ACT ON TESTING AND INSPECTION IN THE FOOD AND DRUG INDUSTRY

[Enforcement Date 31. Jul, 2014.] [Act No.11985, 30. Jul, 2013., New Enactment]

식품의약품안전처 (검사제도과)043-719-1812

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CHAPTER I GENERAL PROVISIONS

Article 1 (Purpose)

The purpose of this Act is to ensure the reliability of tests and inspections by prescribing matters concerning testing and inspection on food and drugs, the management of testing and inspection agencies, etc., and to contribute to the improvement of public health by contributing to facilitating the development of testing and inspection technology and to fostering and developing related industries.

Article 2 (Definitions)

The definitions of terms used in this Act shall be as follows:

1. The term "fields of food and drugs" means fields related to any of the following:

(a) Food (including functional health foods under the Functional Health Foods Act), food additives, appliances, containers, or packaging under the Food Sanitation Act;

(b) Livestock products under the Livestock Products Sanitary Control Act;

(c) Pharmaceutical drugs, non-pharmaceutical items, traditional Korean medicine, and medicinal preparations under the Pharmaceutical Affairs Act;

(d) Medical devices under the Medical Devices Act;

(e) Cosmetics and raw materials used in cosmetics under the Cosmetics Act;

2. The term "testing" means analyzing or measuring an object through physical, chemical, electrical, mechanical, hygienical, preparatory, biological, or microbiological methods;

3. The term "inspection" means inspection as to whether an object meets standards for ingredients, specifications, and other inspection standards;

4. The term "laboratory information management system" means an information system that collects data produced in a laboratory, stores such data electronically, and performs data receipt, transmission, analysis, and management.

Article 3 (Relationship to other Acts)

Except as otherwise expressly provided for by other Acts, this Act shall apply to testing and inspection on food and drugs.

Article 4 (Master Plans for Development of Testing and Inspection) (1) The Minister of Food and Drug Safety shall formulate and implement a master plan for the development of testing and inspection on food and drugs (hereinafter referred to as "master plan") five-yearly for the improvement of the reliability of tests and inspections and the development of related industries, following deliberations by the Deliberative Committee on the Development of Testing and Inspection established under Article 5.

(2) A master plan shall include the following:

1. Objectives and direction-setting for the pursuit of a policy related to testing and inspection;
2. A mid-term and long-term plan to support testing and inspection;
3. Matters concerning the research and development of technology and human resources related to testing and inspection;
4. Matters concerning the improvement of the precision and accuracy of testing and inspection;
5. Matters concerning international cooperation related to testing and inspection;
6. Other matters necessary for the development of testing and inspection.

(3) Where the Minister of Food and Drug Safety intends to formulate or amend a master plan, he/she shall consult with the heads of related central administrative agencies.

Article 5 (Deliberative Committee on Development of Testing and Inspection) (1) The Deliberative Committee on the Development of Testing and Inspection on Food and Drugs (hereinafter referred to as the "Committee") shall be established under the jurisdiction of the Minister of Food and Drug Safety in order to deliberate on the following:

1. Matters concerning a master plan;
2. Matters concerning a testing and inspection management system and policies related to testing and inspection;
3. Other matters concerning testing and inspection, which are referred to discussion by the Minister of Food and Drug Safety.

(2) The Vice Minister of Food and Drug Safety shall serve as the Chairperson of the Committee, and the Committee shall be comprised of not more than ten members, including the Chairperson.

(3) Working committees in each field may be established in the Committee in order to efficiently conduct its affairs.

(4) Other matters necessary for the composition, operation, etc. of the Committee and working committees shall be prescribed by Presidential Decree.

CHAPTER II DESIGNATION, ETC. OF TESTING AND INSPECTION AGENCIES

Article 6 (Designation of Testing and Inspection Agencies) (1) The Minister of Food and Drug Safety

may designate agencies to conduct tests and inspections professionally and efficiently (hereinafter referred to as "testing and inspection agency").

