that may lead to a misunderstanding that the relevant foods are effective in preventing or treating a disease or the relevant foods are medicines;
2. False labeling or exaggerated advertisements;
3. Labeling or advertising any indication that are likely to deceive, mislead or confuse consumers;
4. Labeling or advertising any indication that includes names (including the prescriptions of oriental medicines) used only for medicines;
5. Labeling or advertising any indication that has failed to undergo deliberation under Article 16 (1) or that is different from what has been deliberated.

(2) Necessary matters concerning the scope, etc. of false labeling or exaggerated advertisement under paragraph (1) shall be prescribed by Ordinance of the Ministry

of Health and Welfare. <*Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010*>

Article 19 (Codes of Health Functional Foods)

The Commissioner of the Korea Food and Drug Administration shall prepare and disseminate the codes of health functional foods, which include the standards and specifications of health functional foods prescribed under Article 14, raw materials and ingredients prescribed under Article 15 and standards of labeling prescribed under Article 17.

CHAPTER Ⅳ INSPECTIONS, ETC.

Article 20 (Visit, Inspections, and Collections)

(1) The Commissioner of the Korea Food and Drug Administration (including the heads of affiliated organizations prescribed by Presidential Decree) or the head of a *Si/Gun/Gu* may order business operators or the relevant persons to file necessary reports, or order the relevant public officials to visit the places of business, offices, warehouses, factories, storage facilities, stores or similar places to inspect raw materials, products, containers and packages for sale or used for business, or manufacturing or sales facilities, and to collect the minimum amounts of raw materials, products, containers and packages necessary for inspections free of charge, or allow the relevant public officials to inspect commercial books or documents, when it is deemed necessary for the hygienic management of health functional foods or the maintenance of order in business. <*Amended by Act No. 8941, Mar. 21, 2008*>

(2) Any relevant public official who intends to visit the places of business, etc., conduct an inspection, collect materials or other necessary items or inspect commercial books, etc. under paragraph (1) shall carry a certificate indicating his/her authority and present it to the relevant persons.

Article 21 (Obligation of Quality Control Self-Inspection)

(1) Any person who has obtained a business license to manufacture health functional foods under Article 5 (1) shall inspect whether health functional foods he/she has manufactured meet the standards and specifications under Article 14 and keep the records, as prescribed by Ordinance of the Ministry of Health and Welfare. <*Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010*>

(2) The Commissioner of the Korea Food and Drug Administration may entrust an inspection institution to carry out inspections, when any person who shall conduct an inspection under paragraph (1) is unsuitable to conduct a self-inspection.

(3) Necessary matters concerning the items or procedures, etc. for inspections under paragraphs (1) and (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

CHAPTER V GOOD MANUFACTURING PRACTICE REGULATIONS, ETC.

Article 22 (Good Manufacturing Practice Regulations, etc.)

(1) The Commissioner of the Korea Food and Drug Administration may determine and publicly notify standards for manufacturing and controling the quality of good health functional foods (hereinafter referred to as "Good Manufacturing Practice Regulations"), so as to manufacture good health functional foods and control the quality of health functional foods.

(2) When any person who has obtained a business license to manufacture health functional foods under Article 5 (1) complies with the Good Manufacturing Practice Regulations under paragraph (1), the Commissioner of the Korea Food and Drug Administration may designate his/her place of business as the place of business adopting the Good Manufacturing Practice Regulations and publicly notify such designation.

(3) Necessary matters concerning the procedures for designating places of business adopting the Good Manufacturing Practice Regulations or education and training for business operators or employees, etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(4) When a place of business adopting the Good Manufacturing Practice Regulations falls under any of the following subparagraphs, the Commissioner of the Korea Food and Drug Administration may cancel the designation or issue a corrective order: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

1. When it ceases to meet the Good Manufacturing Practice Regulations;
2. When it is subject to the administrative disposition of business suspension or more severe dispositions under Article 32;
3. When its business operator and employees fail to receive training and education under paragraph (3);
4. When it fails to observe matters prescribed by Ordinance of the Ministry of Health and Welfares, which are deemed necessary for the efficient management

of places of business adopting the Good Manufacturing Practice Regulations.

(5) No person, the place of business of which has not been designated as a place of business adopting the Good Manufacturing Practice Regulations, shall use the name of a place of business adopting the Good Manufacturing Practice Regulations or label or advertise similar contents.

