

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
Act No. 14018, Feb. 3, 2016
Act No. 14476, Dec. 27, 2016
Act No. 15480, Mar. 13, 2018
Act No. 15706, jun. 12, 2018
Act No. 15938, Dec. 11, 2018
Act No. 16295, Jan. 15, 2019
Act No. 16715, Dec. 3, 2019
Act No. 17091, Mar. 24, 2020

CHAPTER I GENERAL PROVISIONS

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 (Responsibilities)

- (1) The State and local governments shall formulate rational policies, and instruct or manage persons who manufacture, process, import, and sell health functional 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 on 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 human health;
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. Deleted; *<Mar. 13, 2018>*
4. Deleted; *<Mar. 13, 2018>*
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 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 health functional foods.

CHAPTER II BUSINESS

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. Manufacturing health functional foods:
 2. Deleted; *<Feb. 3, 2015>*
 3. Selling health functional foods.
- (2) The detailed types of business described in paragraph (1) and the scope thereof shall be prescribed by Presidential Decree.

Article 5 (Permission for Business)

(1) Anyone who intends to engage in commercially manufacturing 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 on May 18, 2015>*

(2) When anyone who has obtained permission under paragraph (1) intends to close the relevant business or modify matters prescribed by Ordinance of the Prime Minister, among the terms and conditions of such permission, he or 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 on May 18, 2015; Feb. 3, 2016>*

1. Where the relevant person fails to meet the standards for facilities referred to in Article 4;
2. Where it 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 of 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 of 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. Other cases that violate any restriction under this Act or other statutes or regulations.

(4) The Minister of Food and Drug Safety shall notify an applicant or reporting person of permission or non-permission, or acceptance or non-acceptance of a report within 20 days from the date he or she receives an application for permission prescribed in paragraph (1) and within seven days from the date he or she receives the report for modification prescribed in paragraph (2). *<Newly Inserted on Jan. 15, 2019>*

(5) Where the Minister of Food and Drug Safety fails to notify the applicant or reporting person of permission or non-permission, or acceptance or non-acceptance of a report, or of the extension of the period of processing prescribed by the statutes or regulations related to processing civil petitions within the periods prescribed in paragraph (4), he or she shall be deemed to grant permission or accept the report on the date following the date the periods (where the period of processing is extended or re-extended by the statutes or regulations related to processing civil petitions, referring to the relevant period of processing) end. *<Newly Inserted on Jan. 15, 2019>*

(6) Procedures for obtaining permission for business, permission for modification, and reporting on modification matters under paragraphs (1) and (2), and other necessary matters shall be prescribed by Ordinance of the Prime Minister. *<Amended on May 18, 2015; Jan. 15, 2019>*

Article 6 (Reporting on Business)

(1) Deleted. *<Feb. 3, 2015>*

(2) Anyone who intends to engage in commercially selling health functional foods referred to in Article 4 (1) 3 shall install facilities prescribed under Article 4 in each place of business, as prescribed by Ordinance of the Prime Minister, and report thereon to the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of the 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 modify matters prescribed by Ordinance of the Prime Minister, he or she shall report thereon to the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of the Si/Gun/Gu. *<Amended on Feb. 3, 2015>*

(4) The Special Self-Governing City Mayor, the Special Self-Governing Province Governor, and the heads of Sis/Guns/Gus shall notify reporting persons of acceptance or non-acceptance of reports within three days from the date they receive the reports prescribed in paragraph (2) or reports for modification prescribed in paragraph (3). *<Newly Inserted on Jan. 15, 2019>*

(6) Where the Minister of Food and Drug Safety fails to notify the reporting person of acceptance or non-acceptance of a report or of the extension of the period of processing prescribed by the statutes or regulations related to processing civil petitions within the period prescribed in paragraph (4), he or she shall be deemed to accept the report on the date following the date the period (where the period of processing is extended or re-extended by the statutes or regulations related to processing civil petitions, referring to the relevant period of processing) ends. *<Newly Inserted on Jan. 15, 2019>*

(6) The Special Self-Governing 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 the competent tax office pursuant to Article 8 of the Value-Added Tax Act, or if the head of the competent tax office cancels his or her business registration. *<Newly Inserted on May 18, 2015; Jan. 15, 2019>*

(7) If necessary to cancel the relevant reported matters ex officio pursuant to paragraph (6), the Special Self-Governing 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 information as to whether the business entity who has reported his or her business under paragraph (2) closes the business. In such case, the head of the competent tax office in receipt of such request shall provide information as to whether the business entity has closed his or her business, pursuant to Article 36 (1) of the Electronic Government Act. *<Newly Inserted on Jun. 12, 2018; Jan. 15, 2019>*

(8) Procedures for reporting business and modification of matters under paragraphs (2) and (3) and other necessary matters shall be prescribed by Ordinance of the Prime Minister. *<Amended on Feb. 3, 2015; May 18, 2015; Jun. 12, 2018; Jan. 15, 2019>*

Article 7 (Reporting 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 or 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 modification of matters prescribed by Ordinance of the Prime Minister among the reported matters.