(2) Types of testing and inspection agencies that may be designated pursuant to paragraph (1) shall be:

1. Food, etc. testing and inspection agency: An agency that conducts inspections of standards, specifications, etc. under Article 7, 9, 19 (2), 19-4, 22 (1), or 31 (2) of the Food Sanitation Act, or Article 14 of the Functional Health Foods Act;
2. Livestock product testing and inspection agency: An agency that conducts reviews or inspections under Article 4 (3), 12, 15 (2), or 19 (1) and (2) of the Livestock Products Sanitary Control Act;
3. Pharmaceutical drugs, etc. testing and inspection agency: An agency that conducts quality inspections of pharmaceutical drugs, etc. in accordance with orders to conduct inspections under Article 73 of the Pharmaceutical Affairs Act;
4. Medical device testing and inspection agency: An agency that conducts tests and inspections of medical devices under Article 27 of the Medical Devices Act;
5. Cosmetic testing and inspection agency: An agency that conducts inspections of cosmetics in accordance with orders to conduct inspections under Article 20 of the Cosmetics Act.

(3) Food, etc. testing and inspection agencies specified in paragraph (2) 1 may be designated as follows within the scope of each inspection:

1. Testing and inspection agency specializing in food: An agency that conducts tests and inspections under Article 7, 9, 19 (2), 19-4, or 22 (1) of the Food Sanitation Act, or Article 14 of the Functional Health Foods Act;
2. Agency entrusted with self quality testing and inspection: An agency that conducts tests and inspections under Article 7, 9, or 31 (2) of the Food Sanitation Act, or Article 14 of the Functional Health Foods Act.

(4) Any person who intends to be designated as a testing and inspection agency falling under any subparagraph of paragraph (2) shall meet requirements for facilities, equipment, human resources, etc. necessary for testing and inspection prescribed by Ordinance of the Prime Minister, and file an application for designation with the Minister of Food and Drug Safety: Provided, That in cases of a testing and inspection agency prescribed by Ordinance of the Prime Minister, it shall be deemed designated pursuant to paragraph (1).

(5) Where a testing and inspection agency designated pursuant to paragraph (1) intends to alter any important matter prescribed by Ordinance of the Prime Minister, including any alteration to the scope of testing and inspection, among the designated matters, it shall obtain approval from the Minister of Food and Drug Safety in advance: Provided, That where it alters any insignificant matter prescribed by Ordinance of the Prime Minister, it shall report thereon to the Minister of Food and Drug Safety within one month from the date such alterations are made.

(6) Designation, requirements, and procedures for alteration, the scope of affairs under the provisions of paragraphs (1) through (5), and other necessary matters, shall be prescribed by Ordinance of the Prime Minister.

(7) Paragraphs (5) and (6), Articles 7, 9, 10, 17, and 27 shall not apply to testing and inspection agencies prescribed by Ordinance of the Prime Minister pursuant to the proviso to paragraph (4).

Article 7 (Period of Validity of Designation of Testing and Inspection Agencies) (1) The period of validity concerning the designation of a testing and inspection agency designated pursuant to Article 6 (1) shall be three years from the date it is designated.

(2) The period of validity under paragraph (1) may be extended by up to not exceeding one year limited to only once, as prescribed by Ordinance of the Prime Minister.

(3) Where a testing and inspection agency whose period of validity expires pursuant to paragraphs (1) and (2), meets requirements for designation under Article 6 (4), its designation may be renewed pursuant to Article 6.

Article 8 (Designation, etc. of Overseas Testing and Inspection Agencies) (1) The Minister of Food and Drug Safety may designate any of the following agencies as an agency that has ability to conduct tests and inspections of imported food, etc. (hereinafter referred to as "overseas testing and inspection agency"):

1. A public inspection agency established by the government of an exporting country (including a local government of such government);
2. An inspection agency authorized by the government of an exporting country (including a branch of such inspection agency);
3. An agency established and operated in a foreign country by a testing and inspection agency specializing in food designated by the Minister of Food and Drug Safety.

(2) Any person who intends to be designated as an overseas testing and inspection agency shall meet requirements for inspection records, inspection equipment, inspection personnel, etc. prescribed by Ordinance of the Prime Minister, and file an application for designation with the Minister of Food and Drug Safety.

(3) Necessary matters concerning requirements and procedures for designation under paragraph (1) shall be prescribed by Ordinance of the Prime Minister.

(4) Article 6 (5) shall apply mutatis mutandis where an overseas testing and inspection agency intends to alter any matter prescribed by Ordinance of the Prime Minister, among those designated pursuant to paragraph (1).

