FUNCTIONAL HEALTH FOODS ACT

[Enforcement Date 21. May, 2014.] [Act No.12669, 21. May, 2014., Partial Amendment]

Ministry of Food and Drug Safety (Department of Health Functional Food Policy), 043-719-2452

CHAPTER I GENERAL PROVISIONS

Article 1 (Purpose)

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 2 (Obligations)(1) The State and local governments shall formulate rational policies, and instruct or manage persons who manufacture, process, import, and sell functional health foods (hereinafter referred to as "business entities"), to ensure that all nationals are able to obtain high-quality functional health foods and accurate information thereon.

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 3 (Definitions)

The terms used in this Act shall be defined as follows:

1. The term "functional health foods" means foods manufactured (including processing; hereinafter the same shall apply) with functional raw materials or ingredients beneficial to for the human body;
2. The term "functionality" means controlling nutrients for the structure or functions of the human body or providing beneficial effects to health purposes, such as physiological effects;
3. The term "labels" means characters, figures, or diagrams marked on containers or packages (including supplements and contents; hereinafter the same shall apply) of functional health foods;
4. The term "advertisements" means showing information on functional health foods or making such information known to the public by radio, television, newspaper, magazine, voices, sounds, images, Internet, prints, signboards, or other means;
5. The term "business" means manufacturing or importing functional health 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 functional health foods" means recording and managing the information on functional health foods in stages from manufacturing and importing, to sale, in order to track the relevant functional health foods, identify the cause of a problem, and take necessary measures, if a problem arises with the safety, etc. of the relevant functional health foods.

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

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. Commercially manufacturing functional health foods;
2. Commercially importing functional health foods;
3. Commercially selling functional health foods.

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 5 (Permission to Run Business, etc.) (1) Anyone who intends to engage in commercially manufacturing functional health foods referred to in Article 4 (1) 1 shall have facilities prescribed under Article 4 for each place of business, as prescribed by Ordinance of the Prime Minister, and obtain permission from the Minister of Food and Drug Safety. This shall also apply to revisions to matters prescribed by Presidential Decree.

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

(3) Procedures for obtaining permission to run business, revised permission, and reporting on revised matters under paragraphs (1) and (2), and other necessary matters shall be prescribed by Ordinance of the Prime Minister.

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 6 (Reporting, etc. on Business)(1) Anyone who intends to engage commercially importing functional health foods referred to in Article 4 (1) 2 shall have facilities prescribed under Article 4 for each place of business, as prescribed by Ordinance of the Prime Minister, and report thereon to the Mayor of a Special Self-Governing City, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu (referring to the head of an autonomous Gu; hereinafter the same shall apply) having jurisdiction over the place of business.

(2) Anyone who intends to engage commercially selling functional health foods referred to in Article 4 (1) 3 shall have facilities prescribed under Article 4 for each place of business, as prescribed by Ordinance of the Prime Minister, and report thereon to the Mayor of a Special Self-Governing City, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu having jurisdiction over the place of business: Provided, That this shall not apply where a pharmacy, the establishment of which has been registered under Article 20 of the Pharmaceutical Affairs Act, sells functional health foods.

(3) When anyone who has filed a report under paragraph (1) or (2) intends to close the relevant business or revise matters prescribed by Ordinance of the Prime Minister, he/she shall report it to the Mayor of a Special Self-Governing City, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu.

(4) Procedures for reporting on the business and revised matters under paragraphs (1) through (3), and other necessary matters shall be prescribed by Ordinance of the Prime Minister.

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 7 (Reporting, etc. on Manufacturing Items)(1) When anyone who has obtained permission to manufacture functional health foods under Article 5 (1) intends to manufacture functional health foods, he/she shall report matters prescribed by Ordinance of the Prime Minister, including manuals for the methods of manufacturing the relevant items, to the Minister of Food and Drug Safety. This shall also apply to revisions to matters prescribed by Ordinance of the Prime Minister among the reported matters.

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 8 (Import Declarations, etc. of Functional Health Foods)(1) Any of the following persons shall file an import declaration to the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 12669, May 21, 2014>

1. Any person who intends to import functional health foods for his/her business;
2. Any person who commercially purchases functional health food at online shopping malls (signified a virtual place of business set to trade goods, etc. with computers, communications facilities, etc.), being a purchasing agent prescribed by Ordinance of the Prime Minister.

