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. 31, 2008
Act No. 9932, Jan. 18, 2010
Act No. 10128, Mar. 17, 2010
Act No. 10219, Mar. 31, 2010
Act No. 11690, Mar. 23, 2013
Act No. 12669, May 21, 2014
Act No. 13201, Feb. 3, 2015
Act No. 13330, May 18, 2015

Article 1 (Purpose)

The purpose of this Act is to ensure 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 protecting consumers.

Article 2 (Obligations)

(1) The State and local governments shall formulate rational policies, and instruct or manage persons who manufacture, process, import, and sell functional health foods (hereinafter referred to as "business entities"), to ensure that all nationals are able to obtain high-quality health functional foods and accurate information thereon.

(2) Business entities shall provide high-quality health functional foods in a safe and sound manner, as prescribed by relevant statutes.

Article 3 (Definitions)

The terms used in this Act shall be defined as follows: *<Amended by Act No. 13201, Feb. 3, 2015>*

1. The term "health functional foods" means foods manufactured (including processing; hereinafter the same shall apply) with functional raw materials or ingredients beneficial to for the human body;

2. The term "functionality" means controlling nutrients for the structure or functions of the human body or providing beneficial effects to health purposes, such as physiological effects;

3. The term "labels" means characters, figures, or diagrams marked on containers or packages (including supplements and contents; hereinafter the same shall apply) of health functional foods;

4. The term "advertisements" means showing information on health functional foods or making such information known to the public by radio, television, newspaper, magazine, voices, sounds, images, Internet, prints, signboards, or other means;

5. The term "business" means manufacturing or importing health functional foods for sale, or selling such foods (including providing such foods to many, unspecified persons free of charge);

6. The term "tracking management of records on health functional foods" means recording and managing the information on health functional foods in stages from manufacturing to sale in order to track the relevant health functional foods, identify the cause of a problem, and take necessary measures, if a problem arises with the safety, etc. of the relevant functional health foods.

Article 4 (Business Types and Facility Standards)

(1) Anyone who intends to engage in any of the following business shall have facilities that meet standards prescribed by Ordinance of the Prime Minister:

1. Commercially manufacturing health functional foods;

2. Deleted; *<by Act No. 13201, Feb. 3, 2015>*

3. Commercially selling health functional foods.

(2) Detailed types and scope of business referred to in paragraph (1) shall be prescribed by Presidential Decree.

Article 5 (Permission for Business, etc.)

(1) Anyone who intends to engage in commercially manufacturing functional health foods referred to in Article 4 (1) 1 shall have facilities prescribed under Article 4 for each place of business, as prescribed by Ordinance of the Prime Minister, and obtain permission from the Minister of Food and Drug Safety. This shall also apply to revisions to matters prescribed by Presidential Decree. *<Amended by Act No. 13330, May 18, 2015>*

(2) When anyone who has obtained permission under paragraph (1) intends to close the relevant business or revise matters prescribed by Ordinance of the Prime Minister, among the terms and conditions of such permission, he/she shall report thereon to the Minister of Food and Drug Safety.

(3) Procedures for obtaining permission for business, revised permission, and reporting on revised matters under paragraphs (1) and (2), and other necessary matters shall be prescribed by Ordinance of the Prime Minister. *<Newly Inserted by Act No. 13330, May 18>*

1. Where the relevant person fails to meet the standards for facilities referred to in Article 4;

2. Where the relevant person falls under any subparagraph of Article 9 (1);

3. Where the relevant person fails to appoint a quality control manager referred to in Article 12 (1) (excluding cases falling under the proviso to Article 12 (1));

4. Where the relevant person fails to undergo training on ensuring the safety of health functional foods and quality control referred to in Article 13 (2) (excluding cases falling under the proviso to Article 13 (2));

5. Where the relevant person violates restrictions placed under this Act or other statutes.

(4) Procedures for obtaining permission for business, revised permission, and reporting on revised matters under paragraphs (1) and (2), and other necessary matters shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 13201, May 18, 2015>*

Article 5 (Permission for Business, etc.)

(1) Anyone who intends to engage in commercially manufacture of health functional foods referred to in Article 4 (1) 1 shall obtain permission from the Minister of Food and Drug Safety for each place of business, as prescribed by Ordinance of the Prime Minister. This shall also apply to modification of matters prescribed by Presidential Decree. *<Amended by Act No. 13330, May 18, 2015>*

(2) When anyone who has obtained permission under paragraph (1) intends to close the relevant business or revise matters prescribed by Ordinance of the Prime Minister, among the terms and conditions of such permission, he/she shall report thereon to the Minister of Food and Drug Safety.

(3) The Minister of Food and Drug Safety shall grant permission referred to in paragraph (1), except in any of the following cases: *<Newly Inserted by Act No. 13330, May 18, 2015; Act No. 14018, Feb. 3, 2016>*

1. Where the relevant person fails to meet the standards for facilities referred to in Article 4;

2. Where the relevant person falls under any subparagraph of Article 9 (1);

3. Where the relevant person fails to appoint a quality control manager referred to in Article 12 (1) (excluding cases falling under the proviso to Article 12 (1));

4. Where the relevant person fails to undergo training on ensuring the safety of functional health foods and quality control referred to in Article 13 (2) (excluding cases falling under the proviso to Article 13 (2));

4-2. Where the relevant person fails to comply with the Regulations for Good Manufacturing Practice referred to in Article 22;

5. Where the relevant person violates restrictions placed under this Act or other statutes.

(4) Procedures for obtaining permission for business, revised permission, and reporting on revised matters under paragraphs (1) and (2), and other necessary matters shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 13330, May 18, 2015>*

Article 6 (Reporting, etc. on Business)

(1) Deleted. *<by Act No. 13201, Feb. 4, 2015>*

(2) Anyone who intends to engage commercially selling health functional foods referred to in Article 4 (1) 3 shall have facilities prescribed under Article 4 for each place of business, as prescribed by Ordinance of the Prime Minister, and report thereon to the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu having jurisdiction over the place of business: Provided, That this shall not apply where a pharmacy, the establishment of which has been registered

under Article 20 of the Pharmaceutical Affairs Act, sells health functional foods.

(3) When anyone who has filed a report under paragraph (2) intends to close the relevant business or revise matters prescribed by Ordinance of the Prime Minister, he/she shall report it to the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu. *<Amended by Act No. 13201, Feb. 3, 2015>*

(4) The Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may cancel relevant reported matters ex officio, if a business entity who has filed a report pursuant to paragraph (2) reports business closure to the head of a competent tax office pursuant to Article 8 of the Value-Added Tax Act, or if the head of a competent tax office cancels his/her business registration. *<Newly Inserted by Act No. 13330, May 18, 2015>*

(5) Procedures for reporting business and revision of matters under paragraphs (2) and (3) and other necessary matters shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 13330, May 18, 2015>*

Article 7 (Reporting, etc. on Manufacturing Items)

(1) When anyone who has obtained permission to manufacture health functional foods under Article 5 (1) intends to manufacture health functional foods, he/she shall report matters prescribed by Ordinance of the Prime Minister, including manuals for the methods of manufacturing the relevant items, to the Minister of Food and Drug Safety. This shall also apply to revisions to matters prescribed by Ordinance of the Prime Minister among the reported matters.

(2) Procedures for reporting on manufacturing items and revised matters under paragraph (1), and other necessary matters shall be prescribed by Ordinance of the Prime Minister.

Article 8 *<by Act No. 13201, Feb. 3, 2015>*

Article 9 (Restrictions on Permission for Business, etc.)

(1) No permission for business shall be granted under Article 5 (1) in any of the following cases: *<Amended by Act No. 14018, Feb. 3, 2016>*

1. When the relevant person, for whom six months have not elapsed since permission for business was revoked under the subparagraphs of Article 32 (1) (excluding subparagraphs 9-2, 10, and 11; hereafter the same shall apply in this Article), intends to run the same type of business in the relevant place of business: Provided, That this shall not apply where permission for business has been revoked due to removal of all business facilities;

2. When the relevant person (including the representative of a corporation), for whom one year has not elapsed since permission for business was revoked under the subparagraphs of Article 32 (1), intends to run the same type of business, the permission for which has been revoked;

3. When the relevant person (including the representative of a corporation) who intends to obtain permission for business is an incompetent under adult guardianship or has been declared bankrupt by the court and has not been reinstated;

4. When the relevant person, for whom the period of business suspension has not elapsed since he/she received a disposition of business suspension under any subparagraph of Article 32 (1) and reported business closure under Article 5 (2), intends to engage in the same type of business in the relevant place of business;

5. When the relevant person (including the representative of a corporation), for whom the period of business suspension has not elapsed since he/she received a disposition of business suspension under any subparagraph of Article 32 (1) and reported business closure under Article 5 (2), intends to engage in the same type of business.

(2) No one shall file a report on his/her business under Article 6 (2) in any of the following cases: *<Amended by Act No. 13201, Feb. 3, 2015; Act No. 14018, Feb. 3, 2016>*

1. When the relevant person, for whom six months have not elapsed since he/she was issued an order to close the place of business under the subparagraphs of Article 32 (1), intends to run the same kind of business in the relevant place of business: Provided, That this shall not apply where he/she has been issued an order to close the place of business due to removal of all business facilities;

2. When the relevant person (including the representative of a corporation), for whom one year has not elapsed since he/she was issued an order to close the place of business under the subparagraphs of Article 32 (1), intends to run the same type of business subject to closure of the business;

3. When the relevant person (including the representative of a corporation) who intends to report on his/her business is an incompetent under adult guardianship or has been declared bankrupt by the court and has not been reinstated;

4. When the relevant person, for whom the period of business suspension has not elapsed since he/she received a disposition of business suspension under any subparagraph of Article 32 (1) and reported business closure under Article 6 (3), intends to engage in the same type of business in the relevant place of business;

5. When the relevant person (including the representative of a corporation), for whom the period of business suspension has not elapsed since he/she received a disposition of business suspension under any subparagraph of Article 32 (1) and reported business closure under Article 6 (3), intends to engage in the same type of business.

