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**ENFORCEMENT RULE OF THE SPECIAL ACT ON IMPORTED FOOD  
SAFETY CONTROL**

[Enforcement Date 04. Feb, 2016.] [Ordinance of the Prime Minister  
No.1253, 04. Feb, 2016., New Enactment]

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# ENFORCEMENT RULE OF THE SPECIAL ACT ON IMPORTED FOOD SAFETY CONTROL

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## Article 1 (Purpose)

The purpose of this Enforcement Rule is to provide for matters delegated by the Special Act on Imported Food Safety Control and the Enforcement Decree of the aforesaid Act, and matters necessary for the enforcement thereof.

**Article 2 (Registration, etc. of Foreign Food Facilities)** (1) Any person who intends to be registered as a foreign food facility pursuant to Article 5 (1) of the Special Act on Imported Food Safety Control (hereinafter referred to as the “ Act ” ) shall submit an application (including an application in electronic form) for registration of a foreign food facility in Form 1 to the Minister of Food and Drug Safety.

(2) “ Matters prescribed by Ordinance of the Prime Minister, such as the name and location of, and items produced by the foreign food facility ” in Article 5 (1) of the Act means the following matters:

1. Name, location, representative, phone number, and email address of the foreign food facility, and the name of the country where the foreign food facility is based;
2. Items produced;
3. Type of business;
4. Whether a food safety management system is implemented.

(3) Any person who intends to file for registration of any change (in cases of a change of the location, including cases where the name of an administrative district is changed) pursuant to Article 5 (2) of the Act shall submit an application for changes to foreign food facility registration information (including an application in electronic form) in Form 1, to the Minister of Food and Drug Safety before the person files an import declaration under Article 20 of the Act.

(4) Where a person registered as a foreign food facility pursuant to Article 5 (1) of the Act intends to renew the registration thereof, he/she shall submit an application (for renewal of the registration of a foreign food facility including an application in electronic form) in Form 1, to the Minister of Food and Drug safety no later than seven days before the period of validity prescribed in Article 5 (6) of the Act expires.

(5) Where the Minister of Food and Drug Safety receives an application under paragraph (1), (3), or (4), he/she shall verify the content of an application and notify an applicant of the registration, registration of any change or the renewal of the registration thereof after he/she has conducted such affairs.

(6) Where the Minister of Food and Drug Safety revokes registration pursuant to Article 5 (4) of the Act or refuses an import declaration filed pursuant to Article 5 (5) of the Act, he/she shall notify the other party of such fact.

(7) Where there is an agreement between the countries concerning procedures for and methods of registration of a foreign food facility, the registration of any change, etc. prescribed in paragraphs (1) through (6) of the Act, the Minister of Food and Drug Safety may comply with such agreement.

**Article 3 (Procedures for Import Suspension and Removal of Import Suspensions) (1)**

Where the Minister of Food and Drug Safety takes measures for import suspension under Article 6 (2) of the Act, he/she shall notify a person who established and operates the relevant foreign food facility of grounds for import suspension and the date of commencement of import suspension in writing (including notification in electronic form; hereafter the same shall apply in this Article). In such cases, the date of commencement of import suspension shall be based on the date of shipment from an exporting country.

(2) Where the Minister of Food and Drug Safety takes measures to remove import suspension under Article 6 (3) of the Act, he/she shall notify the government of the relevant exporting country, the relevant foreign food facility, or a business entity who imports food of such fact.

**Article 4 (Registration, etc. of Good Importers) (1)** Any person who intends to register his/her company as a good importer pursuant to Article 7 (2) of the Act

shall submit an application (including an application in electronic form) for registration of a good importer in Form 2 to the Minister of Food and Drug Safety along with the following documents (including documents in electronic form):

1. Documents including the following matters concerning imported food, etc.:
  - (a) In cases of food (referring to food defined in subparagraph 1 of Article 2 of the Food Sanitation Act; hereinafter the same shall apply) or food additives (referring to food additives defined in subparagraph 2 of Article 2 of the Food Sanitation Act; hereinafter the same shall apply): The names of products, the names of raw materials, and methods of manufacturing or processing;
  - (b) In cases of utensils (referring to utensils defined in subparagraph 4 of Article 2 of the Food Sanitation Act; hereinafter the same shall apply) or containers and packages (referring to containers and packages referred to in subparagraph 5 of Article 2 of the Food Sanitation Act; hereinafter the same shall apply): Matters concerning the quality of materials, uses, base colors, etc.;
  - (c) In cases of health functional foods (referring to health functional foods defined in subparagraph 1 of Article 3 of the Functional Health Foods Act; hereinafter the same shall apply): Kinds and names of health functional foods, methods of manufacturing or processing, the names of raw materials and the mixing ratio thereof;
2. Inspection report of sanitation control conditions of a foreign food facility based on standards prescribed by the Minister of Food and Drug Safety;
3. Documents evidencing that a foreign food facility has been permitted, registered, and reported pursuant to Acts and subordinate statutes related to food, etc. of the exporting country.
  - (2) Where the Minister of Food and Drug Safety verifies as to whether the content of an application filed pursuant to paragraph (1) meets standards prescribed by the Minister of Food and Drug Safety through an on - site inspection, etc. and finds it meets the standards, he/she shall issue a certificate of registration of a good importer in Form 3.
  - (3) The Minister of Food and Drug Safety who has issued a certificate of registration pursuant to paragraph (2) shall prepare and keep a register of good importers in Form 4 or input and manage such data in a computer network .