Article 9 (Succession to Status of Testing and Inspection Agency) (1) Where a person designated as a testing and inspection agency transfers the operation of such agency or corporations are merged, the transferee thereof, or the corporation surviving the merger or the corporation incorporated through the merger shall succeed to the status under this Act based on the designation of the former testing and inspection agency.

(2) Any person who meets requirements for designation under Article 6 (4), who has fully or partially acquired facilities and equipment of a testing and inspection agency in accordance with any of the following procedures, shall succeed to the status under this Act based on the designation of such testing and inspection agency:

1. Auction under the Civil Execution Act;
2. Realization under the Debtor Rehabilitation and Bankruptcy Act;
3. Sale of seized property under the National Tax Collection Act, the Customs Act, or the Local Tax Act;
4. Other procedures corresponding to the provisions of subparagraphs 1 through 3.

(3) Any person who has succeeded to the status of the former testing and inspection agency pursuant to paragraphs (1) and (2) shall report to the Minister of Food and Drug Safety within one month, as prescribed by Ordinance of the Prime Minister.

Article 10 (Revocation, etc. of Designation of Testing and Inspection Agency) (1) Where any person designated as a testing and inspection agency falls under any of the following, the Minister of Food and Drug Safety may revoke his/her designation, or order him/her to fully or partially suspend his/her business for a fixed period not exceeding six months, or take necessary measures, such as issuing a corrective order: Provided, That where he/she falls under any of subparagraphs 1 through 3, the Minister of Food and Drug Safety shall revoke his/her designation:

1. Where he/she has obtained designation fraudulently or deceptively;
2. Where he/she has issued a false test report or inspection report (hereinafter referred to as "test or inspection report") intentionally or by gross negligence;
3. Where he/she has conducted any test or inspection during the period of suspension of business;
4. Where he/she has issued a test or inspection report beyond the scope of testing or inspection designated pursuant to Article 6;
5. Where he/she fails to meet requirements for designation under Article 6 (4);
6. Where he/she has made any alterations without having obtained approval for alterations from the Minister of Food and Drug Safety or fails to report any alteration made, within one month, in violation

of Article 6 (5);

7. Where he/she fails to conduct tests or inspections in accordance with standards, methods, and procedures prescribed by Ordinance of the Prime Minister, in violation of Article 11 (1);
8. Where he/she fails to issue a test or inspection report or has issued a test or inspection report with omissions to be mentioned prescribed by Ordinance of the Prime Minister, in violation of Article 11 (2);
9. Where he/she has made a false report or has neglected to make a report, in violation of Article 11 (3);
10. Where he/she fails to report the yearly results of tests or inspections to the Minister of Food and Drug Safety, in violation of Article 12 (1);
11. Where he/she fails to prepare or store documents, in violation of Article 12 (2);
12. Where he/she has violated matters to be observed under Article 12 (3);
13. Where he/she fails to implement corrective measures based on the result of evaluation of his/her ability to conduct tests or inspections pursuant to Article 16;
14. Where he/she has interfered with relevant public officials' access or reading under Article 22.

(2) Where any person designated as an overseas testing and inspection agency falls under any of the following, the Minister of Food and Drug Safety may revoke his/her designation, or order him/her to fully or partially suspend his/her business for a fixed period not exceeding six months, or take necessary measures, such as issuing a corrective order: Provided, That where he/she falls under any of subparagraphs 1 through 3, the Minister of Food and Drug Safety shall revoke his/her designation::

1. Where he/she has obtained designation fraudulently or deceptively;
2. Where he/she has issued a false test or inspection report;
3. Where he/she has conducted any test or inspection during the period of suspension of business;
4. Where he/she fails to obtain approval for any alterations pursuant to Article 8 (4);
5. Where he/she fails to implement corrective measures based on the result of evaluation of his/her ability to conduct tests or inspections pursuant to Article 16;
6. Where he/she fails to implement other matters to be observed, imposed by the Minister of Food and Drug Safety.

(3) Where any person whose designation as a testing and inspection agency has been revoked pursuant to paragraph (1) falls under any of the following, he/she shall not be designated as a testing and inspection agency under Article 6:

1. Where a person, who established and operated a testing and inspection agency the designation of which was revoked (in cases of a corporation, referring to its representative), in whose case two years have not passed from the date his/her designation was revoked;
2. Where a person intends to establish and operate a testing and inspection agency in the same place within two years from the date his/her designation was revoked.