Article 10 (Matters to be Complied with by Business Entities)

(1) Business entities shall comply with the following matters in order to ensure the safety of health functional foods, manage the quality thereof, maintain distribution order, and improve national health:

1. Manage manufacturing facilities and products (including materials) in such a manner that such facilities and products do not harm health and hygiene, and ensuring the safety thereof;

2. Do not sell products, the use-by dates of which have expired, display and keep them for sale, or use them for manufacturing health functional foods;

3. Exchange decayed, deteriorated, or discarded products, or products, the use-by dates of which have expired, except in extenuating circumstances;

4. Do not incite speculation in selling products, by providing reward gifts, free gifts, etc.;

5. Other matters equivalent to subparagraphs 1 through 4 and deemed necessary and determined by Ordinance of the Prime Minister for ensuring the safety of health functional foods, managing the quality thereof, and improving national health and hygiene.

(2) Manufacturers of health functional foods shall report their production records, etc. to the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister.

Article 11 (Succession to Business)

(1) Any of the following persons shall succeed to the status of the former business entity:

1. The transferee, when a business entity has transferred his/her business to a third person;

2. The successor, when a business entity has died;

3. A corporation surviving a merger or a corporation established in the course of a merger where a corporate business entity has merged with a third corporation.

(2) Any person who has acquired all business facilities and equipment by any of the following procedures shall succeed to the status of the former business entity under this Act:

1. Auctions under the Civil Execution Act;

2. Transfer under the Debtor Rehabilitation and Bankruptcy Act;

3. Sale of seized property under the National Tax Collection Act, the Customs Act, or the Framework Act on Local Taxes;

4. Any other procedures equivalent to those prescribed under subparagraphs 1 through 3.

(3) Any person who has succeeded to the status of any former business entity under paragraph (1) or (2) shall report it to the Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu, within one month after such succession, as prescribed by Ordinance of the Prime Minister.

(4) Article 9 (1) and (2) shall apply mutatis mutandis to 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 9 (2) 3.

Article 12 (Quality Control Managers)

(1) Any person who intends to engage in business with permission for commercially manufacturing health functional foods under Article 5 (1), shall have a quality control manager (hereinafter referred to as "quality control manager"), as prescribed by Ordinance of the Prime Minister: Provided, That this shall not apply when a business entity has qualifications as quality control managers and performs quality control duties.

(2) Quality control managers shall provide guidance to the manufacturers of functional health foods, to ensure that such manufacturers do not violate this Act, or orders or dispositions issued under this Act, and manage products and facilities hygienically.

(3) No manufacturers of health functional foods shall interfere with any quality control manager in performing his/her duties prescribed in paragraph (2) and they, in receipt of a request necessary for

performing the duties of a quality control manager, shall comply with such request, except in extenuating circumstances.

(4) When manufacturers of health functional foods appoint or dismiss a quality control manager, they shall report thereon to the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister.

(5) Qualifications for and duties of quality control managers, and other necessary matters shall be prescribed by Presidential Decree.

Article 12 (Quality Control Managers)

(1) Any person who intends to engage in business with permission for commercially manufacturing health functional foods under Article 5 (1), shall have a quality control manager (hereinafter referred to as "quality control manager"), as prescribed by Ordinance of the Prime Minister: Provided, That this shall not apply when a business entity has qualifications as quality control managers and performs quality control duties.

(2) Quality control managers shall provide guidance to the manufacturers of functional health foods, to ensure that such manufacturers do not violate this Act, or orders or dispositions issued under this Act, and shall perform the following duties: *<Amended by Act No. 14018, Feb. 3, 2016>*

1. Ensuring the safety of health functional foods;
2. Quality control of products and raw materials through self-inspection for quality control, etc. referred to in Article 21;
3. Hygienic management of manufacturing facilities and products;
4. Providing guidance and supervision, and education and training, for employees involved in ensuring the safety, quality control, hygienic management, etc. of functional health foods.

(3) No manufacturers of functional health foods shall interfere with any quality control manager in performing his/her duties and they, in receipt of a request necessary for performing the duties of a quality control manager, shall comply with such request, except in extenuating circumstances. *<Amended by Act No. 14018, Feb. 3, 2016>*

(4) When manufacturers of functional health foods appoint or dismiss a quality control manager, they shall report thereon to the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister.

(5) Quality control managers shall record and retain the details, etc. of the duties they performed under paragraph (2), as prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 14018, Feb. 3, 2016>*

(6) Qualifications for, and matters to be complied with by, quality control managers, and other necessary matters shall be prescribed by Presidential Decree. *<Amended by Act No. 14018, Feb. 3, 2016>*

Article 12-2 (Order to Replace Quality Control Manager)

Where a quality control manager significantly neglects the duties referred to in Article 12 (2), the Minister of Food and Drug Safety may issue an order to replace the quality control manager to the relevant manufacturer of health functional foods: Provided, That where a business entity qualified as a quality control manager is currently engaged in the quality control affairs, the Minister of Food and Drug Safety shall issue an order to place another quality control manager.

Article 13 (Training)

(1) The Minister of Food and Drug Safety may require business entities and employees to undergo training on ensuring the safety of health functional foods and quality control, if deemed necessary for preventing harm to national health.

(2) Any person who intends to engage in business prescribed in Article 4 shall undergo prior training on ensuring the safety of health functional foods and quality control: Provided, That when business entities are unable to undergo prior training due to any grounds prescribed by Ordinance of Prime Minister, they may undergo training, as prescribed by the Minister of Food and Drug Safety, after starting his/her business.

(3) Any person appointed as a quality control manager under Article 12 shall undergo regular training on ensuring the safety of health functional foods or quality control, etc.

(4) When any person obligated to undergo training pursuant to paragraphs (1) and (2) intends to engage in business in at least two places or is unable to undergo training due to any grounds prescribed by Ordinance of the Prime Minister, he/she may appoint a responsible person among his/her employees and require such person to undergo training. *<Amended by Act No. 14018, Feb. 3, 2016>*

1. Where the business entity is not directly engaged in business;
2. Where the same business entity intends to engage in business in two or more places;
3. Where the business entity is unable to undergo training due to any grounds prescribed by Ordinance of the Prime Minister.

(5) Institutions that provide training under paragraphs (1) through (3), the details of training, and the collection of training fees, and other necessary matters shall be prescribed by Ordinance of the Prime Minister.

Article 13 (Training)

(1) The Minister of Food and Drug Safety may require business entities and employees to undergo training on ensuring the safety of health functional foods, quality control, labels, advertisements, etc. (hereinafter referred to as "training on safety and hygiene"), if deemed necessary for preventing harm to national health: Provided, That in cases of a business entity commercially selling health functional foods under Article 4 (1) 3, training on safety and hygiene shall be provided for each place of business annually. *<Amended by Act No. 14018, Feb. 3, 2016>*

(2) Any person who intends to engage in the business under Article 4 shall undergo prior training on safety and hygiene: Provided, That when business entities are unable to undergo prior training due to any grounds prescribed by Ordinance of the Prime Minister, they may undergo training, as prescribed by the Minister of Food and Drug Safety, after starting his/her business. *<Amended by Act No. 14018, Feb. 3, 2016>*

(3) Any person appointed as a quality control manager under Article 12 shall undergo regular training on safety and hygiene. *<Amended by Act No. 14018, Feb. 3, 2016>*

(4) Where a business entity obligated to undergo training on safety and hygiene pursuant to paragraphs (1) and (2) falls under any of the following, he/she may appoint a person responsible for safety and hygiene

among his/her employees and require such person to undergo training on his/her behalf: *<Amended by Act No. 14018, Feb. 3, 2016>*

1. Where the business entity is not directly engaged in business;
2. Where the same business entity intends to engage in business in two or more places;
3. Where the business entity is unable to undergo training due to any grounds prescribed by Ordinance of the Prime Minister.

(5) The Minister of Food and Drug Safety may entrust training on safety and hygiene to a specialized training institution prescribed by Ordinance of the Prime Minister or to an organization established pursuant to Article 28. *<Newly Inserted by Act No. 14018, Feb. 3, 2016>*

(6) The details of, and timing to provide, training on safety and hygiene under paragraphs (1) through (3), the collection of training fees, and other necessary matters shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 14018, Feb. 3, 2016>*

Article 14 (Criteria and Standards)

(1) The Minister of Food and Drug Safety shall determine and publicly notify the criteria and standards for manufacture, use, and preservation of health functional foods for sale.

(2) The Minister of Food and Drug Safety may require the business entities referred to in Article 5 (1), importers or sellers of imported foods, etc. registered pursuant to Article 15 (1) of the Special Act on Imported Food Safety Management, or persons prescribed by Ordinance of the Prime Minister to submit the following data on the criteria and standards for functional health foods, the criteria and standards for which have not been publicly notified under paragraph (1), and examine and recognize such data as the criteria and standards for the health functional foods. In such cases, testing may be entrusted to a testing or inspection agency referred to in subparagraph 2, if necessary: *<Amended by Act No. 13201, Feb. 3, 2015; Act No. 13330, May 18, 2015>*

1. Data on the criteria and standards, safety, functions, etc. of the relevant health functional foods;
2. A test report or inspection report received from a testing or inspection agency specializing in food referred to in Article 6 (3) 1 of the Act on Testing and Inspection in the Food and Drug Industry or from an overseas testing or inspection agency referred to in Article 8 of the same Act.

(3) Where a business entity referred to in Article 5 (1), an importer or seller of imported foods, etc. registered pursuant to Article 15 (1) of the Special Act on Imported Food Safety Management, or a person prescribed by Ordinance of the Prime Minister has obtained recognition for the criteria and standards referred to in paragraph (2) by fraud or other improper means, the Minister of Food and Drug Safety shall revoke such recognition. *<Newly Inserted by Act No. 13330, May 18, 2015>*

(4) The criteria and standards for health functional foods for exportation may follow criteria and standards demanded by importers, notwithstanding paragraphs (1) and (2).