(6) The Commissioner of the Korea Food and Drug Administration may suspend visits to places of business adopting the Good Manufacturing Practice Regulations, etc. for inspection under Article 20 for a specific period prescribed by Ordinance of the Ministry of Health and Welfare, or may offer loans aimed at improving business facilities to such places of business. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

(7) Expenses incurred in providing training and education under paragraph (3) may be collected from persons who shall receive training and education.

Article 22-2 (Registration Standards for Traceability, etc.)

(1) Any health functional food manufacturer or seller who intends to track health functional foods may register the relevant health functional foods, which meet registration standards prescribed by Ordinance of the Ministry of Health and Welfare, with the Commissioner of the Korea Food and Drug Administration. *<Amended by Act No. 9932, Jan. 18, 2010>*

(2) Any person who manufactures or sells health functional foods registered under paragraph (1) shall comply with standards (hereinafter referred to as "standards for the traceability of health functional foods") determined and publicly notified by the Commissioner of the Korea Food and Drug Administration, concerning preparing, keeping and managing records necessary for health functional food traceability.

(3) Any person who has obtained registration under paragraph (1) shall, when registered matters have been revised, report such revisions to the Commissioner of the Korea Food and Drug Administration within one month after a ground for such revisions occurs.

(4) Health functional foods registered under paragraph (1) may be labeled the indications of health functional food traceability, as prescribed and publicly notified by the Commissioner of the Korea Food and Drug Administration.

(5) The term of validity of registration under paragraph (1) shall be three years from the date on which registration is obtained: *Provided,* That the term may be extended in cases where the characteristics of the relevant items require the flexible adoption of valid terms, as prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*

(6) The Minister of Health and Welfare or the Commissioner of the Korea Food and Drug Administration may subsidize funds necessary for health functional food traceability within budgetary limits, to any person who has obtained registration under paragraph (1). *<Amended by Act No. 9932, Jan. 18, 2010>*

(7) When any person registered under paragraph (1) has failed to comply with standards for the traceability of health functional foods, the Commissioner of the Korea Food and Drug Administration may cancel such registration or issue a corrective order.

(8) Necessary matters concerning the procedures for registering the traceability of health functional foods, matters to be registered or other matters shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 9932, Jan. 18, 2010>*

[This Article Newly Inserted by Act No. 8941, Mar. 21, 2008]

CHAPTER VI PROHIBITION AGAINST SALES, ETC.

Article 23 (Prohibition against Sales, etc. of Harmful Health Functional Foods, etc.)

None of the following health functional foods may be sold, or manufactured, imported, used, stored, transported or displayed for sale:

1. Rotten or spoiled foods, which are likely to harm human health;
2. Foods which contain or are likely to contain toxic or harmful materials, or foods which are stained with or are likely to be stained with such materials: *Provided,* That this shall not apply in cases where the Commissioner of the Korea Food and Drug Administration recognizes that the relevant foods are not likely to harm human health;
3. Foods which are contaminated with or likely to be contaminated with pathogenic microorganism, which are feared to harm human health;
4. Foods which are likely to harm human health, due to uncleanness, mixing with or addition of other materials, and other grounds;
5. Foods manufactured by a person who has failed to obtain a business license, in cases where a business license is required under Article 5 (1);
6. Foods, the import of which is banned, or foods which have been imported without declarations, in cases where import declarations are required under Article 8.

Article 24 (Prohibition against Sales, etc. of Health Functional Foods which Violate Standards and Specifications)

(1) Each business operator shall manufacture, use or keep health functional foods,

the standards and specifications of which are determined under Article 14 (1) and (2), in accordance with such standards and specifications, and shall not sell health functional foods which violate such standards and specifications, or manufacture, import, use, store, transport, keep or display such health functional foods for sale.

(2) No business operator shall use materials used only for medicines, manufacture health functional foods, the combinations, mixing proportions, or contents of which are the same or similar with those of medicines, or import, sell or display such health functional foods.

(3) Detailed standards and scope of raw materials used only for medicines and similar health functional foods under paragraph (2) shall be prescribed by the Commissioner of the Korea Food and Drug Administration.