(2) Within 10 days from the date of receiving a report or report for modification prescribed in paragraph (1), the Minister of Food and Drug Safety shall notify the reporting person of acceptance or non-acceptance of the report. *<Newly Inserted on Jan. 15, 2019>*

(3) Where the Minister of Food and Drug Safety fails to notify the reporting person of acceptance or non-acceptance of a report or of the extension of the period of processing prescribed by the statutes or regulations related to processing civil petitions within the period prescribed in paragraph (2), he or she shall be deemed to accept the report on the date following the date the period (where the period of processing is extended or re-extended by the statutes or regulations related to processing civil petitions, referring to the relevant period of processing) ends. *<Newly Inserted on Jan. 15, 2019>*

(4) Procedures for reporting on manufacturing items and on modification of matters under paragraph (1), and other necessary matters shall be prescribed by Ordinance of the Prime Minister. *<Amended on Jan. 15, 2019>*

Article 8 Deleted. *<Feb. 3, 2015>*

Article 9 (Restrictions on Permission for Business)

(1) No permission for business shall be granted under Article 5 (1) in any of the following cases: *<Amended on Feb. 3, 2016; Mar. 13, 2018>*

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) of this Act (excluding subparagraphs 9-2, 10, and 11; hereafter the same shall apply in this Article) or Article 16 (1) and (2) of the Act on Labeling and Advertising of Foods, 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) of this Act or Article 16 (1) and (2) of the Act on Labeling and Advertising of Foods, intends to run the same type of business;

3. When the relevant person (including the representative of a corporation) who intends to obtain permission for business is a person 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 or she received a disposition of business suspension under the subparagraphs of Article 32 (1) of this Act or Article 16 (1) of the Act on Labeling and Advertising of Foods 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 or she received a disposition of business suspension under the subparagraphs of Article 32 (1) of this Act or Article 16 (1) of the Act on Labeling and Advertising of Foods 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 or her business under Article 6 (2) in any of the following cases:

<Amended on Feb. 3, 2015; Feb. 3, 2016; Mar. 13, 2018>

1. When the relevant person, for whom six months have not elapsed since he or she was issued an order to close the place of business under the subparagraphs of Article 32 (1) of this Act or Article 16 (3) and (4) of the Act on Labeling and Advertising of Foods, intends to run the same kind of business in the relevant place of business: Provided, That this shall not apply where he or 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 or she was issued an order to close the place of business under the subparagraphs of Article 32 (1) of this Act or Article 16 (3) and (4) of the Act on Labeling and Advertising of Foods, intends to run the same type of business;

3. When the relevant person (including the representative of a corporation) who intends to report on his or her business is a person 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 or she received a disposition of business suspension under the subparagraphs of Article 32 (1) of this Act or Article 16 (3) of the Act on Labeling and Advertising of Foods 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 or she received a disposition of business suspension under the subparagraphs of Article 32 (1) of this Act or Article 16 (3) of the Act on Labeling and Advertising of Foods and reported business closure under Article 6 (3), intends to engage in the same type of business.

Article 10 (Obligations of 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 10-2 (Report on Adverse Events)

- (1) After recognizing any unfavorable and unintended sign, symptom or disease associated with the use of health functional foods (hereinafter referred to as "adverse event"), business entities (including pharmacy founders registered under Article 20 of the Pharmaceutical Affairs Act and importers and sellers of imported food, etc. registered under Article 15 of the Special Act on Imported Food Safety Control; hereafter in this Article the same shall apply) shall file a report thereon to the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister.
- (2) Upon receipt of a report on adverse events under paragraph (1), the Minister of Food and Drug Safety shall examine and analyze the safety of the health functional foods and their casual relationship with such adverse events. In such cases, where deemed necessary, the Minister of Food and Drug Safety may require the business entity or the interested party to make a statement or to submit materials, articles, etc. necessary for the evaluation.
- (3) The Minister of Food and Drug Safety may publish the findings of the evaluation and analysis pursuant to paragraph (2), as prescribed by Presidential Decree.
- (4) The Minister of Food and Drug Safety may entrust the receipt of a report on adverse events pursuant to paragraph (1) and the evaluation and analysis pursuant to paragraph (2) to a related specialized agency prescribed by Presidential Decree. In such cases, the Minister of Food and Drug Safety may fully or partially subsidize the expenses incurred by the entrusted agency within budgetary limits.