(5) Standards, methods, and procedures for recognition under paragraph (2), and other necessary matters shall be prescribed by the Minister of Food and Drug Safety.

Article 15 (Recognition of Raw Materials, etc.)

(1) The Minister of Food and Drug Safety shall determine and publicly notify raw materials or ingredients of health functional foods for sale.

(2) The Minister of Food and Drug Safety may recognize the raw materials or ingredients of health functional foods not publicly notified under paragraph (1), as materials or ingredients that may be used for health functional foods, after receiving and examining data on the safety and functions, etc. of the relevant raw materials or ingredients from business entities referred to in Article 5 (1), importers or sellers of imported foods, etc. registered pursuant to Article 15 (1) of the Special Act on Imported Food Safety Management, or persons prescribed by Ordinance of the Prime Minister: Provided, That no raw materials or ingredients with effects of treating or preventing diseases or with other functions prescribed by Ordinance of the Prime Minister shall be recognized as such. *<Amended by Act No. 13201, Feb. 3, 2015; Act No. 13330, May 18, 2015>*

(3) Where a business entity referred to in Article 5 (1), an importer or seller of imported foods, etc. registered pursuant to Article 15 (1) of the Special Act on Imported Food Safety Management, or a person prescribed by Ordinance of the Prime Minister has obtained recognition for the raw materials or ingredients referred to in paragraph (2) by fraud or other improper means, the Minister of Food and Drug Safety shall revoke such recognition. *<Newly Inserted by Act No. 13330, May 18, 2015>*

(4) Standards, methods, and procedures for recognition under paragraph (2), and other necessary matters shall be prescribed by the Minister of Food and Drug Safety. *<Amended by Act No. 13330, May 18, 2015>*

Article 15-2 (Reassessment)

(1) The Minister of Food and Drug Safety may reexamine and reassess the matters publicly notified or recognized pursuant to Article 14 (1) and (2) or 15 (1) and (2), and may alter or cancel publicly notified or recognized matters based on the results thereof.

(2) Matters necessary for the criteria, method, procedures, etc. for the reassessment referred to in paragraph (1) shall be prescribed by Ordinance of the Prime Minister.

Article 16 (Deliberation on Labels or Advertisements regarding Functionality)

(1) Anyone who intends to place labels or run advertisements regarding functionality of health functional foods shall undergo deliberation, in accordance with the standards, methods, and procedures for deliberation on the labels or advertisements of health functional foods determined by the Prime Minister.

(2) The Minister of Food and Drug Safety may entrust tasks concerning deliberation on the labels or advertisements regarding functionality of health functional foods under paragraph (1) to organizations established under Article 28.

(3) An organization entrusted with deliberation on labels or advertisements regarding functionality under paragraph (2) (hereinafter referred to as “deliberation agency” in this Article) shall establish and operate a deliberative committee on functionality labels or advertisements.

(4) The members of the deliberative committee referred to in paragraph (3) shall be commissioned by the head of the relevant deliberation agency with approval from the Minister of Food and Drug Safety from

among the following persons. In such cases, persons in the industrial filed shall be less than 1/3 of them:

1. Persons with abundant knowledge about and experience in health functional foods and advertising;
2. Persons recommended by the head of an organization related to health functional foods;
3. Persons recommended by the head of a civil organization (referring to a non-profit, non-governmental organization defined in Article 2 of the Assistance for Non-Profit, Non-Governmental Organizations Act);
4. Persons recommended by the head of an academic society or college related to health functional foods.

(5) The number of members, their terms of office, and other matters necessary for the operation, etc. of deliberative committees referred to in paragraph (3) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 16 (Deliberation on Labels or Advertisements regarding Functionality)

(1) Anyone who intends to place labels or run advertisements regarding functionality of health functional foods shall undergo deliberation, in accordance with the standards, methods, and procedures for deliberation on the labels or advertisements of functional health foods determined by the Prime Minister.

(2) The Minister of Food and Drug Safety may entrust tasks concerning deliberation on the labels or advertisements regarding functionality of health functional foods under paragraph (1) to a consumer organization registered under Article 29 of the Framework Act on Consumers or to an organization established under Article 28. *<Amended by Act No. 14018, Feb. 3, 2016>*

(3) An organization entrusted with deliberation on labels or advertisements regarding functionality under paragraph (2) (hereinafter referred to as “deliberation agency” in this Article) shall establish and operate a deliberative committee on functionality labels or advertisements.

(4) The members of the deliberative committee referred to in paragraph (3) shall be commissioned by the head of the relevant deliberation agency with approval from the Minister of Food and Drug Safety from among the following persons. In such cases, persons in the industrial filed shall be less than 1/3 of them:

1. Persons with abundant knowledge about and experience in health functional foods and advertising;
2. Persons recommended by the head of an organization related to health functional foods;
3. Persons recommended by the head of a civil organization (referring to a non-profit, non-governmental organization defined in Article 2 of the Assistance for Non-Profit, Non-Governmental Organizations Act);
4. Persons recommended by the head of an academic society or college related to functional health foods.

(5) The number of members, their terms of office, and other matters necessary for the operation, etc. of deliberative committees referred to in paragraph (3) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 16-2 (Filing Objections to Deliberation on Advertisements)

(1) Any person who has an objection to the outcomes of deliberation under Article 16 (1) may file an objection with the Minister of Food and Drug Safety within one month after receipt of notice of the outcomes of such deliberation.

(2) Upon receipt of an objection filed under paragraph (1), the Minister of Food and Drug Safety shall examine the objection, seeking advice from the Health Functional Foods Deliberation Committee under Article 27 (1) and notify the outcomes of such examination to the relevant person.

(3) Methods and procedures for filing objections under paragraphs (1) and (2), management thereof, and other necessary matters shall be prescribed by the Minister of Food and Drug Safety.

Article 17 (Labeling Standards)

(1) The following matters shall be indicated on the containers or packages of health functional foods:

1. Words describing health functional foods or diagrams indicating functional health foods;
2. Functional ingredients or nutrients and their proportions to recommended daily nutrient intakes (limited to where recommended nutrient intakes have been determined);
3. Amounts and methods of intake or cautions for taking health functional foods;
4. The use-by dates and methods for preserving health functional foods;
5. Descriptions that health functional foods are not medicines for preventing or treating a disease;
6. Other matters prescribed by the Minister of Food and Drug Safety.

(2) Methods for placing labels under paragraph (1) and other necessary matters shall be prescribed and publicly notified by the Minister of Food and Drug Safety.

Article 17-2 (Labeling, etc. of Genetically Modified Functional Health Foods)

(1) Health functional foods that are manufactured or processed by using, as their materials, agricultural, livestock, fishery products, etc. cultivated or nurtured with any of the following biotechnologies (hereinafter referred to as "genetically modified functional health foods") shall be labeled as genetically modified health functional foods: Provided, That the foregoing shall be limited to genetically modified functional health foods in which genetically modified deoxyribonucleic acid (DNA) or genetically modified protein remains after being manufactured or processed:

1. Technology to artificially recombine genes, or to insert a nucleic acid forming a gene directly into a cell or into a cell organelle;
2. Cell fusion technology that goes beyond families in taxonomy.

(2) No genetically modified functional health foods required to be labelled pursuant to paragraph (1) shall be sold, or imported, displayed or transported for the purpose of sale, or used for business, without labels.

(3) Matters necessary for persons liable for labeling under paragraph (1), subjects, methods, etc. of labeling shall be prescribed by the Minister of Food and Drug Safety.

Article 18 (Prohibiting False, Exaggerative, or Negative Labels or Advertisements)

(1) No one shall place or run false, exaggerative, or negative labels or advertisements as follows, with respect to the names, raw materials, manufacturing methods, nutrients, ingredients, methods of use, or quality of health functional foods, and the tracking management of records on functional health foods:

1. Labels or advertisements likely to mislead consumer into believing that the relevant foods are effective in preventing or treating a disease or confuse consumers about the relevant foods with medicines;

2. False or exaggerated labels or advertisements;

3. Labels or advertisements likely to deceive, mislead, or confuse consumers;

4. Labels or advertisements that include names (including the prescriptions of Oriental medicines) only used for medicines;

5. Negative labels or advertisements against other companies or their products;

6. Labels or advertisements that haven't deliberated upon under Article 16 (1) or bearing different details from details deliberated upon.

(2) The scope of false, exaggerative, or negative labels and advertisements under paragraph (1), and other necessary matters shall be prescribed by Ordinance of the Prime Minister.

Article 19 (Codes of Functional Health Foods)

The Minister of Food and Drug Safety shall prepare and distribute the codes of health functional foods that contain the criteria and standards of health functional foods prescribed under Article 14, raw materials and ingredients prescribed under Article 15, and labeling standards prescribed under Article 17.

Article 19 (Codes of Functional Health Foods)

The Minister of Food and Drug Safety shall prepare and distribute the codes of health functional foods that contain the criteria and standards of health functional foods prescribed under Article 14, raw materials and ingredients prescribed under Article 15, and labeling standards prescribed under Articles 17 and 17-2. *<Amended by Act No. 14018, Feb. 3, 2016>*

Article 20 (Entry, Inspections, Collections, etc.)

(1) If deemed necessary for managing the hygiene of the health functional foods and maintaining business order, the Minister of Food and Drug Safety (including the heads of affiliated organizations prescribed by Presidential Decree), the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may require business entities or relevant persons to file necessary reports, or require relevant public officials to enter the places of business, offices, warehouses, factories, storage facilities, stores, or similar places and to take any of the following measures:

1. Inspecting raw materials, products, containers, and packages for sale or used for business, or manufacturing or sales facilities;

2. Collecting the minimum amounts of raw materials, products, containers, and packages necessary for inspections conducted under subparagraph 1 free of charge;

3. Inspecting business-related books of account or documents.

(2) Any relevant public official who intends to enter the places of business, etc., conduct an inspection, collect materials or other necessary items or inspect business-related books of account, etc. under paragraph (1) shall carry an identification card indicating his/her authority and produce it to relevant persons.