Article 25 (Prohibition against Sales, etc. of Health Functional Foods which Violate Standards of Labeling)

No business operator shall sell health functional foods which violate standards of labeling under Article 17, manufacture, import, display, transport or use such health functional foods for sale.

Article 26 (Prohibition against Similar Labels, etc.)

No person shall label on containers or packages of foods, other than health functional foods, any indication that may mislead consumers to believe that the foods have nutritional or physiological functions and effects for the structure or function of the human body, or make such advertisement, and sell, store or display for sale, foods that are labeled or advertised as health functional foods.

CHAPTER VII HEALTH FUNCTIONAL FOODS DELIBERATION COMMITTEE AND ESTABLISHMENT OF ORGANIZATIONS

Article 27 (Health Functional Foods Deliberation Committee)

(1) The Health Functional Foods Deliberation Committee shall be established at the Ministry of Health and Welfare to investigate and deliberate on the following matters, responding to questions of the Minister of Health and Welfare or the Commissioner of the Korea Food and Drug Administration: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

1. Matters concerning policies on health functional foods;

2. Matters concerning the standards and specifications of health functional foods;
3. Matters concerning the labels or and advertisements of health functional foods;
4. Other important matters concerning health functional foods.

(2) The Health Functional Foods Deliberation Committee may have researchers to examine and study the standards and specifications, and labels or advertisements, etc. of health functional foods.

(3) Necessary matters concerning the organization and operation of the Health Functional Foods Deliberation Committee under paragraphs (1) and (2) shall be prescribed by Presidential Decree.

Article 28 (Establishment of Organizations)

(1) Business operators may establish organizations by type of business prescribed by Presidential Decree, so as to secure the safety of health functional foods, improve the quality thereof and contribute to improving the public health by promoting the sound development of the relevant business.

(2) Organizations shall be corporations.

(3) In cases of the establishment of an organization, at least 1/10 (20 persons, when not less than 20 persons exist) of the promoters qualified as members of the aforementioned organization shall prepare the articles of association and obtain an authorization for such establishment from the Minister of Health and Welfare, as prescribed by Presidential Decree. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

CHAPTER Ⅷ ADMINISTRATIVE SANCTIONS, INCLUDING CORRECTIVE ORDERS AND REVOCATION OF LICENSES

Article 29 (Corrective Orders)

The Commissioner of the Korea Food and Drug Administration or the head of a *Si/Gun/Gu* may issue corrective orders, when it is deemed necessary for persons who violate this Act. *<Amended by Act No. 8941, Mar. 21, 2008>*

Article 30 (Dispositions of Discard, etc.)

(1) When business operators violate Articles 23 through 26, the Commissioner of the Korea Food and Drug Administration or the head of a *Si/Gun/Gu* may order the relevant public officials to seize or discard the relevant health functional foods,

or order business operators to take measures to remove harm to food sanitation. <*Amended by Act No. 8941, Mar. 21, 2008*>

(2) The Commissioner of the Korea Food and Drug Administration or the head of a *Si/Gun/Gu* may order the relevant public officials to seize or discard health functional foods manufactured without a business license under Article 5 (1) or equipment, containers, or packages used for such health functional foods. <*Amended by Act No. 8941, Mar. 21, 2008*>

(3) When health functional foods have cause or are likely to cause harm to sanitation, the Commissioner of the Korea Food and Drug Administration or the head of a *Si/Gun/Gu* may order business operators to recall or discard the relevant health functional foods in circulation or change the materials, manufacturing methods, ingredients or mixing proportion of the relevant health functional foods. <*Amended by Act No. 8941, Mar. 21, 2008*>

(4) When health functional foods are seized or discarded under paragraphs (1) and (2), the relevant public officials shall carry certificates indicating their authority and present such certificates to the relevant persons.

(5) Necessary matters concerning seizure or discard under paragraphs (1) and (2), or standards for health functional foods to be recalled under paragraph (3) shall be prescribed by Ordinance of the Ministry of Health and Welfare. <*Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010*>

Article 31 (Order, etc. to Repair Facilities)

(1) The Commissioner of the Korea Food and Drug Administration or the head of a *Si/Gun/Gu* may order business operators to repair facilities by fixing a period, in cases where the relevant business facilities fail to meet standards for facilities under Article 4 (1). <*Amended by Act No. 8941, Mar. 21, 2008*>

(2) When the owner and the business operator of a building are not the same person, the owner shall exert every effort to cooperate in repairing facilities in accordance with orders issued under paragraph (1).