(2) The Minister of Food and Drug Safety shall require relevant public officials or inspection institutions to conduct a necessary inspection of functional health foods reported under paragraph (1), before completion of customs clearance procedures, when any of the grounds prescribed by Ordinance of the Prime Minister arises. <Amended by Act No. 12669, May 21, 2014>

(3) The Minister of Food and Drug Safety may fully or partially omit an inspection, notwithstanding paragraph (2), if functional health foods reported under paragraph (1) fall under any of the following: <Amended by Act No. 12669, May 21, 2014>

1. When it has been pre-verified and publicly notified (hereinafter referred to as "prior verification and registration of imported functional health foods") by the Minister of Food and Drug Safety that the functional health foods meet facility standards, criteria and standards prescribed in Articles 4, 14, 15, and 17, and such foods do not constitute any of the grounds for prohibiting advertisements and sale under Articles 18 and 23 through 25;
2. When the importers of the functional health foods have undergone an inspection conducted by a testing and inspection institution of foods, etc. (hereinafter referred to as "inspection institutions") designated by the Minister of Food and Drug Safety pursuant to Article 6 of the Act on Testing and Inspection in the Food and Drug Industry or a foreign testing and inspection institution designated by the Minister of Food and Drug Safety under Article 8 of the same Act, and submit inspection records or inspection certificates;
3. Circumstances equivalent to subparagraph 1 or 2 and falling under grounds prescribed by Ordinance of the Prime Minister.

(4) Procedures for filing import declarations under paragraph (1), the types, subject matter, and methods of inspections under paragraph (2), the standards for, and procedures for recognition of prior verification and registration of imported functional health foods under paragraph (3), and other necessary matters shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 12669, May 21, 2014>

Article 9 (Restrictions on Permission to Run Business, etc.) (1) No permission to run business shall be granted under Article 5 (1) in any of the following cases:

1. When the relevant person, for whom six months have not elapsed since permission to run business was revoked under the subparagraphs of Article 32 (1) (excluding subparagraph 10; hereafter the same shall apply in this Article), intends to run the same type of business in the relevant place of business: Provided, That this shall not apply where permission to run 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 to run business was revoked under the subparagraphs of Article 32 (1), intends to run the same type of business, the permission for which has been revoked;
3. When the relevant person (including the representative of a corporation) who intends to obtain permission to run business is an incompetent under adult guardianship or has been declared bankrupt by the court and has not been reinstated.

(2) No one shall file a report on his/her business under Article 6 (1) and (2) in any of the following cases:

1. When the relevant person, for whom six months have not elapsed since he/she was issued an order to close the place of business under the subparagraphs of Article 32 (1), intends to run the same kind of business in the relevant place of business: Provided, That this shall not apply where he/she has been issued an order to close the place of business due to removal of all business facilities;
2. When the relevant person (including the representative of a corporation), for whom one year has not elapsed since he/she was issued an order to close the place of business under the subparagraphs of Article 32 (1), intends to run the same type of business subject to closure of the business;
3. When the relevant person (including the representative of a corporation) who intends to report on his/her business is an incompetent under adult guardianship or has been declared bankrupt by the court and has not been reinstated.

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 10 (Matters to be Complied with by Business Entities)(1) Business entities shall comply with the following matters in order to ensure the safety of functional health 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 functional health 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 functional health foods, managing the quality thereof, and improving national health and hygiene.

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 11 (Succession to Business)(1) Any of the following persons shall succeed to the status of the former business entity:

1. The transferee, when a business entity has transferred his/her business to a third person;
2. The successor, when a business entity has died;
3. A corporation surviving a merger or a corporation established in the course of a merger where a corporate business entity has merged with a third corporation.

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

1. Auctions under the Civil Execution Act;
2. Transfer under the Debtor Rehabilitation and Bankruptcy Act;
3. Sale of seized property under the National Tax Collection Act, the Customs Act, or the Framework Act on Local Taxes;
4. Any other procedures equivalent to those prescribed under subparagraphs 1 through 3.