Article 11 (Succession of Business)

- (1) Any of the following persons shall succeed to the status of the former business entity:
1. A transferee where the business operator has transferred his or her business;
 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: *<Amended on Dec. 27, 2016>*
 1. Auction under the Civil Execution Act;
 2. Transfer under the Debtor Rehabilitation and Bankruptcy Act;
 3. Sales of seized property provided in the National Tax Collection Act, the Customs Act or the Local Tax Collection Act;
 4. Other procedures similar to those prescribed in 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 Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of the 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 (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 employ 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 is qualified as a quality control manager and performs quality control duties.
- (2) Quality control managers shall provide guidance to the manufacturers of health functional 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 on 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, to employees involved in safety assurance, quality control, hygienic management, etc. of health functional foods.
- (3) No manufacturers of health functional foods shall interfere with any quality control manager in performing his or her duties and they, in receipt of a request necessary for performing the duties of a quality control manager, shall comply with such request, unless there is good cause. *<Amended on Feb. 3, 2016>*
- (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) Within three days from the date of receiving a report prescribed in paragraph (4), the Minister of Food and Drug Safety shall notify the reporting person of acceptance or non-acceptance of the report. <Newly Inserted on Jan. 15, 2019>

(6) Where the Minister of Food and Drug Safety fails to notify the reporting person of acceptance or non-acceptance of a report or of the extension of the period of processing prescribed by the statutes or regulations related to processing civil petitions within the period prescribed in paragraph (5), he or she shall be deemed to accept the report on the date following the date the period (where the period of processing is extended or re-extended by the statutes or regulations related to processing civil petitions, referring to the relevant period of processing) ends. <Newly Inserted on Jan. 15, 2019>

(7) 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. <Newly Inserted on Feb. 3, 2016; Jan. 15, 2019>

(8) Qualifications for, and matters to be observed by, quality control managers, and other necessary matters shall be prescribed by Presidential Decree. <Amended on Feb. 3, 2016; Jan. 15, 2019>

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 (Education)

(1) The Minister of Food and Drug Safety may order business entities and employees to undergo education on safety assurance, quality control, labeling and advertising of health functional foods under the Act on Labeling and Advertising of Foods (hereinafter referred to as "education on safety and sanitation"), if deemed necessary for preventing harm to national health: Provided, That a business entity commercially selling health functional foods under Article 4 (1) 3, shall annually undergo education on safety and sanitation for each place of business. <Amended on Feb. 3, 2016; Mar. 13, 2018>

(2) Any person who intends to engage in business under Article 4 shall undergo prior education on safety and sanitation: Provided, That when business entities are unable to undergo prior education due to any grounds prescribed by Ordinance of the Prime Minister, they may undergo such education, as prescribed by the Minister of Food and Drug Safety, after starting his or her business. <Amended on Feb. 3, 2016>

(3) Any person appointed as a quality control manager under Article 12 shall undergo regular education on safety and sanitation. <Amended on Feb. 3, 2016>

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

sanitation among his or her employees and require the person to undergo such education on his or her behalf: *<Amended on 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 education due to any grounds prescribed by Ordinance of the Prime Minister.

(5) The Minister of Food and Drug Safety may entrust education on safety and sanitation to a specialized education institution prescribed by Ordinance of the Prime Minister or to an organization established pursuant to Article 28. *<Newly Inserted on Feb. 3, 2016>*

(6) Details of, and timing to provide, education on safety and sanitation under paragraphs (1) through (3), the collection of education fees, and other necessary matters shall be prescribed by Ordinance of the Prime Minister. *<Amended on Feb. 3, 2016>*

CHAPTER III STANDARDS, SPECIFICATIONS

Article 14 (Standards and Specifications)

(1) The Minister of Food and Drug Safety shall determine and publicly notify standards and specifications for the manufacture, use, preservation, etc. of health functional foods for sale. In such case, he or she shall separately determine standards and specifications for the use, etc. of food additives for health functional foods manufactured to be taken by children (referring to children defined in subparagraph 1 of Article 2 of the Special Act on Safety Management of Children's Dietary Lifestyle). *<Amended on Dec. 11, 2018>*

(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 Control, or persons prescribed by Ordinance of the Prime Minister to submit the following data on the standards and specifications for health functional foods, the standards and specifications for which have not been publicly notified under paragraph (1), and review and recognize such data as the standards and specifications for the health functional foods. In such case, testing may be entrusted to a testing or inspection agency referred to in subparagraph 2, if necessary: *<Amended on Feb. 3, 2015; May 18, 2015>*

1. Data on the standards, specifications, 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 Control, or a person prescribed by Ordinance of the Prime Minister has obtained recognition for the standards and specifications referred to in paragraph (2) by fraud or other improper means, the Minister of Food and

Drug Safety shall revoke such recognition. <Newly Inserted on May 18, 2015>

(4) The standards and specifications for health functional foods for exportation may follow standards and specifications demanded by importers, notwithstanding paragraphs (1) and (2). <Amended on May 18, 2015>

(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. <Amended on May 18, 2015>

Article 15 (Recognition of Raw Materials)

(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 on Feb. 3, 2015; 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 on 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 on May 18, 2015>