(4) Detailed criteria for administrative dispositions under paragraphs (1) and (2) shall be prescribed by Ordinance of the Prime Minister, in consideration of types of offense, the degree of violation, etc.

Article 11 (Procedures, etc. for Testing and Inspection) (1) Where a testing and inspection agency receives a request for testing or inspection, it shall conduct a test or inspection in accordance with standards, methods, and procedures prescribed by Ordinance of the Prime Minister.

(2) Where a testing and inspection agency has conducted a test or inspection pursuant to paragraph (1), it shall immediately issue a test or inspection report mentioning matters prescribed by Ordinance of the Prime Minister to a person who requested such agency to conduct the test or inspection.

(3) Where the result of a test or inspection under paragraph (1) is determined inappropriate, a testing and inspection agency shall immediately report the result thereof to the Minister of Food and Drug Safety and agencies prescribed by Ordinance of the Prime Minister. In such cases, it shall immediately notify the requester of such fact.

Article 12 (Matters to be Observed by Testing and Inspection Agencies) (1) Each testing and inspection agency shall report the yearly results of tests and inspections to the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister.

(2) Each testing and inspection agency shall prepare and store documents related to tests and inspections (including documents using a laboratory information management system) prescribed by Ordinance of the Prime Minister for a period prescribed by Ordinance of the Prime Minister.

(3) Each testing and inspection agency shall observe matters prescribed by Ordinance of the Prime Minister, including quality control.

Article 13 (Designation of Exemplary Testing and Inspection Agencies) (1) Any of the following testing and inspection agencies that meet requirements for inspection personnel, inspection equipment, quality assurance system, etc. may be designated as an exemplary testing and inspection agency (hereinafter referred to as "exemplary testing and inspection agency"):

1. A testing and inspection agency designated pursuant to Article 6;
2. A testing and inspection agency or facility for manufacturers, processors, and importers of food and drugs;
3. A government-funded agency or research institute that conducts tests and inspections on food and drugs.

(2) Any person who intends to be designated as an exemplary testing and inspection agency pursuant to paragraph (1) shall file an application for designation with the Minister of Food and Drug Safety, as

prescribed by Ordinance of the Prime Minister. The foregoing shall also apply where he/she intends to alter any important matter prescribed by Ordinance of the Prime Minister among designated matters.

(3) Notwithstanding paragraph (1), the Minister of Food and Drug Safety shall not designate any of the following persons as an exemplary testing and inspection agency:

1. A person in whose case six months have not passed from the date he/she was determined impossible to be designated as an exemplary testing and inspection agency;
2. A person in whose case one year has not passed from the date his/her designation as an exemplary testing and inspection agency was revoked pursuant to paragraph (4).

(4) Where any exemplary testing and inspection agency falls under any of the following, the Minister of Food and Drug Safety shall revoke its designation, or order it to take corrective measures: Provided, That where it falls under subparagraph 1 or 2, the Minister of Food and Drug Safety shall revoke its designation:

1. Where it has filed an application for designation fraudulently or deceptively;
2. Where a person whose result of evaluation under paragraph (5) was determined insufficient, fails to appropriately implement corrective measures;
3. Where it fails to meet requirements for designation under paragraph (6).

(5) The Minister of Food and Drug Safety may conduct evaluations of exemplary testing and inspection agencies designated pursuant to paragraph (1).

(6) Necessary matters concerning requirements, methods, and procedures for designation of exemplary testing and inspection agencies under paragraphs (1) and (2), and a cycle and methods of evaluation under paragraph (5) shall be prescribed by Ordinance of the Prime Minister.

Article 14 (Use of Laboratory Information Management System) (1) The Minister of Food and Drug Safety may establish and operate a laboratory information management system to efficiently manage information about the results of tests, inspections, etc.

(2) Any testing and inspection agency may use a laboratory information management system: Provided, That in cases of an exemplary testing and inspection agency, it shall use a laboratory information management system without fail.

(3) The Minister of Food and Drug Safety shall endeavor to disseminate a laboratory information management system.

(4) Matters necessary for the establishment, operation, etc. of a laboratory information management system shall be prescribed by Presidential Decree.