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

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 12 (Quality Control Managers)(1) Any person who intends to engage in business with permission for commercially manufacturing functional health foods under Article 5 (1), shall have a quality control manager (hereinafter referred to as "quality control manager"), as prescribed by Ordinance of the Prime Minister: Provided, That this shall not apply when a business entity has qualifications as quality control managers and performs quality control duties.

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

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

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

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 13 (Training)(1) The Minister of Food and Drug Safety may require business entities and employees to undergo training on ensuring the safety of functional health foods and quality control, if deemed necessary for preventing harm to national health.

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

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

(4) When any person obligated to undergo training pursuant to paragraphs (1) and (2) intends to engage in business in at least two places or is unable to undergo training due to any grounds prescribed by Ordinance of the Prime Minister, he/she may appoint a responsible person among his/her employees and require such person to undergo training.

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

CHAPTER III CRITERIA, STANDARDS, LABELS AND ADVERTISEMENTS

Article 14 (Criteria and Standards)(1) The Minister of Food and Drug Safety shall determine and publicly notify the criteria and standards for manufacture, use, and preservation of functional health foods for sale.

(2) The Minister of Food and Drug Safety may require the business entities referred to in Article 5 (1) or 6 (1) to submit data on the criteria, standards, safety, and functions of foods, the criteria and standards for which have not been publicly notified under paragraph (1), and recognize such data as the criteria and standards of functional health foods, after undergoing inspections conducted by inspection institutions.

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

(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.

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 15 (Recognition of Raw Materials, etc.)(1) The Minister of Food and Drug Safety shall determine and publicly notify raw materials or ingredients of functional health foods for sale.

(2) The Minister of Food and Drug Safety may recognize the raw materials or ingredients of functional health foods not publicly notified under paragraph (1), as materials or ingredients that may be used for functional health 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) or 6 (1).

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 16 (Deliberation on Labels or Advertisements regarding Functionality)(1) Anyone who intends to place labels or run advertisements regarding functionality of functional health foods shall undergo deliberation, in accordance with the standards, methods, and procedures for deliberation on the labels or advertisements of functional health foods determined by the Prime Minister.

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

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

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

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

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 16-2 (Filing Objections to Deliberation on Advertisements)(1) Any person who has an objection to the outcomes of deliberation under Article 16 (1) may file an objection with the Minister of Food and Drug Safety within one month after receipt of notice of the outcomes of such deliberation.

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

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 17 (Labeling Standards)(1) The following matters shall be indicated on the containers or packages of functional health foods:

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

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 18 (Prohibiting False, Exaggerative, or Negative Labels or Advertisements)(1) No one shall place or run false, exaggerative, or negative labels or advertisements as follows, with respect to the names, raw materials, manufacturing methods, nutrients, ingredients, methods of use, or quality of functional health foods, and the tracking management of records on functional health foods:

1. Labels or advertisements likely to mislead consumer into believing that the relevant foods are effective in preventing or treating a disease or confuse consumers about the relevant foods with medicines;
2. False or exaggerated labels or advertisements;
3. Labels or advertisements likely to deceive, mislead, or confuse consumers;
4. Labels or advertisements that include names (including the prescriptions of Oriental medicines) only used for medicines;
5. Negative labels or advertisements against other companies or their products;
6. Labels or advertisements that haven’t deliberated upon under Article 16 (1) or bearing different details from details deliberated upon.

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 19 (Codes of Functional Health Foods)

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

CHAPTER IV INSPECTIONS, ETC.

Article 20 (Entry, Inspections, Collections, etc.)(1) If deemed necessary for managing the hygiene of the functional health foods and maintaining business order, the Minister of Food and Drug Safety (including the heads of affiliated organizations prescribed by Presidential Decree), the Mayor of a Special Self-Governing City, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu may require business entities or relevant persons to file necessary reports, or require relevant public officials to enter the places of business, offices, warehouses, factories, storage facilities, stores, or similar places and to take any of the following measures:

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

2. Collecting the minimum amounts of raw materials, products, containers, and packages necessary for inspections conducted under subparagraph 1 free of charge;
3. Inspecting business-related books of account or documents.

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 21 (Obligations of Self-Inspection for Quality Control)(1) Any person who has obtained permission to commercially manufacture functional health foods pursuant to Article 5 (1) shall conduct an inspection to verify whether the relevant functional health foods that he/she manufactures meet the criteria and standards prescribed under Article 14 and shall keep the records thereof, as prescribed by Ordinance of the Prime Minister.