Article 32 (Cancellation, etc. of Business License)

(1) The Commissioner of the Korea Food and Drug Administration or the head of a *Si/Gun/Gu* may cancel a business license, suspend, fully or partially, the relevant business by fixing a period within six months or issue an order to close down the places of business (limited to business notified under Article 6; hereafter the same shall apply in this Article), as prescribed by Presidential Decree, when a business operator falls under any of the following subparagraphs: <*Amended by Act No. 8941, Mar. 21, 2008*>

1. When he/she violates the latter part of Article 5 (1), the former part of Article 7 (1), Article 8 (1), the subparagraphs of Article 10 (1) (excluding subparagraphs 1 and 5) or Article 11 (3);
2. When he/she violates Article 12 (1);
3. When he/she violates Article 18 (1);
4. When he/she fails to conduct a quality control self-inspection under Article 21;
5. When he/she violates Article 22 (5);
6. When he/she violates prohibitions against sales or similar labeling, etc. under Articles 23, 24 (1) and (2), 25 or 26;
7. When he/she violates orders under Article 29, 30 (1) and (3), 31 (1) or 33 (1);
8. When he/she continues to conduct business, in violation of suspension orders;
9. When he/she ceases to perform business for six or more months without any justifiable ground.

(2) Detailed standards for administrative dispositions under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare, taking into account the type and severity of a violation. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 33 (Suspension, etc. of Manufacturing Products)

(1) When a business operator violates Article 18 (1), 21 (1), 23, 24 (1) and (2), 25 or 26, the Commissioner of the Korea Food and Drug Administration may order him/her to suspend manufacturing the relevant products or the relevant types of products (referring to all products manufactured in accordance with the same standards and specifications, from among standards and specifications for health functional foods determined under Article 14) fixing a period within six months, as prescribed by Presidential Decree.

(2) Detailed standards for administrative dispositions under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare, taking into account the type and severity of a violation. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 34 (Succession to Effects of Administrative Sanctions)

When a business operator transfers the relevant business to any other person or a merger between corporations is carried out, the effects of administrative sanctions imposed against the pervious business operator due to any violation of any subparagraph of Article 32 (1) or Article 33 (1) shall succeed to any transferee or corporation which survives such merger for one year after the date on which the period for administrative sanctions expires, or, when the procedures for administrative sanctions

are in progress, such procedures may continue for any transferee or corporation which survives such merger.

Article 35 (Measures for Closure, etc.)

(1) The Commissioner of the Korea Food and Drug Administration or the head of a *Si/Gun/Gu* may allow the relevant public officials to take the following measures to close down the relevant places of business, when business operators conduct business without obtaining a business license or filing notification in violation of the former part of Article 5 (1) or Article 6 (1) and (2), or continue to conduct business after his/her business license is cancelled or an order to close down the places of business is issued under the subparagraphs of Article 32 (1): *<Amended by Act No. 8941, Mar. 21, 2008>*

1. Removing or eliminating signboards of the relevant place of business or other business marks;
2. Posting a notice showing that the relevant places of business are illegal places of business;
3. Sealing to make the relevant business facilities and apparatuses unavailable.

(2) The Commissioner of the Korea Food and Drug Administration or the head of a *Si/Gun/Gu* may remove seals, when it is deemed that seals are not needed any more, or the relevant business operators or their agents promise to close down the relevant place of business and when they request removal of seals with other justifiable reasons, after sealing is completed under paragraph (1) 3. This shall also apply to notices, etc. under paragraph (1) 2. *<Amended by Act No. 8941, Mar. 21, 2008>*

(3) When the Commissioner of the Korea Food and Drug Administration or the head of a *Si/Gun/Gu* intends to take measures under paragraph (1), he/she shall give prior written notice to the relevant business operators or their agents: *Provided*, That this shall not apply in cases where grounds prescribed by Ordinance of the Ministry of Health and Welfare exist. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 8941, Mar. 21, 2008; Act No. 9932, Jan. 18, 2010>*

(4) Measures taken under paragraph (1) shall be discontinued to the minimum extent necessary to make it impossible to conduct the relevant business.