Article 15-2 (Reassessment)

(1) The Minister of Food and Drug Safety may review 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 Deleted. <Mar. 13, 2018>

Article 16-2 Deleted. <Mar. 13, 2018>

Article 17 Deleted. <Mar. 13, 2018>

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

(1) A business entity (including importers and sellers of imported foods, etc. registered pursuant to Article 15 of the Special Act on Imported Food Safety Control; hereafter in this Article the same shall apply) shall place a label indicating genetically modified health functional foods on 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 biotechnology (hereinafter referred to as "genetically modified health functional food"): Provided, That the foregoing shall be limited to genetically modified health functional foods in which genetically modified deoxyribonucleic acid (DNA) or genetically modified protein remains after being manufactured or processed: <Amended on Jan. 15, 2019>

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) A business entity shall not sell; import, display, or transport for the purpose of sale; or use for business genetically modified health functional foods subject to placing a label pursuant to paragraph (1) without placing a label. <Amended on Jan. 15, 2019>

(3) Matters necessary for the subject matter, methods, etc. of placing labels under paragraph (1) shall be determined by the Minister of Food and Drug Safety. <Amended on Jan. 15, 2019>

Article 18 Deleted. <Mar. 13, 2018>

Article 19 (Codes of Health Functional Foods)

The Minister of Food and Drug Safety shall prepare and distribute the codes of health functional foods that contain the standards and specifications of health functional foods prescribed under Article 14, raw materials and ingredients prescribed under Article 15, and labeling standards prescribed under Article 17-2. <Amended on Feb. 3, 2016; Mar. 13, 2018>

CHAPTER IV INSPECTIONS

Article 20 (Visit, Inspections, and Collection.)

(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 Special Self-Governing 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 or her authority and produce it to relevant persons.

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

(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 health functional 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 Special Self-Governing 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 Special Self-Governing 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 Special Self-Governing 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 or 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 (Obligation of Self-Quality Inspection)

(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 or she manufactures meet the standards and specifications 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 on 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 on 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 on Feb. 3, 2016>*

Article 21-2 (Obligations 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)

(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 health functional 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 foods in which harmful substances have been detected in or outside the Republic of Korea;
2. Other health functional foods 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.

CHAPTER V REGULATIONS FOR GOOD MANUFACTURING PRACTICE

Article 22 (Regulations for Good Manufacturing Practice)

(1) Business entities that commercially manufacture health functional 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 on 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 on 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 on Feb. 3, 2016>*

(4) Deleted *<Feb. 3, 2016>*

(5) Deleted. *<Feb. 3, 2016>*

(6) Deleted. *<Feb. 3, 2016>*

(7) Deleted. *<Feb. 3, 2016>*

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

(1) Any person who intends to perform tracking management of records on health functional 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 on 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 on 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 on 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 or 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.

CHAPTER VI PROHIBITION AGAINST SALE

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

No one shall sell, or manufacture, import, use, store, transport or display any of the following health functional foods for sale: <Amended on 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 prohibited, or foods imported without making an import declaration under Article 20 (1) of the Special Act on Imported Food Safety Control;

Article 24 (Prohibition against Sale of Health Functional Foods which Violate Standards and Specifications)

(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 standards and specifications for which are determined under Article 14 (1) and (2), in accordance with such standards and specifications, and shall not sell any health functional foods which violate such standards and specifications, or manufacture, import, use, store, transport, keep, or display such health functional foods for sale. *<Amended on Feb. 3, 2015>*

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

Article 25 Deleted. *<Mar. 13, 2018>*

Article 26 Deleted. *<Mar. 13, 2018>*

**CHAPTER VII HEALTH FUNCTIONAL FOODS
DELIBERATION COMMITTEE AND
ESTABLISHMENT OF ORGANIZATIONS**

Article 27 (Health Functional Foods Deliberation Committee)

(1) The Health Functional Foods Deliberation Committee (hereinafter referred to as the "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: *<Amended on Jan. 15, 2019>*

1. Matters concerning policies on health functional foods;
2. Matters concerning the standards and specifications for health functional foods;
3. Matters concerning the labelling and advertisement of health functional foods;
4. Other important matters concerning health functional foods.

(2) The Committee shall be comprised of at least 30 but not exceeding 80 members, including one chairperson and two vice-chairpersons. In such case, a majority of the members shall not be public officials. *<Newly Inserted on Jan. 15, 2019>*

(3) The chairperson shall be elected among and by the members, and the vice-chairpersons shall be nominated by the chairperson. *<Newly Inserted on Jan. 15, 2019>*

(4) Members shall be commissioned or appointed by the Minister of Food and Drug Safety from among the following: *<Newly Inserted on Jan. 15, 2019>*

1. Persons with considerable knowledge and experience in foods, drugs, nutrition, and health care;
2. Persons recommended by the heads of health functional food-related organizations, the heads of non-profit, non-governmental organizations defined in Article 2 of the Assistance for Non-Profit, Non-Governmental Organizations Act, the heads of health functional food-related societies, or the heads of colleges, universities, or industrial colleges prescribed in subparagraphs 1 and 2 of Article 2 of the Higher Education Act, respectively;
3. At least Grade V public officials in charge of affairs related to health functional foods or public officials in general service of the Senior Executive Service.