Article 20-2 (Requests by Consumers, etc. for Hygiene Inspection, etc.)

(1) Where consumers exceeding a certain number prescribed by Presidential Decree, a consumer organization registered pursuant to Article 29 of the Framework Act on Consumers, or a testing or inspection agency prescribed by Ordinance of the Prime Minister among the testing or inspection agencies referred to in Article 6 of the Act on Testing and Inspection in the Food and Drug Industry (hereinafter referred to as "consumers, etc." in this Article) requests entry, inspection, collection, etc. referred to in Article 20 (hereafter referred to as "hygiene inspection, etc." in this Article) for functional health foods, business facilities, etc., the Minister of Food and Drug Safety (including the heads of affiliated agencies prescribed by Presidential Decree; hereafter the same shall apply in this Article), the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu shall comply with such request: Provided, That the same shall not apply to any of the following cases:

1. Where identical consumers, etc. repeatedly request the same hygiene inspection, etc. for the purpose of hindering a particular business entity's business;
2. Where the Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu deems it impossible to conduct hygiene inspection, etc. due to technology, facilities, financial resources, etc.

(2) Where the Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu complies with a request for hygiene inspection, etc. pursuant to paragraph (1), he/she shall conduct the hygiene inspection, etc. within 14 days, and shall inform consumers, etc. who have made such request of the results thereof and publish the results on the relevant Internet website, as prescribed by Presidential Decree.

(3) The requirements and procedures for the requests for hygiene inspection, etc. and other necessary matters shall be prescribed by Presidential Decree.

Article 21 (Obligations of Self-Inspection for Quality Control)

(1) Any person who has obtained permission to commercially manufacture health functional foods pursuant to Article 5 (1) shall conduct an inspection to verify whether the relevant health functional foods that he/she manufactures meet the criteria and standards prescribed under Article 14 and shall keep the records thereof, as prescribed by Ordinance of the Prime Minister.

(2) The Minister of Food and Drug Safety may outsource inspections to an agency entrusted with self quality testing and inspection referred to in Article 6 (3) 2 of the Act on Testing and Inspection in the Food and Drug Industry, when any person obligated to conduct inspections under paragraph (1) is incapable of conducting self-inspections. *<Amended by Act No. 14018, Feb. 3, 2016>*

(3) Where the relevant health functional foods is found to cause, or likely to cause, harm to public health due to a violation of Article 23 or 24 (1) in the inspection referred to in paragraph (1), the business entity conducting self-inspection pursuant to paragraph (1) shall report such fact to the Minister of Food and Drug Safety without delay. *<Newly Inserted by Act No. 14018, Feb. 3, 2016>*

(4) Items of, and procedures for inspections under paragraphs (1) and (2), and other necessary matters shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 14018, Feb. 3, 2016>*

Article 21-2 (Obligations, etc. to Inspect and Confirm Materials)

(1) A person who has obtained permission to commercially manufacture health functional foods pursuant to Article 5 (1) shall inspect and confirm the following materials, among materials used for raw materials or ingredients publicly notified pursuant to Article 15 (1) or recognized pursuant to Article 15 (2), and shall retain the records thereof:

1. Materials publicly notified by the Minister of Food and Drug Safety because it is impossible to distinguish them from other materials with the naked eye;
2. Other materials deemed necessary by the Minister of Food and Drug Safety for the safety of health functional foods.

(2) The subjects, procedures, and method for the inspection referred to in paragraph (1) and other necessary matters shall be prescribed by Ordinance of the Prime Minister.

Article 21-3 (Order of Inspection, etc.)

(1) The Minister of Food and Drug Safety may issue an order to undergo inspection conducted by a testing or inspection agency specializing in food referred to in Article 6 (3) 1 of the Act on Testing and Inspection in the Food and Drug Industry (hereinafter referred to as "inspection order"), to a business entity that commercially manufactures any of the following functional health foods: Provided, That such inspection may be substituted by relevant data, etc., if the Minister of Food and Drug Safety deems it impossible to confirm harmful ingredients by inspections:

1. Health functional food in which harmful substances have been detected in or outside the Republic of Korea;
2. Other health functional food over which concerns about potential harm have been raised in or outside the Republic of Korea.

(2) Upon receipt of an inspection order, a business entity shall have the relevant health functional food inspected within the time limit for inspection prescribed by Ordinance of the Prime Minister, or submit relevant data, etc.

(3) The scope of health functional foods subject to the inspection order referred to in paragraphs (1) and (2), data to be submitted, and other details shall be determined and publicly notified by the Minister of Food and Drug Safety.

Article 22 (Regulations for Good Manufacturing Practice, etc.)

(1) Business entities that commercially manufacture functional health foods shall comply with the standards for manufacturing good health functional foods and managing the quality thereof (hereinafter referred to as "Regulations for Good Manufacturing Practice") determined and publicly notified by the Minister of Food and Drug Safety in order to manufacture good health functional foods and manage the quality thereof. *<Amended by Act No. 14018, Feb. 3, 2016>*

(2) The Minister of Food and Drug Safety shall investigate and evaluate, annually, whether the Regulations for Good Manufacturing Practice are complied with. *<Amended by Act No. 14018, Feb. 3, 2016>*

(3) The method and procedures for investigating and evaluating the Regulations for Good Manufacturing Practice, and other necessary matters shall be prescribed by Ordinance of the Prime Minister. *<Amended by Act No. 14018, Feb. 3, 2016>*

(4) through (7) Deleted. *<by Act No. 14018, Feb. 3, 2016>*

Article 22-2 (Registration Standards, etc. for Tracking Management of Records on Functional Health Foods)

(1) Any person who intends to perform tracking management of records on functional health foods, among those who manufacture or sell health functional foods, may register the relevant health functional foods with the Minister of Food and Drug Safety, upon fulfilling registration standards prescribed by Ordinance of the Prime Minister: Provided, That any person whose turnover, etc. falls within the turnover or store area prescribed by Ordinance of the Prime Minister shall file for registration with the Minister of Food and Drug Safety. *<Amended by Act No. 13201, Feb. 3, 2015>*

(2) Any person who manufactures or sells health functional foods registered under paragraph (1) shall comply with standards (hereinafter referred to as "standards for tracking management of records on health functional foods") determined and publicly notified by the Minister of Food and Drug Safety, concerning preparation, keeping, and maintenance of records necessary for tracking management of records on health functional foods. *<Amended by Act No. 13201, Feb. 3, 2015>*

(3) When any of the registered matters are revised, any person who has obtained registration under paragraph (1) shall report such revision to the Minister of Food and Drug Safety within one month after a ground for such revision arises.

(4) Health functional foods registered under paragraph (1) may bear the indication of tracking management of records on health functional foods, as prescribed and publicly notified by the Minister of Food and Drug Safety.

(5) The Minister of Food and Drug Safety shall inspect and evaluate persons who manufacture or sell health functional foods registered under paragraph (1) to verify whether they comply with the standards for tracking management of records on health functional foods: Provided, That the Minister of Food and Drug Safety shall conduct such inspection and evaluation for persons who manufacture or sell health functional foods registered under the proviso to paragraph (1), every two years. *<Amended by Act No. 13201, Feb. 3, 2015>*

(6) The Minister of Food and Drug Safety may provide funds necessary for tracking management of records on health functional foods within budgetary limits, to any person who has obtained registration under paragraph (1).

(7) When any person who has obtained registration under paragraph (1) fails to comply with any standard for tracking management of records on health functional foods, the Minister of Food and Drug Safety may revoke such registration or issue a corrective order to him/her.

(8) Procedures for registration for tracking management of records on health functional foods, matters to be registered, standards for revocation of registration, etc., and inspections and evaluations, and other matters necessary for registration shall be prescribed by Ordinance of the Prime Minister.

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

No one shall sell, or manufacture, import, use, store, transport or display any of the following health functional foods for sale: *<Amended by Act No. 13201, Feb. 3, 2015>*

1. Rotten or spoiled foods likely to harm human health;
2. Foods that contain or are suspected of containing toxic or harmful materials, or foods stained with or likely to be stained with such materials: Provided, That this shall not apply where the Minister of Food and Drug Safety recognizes that the relevant foods are not likely to harm human health;
3. Foods contaminated with or likely to be contaminated with pathogenic microorganism feared to harm human health;
4. Foods likely to harm human health, due to uncleanness, mixing with, or addition of, other materials, and on other grounds;
5. Foods manufactured by any person who has failed to obtain permission required under Article 5 (1);
6. Foods, the import of which is banned, or foods imported without import declarations required under Article 20 (1) of the Special Act on Imported Food Safety Management.

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

(1) Business entities shall manufacture, use, or keep health functional foods, the criteria and standards for which are determined under Article 14 (1) and (2), in accordance with such criteria and standards, and shall not sell any health functional foods which violate such criteria and standards, or manufacture, import, use, store, transport, keep, or display such health functional foods for sale. *<Amended by Act No. 13201, Feb. 3, 2015>*

(2) No business entity shall engage in any of the following activities:

1. Manufacturing health functional foods using materials only used for medicines;
2. Manufacturing health functional foods, the combinations, mixing proportions, or contents of which are the same as or similar to those of medicines;
3. Importing, selling, or displaying functional health foods manufactured under subparagraph 1 or 2.

(3) Detailed criteria and scopes concerning raw materials used only for medicines and similar health functional foods referred to in paragraph (2) shall be prescribed by the Minister of Food and Drug Safety.

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

(1) Business entities (including importers or sellers of imported foods, etc. registered pursuant to Article 15 of the Special Act on Imported Food Safety Management; hereafter the same shall apply in this Article) shall manufacture, use, or keep health functional foods, the criteria and standards for which are determined under Article 14 (1) and (2), in accordance with such criteria and standards, and shall not sell any health

functional foods which violate such criteria and standards, or manufacture, import, use, store, transport, keep, or display such health functional foods for sale. *<Amended by Act No. 13201, Feb. 3, 2015>*

(2) No business entity shall engage in any of the following activities: *<Amended by Act No. 14018, Feb. 3, 2016>*

1. Manufacturing health functional foods using materials only used for medicines;
2. Manufacturing health functional foods, the combinations, mixing proportions, or contents of which are the same as or similar to those of medicines;
2-2. Manufacturing health functional foods by using raw materials that are toxic or cause adverse effects to the human body;
3. Importing, selling, or displaying health functional foods manufactured under subparagraph 1, 2, or 2-2.