(5) The relevant public official shall carry a certificate indicating his/her authority and present it to the relevant persons in cases under paragraph (1).

Article 36 (Hearings)

When the Commissioner of the Korea Food and Drug Administration or the head of a *Si/Gun/Gu* intends to cancel a business license or close down a place of business under Article 32 (1), he/she shall hold a hearing. *<Amended by Act No. 8941, Mar.*

21, 2008>

Article 37 (Imposition of Penalty Surcharges)

(1) The Commissioner of the Korea Food and Drug Administration or the head of a *Si/Gun/Gu* may impose penalty surcharges not exceeding 200 million won, in lieu of suspending business or suspending manufacturing of the relevant products or the relevant types of products, as prescribed by Presidential Decree, when business operators fall under the subparagraphs (excluding subparagraphs 8 and 9) of Article 32 (1) or Article 33 (1): *Provided*, That this shall not apply to cases determined by Ordinance of the Ministry of Health and Welfare, from among cases falling under Article 32 (1) or 33 (1) due to violations of the latter part of Article 5 (1), 10 (1), 18 (1), 23, 24 (1) and (2), 25 or 26. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 8941, Mar. 21, 2008; Act No. 9932, Jan. 18, 2010>*

(2) Necessary matters concerning the amounts, etc. of penalty surcharges under paragraph (1), depending on the types or severity of violations, shall be prescribed by Presidential Decree.

(3) When penalty surcharges under paragraph (1) are not paid by a deadline, the Commissioner of the Korea Food and Drug Administration or the head of a *Si/Gun/Gu* shall revoke the imposition of penalty surcharges under paragraph (1) and take administrative dispositions, such as suspension of business under Article 32 or 33. *<Amended by Act No. 8941, Mar. 21, 2008>*

(4) Penalty surcharges imposed and collected by the Commissioner of the Korea Food and Drug Administration, from among penalty surcharges collected under paragraph (1), shall devolve on the State, and penalty surcharges imposed and collected by the head of a *Si/Gun/Gu* shall devolve on the relevant City/*Do* or *Si/Gun/Gu* Food Promotion Fund (referring to a Food Promotion Fund under Article 71 of the Food Sanitation Act). *<Amended by Act No. 8941, Mar. 21, 2008>*

(5) Deleted. *<by Act No. 8941, Mar. 21, 2008>*

CHAPTER IX SUPPLEMENTARY PROVISIONS

Article 38 (Relations with other Acts)

(1) The provisions on standards and specifications for food additives under Article 7 of the Food Sanitation Act shall apply *mutatis mutandis* to food additives used for health functional foods not prescribed in this Act, the provisions on the reinspection of foods, etc. under Article 17-2 of the same Act to the reinspection of health functional foods, the provisions on the designation of food sanitary inspection institutions under

Article 18 of the same Act to the designation of health functional foods inspection institutions, the provisons on watchdogs of food sanitation under Article 20 of the same Act to watchdogs of health functional food sanitation, the provisions on honorary watchdogs of food sanitation under Article 20-2 of the same Act to honorary watchdogs of health functional food sanitation, the provisions on medical examination under Article 26 of the same Act to medical examination, the provisons on the voluntary recall of foods under Article 31-2 of the same Act to the voluntary recall of health functional foods, the provisions on Hazard Analysis Critical Control Points under Article 32-2 of the same Act to Hazard Analysis Critical Control Points, the provisions on publication under Article 56-2 of the same Act to publication, the provisions on investigation and reporting on food poisoning under Article 67 of the same Act to investigation and reporting on food poisoning.

(2) When provisions to which the Food Sanitation Act shall apply *mutatis mutandis* under paragraph (1), are violated, measures may be taken, such as corrective orders under Article 55 of the same Act, the dispositions of discard under Article 56 of the same Act, the cancellation of a license under Article 58 of the same Act and the suspension of manufacturing products under Article 59 of the same Act, and such violations may be punished under the provisions of Articles 75 and 78 through 80 of the same Act.