CHAPTER III MANAGEMENT OF ABILITY OF TESTING AND INSPECTION AGENCIES

Article 15 (Establishment of Testing and Inspection Management System) (1) The Minister of Food and Drug Safety may promote the following activities to establish, maintain, and develop a testing and inspection management system:

1. Activities to improve the precision and accuracy of testing and inspection technology;
2. Activities concerning the maintenance of retroactivity defined in subparagraph 17 of Article 3 of the Framework Act on National Standards on testing and inspection devices;
3. Activities to improve the reliability of agencies that conduct tests and inspections;
4. Activities for advancement of a testing and inspection management system;
5. Activities concerning the manufacture and management of prototypes and samples used in testing and inspection.

(2) The Minister of Food and Drug Safety may provide technical, administrative, and financial support to agencies, organizations, or business operators prescribed by Presidential Decree, including testing and inspection agencies designated pursuant to Article 6 or national or public research institutions, to conduct activities specified under paragraph (1).

Article 16 (Evaluation and Management of Ability of Testing and Inspection) (1) The Minister of Food and Drug Safety may measure and evaluate the ability of testing and inspection, as prescribed by Ordinance of the Prime Minister, in order to improve the ability of testing and inspection and ensure the reliability of testing and inspection agencies designated pursuant to Article 6 and overseas testing and inspection agencies designated pursuant to Article 8: Provided, That any exemplary testing and inspection agency may be exempted from evaluation.

(2) Necessary matters concerning a cycle, methods of, procedures for evaluation of the ability of testing and inspection, and measures, etc. based on the result of the evaluation thereof under paragraph (1) shall be prescribed by Ordinance of the Prime Minister.

Article 17 (Education) (1) The Minister of Food and Drug Safety shall formulate a policy concerning education for the improvement of expertise of human resources who conduct tests and inspections, and the securing, management, etc. of experts.

(2) Representatives of testing and inspection agencies and testing and inspection personnel shall receive education necessary for quality control of testing and inspection, testing and inspection ethics, etc. prescribed by the Minister of Food and Drug Safety in an educational institution under Article 18 every year.

(3) Detailed matters concerning persons subject to education, hours of education, details of education, etc. under paragraph (2) shall be prescribed by Ordinance of the Prime Minister.

Article 18 (Educational Institutions) (1) The Minister of Food and Drug Safety may designate an institution that conducts education (hereinafter referred to as "educational institution") for representatives and human resources of testing and inspection agencies under Article 17.

(2) Where any educational institution designated pursuant to paragraph (1) falls under any of the following, the Minister of Food and Drug Safety shall revoke its designation:

1. Where it has obtained designation fraudulently or deceptively;
2. Where it has issued a false certificate of completion of education.

(3) Necessary matters concerning the designation of an educational institution, its field, details of education based on its field, etc. under paragraph (1) shall be prescribed by Ordinance of the Prime Minister.

Article 19 (Closure, etc.) (1) Where a testing and inspection agency continues to conduct its affairs after its designation has been revoked pursuant to Article 10, the Minister of Food and Drug Safety may require relevant public officials to take the following measures to close the relevant testing and inspection agency:

1. Removing or eliminating a business sign, such as the signboard of the relevant testing and inspection agency;
2. Sealing to prohibit the use of facilities of the relevant testing and inspection agency, and other devices, equipment, etc. used for testing and inspection;
3. Affixing a notice, etc. that the relevant testing and inspection agency is prohibited from conducting its affairs.

(2) Where the Minister of Food and Drug Safety deems that it is unnecessary to continue sealing after he/she has put the seal pursuant to paragraph (1) 2 or the head of the relevant testing and inspection agency or his/her agent requests unsealing on justifiable grounds, the Minister of Food and Drug Safety may break the seal. The foregoing shall also apply to cases of a notice, etc. under paragraph (1) 3.

(3) In cases falling under paragraph (1), the Minister of Food and Drug Safety shall notify the representative of the relevant testing and inspection agency or his/her agent of measures to be taken in writing in advance: Provided, That the foregoing shall not apply in an emergency.

(4) Measures under paragraph (1) shall be limited to the minimum extent necessary to prevent the relevant testing and inspection agency conducting tests and inspections.