(3) Detailed criteria and scopes concerning raw materials used only for medicines referred to in paragraph (2), health functional foods that are similar to medicines in their mixing or blending proportions or contents, or raw materials causing adverse effects to the human body shall be prescribed by the Minister of Food and Drug Safety. *<Amended by Act No. 14018, Feb. 3, 2016>*

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

No business entity (including importers or sellers of imported foods, etc. registered pursuant to Article 15 (1) of the Special Act on Imported Food Safety Management) shall sell any health functional foods which violate labeling standards prescribed under Article 17, manufacture, import, display, transport, or use such health functional foods for sale. *<Amended by Act No. 13201, Feb. 3, 2015>*

Article 26 (Prohibition against Similar Labels, etc.)

No foods, other than health functional foods, shall bear labels or advertisements, on their containers or packages, which are likely to mislead consumers to believe that the foods have nutritional or physiological functions and effects for the structure or function of the human body, and no business entities shall sell, store or display any foods, the labels or advertisements of which are similar to those of health functional foods, for sale.

Article 27 (Health Functional Foods Deliberation Committee)

(1) The Health Functional Foods Deliberation Committee shall be established under the Ministry of Food and Drug Safety to examine and deliberate on the following matters to advise the Minister of Food and Drug Safety thereon:

1. Matters concerning policies on health functional foods;
2. Matters concerning the criteria and standards for health functional foods;
3. Matters concerning the labels 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 criteria and standards for, and labels, advertisements, etc. of health functional foods.

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

Article 28 (Establishment of Organizations)

(1) Business entities may establish organizations according to the type of business prescribed by Presidential Decree, in order to ensure the safety of health functional foods, improve the quality thereof, and contribute to improving national health by promoting the sound development of the relevant business.

(2) Organizations shall be corporate bodies.

(3) To establish an organization, at least 1/10 (20 persons, when more than 20 founders exist) of the promoters qualified as members of the aforementioned organization shall formulate the articles of association and obtain authorization for establishment from the Minister of Food and Drug Safety, as prescribed by Presidential Decree.

Article 29 (Corrective Orders)

The Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may issue corrective orders to persons who fail to comply with this Act, if deemed necessary.

Article 30 (Disposition of Discard, etc.)

(1) When a business entity violates any of the Articles 23 through 26, the Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may order relevant public officials to seize or discard the relevant health functional food, or order the business entity to take measures to remove harm to food hygiene. *<Amended by Act No. 13201, Feb. 3, 2015>*

(2) The Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may order relevant public officials to seize or discard the relevant health functional food manufactured without permission required under Article 5 (1), or equipment, containers, packages, etc. used for manufacturing such functional health foods.

(3) When hygiene is or is likely to be compromised, the Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may order the relevant business entity to recall or discard the relevant health functional food in the market or change the raw materials, manufacturing methods, ingredients, or mixing proportion of the relevant health functional food.

(4) A relevant public official who seizes or discard health functional foods under paragraphs (1) and (2) shall carry an identification card indicating his/her authority and produce it to relevant persons.

(5) Matters necessary for seizure or discard under paragraphs (1) and (2), standards for health functional foods to be recalled under paragraph (3), and other necessary matters shall be prescribed by Ordinance of the Prime Minister.

Article 30 (Disposition of Discard, etc.)

(1) When a business entity (including importers or sellers of imported foods, etc. registered pursuant to Article 15 of the Special Act on Imported Food Safety Management; hereinafter the same shall apply in this Article) violates any provision of Articles 17-2 (2) or 23 through 26, the Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may order relevant public officials to seize or discard the relevant health functional food, or order the business entity to take measures to remove harm to food hygiene. *<Amended by Act No. 13201, Feb. 3, 2015; Act No. 14018, Feb. 3, 2016>*

(2) The Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may order relevant public officials to seize or discard the relevant health functional food manufactured without permission required under Article 5 (1), or equipment, containers, packages, etc. used for manufacturing such health functional foods.

(3) When hygiene is or is likely to be compromised, the Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may order the relevant business entity to recall or discard the relevant health functional food in the market or change the raw materials, manufacturing methods, ingredients, or mixing proportion of the relevant health functional food.

(4) A relevant public official who seizes or discard health functional foods under paragraphs (1) and (2) shall carry an identification card indicating his/her authority and produce it to relevant persons.

(5) Matters necessary for seizure or discard under paragraphs (1) and (2), standards for health functional foods to be recalled under paragraph (3), and other necessary matters shall be prescribed by Ordinance of the Prime Minister.

Article 31 (Orders, etc. to Repair Facilities)

(1) The Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may order business entities to repair facilities within a specified period if their business facilities fail to meet any of the standards for facilities prescribed under Article 4 (1).

(2) When the owner of, and the business entity in 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 (Revocation, etc. of Permission for Business)

(1) The Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may revoke permission for business, fully or partially suspend the relevant business for a specified period not exceeding six months or issue an order to close the place of business (limited to business reported under Article 6; hereafter the same shall apply in this Article), as prescribed by Presidential Decree, if a business entity falls under any of the following cases: *<Amended by Act No. 13201, Feb. 3, 2015; Act No. 14018, Feb. 3, 2016>*

1. When it 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 it violates Article 12 (1);

3. When it violates Article 18 (1);

4. When it violates to conduct a self-inspection for quality control under Article 21;

5. When it violates Article 22 (5);

6. When it violates the proviso to Article 22-2 (1);

7. When it violates the prohibition against sale or similar labels, etc. under Article 23, 24 (1) and (2), 25, or 26;

8. When it violates an order issued under Article 29, 30 (1) and (3), 31 (1) or 33 (1);

9. When it continues to conduct his/her business, in violation of an order of business suspension.

9-2. When it becomes an incompetent under adult guardianship, or is declared bankrupt;

10. When it suspends business continuously for at least six months without any justifiable grounds;

11. When a person who has obtained permission for business pursuant to Article 5 (1) reports business closure to the head of the competent tax office pursuant to Article 8 of the Value-Added Tax Act, or when the head of the competent tax office revokes his/her business registration.

(2) The detailed standards for administrative dispositions under paragraph (1) shall be prescribed by Ordinance of the Prime Minister, considering the types, severity, etc. of violations.

Article 32 (Revocation, etc. of Permission for Business)

(1) The Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may revoke permission for business, fully or partially suspend the relevant business for a specified period not exceeding six months or issue an order to close the place of business (limited to business reported under Article 6; hereafter the same shall apply in this Article), as prescribed by Presidential Decree, if a business entity falls under any of the following cases: Provided, That in cases falling under subparagraph 9-2, permission for business shall be revoked: *<Amended by Act No. 13201, Feb. 3, 2015; Act No. 14018, Feb. 3, 2016>*

1. When it violates Article 4 (1), the latter part of Article 5 (1), Article 5 (2), the former part of Article 7 (1), the subparagraphs of Article 10 (1) (excluding subparagraphs 1 and 5), Article 11 (3), or Article 17-2 (2);

2. When it violates Article 12 (1);

3. When it violates Article 18 (1);

4. When it violates Article 21 (1) and (3);

4-2. When it violates Article 21-2 (1);

5. When it violates Article 22;

6. When it violates the proviso to Article 22-2 (1);

7. When it violates the prohibition against sale or similar labels, etc. under Article 23, 24 (1) and (2), 25, or 26;

8. When it violates an order issued under Article 29, 30 (1) and (3), 31 (1) or 33 (1);

9. When it continues to conduct his/her business, in violation of an order of business suspension;

9-2. When it becomes an incompetent under adult guardianship, or is declared bankrupt;

10. When it suspends business continuously for at least six months without any justifiable grounds;

11. When a person who has obtained permission for business pursuant to Article 5 (1) reports business closure to the head of the competent tax office pursuant to Article 8 of the Value-Added Tax Act, or when the head of the competent tax office revokes his/her business registration.

(2) The detailed standards for administrative dispositions under paragraph (1) shall be prescribed by Ordinance of the Prime Minister, considering the types, severity, etc. of violations.

Article 33 (Suspension, etc. of Manufacturing Items)

(1) The Minister of Food and Drug Safety may issue an order to suspend manufacturing the relevant item or the relevant type of item (referring to all items manufactured in accordance with the same criteria and standards, among criteria and standards for health functional foods determined under Article 14) for a specified period not exceeding six months, as prescribed by Presidential Decree, when a business entity violates Article 17-2 (2), 18 (1), 21 (1), 21-2 (1), 22, 23, 24 (1) and (2), 25 or 26. *<Amended by Act No. 14018, Feb. 3, 2016>*

(2) The detailed standards for administrative dispositions under paragraph (1) shall be prescribed by Ordinance of the Prime Minister, by taking into account the type, severity, etc. of violation.

Article 34 (Succession to Effects of Administrative Sanctions)

When a business entity transfers his/her business to a third person or a corporate business entity merges with a third corporation, the effects of an administrative sanction imposed against the former business entity for a violation of any subparagraph of Article 32 (1) (excluding subparagraph 10) or Article 33 (1) shall succeed to the transferee or corporation surviving the merger for one year after the date the period for the administrative sanction expires, or, when the procedure for an administrative sanction are in progress, such procedure may continue for the transferee or corporation surviving the merger.

Article 35 (Measures for Closure, etc.)

(1) The Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may require relevant public officials to take the following measures to close the relevant place of business, when a business entity runs his/her business without obtaining permission or filing a report, in violation of the former part of Article 5 (1) or Article 6 (2), or continues to run his/her business after permission for business is revoked, or an order to close the place of business is issued under the subparagraphs of Article 32 (1): *<Amended by Act No. 13201, Feb. 3, 2015>*

1. Removing or eliminating signboards of the relevant place of business or other business marks;

2. Posting notices indicating that the relevant place of business is illegal;

3. Sealing facilities of the relevant place of business or other equipment, etc. used for running business to be unusable.