Article 39 (State Subsidy)

The Minister of Health and Welfare or the Commissioner of the Korea Food and Drug Administration may subsidize full or some of the following expenses within budgetary limits: <*Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010*>

1. Expenses incurred in collecting health functional foods, etc. under Article 20 (1);
2. Financing funds for the facilities of places of business adopting the Good Manufacturing Practice Regulations under Article 22 (6);
3. Expenses incurred in improving the quality of health functional foods, preventing false labels or exaggerated advertisements, or promoting research and development, etc.;
4. Expenses for the activities of private organizations aimed at improving the safety of health functional foods.

Article 40 (Payment of Rewards)

(1) The Commissioner of the Korea Food and Drug Administration or the head of a *Si/Gun/Gu* may pay reward money within the scope of ten million won to any person who has accused or reported persons who have violated Article 5 (1),

6 (1) and (2), 23 or 26 to the relevant administrative agencies or investigative agencies. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 8941, Mar. 21, 2008>*

(2) Necessary matters concerning the standards, methods and procedures for paying reward money under paragraph (1) shall be prescribed by Presidential Decree. *<Newly Inserted by Act No. 8941, Mar. 21, 2008>*

Article 41 (Delegation or Entrustment of Authority)

(1) The Commissioner of the Korea Food and Drug Administration may entrust part of his/her authority under this Act to the Commissioner of a Regional Korea Food and Drug Administration, a Special Metropolitan City Mayor, a Metropolitan City Mayor, a *Do* Governor, the Governor of a Special Self-Governing Province, or the head of a *Si/Gun/Gu*, as prescribed by Presidential Decree. *<Amended by Act No. 10128, Mar. 17, 2010>*

(2) Deleted. *<by Act No. 8941, Mar. 21, 2008>*

(3) The Minister of Health and Welfare or the Commissioner of the Korea Food and Drug Administration may entrust part of his/her authority under this Act to organizations under Article 28, as prescribed by Presidential Decree. *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 9932, Jan. 18, 2010>*

Article 42 (Fees)

Any person who intends to obtain a license, file notification or application or undergo an inspection falling under any of the following subparagraphs shall pay fees, as prescribed by Ordinance of the Ministry of Health and Welfare: *<Amended by Act No. 8852, Feb. 29, 2008; Act No. 8941, Mar. 21, 2008; Act No. 9932, Jan. 18, 2010>*

1. Business licenses or amended business licenses under Article 5 (1) or amended notification under Article 5 (2);
2. Business notification or amended business notification under Article 6 (1) through (3);
3. Product manufacturing notification or amended notification under Article 7;
4. Declaration of importing health functional foods, inspections, or applications for preconfirmation based registration of imported health functional foods under Article 8 (1) through (3);
5. Inspections for recognizing the standards, specifications, materials, etc. of health functional foods under Article 14 (2) or 15 (2);
6. Applications for deliberation on labels or advertisements regarding functionality under Article 16 (1);
7. Entrusting performance of quality control self-inspections under Article 21 (2);
8. Applications for designation as places of business adopting the Good Manufacturing

Practice Regulations under Article 22 (2);

9. Registration of the traceability of health functional foods under Article 22-2 (1).

CHAPTER X PENAL PROVISIONS

Article 43 (Penal Provisions)

Any person who violates Articles 5 (1) and 23 shall be punished by imprisonment for not more than seven years or by a fine not exceeding 100 million won. In such cases, imprisonment and fines may be imposed in parallel.

Article 44 (Penal Provisions)

Any person falling under any of the following subparagraphs shall be punished by imprisonment for not more than five years or by a fine not exceeding 50 million won. In such cases, imprisonment and fines may be imposed in parallel:

1. A person who conducts business without filing business notification under Article 6 (1) or (2);
2. A person who manufactures or sells products without filing product manufacturing notification under the former part of Article 7 (1);
3. A person who sells products, in violation of Article 10 (1) 4;
4. A person who marks false labels or makes exaggerated advertisements, in violation of Article 18 (1);
5. A person who fails conduct a quality control self-inspection under Article 21 (1);
6. A person who marks labels or makes advertisements, in violation of Article 22 (5);
7. A person who sells products, etc., in violation of Articles 24 through 26;
8. A person who fails to comply with orders under Article 29 or 30 (1) and (3);
9. A person who violates a business suspension order under Article 32 (1).