(2) The Minister of Food and Drug Safety may outsource inspections to inspection institutions, when any person obligated to conduct inspections under paragraph (1) is incapable of conducting self-inspections.

(3) Items of, and procedures for inspections under paragraphs (1) and (2), and other necessary matters shall be prescribed by Ordinance of the Prime Minister.

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

CHAPTER V REGULATIONS FOR GOOD MANUFACTURING PRACTICE, ETC.

Article 22 (Regulations for Good Manufacturing Practice, etc.)(1) The Minister of Food and Drug Safety may determine and publicly notify the standards for manufacturing good functional health foods and managing the quality thereof (hereinafter referred to as "Regulations for Good Manufacturing Practice") in order to manufacture good functional health foods and manage the quality thereof.

(2) When any person who has obtained permission to commercially manufacture functional health foods pursuant to Article 5 (1) complies with the Regulations for Good Manufacturing Practice, the Minister of Food and Drug Safety may designate his/her business place as the place of business adopting the Regulations for Good Manufacturing Practice and publicly notify such designation.

(3) Procedures for designating places of business adopting the Regulations for Good Manufacturing Practice, education and training for business entities or employees, and other necessary matters shall be prescribed by Ordinance of the Prime Minister.

(4) When any of the following applies to a place of business adopting the Regulations for Good Manufacturing Practice, the Minister of Food and Drug Safety may revoke the designation thereof or issue a corrective order thereto:

1. When it fails to comply with any of the Regulations for Good Manufacturing Practice;
2. When it is subjected to business suspension or a severer administrative sanction under Article 32;
3. When a business entity or any of its employees fails to undergo training and education under paragraph (3);
4. When it fails to comply with any of the matters deemed necessary for efficiently managing the places of business adopting the Regulations for Good Manufacturing Practice and prescribed by Ordinance of the Prime Minister.

(5) No one whose place of business has not been designated as a place of business adopting the Regulations for Good Manufacturing Practice shall use a name that includes the words “a place of business adopting the Regulations for Good Manufacturing Practice” or indicate or advertise similar details.

(6) The Minister of Food and Drug Safety may provide loans for improvement of business facilities or require relevant public officials to omit the entry and inspections under Article 20 for a specific period prescribed by Ordinance of the Prime Minister, for places of business adopting the Regulations for Good Manufacturing Practice.

(7) Expenses incurred in providing training and education under paragraph (3) may be collected from persons required to undergo such training and education.

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 22-2 (Registration Standards, etc. for Tracking Management of Records on Functional Health Foods)(1) Any person who intends to perform tracking management of records on functional health foods, among those who manufacture, import, or sell functional health foods, may register the relevant functional health 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.

(2) Any person who manufactures, imports, or sells functional health foods registered under paragraph (1) shall comply with standards (hereinafter referred to as "standards for tracking management of records on functional health 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 functional health foods.

(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) Functional health foods registered under paragraph (1) may bear the indication of tracking management of records on functional health 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 person who manufactures, imports, or sells functional health foods registered under paragraph (1) to verify whether they comply with the standards for tracking management of records on functional health foods: Provided, That the Minister of Food and Drug Safety shall conduct such inspection and evaluation for any person who manufactures, imports, or sells functional health foods registered under the proviso to paragraph (1), every two years.

(6) The Minister of Food and Drug Safety may provide funds necessary for tracking management of records on functional health 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 functional health foods, the Minister of Food and Drug Safety may revoke such registration or issue a corrective order to him/her.

(8) Procedures for registration for tracking management of records on functional health 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.

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

CHAPTER VI PROHIBITION AGAINST SALE, ETC.

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

No one shall sell, or manufacture, import, use, store, transport or display any of the following functional health foods for sale:

1. Rotten or spoiled foods likely to harm human health;
2. Foods that contain or are suspected of containing toxic or harmful materials, or foods stained with or likely to be stained with such materials: Provided, That this shall not apply where the Minister of Food and Drug Safety recognizes that the relevant foods are not likely to harm human health;
3. Foods contaminated with or likely to be contaminated with pathogenic microorganism feared to harm human health;

4. Foods likely to harm human health, due to uncleanness, mixing with, or addition of, other materials, and on other grounds;
5. Foods manufactured by any person who has failed to obtain permission required under Article 5 (1);
6. Foods, the import of which is banned, or foods imported without import declarations required under Article 8.