(5) Any relevant public official who takes measures under paragraph (1) shall carry a certificate evidencing his/her authority and produce it to relevant persons.

Article 20 (Penalty Surcharges) (1) Where the Minister of Food and Drug Safety should require a testing and inspection agency designated pursuant to Article 6 or an overseas testing and inspection agency designated pursuant to Article 8 to suspend its operations, but such suspension of operations is likely to cause serious inconvenience to users of the relevant testing and inspection agency or to undermine the public interest, he/she may impose a penalty surcharge not exceeding 200 million won in lieu of the suspension of operations, as prescribed by Presidential Decree.

(2) Where necessary to collect penalty surcharges, the Minister of Food and Drug Safety may request the head of the competent tax office to provide tax information through documents stating the following:

1. Personally identifiable information about taxpayers;
2. Objectives of the use thereof;
3. Sales amount which serves as criteria for the imposition of penalty surcharges.

(3) Types of offense based on which a penalty surcharge is imposed pursuant to paragraph (1), the amount of a penalty surcharge based on the degree of violation, and other necessary matters, shall be prescribed by Presidential Decree.

(4) Where any person subjected to a penalty surcharge pursuant to paragraph (1) fails to pay the penalty surcharge by the deadline for payment, the Minister of Food and Drug Safety may revoke the disposition of a penalty surcharge under paragraph (1), and revoke the designation under Article 10 (1) or order the suspension of operations under Article 10 (2), or collect the penalty surcharge in the same manner dispositions on default of national taxes are conducted: Provided, That where he/she is unable to revoke the designation or order the suspension of operations due to the closure of business, etc., he/she shall collect the penalty surcharge in the same manner dispositions on default of national taxes are conducted.

CHAPTER IV SUPPLEMENTARY PROVISIONS

Article 21 (Government Subsidies)

In order to ensure the reliability of tests and inspections on food and drugs, the Minister of Food and Drug Safety may provide technical support or fully or partially subsidize expenses incurred in installing facilities and equipment necessary for testing and inspection, and conducting tests and inspections to agencies designated pursuant to Article 6.

Article 22 (Reporting, Access, etc.) (1) Where the Minister of Food and Drug Safety (including the head of an agency under his/her jurisdiction prescribed by Presidential Decree) deems necessary to ensure the appropriateness and reliability of tests and inspections conducted by testing and inspection agencies designated pursuant to Article 6, overseas testing and inspection agencies designated pursuant to Article

8, or exemplary testing and inspection agencies designated pursuant to Article 13, he/she may require persons who conduct tests and inspections, or other relevant persons, to make necessary reports, or relevant public officials to access offices, places of inspection, or other similar places of testing and inspection agencies to make inquiries of the relevant persons or read related books or documents, or to require the relevant persons to submit related books or documents.

(2) Any person who accesses offices, etc. pursuant to paragraph (1) shall carry a certificate evidencing his/her authority and produce it to relevant persons.

Article 23 (Cooperation from Relevant Agencies) (1) Where the Minister of Food and Drug Safety deems necessary to achieve the objectives of this Act, he/she may request the heads of relevant administrative agencies, other agencies, and organizations to provide cooperation.

(2) Any person in receipt of a request under paragraph (1) shall comply with such request unless there is just cause.

Article 24 (Fees) (1) Any of the following persons shall pay a fee:

1. A person who files an application for designation of a testing and inspection agency pursuant to Article 6;
2. A person who files an application for designation of an overseas testing and inspection agency pursuant to Article 8;
3. A person who files an application for designation of an exemplary testing and inspection agency pursuant to Article 13;
4. A person who files an application for designation of an educational institution pursuant to Article 18;

(2) Necessary matters concerning the amounts of fees under paragraph (1), methods of payment, etc. shall be prescribed by Ordinance of the Prime Minister.

Article 25 (Hearings)

Where the Minister of Food and Drug Safety intends to make any of the following dispositions, he/she shall hold hearings: Provided, That in cases of an overseas testing and inspection agency, giving it an opportunity to submit its opinion may be done in lieu of hearings:

1. Revocation of the designation of a testing and inspection agency under Article 10 (1) or an overseas testing and inspection agency under Article 10 (2);
2. Revocation of the designation of an exemplary testing and inspection agency under Article 13 (4);
3. Revocation of the designation of an educational institution under Article 18 (2).