(2) The Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may eliminate posted notices, etc. or remove seals in any of the following subparagraphs, after taking measures referred to in paragraph 1 (2) or (3):

1. When posting notices etc. or seals are deemed no longer necessary;

2. The relevant business entity or his/her agent promises to close the relevant place of business or requests removal of seals by citing other just grounds.

(3) The Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu shall give prior written notice to the relevant business entity or his/her agent before taking measures prescribed in paragraph (1): Provided, That this shall not apply where any grounds prescribed by Ordinance of the Prime Minister exist.

(4) Measures prescribed in paragraph (1) shall be taken to the minimum extent necessary to incapacitate the relevant business.

(5) In cases falling under paragraph (1), a relevant public official shall carry an identification card indicating his/her authority and produce it to relevant persons.

Article 36 (Hearings)

When the Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu intends to revoke permission for business or to take a disposition equivalent to closure of the place of business under Article 32 (1), he/she shall hold a hearing.

Article 37 (Imposition of Penalty Surcharges in Lieu of Suspension of Business)

(1) The Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may impose a penalty surcharge not exceeding 200 million won, in lieu of suspension of business or suspension of manufacturing of the relevant item or relevant type of item, as prescribed by Presidential Decree, when a business entity falls under any of 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 Prime Minister, among cases falling under Article 32 (1) or 33 (1) for a violation of the latter part of Article 5 (1), 10 (1), 18 (1), 23, 24 (1) and (2), 25, or 26. *<Amended by Act No. 14018, Feb. 3, 2016>*

(2) Amounts of penalty surcharges depending on the type, severity, etc. of violations subject to penalty surcharges under paragraph (1), and other necessary matters shall be prescribed by Presidential Decree.

(3) When a business entity liable to pay a penalty surcharge imposed under paragraph (1) fails to do so by the payment due date, the Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu shall revoke the imposition of the penalty surcharge under paragraph (1) and take an administrative disposition, such as suspension of business under Article 32 or 33.

(4) Penalty surcharges imposed and collected by the Minister of Food and Drug Safety, among penalty surcharges collected under paragraph (1), shall devolve on the State, and penalty surcharges imposed and

collected by the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu (referred to an autonomous Gu) shall devolve on the Food Promotion Fund (referring to the Food Promotion Fund established under Article 71 of the Food Sanitation Act) of a Special City, Metropolitan City, Self-Governing City, Do, Special Self-Governing Province, or Si/Gun/Gu.

Article 37 (Imposition of Penalty Surcharges in Lieu of Suspension of Business)

(1) The Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may impose a penalty surcharge not exceeding 200 million won, in lieu of suspension of business or suspension of manufacturing of the relevant item or relevant type of item, as prescribed by Presidential Decree, when a business entity falls under any of the subparagraphs (excluding subparagraphs 9, 9-2, 10, and 11) of Article 32 (1) or Article 33 (1): Provided, That this shall not apply to cases determined by Ordinance of the Prime Minister, among cases falling under Article 32 (1) or 33 (1) for a violation of the latter part of Article 5 (1), 10 (1), 18 (1), 23, 24 (1) and (2), 25, or 26. *<Amended by Act No. 14018, Feb. 3, 2016>*

(2) Amounts of penalty surcharges depending on the type, severity, etc. of violations subject to penalty surcharges under paragraph (1), and other necessary matters shall be prescribed by Presidential Decree.

(3) The Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may request the head of the competent tax office to provide taxation information, in writing, stating the following, if necessary to impose a penalty surcharge referred to in paragraph (1): *<Newly Inserted by Act No. 14018, Feb. 3, 2016>*

2. Purpose of using the taxation information;

3. Sales amount based on which a penalty surcharge is imposed;

(4) When a business entity liable to pay a penalty surcharge imposed under paragraph (1) fails to do so by the payment due date, the Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu shall revoke the imposition of the penalty surcharge under paragraph (1) and take an administrative disposition, such as suspension of business under Article 32 or 33, as prescribed by Presidential Decree, or shall collect the penalty surcharge in the same manner as delinquent national taxes are collected or in accordance with the Act on the Collection, etc. of Local Non-Tax Revenue: Provided, That where it is impossible to issue an administrative disposition, such as business suspension under Article 32 or 33, due to business closure, etc. referred to in Article 5 (2) or 6 (3), the penalty surcharge shall be collected in the same manner as delinquent national taxes are collected or in accordance with the Act on the Collection, etc. of Local Non-Tax Revenue. *<Amended by Act No. 14018, Feb. 3, 2016>*

(5) The Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may request the relevant person to provide the data or information falling under any of the following subparagraph, if necessary to collect a delinquent penalty surcharge pursuant to paragraph (4). In such cases, the person so requested shall comply with such

request, except in extenuating circumstances: <*Newly Inserted by Act No. 14018, Feb. 3, 2016*>

1. A certified copy of the building register referred to in Article 38 of the Building Act: Minister of Land, Infrastructure and Transport;

2. A certified copy of the land cadastre referred to in Article 71 of the Act on the Establishment, Management, etc. of Spatial Data: Minister of Land, Infrastructure and Transport;

3. A certified copy of the motor vehicle register referred to in Article 7 of the Motor Vehicle Management Act: The Special Metropolitan City Mayor, a Metropolitan City Mayor, the Metropolitan Autonomous City Mayor, a Do Governor, or the Special Self-Governing Province Governor. <*Newly Inserted by Act No. 14018, Feb. 3, 2016*>

(6) Penalty surcharges imposed and collected by the Minister of Food and Drug Safety, among penalty surcharges collected under paragraph (1) or (4), shall devolve on the State, and penalty surcharges imposed and collected by the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu (referred to an autonomous Gu) shall devolve on the Food Promotion Fund (referring to the Food Promotion Fund established under Article 71 of the Food Sanitation Act) of a Special City, Metropolitan City, Self-Governing City, Do, Special Self-Governing Province, or Si/Gun/Gu. <*Amended by Act No. 14018, Feb. 3, 2016*>

Article 37-2 (Imposition, etc. of Penalty Surcharges for Sale, etc. of Harmful Functional Health Foods, etc.)

(1) The Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu shall impose a penalty surcharge on any of the following persons in an amount equivalent to the retail price of the health functional foods:

1. A person subject to suspension of business for at least two months, revocation of his/her permission for business, or closure of the place of business under Article 32 for a violation of Article 18 (1) 1;

2. A person subject to suspension of business for at least two months, revocation of his/her permission for business, or closure of the place of business under Article 32 for a violation of Article 23 2, 3, 5, or 6;

3. A person subject to suspension of business for at least two months, revocation of his/her permission for business, or closure of the place of business under Article 32 for a violation of Article 24 (2).

(2) The amount of penalty surcharges calculated under paragraph (1) shall be assessed and imposed, as prescribed by Presidential Decree.

(3) When a business entity fails to pay a penalty surcharge imposed under paragraph (2) by the payment due date or closes his/her business under Article 5 (2) or 6 (3), the penalty surcharge shall be collected in the same manner as delinquent national taxes are collected or as prescribed by the Act on the Collection, etc. of Local Non-Tax Revenue.

(4) Article 37 (4) shall apply mutatis mutandis to the reversion of penalty surcharges imposed under paragraph (2), the ratio of reversion, procedures for collection, and other necessary matters.

Article 37-2 (Imposition, etc. of Penalty Surcharges for Sale, etc. of Harmful Health Functional Foods, etc.)

(1) The Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu shall impose a penalty surcharge on any of the following persons in an amount equivalent to the retail price of the functional health foods:

1. A person subject to suspension of business for at least two months, revocation of his/her permission for business, or closure of the place of business under Article 32 for a violation of Article 18 (1) 1;
2. A person subject to suspension of business for at least two months, revocation of his/her permission for business, or closure of the place of business under Article 32 for a violation of Article 23 2, 3, 5, or 6;
3. A person subject to suspension of business for at least two months, revocation of his/her permission for business, or closure of the place of business under Article 32 for a violation of Article 24 (2).

(2) The amount of penalty surcharges calculated under paragraph (1) shall be assessed and imposed, as prescribed by Presidential Decree.

(3) When a business entity fails to pay a penalty surcharge imposed under paragraph (2) by the payment due date or closes his/her business under Article 5 (2) or 6 (3), the penalty surcharge shall be collected in the same manner as delinquent national taxes are collected or as prescribed by the Act on the Collection, etc. of Local Non-Tax Revenue.

(4) Article 37 (3), (5), and (6) shall apply mutatis mutandis to requests for the provision of information or data for imposition or collection of penalty surcharges under paragraph (1), and reversion, the ratio of reversion, etc. of penalty surcharges imposed and collected. *<Amended by Act No. 14018, Feb. 3, 2016>*

Article 37-3 (Publication of Violations)

The Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Mayor, or the head of a Si/Gun/Gu shall publicize the details of an administrative disposition confirmed against a business entity pursuant to Article 30, 32, 33, 35, 37, or 37-2 and business information relating to the disposition, such as the relevant place of business and the name of the health functional food, as prescribed by Presidential Decree.