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 24 (Prohibition against Sale, etc. of Functional Health Foods which Violate Criteria and Standards)(1) Business entities shall manufacture, use, or keep functional health foods, the criteria and standards for which are determined under Article 14 (1) and (2), in accordance with such criteria and standards, and shall not sell any functional health foods which violate such criteria and standards, or manufacture, import, use, store, transport, keep, or display such functional health foods for sale.

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

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

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

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

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 26 (Prohibition against Similar Labels, etc.)

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

CHAPTER VII FUNCTIONAL HEALTH FOODS DELIBERATION COMMITTEE AND ESTABLISHMENT OF ORGANIZATIONS

Article 27 (Functional Health Foods Deliberation Committee)(1) The Functional Health Foods Deliberation Committee shall be established under the Ministry of Food and Drug Safety to examine and deliberate on the following matters to advise the Minister of Food and Drug Safety thereon:

1. Matters concerning policies on functional health foods;
2. Matters concerning the criteria and standards for functional health foods;
3. Matters concerning the labels and advertisements of functional health foods;
4. Other important matters concerning functional health foods.

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

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

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 functional health foods, improve the quality thereof, and contribute to improving national health by promoting the sound development of the relevant business.

(2) Organizations shall be corporate bodies.

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

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

Article 29 (Corrective Orders)

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 30 (Disposition of Discard, etc.)(1) When a business entity violates any of the Articles 23 through 26, the Minister of Food and Drug Safety, the Mayor of a Special Self-Governing City, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu may order relevant public officials to seize or discard the relevant functional health food, or order the business entity to take measures to remove harm to food hygiene.

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

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

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

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 31 (Orders, etc. to Repair Facilities)(1) The Minister of Food and Drug Safety, the Mayor of a Special Self-Governing City, the Governor of a Special Self-Governing Province, 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).

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 32 (Revocation, etc. of Permission to Run Business)(1) The Minister of Food and Drug Safety, the Mayor of a Special Self-Governing City, the Governor of a Special Self-Governing Province, or the head of a

Si/Gun/Gu may revoke permission to run business, fully or partially suspend the relevant business for a specified period not exceeding six months or issue an order to close the place of business (limited to business reported under Article 6; hereafter the same shall apply in this Article), as prescribed by Presidential Decree, if a business entity falls under any of the following cases:

1. When it violates the latter part of Article 5 (1), the former part of Article 7 (1), Article 8 (1), the subparagraphs of Article 10 (1) (excluding subparagraphs 1 and 5) or Article 11 (3);
2. When it violates Article 12 (1);
3. When it violates Article 18 (1);
4. When it violates to conduct a self-inspection for quality control under Article 21;
5. When it violates Article 22 (5);
6. When it violates the proviso to Article 22-2 (1);
7. When it violates the prohibition against sale or similar labels, etc. under Article 23, 24 (1) and (2), 25, or 26;
8. When it violates an order issued under Article 29, 30 (1) and (3), 31 (1) or 33 (1);
9. When it continues to conduct his/her business, in violation of an order of business suspension.

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 33 (Suspension, etc. of Manufacturing Items)(1) The Minister of Food and Drug Safety may issue an order to suspend manufacturing the relevant item or the relevant type of item (referring to all items manufactured in accordance with the same criteria and standards, among criteria and standards for functional health foods determined under Article 14) for a specified period not exceeding six months, as prescribed by Presidential Decree, when a business entity violates Article 18 (1), 21 (1), 23, 24 (1) and (2), 25 or 26.

(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.

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 34 (Succession to Effects of Administrative Sanctions)

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 35 (Measures for Closure, etc.)(1) The Minister of Food and Drug Safety, the Mayor of a Special Self-Governing City, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu may require relevant public officials to take the following measures to close the relevant place of business, when a business entity runs his/her business without obtaining permission or filing a report, in violation of the former part of Article 5 (1) or Article 6 (1) and (2), or continues to run his/her business after permission to run business is revoked, or an order to close the place of business is issued under the subparagraphs of Article 32 (1):

1. Removing or eliminating signboards of the relevant place of business or other business marks;
2. Posting notices indicating that the relevant place of business is illegal;
3. Sealing facilities of the relevant place of business or other equipment, etc. used for running business to be unusable.