Article 26 (Delegation of Authority)

The Minister of Food and Drug Safety may partially delegate his/her authority under this Act to the head of a regional food and drug safety authority, as prescribed by Presidential Decree.

Article 27 (Legal Fiction as Public Officials for Purposes of Penal Provisions)

Executives and employees of any testing and inspection agency designated pursuant to Article 6 shall be deemed public officials for the purposes of penal provisions applied under the provisions of Articles 129 through 132 of the Criminal Act.

CHAPTER V PENAL PROVISIONS

Article 28 (Penal Provisions) (1) Any of the following persons shall be punished by imprisonment with prison labor for not more than five years or by a fine not exceeding 50 million won, or by both the aforesaid imprisonment and fine:

1. A person who has obtained the designation of a testing and inspection agency or an exemplary testing and inspection agency fraudulently or deceptively;
2. A person who has issued or notified a false test or inspection report intentionally in a testing and inspection agency designated pursuant to Article 6;
3. A person who has conducted a test or inspection after revocation of the designation of a testing and inspection agency or during the period of suspension of its operations under Article 10;
4. A person who has conducted affairs of a testing and inspection agency without having obtained the designation thereof.

(2) Any person who has issued a false test or inspection report by gross negligence in a testing and inspection agency designated pursuant to Article 6 shall be punished by imprisonment with prison labor for not more than three years or by a fine not exceeding 30 million won, or by both the aforesaid imprisonment and fine.

Article 29 (Joint Penal Provisions)

Where the representative of a corporation (including an organization that does not have legal personality), or an agent, employee, or other worker of a corporation or individual commits an offense under Article 28 relating to the business of such corporation or individual, not only a person who commits such offense shall be punished, but the 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 individual has not neglected to pay due attention to and exercise reasonable supervision over the relevant business in order to prevent such offense.

Article 30 (Fines for Negligence) (1) Any of the following persons shall be punished by a fine for negligence not exceeding three million won:

1. A person who alters any insignificant matter without having made a report thereon within one month, in violation of the proviso to Article 6 (5);
2. A person who fails to report the succession to the status within one month, in violation of Article 9 (3).

(2) The Minister of Food and Drug Safety shall impose and collect fines for negligence under paragraph (1), as prescribed by Presidential Decree.

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

Article 1 (Enforcement Date)

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

Article 2 (Transitional Measures concerning Designation of Testing and Inspection Agencies, etc.)

Any food sanitation inspection agency, livestock products sanitation inspection agency, pharmaceutical drug, etc. quality inspection agency, agency conducting quality inspection of traditional Korean medicinal materials, cosmetic inspection agency, and medical device testing and inspection agency designated by the Minister of Food and Drug Safety pursuant to the former provisions as at the time this Act enters into force shall be deemed a testing and inspection agency designated by the Minister of Food and Drug Safety pursuant to Article 6 (1), any overseas inspection agency authorized by the Minister of Food and Drug Safety shall be deemed an overseas testing and inspection agency designated by the Minister of Food and Drug Safety pursuant to Article 8, and any educational institution on food sanitation inspection or any educational institution on livestock product inspection designated by the Minister of Food and Drug Safety shall be deemed an educational institution designated by the Minister of Food and Drug Safety pursuant to Article 18 (1).

Article 3 (Transitional Measures concerning Grounds for Restriction on Designation of Testing and Inspection Agencies)

Where a testing and inspection agency designated pursuant to the former provisions as at the time this Act enters into force, constitutes new grounds for restriction of designation pursuant to Article 10 (3) due to grounds which occurred before this Act enters into force, the former provisions shall apply to such testing and inspection agency for three years from the date this Act enters into force.

Article 4 (Transitional Measures concerning Period of Validity of Designation of Testing and Inspection Agencies)

The period of validity of any food sanitation inspection agency, livestock product sanitation inspection agency, pharmaceutical drug, etc. quality inspection agency, and any agency conducting quality inspection of traditional Korean medicinal materials designated pursuant to the former provisions as at the time this Act enters into force shall be calculated pursuant to the former provisions, and the period of validity under Article 7 (1) of any cosmetic inspection agency and medical device testing and inspection agency, shall be calculated from the date this Act enters into force.

Article 5 Omitted.