(5) The term of office of members shall be two years: Provided, That the term of office of members who are public officials shall be the period during which they hold the relevant positions. *<Newly Inserted on Jan. 15, 2019>*

(6) The Committee may have researchers to examine and study the standards and specifications for, and labelling, advertisement, etc. of health functional foods. *<Amended on Jan. 15, 2019>*

(7) Other matters necessary for the composition, operation, etc. of the Committee shall be prescribed by Presidential Decree. *<Amended on Jan. 15, 2019>*

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) The Association shall be a juristic person.

(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.

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

Article 29 (Corrective Orders)

The Minister of Food and Drug Safety, the Special Self-Governing 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 (Dispositions of Discarding)

(1) When a business entity (including importers of foods, etc. or sellers of imported foods, etc. registered pursuant to Article 15 of the Special Act on Imported Food Safety Control; hereafter the same shall apply in this Article) violates any provision of Article 17-2 (2), 23, or 24, the Minister of Food and Drug Safety, the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of the 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 sanitation. *<Amended on Feb. 3, 2015; Feb. 3, 2016; Mar. 13, 2018>*

(2) The Minister of Food and Drug Safety, the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of the Si/Gun/Gu may order relevant public officials to seize or discard the 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 sanitation hazards occur or are likely to occur, the Minister of Food and Drug Safety, the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of the Si/Gun/Gu may order the relevant business entity to recall or discard the relevant health functional food in the market; to change the raw materials, manufacturing methods, ingredients or mixing proportion of the relevant health functional food; or to amend (including newly inserting) precautions in consumption of the relevant health functional food. *<Amended on Jun. 12, 2018>*

(4) A relevant public official who seizes or discards health functional foods under paragraphs (1) and (2) shall carry an identification card indicating his or 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 to Repair Facilities)

(1) The Minister of Food and Drug Safety, the Special Self-Governing 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 of Permission for Business)

(1) The Minister of Food and Drug Safety, the Special Self-Governing 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 of up to six months or issue an order to close the place of business (limited to business reported under Article 6; hereafter in this Article the same shall apply), 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 on Feb. 3, 2015; Feb. 3, 2016; Mar. 3, 2018; Jan. 15, 2019>*

1. Where it violates Article 4 (1), the latter part of Article 5 (1), Article 5 (2), Article 6 (3), 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. Where he or she violates Article 12 (1);

3. Deleted; *<Mar. 13, 2018>*

3-2. Where it fails to file a report prescribed in Article 20 (1) or files a false report, or refuses, interferes with, or evades the access, inspection, collection, or public reading prescribed in the same paragraph without good cause;

4. Where he or she violates Article 21 (1) and (3);

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

5. Where it violates Article 22;

6. Where it violates the proviso of Article 22-2 (1);

7. Where it violates the prohibition against sale, etc. under Article 23 or 24 (1) and (2);

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

8-2. Where it refuses, interferes with, or evades seizure or discarding under Article 30 (2) without good cause;

9. Where it continues to conduct business, in violation of an order to suspend business;

9-2. Where it becomes a person under adult guardianship, or is declared bankrupt by the court;

10. Where it suspends business for at least six consecutive months without good cause;
 11. Where 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 or her business registration.
- (2) If necessary to revoke permission for business pursuant to paragraph (1) 11, the Minister of Food and Drug Safety may request the head of the competent tax office to provide information as to whether the business entity who has obtained permission for business under Article 5 (1) closes his or her business. In such case, the head of the competent tax office in receipt of such request shall provide information as to whether the business entity has closed his or her business, pursuant to Article 36 (1) of the Electronic Government Act. *<Newly Inserted on Jun. 12, 2018>*
- (3) Detailed standards for administrative dispositions under paragraph (1) shall be prescribed by Ordinance of the Prime Minister, based on the types, severity, etc. of violations. *<Amended on Jun. 12, 2018>*
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 33 (Suspension of Manufacturing Specific Products)

- (1) The Minister of Food and Drug Safety may issue an order to suspend manufacturing the relevant product or the relevant type of products (referring to all products manufactured under the same standards and specifications, among standards and specifications for health functional foods determined under Article 14) for a specified period of up to six months, as prescribed by Presidential Decree, when a business entity violates Article 17-2 (2), 21 (1), 21-2 (1), 23, or 24 (1) and (2). *<Amended on Feb. 3, 2016; Mar. 13, 2018>*
- (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.
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 34 (Succession to Administrative Sanctions)

When a business entity transfers his or 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)

(1) The Minister of Food and Drug Safety, the Special Self-Governing 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 or 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 or 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 on 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 for making facilities of the relevant place of business or its apparatuses, etc. used for its business operations unavailable.