Article 45 (Penal Provisions)

Any person falling under any of the following subparagraphs shall be punished by imprisonment for not more than three years or by a fine not exceeding 30 million won:

1. A business operator who violates standards for facilities under Article 4;
2. A person who fails to comply with matters to be observed by business operators under Article 10 (1) 2 and 3;
3. A person who fails to notify business succession under Article 11 (3);
4. A person who fails to employ quality control managers under Article 12 (1);

5. A person who rejects, interferes with or evades visit, inspection or collection under Article 20 (1);
6. A person who rejects, interferes with or evades seizure or discard under Article 30 (2);
7. A person who violates an order to suspend manufacturing products under Article 33 (1);
8. A person who removes or damages seals or notices attached by the relevant public officials without permission under Article 35.

Article 46 (Joint Penal Provisions)

Where a representative of a corporation, or an agent, employee or any other person employed by a corporation or individual commits an offence under Articles 43 through 45 in connection with the business of the corporation or individual, in addition to the punishment of such offender, the corporation or individual shall be punished by a fine under the respective provisions: *Provided*, That where such corporation or individual has not been negligent in giving due attention and supervision concerning the relevant duties to prevent such offence, this shall not apply.

[This Article Wholly Amended by Act No. 10128, Mar. 17, 2010]

Article 47 (Fines for Negligence)

(1) Any person falling under any of the following paragraphs shall be punished by a fine for negligence not exceeding three million won: *<Amended by Act No. 8941, Mar. 21, 2008>*

1. A person who fails to file notification on amended licenses under Article 5 (2);
2. A person who fails to report on amended notification under Article 6 (3);
3. A person who fails to report on amended product manufacturing notification under the latter part of Article 7 (1);
4. A person who fails to comply with matters to be observed by business operators under Article 10 (1) 1 and 5, or who violates Article 10 (2);
5. A person who interferes with the performance of duties of a quality control manager under Article 12 (3) or who fails to notify the appointment or dismissal of quality control managers under Article 12 (4);
6. A person who fails to receive education under Article 13 (1) through (3);
7. A person who fail to keep records after conducting a quality control self-inspection under Article 21 (1), or who makes a false record;

7-2. A person who fails to file notification within one month, in violation of Article 22-2 (3);

8. A person who fail to comply with an order to repair facilities under Article

31 (1).

(2) Fines for negligence under paragraph (1) shall be imposed and collected by the Commissioner of the Korea Food and Drug Administration or the head of *Si/Gun/Gu*, as prescribed by Presidential Decree. <*Amended by Act No. 8941, Mar. 21, 2008*>

(3) Any person who is dissatisfied with the disposition of a fine for negligence under paragraph (2) may raise an objection to the Commissioner of the Korea Food and Drug Administration or the head of *Si/Gun/Gu*, within 30 days after he/she is notified of the aforementioned disposition. <*Amended by Act No. 8941, Mar. 21, 2008*>

(4) If any person who is subject to the disposition of the fine for negligence under paragraph (2) raises an objection under paragraph (3), the Commissioner of the Korea Food and Drug Administration or the head of *Si/Gun/Gu* shall promptly notify the competent courts, which in turn, shall proceed to a trial on the fine for negligence pursuant to the Non-Contentions Case Litigation Procedure Act. <*Amended by Act No. 8941, Mar. 21, 2008*>

(5) If neither is an objection raised nor is a fine for negligence paid within a period under paragraph (3), the fine for negligence shall be collected in the same manner of dispositions on the default of national or local taxes.

Article 48 (Special Cases concerning Application of Provisions on Fines for Negligence)

For the purpose of the provisions on fines for negligence under Article 47, no fines for negligence may be imposed against acts, for which penalty surcharges have been imposed under Article 37.

ADDENDA

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation.

Article 2 (Transitional Measures concerning Permission for Business of Manufacturing Health Functional Foods)

(1) When any person who has reported a business of manufacturing or processing foods under Article 22 (5) of the Food Sanitation Act at the time this Act enters into force, manufactures health functional foods which meet the standards and specifications under Article 14 (1), he/she shall be deemed a business operator engaged in the business of manufacturing health functional foods under this Act. In such cases, he/she shall obtain a license from the Commissioner of the Korea Food and Drug Administration under Article 5 within six months after this Act enters into

force, and he/she shall be exempted from paying fees.