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

1. When posting notices etc. or seals are deemed no longer necessary;
2. The relevant business entity or his/her agent promises to close the relevant place of business or requests removal of seals by citing other just grounds.

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

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

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 36 (Hearings)

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 37 (Imposition of Penalty Surcharges in Lieu of Suspension of Business)(1) The Minister of Food and Drug Safety, the Mayor of a Special Self-Governing City, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu may impose a penalty surcharge not exceeding 200 million won, in lieu of suspension of business or suspension of manufacturing of the relevant item or relevant type of item, as prescribed by Presidential Decree, when a business entity falls under any of the subparagraphs (excluding subparagraphs 8 and 9) of Article 32 (1) or Article 33 (1): Provided, That this shall not apply to cases determined by Ordinance of the Prime Minister, among cases falling under Article 32 (1) or 33 (1) for a violation of the latter part of Article 5 (1), 10 (1), 18 (1), 23, 24 (1) and (2), 25, or 26.

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

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

(4) Penalty surcharges imposed and collected by the Minister of Food and Drug Safety, among penalty surcharges collected under paragraph (1), shall devolve on the State, and penalty surcharges imposed and collected by the Mayor of a Special Self-Governing City, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu (referred to an autonomous Gu) shall devolve on the Food Promotion Fund (referring to the Food Promotion Fund established under Article 71 of the Food Sanitation Act) of a Special City, Metropolitan City, Self-Governing City, Do, Special Self-Governing Province, or Si/Gun/Gu.

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 37-2 (Imposition, etc. of Penalty Surcharges for Sale, etc. of Harmful Functional Health Foods, etc.)(1) The Minister of Food and Drug Safety, the Mayor of a Special Self-Governing City, the Governor of a

Special Self-Governing Province, or the head of a Si/Gun/Gu shall impose a penalty surcharge on any of the following persons in an amount equivalent to the retail price of the functional health foods:

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

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

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

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

[This Article Newly Inserted by Act No. 12669, May 21, 2014]

CHAPTER IX SUPPLEMENTARY PROVISIONS

Article 38 (Relationships with other Acts)(1) Unless otherwise expressly provided for in this Act, the following provisions shall apply:

1. Food additives used for functional health foods: Standards and specification for food additives provided for in Article 7 of the Food Sanitation Act;
2. Re-inspection of functional health foods: Provisions on re-inspections of foods, etc. under Article 23 of the Food Sanitation Act;
3. Designation of functional health 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;
4. Functional health food hygiene inspectors: Provisions on food sanitation supervisors under Article 32 of the Food Sanitation Act;
5. Consumer functional health 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 functional health foods: Provisions on recall of harmful foods, etc. under Article 45 of the Food Sanitation 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, and 100 through 102 of the same Act.

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 39 (State Subsidies)

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

1. Expenses incurred in collecting functional health foods, etc. under Article 20 (1) 2;
2. Provide funding for the business facilities of places of business adopting the Regulations for Good Manufacturing Practice under Article 22 (6);
3. Expenses incurred in improving the quality of functional health foods, preventing false, exaggerative, or negative labels or advertisements, or promoting research and development, etc.;
4. Expenses incurred in relation to activities done by private organizations to improve the safety of functional health foods.

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 40 (Payment of Monetary Rewards)(1) The Minister of Food and Drug Safety, the Mayor of a Special Self-Governing City, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu may pay a monetary reward not exceeding ten million won to any person who accuses or reports any person who violates any of Article 5 (1), 6 (1) and (2), 23 or 26 to the relevant administrative agencies or investigation agencies.

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 41 (Delegation or Entrustment of Authority)(1) The Minister of Food and Drug Safety may partially delegate his/her authority under this Act to the head of a Regional Ministry of Food and Drug Safety, a Special Metropolitan City Mayor, a Metropolitan City Mayor, the Mayor of a Special Self-Governing City, a Do Governor, the Governor of a Special Self-Governing Province, or the head of a Si/Gun/Gu, as prescribed by Presidential Decree. <Amended by Act No. 12669, May 21, 2014>

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

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

Article 42 (Fees, etc.)