(2) The Minister of Food and Drug Safety, the Special Self-Governing 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 or 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 Special Self-Governing 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 or 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 or her authority and produce it to relevant persons.

Article 36 (Hearings)

When the Minister of Food and Drug Safety, the Special Self-Governing 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 or 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 Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may impose a penalty surcharge not exceeding one billion won, in lieu of suspension of business or suspension of manufacturing of the relevant product or relevant type of products, 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, where the business entity falls under Article 32 (1) or 33 (1) for a violation of the latter part of Article 5 (1), 10 (1), 23, or 24 (1) and (2). *<Amended on Feb. 3, 2016; Mar. 13, 2018; Jun. 12, 2018>*

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

(3) The Minister of Food and Drug Safety, the Special Self-Governing 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 on Feb. 3, 2016>*

1. The relevant taxpayer's personal information;
2. The purpose of using the tax information;
3. Sales served as a basis for assessing the penalty surcharge.

(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 Special Self-Governing 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 of Local Administrative Penalty Charges: 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 of Local Administrative Penalty Charges. *<Amended on Feb. 3, 2016; Mar. 24, 2020>*

(5) The Minister of Food and Drug Safety, the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu may request the relevant person to provide any of the following data or information, 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 on Feb. 3, 2016>*

1. Certified copy of registered building ledger under Article 38 of the Building Act: The Minister of Land, Infrastructure and Transport;
2. Certified copy of land cadastre under Article 71 of the Act on the Establishment and Management of Spatial Data: The Minister of Land, Infrastructure and Transport;

3. A certified copy of motor vehicle register under Article 7 of the Motor Vehicle Management Act: The Special Metropolitan City Mayor, Metropolitan City Mayors, Special Self-Governing City Mayors, Do Governors, or Special Self-Governing Province Governor.

(6) Penalty surcharges imposed and collected under paragraphs (1) and (4) by the Minister of Food and Drug Safety, shall devolve on the State, and penalty surcharges imposed and collected by the Special Self-Governing 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 89 of the Food Sanitation Act) of the Special Metropolitan City, Metropolitan City, Special Self-Governing City, Do, Special Self-Governing Province, or Si/Gun/Gu. <Amended on Feb. 3, 2016>

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

(1) The Minister of Food and Drug Safety, the Special Self-Governing 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 selling price of the health functional foods: <Amended on Jun. 12, 2018>

1. Deleted; <Mar. 13, 2018>

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

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

(2) The calculated amount of a penalty surcharge referred to in 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 or 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 of Local Administrative Penalty Charges. <Amended on Mar. 24, 2020>

(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 on Feb. 3, 2016>

Article 37-3 (Publication of Violations)

The Minister of Food and Drug Safety, the Special Self-Governing 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.

CHAPTER IX SUPPLEMENTARY RULES

Article 38 (Relationship to Other Statutes)

(1) Unless otherwise expressly provided for in this Act, the following provisions shall apply: *<Amended on Feb. 3, 2015; Feb. 3, 2016>*

1. Food additives used for health functional foods: Standards and specifications 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 on Feb. 3, 2016>*

Article 39 (State Subsidies)

The Minister of Food and Drug Safety may fully or partially subsidize the following within budgetary limits: *<Amended on Mar. 13, 2018>*

1. Expenses incurred in collecting health functional foods, etc. under Article 20 (1) 2;
2. Deleted; *<Feb. 3, 2016>*
3. Expenses incurred in improving the quality of health functional foods 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.
 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 40 (Payment of Monetary Rewards)

(1) The Minister of Food and Drug Safety, the Special Self-Governing 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 a person who accuses or reports a person who violates Article 5 (1), 6 (2), 23, or 24 to the relevant administrative agencies or investigation agencies. *<Amended on Feb. 3, 2015; Mar. 13, 2018>*

(2) The standards and procedures for, and methods of, the payment of monetary rewards under paragraph (1) and other necessary matters shall be prescribed by Presidential Decree.