(2) When products, manufactured and reported under Article 22 (6) of the Food Sanitation Act by business operators under the former part of paragraph (1) at the time this Act enters into force, fall under health functional foods which meet standards and specifications under Article 14 (1), business operators may continue to manufacture and sell such products. In such cases, business operators shall prepare documents prescribed by Ordinance of the Ministry for Health, Welfare and Family Affairs, including the methods of manufacturing products under Article 7, and file notification with the Commissioner of the Korea Food and Drug Administration within six months after this Act enters into force, and they shall be exempted from paying fees.

Article 3 (Transitional Measures concerning Notification of Business of Importing Health Functional Foods)

When any person, who has notified the businesses of importing and selling foods under Article 16 (1) of the Food Sanitation Act at the time this Act enters into force, imports and sells health functional foods which meet the standards and specifications under Article 14 (1), he/she shall be deemed a business operator engaged in the business of importing health functional foods under this Act. In such cases, a business operator shall file notification with the Commissioner of the Korea Food and Drug Administration under Article 6 (1) within six months after this Act enters into force, and he/she shall be exempted from paying fees.

Article 4 (Transitional Measures concerning Persons whose Business License has been Cancelled)

A period for restricting licenses or notification of persons whose business license has been cancelled or who have been issued an order to close down the place of business under the Food Sanitation Act before this Act enters into force, shall be governed by the Food Sanitation Act.

Article 5 (Transitional Measures concerning Penal Provisions and Fines for Negligence)

The application of penal provisions or fines for negligence to acts committed before this Act enters into force shall be governed by the Food Sanitation Act.

Article 6 (Transitional Measures concerning Dispositions)

Dispositions, applications, declarations, reports or other acts to administrative agencies under the Food Sanitation Act before this Act enters into force, shall be deemed dispositions, applications, declarations, reports or other acts to administrative agencies under this Act.

Article 7 (Transitional Measures concerning Organizations)

Organizations under Article 28, from among trade associations established under Article 44 of the Food Sanitation Act at the time this Act enters into force, shall

be deemed to be established under this Act.

Article 8 (Relations with other Acts and Subordinate Statutes)

A citation of the provisions of the Food Sanitation Act by any other Act or subordinate statute in force at the time this Act enters into force shall be deemed to be a citation of this Act or the corresponding provisions hereof in lieu of the former provisions, if such corresponding provisions exist herein.

Article 9 Omitted.

ADDENDUM <*Act No. 7211, Mar. 22, 2004*>

This Act shall enter into force on the date of its promulgation.

ADDENDA <*Act No. 7428, Mar. 31, 2005*>

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation.

Articles 2 through 6 Omitted.

ADDENDUM <*Act No. 8033, Oct. 4, 2006*>

This Act shall enter into force six months after the date of its promulgation.

ADDENDA <*Act No. 8365, Apr. 11, 2007*>

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation. (Proviso Omitted.)

Articles 2 through 22 Omitted.

ADDENDA <*Act No. 8852, Feb. 29, 2008*>

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation. (Proviso Omitted.)

Articles 2 through 7 Omitted.

ADDENDUM <*Act No. 8941, Mar. 21, 2008*>

This Act shall enter into force six months after the date of its promulgation.

ADDENDA <*Act No. 9932, Jan. 18, 2010*>

Article 1 (Enforcement Date)

This Act shall enter into force from the date on which two months lapse after the promulgation of this Act. (Proviso Omitted.)

Articles 2 through 5 Omitted.

ADDENDA <*Act No. 10128, Mar. 17, 2010*>

(1) (Enforcement Date)

This Act shall enter into force on the date of its promulgation: *Provided*, That the amended provisions of Article 6 (1) shall enter into force on January 1, 2011.

(2) (Transitional Measures concerning Notification of Business of Importing Health Functional Foods)

An act performed by or in relation to the Commissioner of the Korea Food and Drug Administration in connection to reporting on the business of importing health functional foods under the former Article 6 (1) as at the time this Act enters into force shall be deemed an act performed by or in relation to the Governor of the competent Special Self-Governing Province, or the head of the competent *Si/Gun/Gu* pursuant to the amended provisions of Article 6 (1).

ADDENDA <*Act No. 10219, Mar. 31, 2010*>

Article 1 (Enforcement Date)

This Act shall enter into force on January 1, 2011.

Articles 2 through 11 Omitted.