Article 38 (Relationships with other Acts)

(1) Unless otherwise expressly provided for in this Act, the following provisions shall apply: *<Amended by Act No. 13201, Feb. 3, 2015; Act No. 14018, Feb. 3, 2016>*

1. Food additives used for health functional foods: Standards and specification for food additives provided for in Article 7 of the Food Sanitation Act;
2. Re-inspection of health functional foods: Provisions on re-inspections of foods, etc. under Article 23 of the Food Sanitation Act;
3. Designation of health functional foods inspection agencies: Provisions on designation of testing and inspection agencies of foods, etc. under Article 6 of the Act on Testing and Inspection in the Food and Drug Industry;

3-2. Urgent measures: Provisions on urgent measures under Article 17 of the Food Sanitation Act;

4. Health functional food hygiene inspectors: Provisions on food sanitation supervisors under Article 32 of the Food Sanitation Act;

5. Consumer health functional food hygiene inspectors: Provisions on consumer food sanitation supervisors under Article 33 of the Food Sanitation Act;

6. Medical examinations: Provisions on medical examinations under Article 40 of the Food Sanitation Act;

7. Voluntary recall of health functional foods: Provisions on recall of harmful foods, etc. under Article 45 of the Food Sanitation Act (In this case, business entities shall include importers or sellers of imported foods, etc. registered pursuant to Article 15 of the Special Act on Imported Food Safety Management, and health functional foods shall include health functional foods imported pursuant to the same Act);

8. Hazard Analysis Critical Control Points: Provisions on food safety management certification standards under Article 48 of the Food Sanitation Act;

9. Public announcements: Provisions on public announcements under Article 73 of the Food Sanitation Act;

10. Investigations into and reporting on food poisoning: Provisions on investigations into and reporting on food poisoning under Article 86 of the Food Sanitation Act.

(2) When a business entity violates any of the provisions of the Food Sanitation Act applied mutatis mutandis pursuant to paragraph (1), it may be subjected to a corrective order under Article 71 of the same Act, disposition of discard under Article 72 of the same Act, revocation of permission under Article 75 of the same Act, and suspension of manufacturing products under Article 76 of the same Act, and may be punished pursuant to Articles 95, 97, 98, and 100 through 102 of the same Act. *<Amended by Act No. 14018, Feb. 3, 2016>*

Article 39 (State Subsidies)

The Minister of Food and Drug Safety may fully or partially subsidize the following within budgetary limits:

1. Expenses incurred in collecting health functional foods, etc. under Article 20 (1) 2;

2. Deleted; *<by Act No. 14018, Feb. 3, 2016>*

3. Expenses incurred in improving the quality of health functional foods, preventing false, exaggerative, or negative labels or advertisements, or promoting research and development, etc.;

4. Expenses incurred in relation to activities done by private organizations to improve the safety of health functional foods.

Article 40 (Payment of Monetary Rewards)

(1) The Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may pay a monetary reward not exceeding ten million won to any person who accuses or reports any person who violates any of Article 5 (1), 6 (2), 23 or

26 to the relevant administrative agencies or investigation agencies. *<Amended by Act No. 13201, Feb. 3, 2015>*

(2) Standards, methods, and procedures for paying monetary rewards under paragraph (1), and other necessary matters shall be prescribed by Presidential Decree.

Article 41 (Delegation or Entrustment of Authority)

(1) The Minister of Food and Drug Safety may partially delegate his/her authority under this Act to the head of a Regional Ministry of Food and Drug Safety, a Special Metropolitan City Mayor, a Metropolitan City Mayor, the Metropolitan Autonomous City Mayor, a Do Governor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu, as prescribed by Presidential Decree. *<Amended by Act No. 12669, May 21, 2014>*

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

(3) The Minister of Food and Drug Safety may partially delegate his/her authority under this Act to any organization established under Article 28, as prescribed by Presidential Decree. *<Amended by Act No. 12669, May 21, 2014>*

Article 42 (Fees, etc.)

Anyone who intends to obtain permission, file a report or an application, or undergo an inspection as follows shall pay fees, as prescribed by Ordinance of the Prime Minister: *<Amended by Act No. 13201, Feb. 3, 2015; Act No. 14018, Feb. 3, 2016>*

1. Permission for business or revised permission under Article 5 (1) or reporting on revisions under Article 5 (2);
2. Reporting on business or reporting on revisions under Article 6 (2) and (3);
3. Reporting on manufacturing items or reporting on revisions under Article 7;
4. Deleted; *<by Act No. 13201, Feb. 3, 2015>*

4-2. Reporting on succession to the status of a business entity under Article 11 (3);

5. Inspections for recognizing the criteria, standards, 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. Self-inspections for quality control outsourced under Article 21 (2);
8. Deleted; *<by Act No. 14018, Feb. 3, 2016>*
9. Registration for tracking management of records on health functional foods under Article 22-2 (1).

Article 42-2 (Legal Fiction as Public Officials in Application of Penalty Provisions)

The following persons shall be deemed public officials for the purposes of applying Articles 129 through 132 of the Criminal Act:

1. An employee of an organization engaged in the business affairs entrusted pursuant to Article 16 (2);
2. A member of the deliberative committee referred to in Article 16 (3).

Article 43 (Penalty Provisions)

(1) Any of the following persons shall be punished by imprisonment with labor for not more than ten years, or by a fine not exceeding 100 million won. In such cases, imprisonment with labor and fines may be imposed concurrently:

1. A person who violates Article 5 (1);
2. A person who violates Article 18 (1) 1;
3. A person who violates Article 23.

(2) If a person sentenced to imprisonment without labor or heavier punishment for any of the violations referred to in paragraph (1) recommits any of the violations referred to in paragraph (1) within five years since such sentence has become final and conclusive shall be punished by imprisonment with labor for at least one up to ten years.

(3) In cases falling paragraph (2), if a person sells the relevant health functional food, a fine at least four times but not exceeding ten times the retail price thereof shall be imposed on the person.

Article 43 (Penalty Provisions)

(1) Any of the following persons shall be punished by imprisonment with labor for not more than ten years, or by a fine not exceeding 100 million won. In such cases, imprisonment with labor and fines may be imposed concurrently: *<Amended by Act No. 14018, Feb. 3, 2016>*

1. A person who violates Article 5 (1);
2. A person who violates Article 18 (1) 1;
3. A person who violates Article 23;
4. A person who violates Article 24 (2).

(2) If a person sentenced to imprisonment without labor or heavier punishment for any of the violations referred to in paragraph (1) recommits any of the violations referred to in paragraph (1) within five years since such sentence has become final and conclusive shall be punished by imprisonment with labor for at least one up to ten years.

(3) In cases falling paragraph (2), if a person sells the relevant health functional food, a fine at least four times but not exceeding ten times the retail price thereof shall be imposed on the person.

Article 44 (Penalty Provisions)

Any of the following persons shall be punished by imprisonment with labor for not more than five years, or by a fine not exceeding 50 million won. In such cases, imprisonment with labor and fines may be imposed concurrently: *<Amended by Act No. 13201, Feb. 3, 2015; Act No. 13330, May 18, 2015>*

1. Any person who run his/her business without filing a report thereon under Article 6 (1) or (2);
2. Any person who manufactures or sells products without reporting on manufacturing items under the former part of Article 7 (1);
3. Any person who sells products, in violation of Article 10 (1) 4;
4. Any person who makes a false, exaggerative, or negative label or advertisement in violation of Article 18 (1) 2 through 6;

5. Any person who fails to conduct a self-inspection for quality control under Article 21 (1);

6. Any person who has placed a label or run an advertisement in violation of Article 22 (5);

7. Any person who engages in sales, etc. in violation of Articles 24 through 26;

8. Any person who fails to comply with an order issued under Article 29, 30 (1), or (3);

9. Any person who violates an order to suspend his/her business issued under Article 32 (1).

Article 44 (Penalty Provisions)

Any of the following persons shall be punished by imprisonment with labor for not more than five years, or by a fine not exceeding 50 million won. In such cases, imprisonment with labor and fines may be imposed concurrently: *<Amended by Act No. 13201, Feb. 3, 2015; Act No. 13330, May 18, 2015; Act No. 14018, Feb. 3, 2016>*

1. Any person who engages in the business without filing a report for business under Article 6 (2);

2. Any person who manufactures or sells products without reporting on manufacturing items under the former part of Article 7 (1);

3. Any person who sells products, in violation of Article 10 (1) 4;

3-2. Any person who obtains recognition under Article 14 (2) or 15 (2) by fraudulent or other wrongful means;

4. Any person who makes a false, exaggerative, or negative label or advertisement in violation of Article 18 (1) 2 through 6;

4-2. Any person who engages in sales, etc. in violation of Article 17-2 (2);

5. Any person who fails to conduct a self-inspection for quality control under Article 21 (1);

6. Deleted; *<by Act No. 14018, Feb. 3, 2016>*

7. Any person who engages in sales, etc. in violation of Article 24 (1), 25, or 26;

8. Any person who fails to comply with an order issued under Article 29, 30 (1), or (3);

9. Any person who violates an order to suspend his/her business issued under Article 32 (1).

Article 45 (Penalty Provisions)

Any of the following business entities or persons shall be punished by imprisonment with labor for not more than three years, or a fine not exceeding 30 million won: *<Amended by Act No. 14018, Feb. 3, 2016>*

1. Any business entity that violates any of the standards for facilities under Article 4;

2. Any business entity that fails to comply with any of the matters to be observed under Article 10 (1) 2 and 3;

3. Any person who fails to report on succession to business under Article 11 (3);

4. Any person who fails to employ a quality control manager under Article 12 (1);

5. Any person who refuses, interferes with, or evades entry, an inspection, or collection under Article 20 (1);

6. Any person who fails to register tracking management of records on health functional foods under the proviso to Article 22-2 (1);

7. Any person who refuses, interferes with, or evades seizure or discard under Article 30 (2);

8. Any person who violates an order to suspend manufacturing items under Article 33 (1);

9. Any person who removes or damages a seal or notice placed by a relevant public official under Article 35 without permission.

Article 45 (Penalty Provisions)

Any of the following business entities or persons shall be punished by imprisonment with labor for not more than three years, or a fine not exceeding 30 million won: <*Amended by Act No. 14018, Feb. 3, 2016*>

1. Any business entity that violates any of the standards for facilities under Article 4;

2. Any business entity that fails to comply with any of the matters to be observed under Article 10 (1) 2 and 3;

3. Any person who fails to report on succession to business under Article 11 (3);

4. Any person who fails to employ a quality control manager under Article 12 (1);

4-2. Any person who engages in sales, etc. in violation of Article 17-2 (2);

5. Any person who refuses, interferes with, or evades entry, an inspection, or collection under Article 20 (1);

5-2. Any person who violates Article 21 (1) or (3);

5-3. Any person who fails to comply with the Regulations for Good Manufacturing Practice, in violation of Article 22 (1);

6. Any person who fails to register tracking management of records on health functional foods under the proviso to Article 22-2 (1);

7. Any person who refuses, interferes with, or evades seizure or discard under Article 30 (2);

8. Any person who violates an order to suspend manufacturing items under Article 33 (1);

9. Any person who removes or damages a seal or notice placed by a relevant public official under Article 35 without permission.