Article 41 (Delegation and Entrustment of Authority)

(1) The Minister of Food and Drug Safety may partially delegate his or her authority under this Act to the Director General of the National Institute of Food and Drug Safety Evaluation, the heads of regional offices of Food and Drug Safety, the Special Metropolitan City Mayor, Metropolitan City Mayors, the Special Self-Governing City Mayor, Do Governors, the Special Self-Governing Province Governor, or the heads of Sis/Guns/Gus, as prescribed by Presidential Decree. *<Amended on May 21, 2014; Jan. 15, 2019>*

(2) Deleted. *<Feb. 21, 2008>*

(3) The Minister of Food and Drug Safety may partially delegate his or her authority under this Act to any organization established under Article 28, as prescribed by Presidential Decree. *<Amended on May 21, 2014>*

Article 42 (Service Charges)

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 on Feb. 3, 2015; Feb. 3, 2016>

1. Permission for business or revised permission under Article 5 (1) or reporting on revision under Article 5 (2);
2. Reporting on business or reporting on revision under Article 6 (2) and (3);
3. Reporting on manufacturing items or reporting on revision under Article 7;
4. Deleted; <Feb. 3, 2015>
- 4-2. Reporting on succession to the status of a business entity under Article 11 (3);
5. Inspections for recognizing the standards, specifications, materials, etc. of health functional foods under Article 14 (2) or 15 (2);
6. Deleted; <Mar. 13, 2018>
7. Self-inspections for quality control outsourced under Article 21 (2);
8. Deleted; <Feb. 3, 2016>
9. Registration for tracking management of records on health functional foods under Article 22-2 (1).
 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 42-2 Deleted. <Mar. 13, 2018>

CHAPTER X PENALTY PROVISIONS

Article 43 (Penalty Provisions)

(1) Any of the following persons shall be punished by imprisonment with labor for not more than 10 years, or by a fine not exceeding 100 million won. In such cases, imprisonment with labor and fines may be imposed concurrently: <Amended on Feb. 3, 2016>

1. A person that violates Article 5 (1);
2. Deleted; <Mar. 13, 2018>
3. Any person who violates Article 23;
4. A person that 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) recommit 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. <Amended on Jun. 12, 2018>

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 on Feb. 3, 2015; May 18, 2015; Feb. 3, 2016; Mar. 13, 2018>

1. Any person who engages in business without filing a report for business under Article 6 (2);
2. Any person who manufactures or sells products without reporting on product manufacture 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. Deleted; <Mar. 13, 2018>
5. Any person who fails to conduct a self-inspection for quality control under Article 21 (1);
6. Deleted; <Feb. 3, 2016>
7. Any person who engages in sales, etc. in violation of Article 24 (1);
8. Any person who fails to comply with an order issued under Article 29 or 30 (1) or (3);
9. Any person who violates an order to suspend his or her business issued under Article 32 (1).
 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 45 (Penalty Provisions)

A person who falls under any of the following shall be punished by imprisonment with labor for not more than three years or by a fine not exceeding 30 million won: <Amended on Feb. 3, 2016>

1. Any business entity that ceases to meet 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 the succession of 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, obstructs, or evades an emergency safety examination 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, obstructs, or evades an emergency safety examination 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.

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 46 (Joint Penalty Provisions)

Where the representative of a corporation, or an agent, or employee of or other persons employed by a corporation or an individual commits an offense falling under any of Articles 43 through 45 in relation to affairs of such corporation or individual, not only shall the person who commits such offense be punished but such corporation or individual also shall be punished by a fine under the relevant provisions: Provided, That the foregoing shall not apply where the corporation or the individual has not neglected to pay due attention to or exercise reasonable supervision over the relevant affairs to prevent such offense.

Article 47 (Administrative Fines)

(7) A person falling under any of the following subparagraphs shall be punished by an administrative fine not exceeding three million won: *<Amended on Feb. 3, 2016; Jan. 15, 2019>*

1. Any person who fails to file a report on modification to permitted matters in accordance with Article 5 (2);

2. Any person who fails to report the modification of matters reported under Article 6 (3);

3. Any person who fails to report the modification of 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 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 or she has performed, in violation of Article 12 (7);

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, in violation of Article 22-2 (3);
 9. Deleted. <Jan. 15, 2019>
- (2) Any person who fails to file a report on adverse events in violation of Article 10-2 (1) shall be subject to an administrative fine of not more than one million won. <Amended on Dec. 3, 2019>
- (3) Administrative fines under paragraphs (1) and (2) shall be imposed and collected by the Minister of Food and Drug Safety, the Special Self-Governing City Mayor, the Special Self-Governing Province Governor, or the head of a Si/Gun/Gu, as prescribed by Presidential Decree. <Amended on Dec. 3, 2019>

Article 48 (Special Exemption to Application of Provisions on Administrative Fines)

In applying provisions regarding administrative fines under Article 47, administrative fines shall not be imposed for acts for which penalty surcharges are imposed pursuant to Article 37.

ADDENDA <Act No. 6727, Aug. 26, 2002>

Article 1 (Enforcement Date)

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

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

(1) When any person who has reported a business of manufacturing or processing foods under Article 22 (5) of the Food Sanitation Act at the time this Act enters into force, manufactures health functional foods which meet the standards and specifications under Article 14 (1), he or she shall be deemed a business entity engaged in the business of manufacturing health functional foods under this Act. In such cases, he or 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 or 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 standards and specifications 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 standards and specifications under Article 14 (1), he or 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 or 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 Penalty Provisions and Administrative Fines)

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 Statutes)

A citation of the provisions of the Food Sanitation Act by any other 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 promulgation.