Anyone who intends to obtain permission, file a report or an application, or undergo an inspection as follows shall pay fees, as prescribed by Ordinance of the Prime Minister:

1. Permission to run business or revised permission under Article 5 (1) or reporting on revisions under Article 5 (2);
2. Reporting on business or reporting on revisions under Article 6 (1) through (3);
3. Reporting on manufacturing items or reporting on revisions under Article 7;
4. Import declarations of functional health foods and applications for prior verification and registration of imported functional health foods or inspections under Article 8 (1) through (3);
5. Inspections for recognizing the criteria, standards, materials, etc. of functional health foods under Article 14 (2) or 15 (2);
6. Applications for deliberation on labels or advertisements regarding functionality under Article 16 (1);
7. Self-inspections for quality control outsourced under Article 21 (2);
8. Applications for designation as places of business adopting the Regulations for Good Manufacturing Practice under Article 22 (2);
9. Registration for tracking management of records on functional health foods under Article 22-2 (1).

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

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 ten years, or by a fine not exceeding 100 million won. In such cases, imprisonment with labor and fines may be imposed concurrently:

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

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

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

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:

1. Any person who run his/her business without filing a report thereon under Article 6 (1) or (2);
2. Any person who manufactures or sells products without reporting on manufacturing items under the former part of Article 7 (1);
3. Any person who sells products, in violation of Article 10 (1) 4;
4. Any person who makes a false, exaggerative, or negative label or advertisement in violation of Article 18 (1) 2 through 6;
5. Any person who fails to conduct a self-inspection for quality control under Article 21 (1);
6. Any person who has placed a label or run an advertisement in violation of Article 22 (5);
7. Any person who engages in sales, etc. in violation of Articles 24 through 26;
8. Any person who fails to comply with an order issued under Article 29, 30 (1), or (3);
9. Any person who violates an order to suspend his/her business issued under Article 32 (1).

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 45 (Penalty Provisions)

Any of the following business entities or persons shall be punished by imprisonment with labor for not more than three years, or a fine not exceeding 30 million won:

1. Any business entity that violates any of the standards for facilities under Article 4;
2. Any business entity that fails to comply with any of the matters to be observed under Article 10 (1) 2 and 3;
3. Any person who fails to report on succession to business under Article 11 (3);
4. Any person who fails to employ a quality control manager under Article 12 (1);
5. Any person who refuses, interferes with, or evades entry, an inspection, or collection under Article 20 (1);
6. Any person who fails to register tracking management of records on functional health foods under the proviso to Article 22-2 (1);
7. Any person who refuses, interferes with, or evades seizure or discard under Article 30 (2);
8. Any person who violates an order to suspend manufacturing items under Article 33 (1);
9. Any person who removes or damages a seal or notice placed by a relevant public official under Article 35 without permission.

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

Article 46 (Joint Penalty Provisions)

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

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

Article 47 (Administrative Fines)(1) Any of the following persons shall be punished by administrative fines not exceeding three million won:

1. Any person who fails to report on a revision to any terms and conditions of permission under Article 5 (2);
2. Any person who fails to report on a revision to matters reported under Article 6 (3);
3. Any person who fails to report on a revision to matters on reporting of manufacturing items under the latter part of Article 7 (1);
4. Any person who fails to comply with any of the matters to be observed by business entities under Article 10 (1) 1 and 5, or who violates Article 10 (2);
5. Any person who interferes with the performance of duties of a quality control manager under Article 12 (3) or who fails to report on the appointment or dismissal of a quality control manager under Article 12 (4);
6. Any person who fails to undergo training under Article 13 (1) through (3);
7. Any person who fails to keep records after conducting a self-inspection for quality control under Article 21 (1), or who keeps a false record;
8. Any person who fails to file a report within one month under Article 22 (3);
9. Any person who fails to comply with an order to repair facilities under Article 31 (1).

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

[This Article Wholly Amended by Act No. 12669, May 21, 2014]

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

In applying provisions concerning administrative fines under Article 47, no administrative fines shall be imposed against an act for which penalty surcharges have been imposed under Article 37.

[This Article Wholly Amended by Act No. 12669, May 21, 2014]