Article 46 (Joint Penalty Provisions)

Where the representative of a corporation, or an agent, employee, or other servant of the corporation or an individual commits a violation under Articles 43 through 45 in connection with the business of the corporation or the individual, not only shall such violator be punished, but also the corporation or the individual shall be punished by a fine under the relevant Articles: Provided, That this shall not apply where such corporation or individual has not been negligent in giving due attention and supervision to prevent such violation.

Article 47 (Administrative Fines)

(1) Any of the following persons shall be punished by administrative fines not exceeding three million won:

1. Any person who fails to report on a revision to any terms and conditions of permission under Article 5 (2);

2. Any person who fails to report on a revision to matters reported under Article 6 (3);

3. Any person who fails to report on a revision to matters on reporting of manufacturing items under the latter part of Article 7 (1);

4. Any person who fails to comply with any of the matters to be observed by business entities under Article 10 (1) 1 and 5, or who violates Article 10 (2);

5. Any person who interferes with the performance of duties of a quality control manager under Article 12 (3) or who fails to report on the appointment or dismissal of a quality control manager under Article 12 (4);

6. Any person who fails to undergo training under Article 13 (1) through (3);

7. Any person who fails to keep records after conducting a self-inspection for quality control under Article 21 (1), or who keeps a false record;

8. Any person who fails to file a report within one month under Article 22 (3);

9. Any person who fails to comply with an order to repair facilities under Article 31 (1).

(2) Administrative fines referred to in paragraph (1) shall be imposed and collected by the Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of Si/Gun/Gu, as prescribed by Presidential Decree.

Article 47 (Administrative Fines)

(1) Any of the following persons shall be punished by administrative fines not exceeding three million won: *<Amended by Act No. 14018, Feb. 3, 2016>*

1. Any person who fails to report on a revision to any terms and conditions of permission under Article 5 (2);

2. Any person who fails to report on a revision to matters reported under Article 6 (3);

3. Any person who fails to report on a revision to matters on reporting of manufacturing items under the latter part of Article 7 (1);

4. Any person who fails to comply with any of the matters to be observed by business entities under Article 10 (1) 1 and 5, or who violates Article 10 (2);

5. Any person who interferes with the performance of duties of a quality control manager under Article 12 (3) or who fails to report on the appointment or dismissal of a quality control manager under Article 12 (4);

5-2. Any person who fails to record and retain, or falsely records and retains, the details of the duties, etc. he/she has performed, in violation of Article 12 (5);

6. Any person who fails to undergo training under Article 13 (1) through (3);

7. Any person who fails to keep records after conducting a self-inspection for quality control under Article 21 (1), or who keeps a false record;

8. Any person who fails to file a report within one month under Article 22 (3);

9. Any person who fails to comply with an order to repair facilities under Article 31 (1).

(2) Administrative fines referred to in paragraph (1) shall be imposed and collected by the Minister of Food and Drug Safety, the Metropolitan Autonomous City Mayor, the Special Self-Governing Province Governor, or the head of Si/Gun/Gu, as prescribed by Presidential Decree.

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

In applying provisions concerning administrative fines under Article 47, no administrative fines shall be imposed against an act 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 criteria and standards under Article 14 (1), he/she shall be deemed a business entity engaged in the business of manufacturing health functional foods under this Act. In such cases, he/she shall obtain permission 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 items, manufactured and reported under Article 22 (6) of the Food Sanitation Act by business entities under the former part of paragraph (1) as at the time this Act enters into force, fall under health functional foods which meet criteria and standards under Article 14 (1), business entities may continue to manufacture and sell such items. In such cases, business entities shall prepare documents prescribed by Ordinance of the Ministry of Health and Welfare, including manuals for the methods of manufacturing items under Article 7, and file a report thereon to the Commissioner of the Korea Food and Drug Administration within six months after this Act enters into force, and they shall be exempt from fees.

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

When any person who has reported the businesses of importing and selling foods under Article 16 (1) of the Food Sanitation Act as at the time this Act enters into force imports and sells health functional foods which meet the criteria and standards under Article 14 (1), he/she shall be deemed a business entity running the business of importing health functional foods under this Act. In such cases, a business entity shall file a report thereon to 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 exempt from fees.

Article 4 (Transitional Measures concerning Persons whose Business Permission has been Revoked)

A period for restricting reports or permission for persons whose business permission has been revoked or who have been issued an order to close 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 done 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 two months after the date of its promulgation. (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 Reporting on Business of Importing Health Functional Foods)Acts done towards or by the Commissioner of the Korea Food and Drug Administration in connection with reporting on the business of importing health functional foods pursuant to the former Article 6 (1) shall be deemed acts done towards or by 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 12 Omitted.

ADDENDUM *<Act No. 11508, Oct. 22, 2012>*

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

ADDENDA *<Act No. 11690, Mar. 23, 2013>*

Article 1 (Enforcement Date)

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

(2) Omitted.

Articles 2 through 7 Omitted.

ADDENDA *<Act No. 11985, Jul. 30, 2013>*

Article 1 (Enforcement Date)

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

Article 2 through 5 Omitted.

ADDENDUM *<Act No. 12106, Aug. 13, 2013>*

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

ADDENDUM *<Act No. 12389, Jan. 28, 2014>*

This Act shall enter into force three months after the date of its promulgation: Provided, That the amended provisions of Article 8 (1) shall enter into force one year after the date of its promulgation.

ADDENDA *<Act No. 12669, May 21, 2014>*

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation: Provided, That the amended provisions of Article 8 (3) and 38 shall enter into force on July 31, 2014; the amended provisions of Article 8 (1) of the partially amended Health Functional Foods Act (Act No. 12389) shall enter into force on January 29, 2015; and the amended provisions of Articles 37 (2), 43, and 44 shall enter into force one year after the date of its promulgation.

Article 2 (Transitional Measures concerning Incompetents)

An incompetent under adult guardianship referred to in the amended provisions of Article 9 shall be deemed to include a person already declared incompetent, in whose case such declaration remains valid under Article 2 of the Addenda to the partially amended Civil Act (Act No. 10429)

Article 3 (Transitional Measures concerning Penalty Provisions)

The former penalty provisions shall apply to violations committed before this Act enters into force.

ADDENDA *<Act No. 13201, Feb. 3, 2015>*

Article 1 (Enforcement Date)

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

Articles 2 through 9 Omitted.

ADDENDA *<Act No. 13330, May 18, 2015>*

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation: Provided, That the amended provisions of paragraphs (4) and (5) of Article 6 (referring to the provisions amended pursuant to Article 8 (1) of the Addenda to the Special Act on Imported Food Safety Management (Act No. 13201)) shall enter into force on February 4, 2016, and the amended provisions of Articles 14 (2) and (3), 15 (2) and (3), 15-2, 37-3, and 44 shall enter into force one year after the date of its promulgation.

Article 2 (Applicability to Submission of Test Report, etc. of Testing or Inspection Agency, etc.)

The amended provisions of Article 14 (2) shall apply, starting with the first criteria and standards for health functional foods examined and recognized after the said amended provisions enter into force.

Article 3 (Transitional Measures concerning Recognition of Raw Materials, etc.)

Notwithstanding the amended provisions of Article 15 (2), former provisions shall apply to raw materials or ingredients pending examination for recognition at the time this Act enters into force.

ADDENDA <*Act No. 14018, Feb. 3, 2016*>

Article 1 (Enforcement Date)

(1) This Act shall enter into force one year after the date of its promulgation: Provided, That the amended provisions of Articles 9 (1) 1, 4, and 5, 9 (2) 4 and 5, 13 (4), 21 (2) and (3), the proviso to the provisions of Article 32 (1) other than each subparagraph, the provisions relating to violation of Article 4 (1), Article 5 (2) and Article 6 (3) in subparagraph 1 of Article 32 (1), the provisions relating to Article 32 (1) 9-2 and 11 in the main sentence of Article 32 (1) 4, 9-2 and 11 and Article 37 (1), Article 38, subparagraph 4-2 of Article 42, Article 42-2, and subparagraph 5-2 of Article 45 shall enter into force on the date of its promulgation.

(2) Notwithstanding paragraph (1), the amended provisions of Article 22, 32 (1) 5, subparagraph 2 of Article 39, subparagraph 8 of Article 42, subparagraph 6 of Article 44, subparagraph 5-3 of Article 45, and the provisions relating to violation of Article 22 in Article 33 (1) shall enter into force on the following respective dates:

1. Manufacturer with a turnover of at least two billion won for 2017: December 1, 2018;
2. Manufacturer with a turnover of at least one billion and less than two billion won for 2017: December 1, 2019;
3. Manufacturer with a turnover of less than one billion won for 2017: December 1, 2020.

Article 2 (Applicability to Restrictions on Permission for Business, etc.)

The amended provisions of Article 9 (1) 4 and 5 and 9 (2) 4 and 5 shall apply, starting with a case where business closure is reported pursuant to Article 5 (2) or 6 (3) after the said amended provisions enter into force.

Article 3 (Applicability to Revocation, etc. of Permission for Business)

The amended provisions of Article 32 (1) shall apply, starting with a case where a business entity falls under the amended provisions of Article 32 (1) 1, 4, 4-2, 5, 9-2, or 11 after this Act enters into force.

Article 4 (Transitional Measures concerning Imposition of Penalty Surcharges)

Former provisions shall apply where a disposition of imposing a penalty surcharge has been issued pursuant to Article 37 (1) before this Act enters into force, notwithstanding the amended provisions of Article 37 (4).