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

Article 1 (Enforcement Date)

This Act shall enter into 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: Provided, That, among the Acts amended pursuant to Article 6 of the Addenda, the amendments to the Acts promulgated before this Act enters into force, but the enforcement dates of which have yet to arrive, shall enter into force on the dates on which the respective Acts take effect.

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 1/1/2011.

(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 1/1/2011.

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 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 one year after the date of its promulgation.

Articles 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)

Where penalty provisions are applied to an act performed before this Act enters into force, the former provisions shall apply to such act.

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

Article 1 (Enforcement Date)

This Act shall enter into 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 of Testing or Inspection Agency)

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

Article 3 (Transitional Measures concerning Recognition of Raw Materials)

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)

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 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 Dispositions of 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).

ADDENDA <Act No. 14476, Jun. 27, 2016>

Article 1 (Enforcement Date)

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

Articles 2 through 5 Omitted.

ADDENDA <Act No. 15480, Mar. 13, 2018>

Article 1 (Enforcement Date)

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

Article 2 (Transitional Measures concerning Labeling of Health Functional Foods)

The labeling standards under former Article 17 may apply to health functional foods manufactured, processed, or imported within two years after this Act enters into force, notwithstanding the amended provisions of Article 17 and the Act on Labeling and Advertising of Foods. In such cases, the relevant health functional foods may be sold, displayed or transported for the purpose of sale until its shelf life, or used for business.

Article 3 (Transitional Measures concerning Deliberation on Labels and Advertisements regarding Functionality)

Former provisions shall apply to deliberations and objections on labels and advertisements regarding functionality of health functional foods filed pursuant to former Article 16 or 16-2 before this Act enters into force, notwithstanding the amended provisions of Articles 16 and 16-2 and the Act on Labeling and Advertising of Foods.

Article 4 (Transitional Measures concerning Administrative Dispositions and Imposition and Collection of Penalty Surcharges)

Former provisions shall apply to administrative dispositions and imposition and collection of penalty surcharges against violations on labels or advertisements of health functional foods before this Act enters into force.

Article 5 (Transitional Measures concerning Penalty Provisions)

Former provisions shall apply to penalty provisions on acts done in connection with labels or advertisements of health functional foods before this Act enters into force.

ADDENDUM <Act No. 15706, Jun. 12, 2018>

This Act shall enter into force on the date of its promulgation: Provided, That the amended provisions of Articles 30 (3) and 37 (1) shall enter into force six months after the date of its promulgation.

ADDENDA <Act No. 15938, Jun. 11, 2018>**Article 1 (Enforcement Date)**

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

Article 2 (Applicability to Health Functional Foods Manufactured To Be Taken by Children)

The amended provisions of the latter part of Article 14 (1) shall begin to apply from the first health functional food manufactured after this Act enters into force.

ADDENDA <Act No. 16295, Jan. 15, 2019>

Article 1 (Enforcement Date)

This Act shall enter into force one month after the date of its promulgation: Provided, That the amended provisions of Articles 27 and 32 (1) 3-2 and 8-2 shall enter into force six months after the date of its promulgation.

Article 2 (Applicability to Permission for Health Functional Food Manufacturing Business and Permission for Change Thereof)

The amended provisions of Article 5 (4) and (5) shall begin to apply from cases of applying for permission for health functional food manufacturing business or permission for the change thereof or reporting the change of health functional food manufacturing business after this Act enters into force.

Article 3 (Applicability to Reporting Health Functional Food Sale Business)

The amended provisions of Article 6 (4) and (5), 7 (2) and (3), and 12 (5) and (6) shall begin to apply from cases of reporting health functional food sale business or reporting the change thereof, reporting the manufacture of items or reporting for the change thereof, or reporting the appointment or dismissal of quality control managers after this Act enters into force.

Article 4 (Transitional Measures concerning Composition of Members of the Committee)

(1) Where the amended provisions of the latter part of Article 27 (2) fail to be met at the time of appointing or commissioning a member after the amended provisions of Article 27 enter into force, a member who is not a public official shall be commissioned until the requirements in the relevant amended provisions are met.

(2) The composition of members of the Committee shall be governed by the former provisions until the amended provisions of the latter part of Article 27 (2) are met pursuant to paragraph (1).

Article 5 (Transitional Measures concerning Administrative Fines)

Notwithstanding the amended provisions of Article 47 (1) 9, the application of administrative fines against failure to perform an order to repair facilities prescribed in Article 31 (1) before this Act enters into force shall be governed by the former provisions.

ADDENDUM <Act No. 16715, Dec. 3, 2019>

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

ADDENDA <Act No. 17091, Mar. 24, 2020>

Article 1 (Enforcement Date)

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

Articles 2 through 5 Omitted.

Last updated : 2022-01-19