(4) “ Any important matter prescribed by Ordinance of the Prime Minister ” in the latter part of Article 7 (3) of the Act means any of the following matters:

1. Name of a business entity (in cases of a corporation, referring to the name of its representative);
2. Name and location of a good importer;
3. Name and location of a relevant foreign food facility;
4. Product name, raw materials (in cases of health functional food, the mixing ratio shall be included), and manufacturing or processing method of imported food, etc. registered.

(5) Any person who intends to register any change pursuant to the latter part of Article 7 (3) of the Act shall submit an application for changes to good importer registration information in Form 5 to the Minister of Food and Drug Safety along with a certificate of registration of a good importer within 30 days from the date any of the matters under the subparagraphs of paragraph (4) are changed.

(6) “ Where a good importer fails to comply with matters prescribed by Ordinance of the Prime Minister ” in Article 7 (6) 3 of the Act means any of the following cases:

1. Where the good importer fails to maintain and manage sanitation control conditions of a foreign food facility required to meet standards prescribed by the Minister of Food and Drug Safety pursuant to Article 7 (1) of the Act;
2. Where the good importer fails to report the results of an inspection of sanitation control conditions to the Minister of Food and Drug Safety at least annually pursuant to Article 7 (1) of the Act, or reports falsely to him/her;
3. Where the good importer fails to file for registration of any change under the latter part of Article 7 (3) of the Act.

(7) Criteria for the revocation, etc. of registration of a good importer under Article 7 (6) of the Act shall be as specified in attached Table 1.

(8) Detailed matters necessary for the registration, management, etc. of good importers under paragraphs (1) through (7) shall be prescribed and notified by the Minister of Food and Drug Safety.

**Article 5 (Registration, etc. of Good Foreign Food Facilities)** (1) Any person who intends to register a foreign food facility as a good foreign food facility pursuant to Article 8 (1) of the Act shall file an application (including an application in electronic

form) for the registration of a good foreign food facility in Form 6 to the Minister of Food and Drug Safety along with the following documents (including documents in electronic form):

1. Documents stating the following matters concerning imported food, etc.:
    - (a) In cases of food or food additives: Product names, names of raw materials, and manufacturing or processing methods;
    - (b) In cases of utensils, containers, or packages: Matters concerning the quality of materials, uses, base colors, etc.;
    - (c) In cases of health functional foods: Kinds and names of health functional foods, manufacturing or processing methods, names of raw materials and the mixing ratio thereof;
  2. Documents concerning the location of a manufacturing or processing factory producing imported food, etc., a plot plan, a ground plan of a workplace, etc.;
  3. Documents evidencing that a foreign food facility has been permitted, registered, and reported pursuant to Acts and subordinate statutes related to food, etc. of the relevant exporting country.
- (2) Where the Minister of Food and Drug Safety verifies whether the content of an application filed pursuant to paragraph (1) meets standards for registration through an on - site inspection, etc. and confirms that it meets the standards, he/she shall issue the applicant a certificate of registration of a good foreign food facility in Form 7.
- (3) The Minister of Food and Drug Safety who has issued a certificate of registration pursuant to paragraph (2) shall prepare and keep a register of good foreign food facilities in Form 8 or manage the register by inputting the data of the register into a computer network.
- (4) A person who intends to file for registration of any change pursuant to the latter part of Article 8 (2) of the Act shall submit an application for changes to good foreign food facility registration information in Form 9 to the Minister of Food and Drug Safety along with a certificate of registration of the good foreign food facility within 30 days from the date he/she changes any of the matters required under the subparagraphs of paragraph (5).

(5) “ Important matters prescribed by Ordinance of the Prime Minister ” in the latter part of Article 8 (2) of the Act means the following matters:

1. Name and location of a good foreign food facility;
2. Product names, raw materials (in cases of health functional foods, the mixing ratio thereof shall be included), and manufacturing or processing process of imported food, etc. registered.

(6) “ Where the good foreign food facility fails to comply with matters prescribed by Ordinance of the Prime Minister ” in Article 8 (5) 2 of the Act means any of the following cases:

1. Where the good foreign food facility fails to conduct maintenance and management in compliance with standards for registration as required under Article 8 (1) of the Act;
2. Where the good foreign food facility fails to report the results of an inspection of sanitation control conditions to the Minister of Food and Drug Safety at least annually pursuant to standards for registration as required under Article 8 (1) of the Act, or reports falsely to him/her;
3. Where the good foreign food facility fails to file for registration of any change as required under the latter part of Article 8 (2) of the Act.

(7) Criteria for the revocation, etc. of registration of a good foreign food facility under Article 8 (5) of the Act shall be as specified in attached Table 1.

(8) Detailed matters necessary for the registration, management, etc. of good foreign food facilities under paragraphs (1) through (7) shall be prescribed and notified by the Minister of Food and Drug Safety.

**Article 6 (Reporting of Results of On - Site Inspections, etc.)** (1) Where an imported food sanitation audit institution reports the results of an on - site inspection, etc. pursuant to Article 9 (2) of the Act, it shall include the following matters in the report:

1. The institution to which a person who has made an official trip belongs, his/her name, and the period of the official trip;
2. Name, representative, location, and relevant items of a good foreign food facility;
3. Detailed statement of travel expenses and evidential documents;

4. Other matters the Minister of Food and Drug Safety deems necessary.

(2) An imported food sanitation audit institution shall report under paragraph (1) within ten days after it conducts an on - site inspection, etc.

**Article 7 (Designation, etc. of Imported Food Sanitation Audit Institutions)** (1) The Minister of Food and Drug Safety may designate any of the following institutions as an imported food sanitation audit institution pursuant to Article 10 (1) of the Act:

1. The Korea Institute for Food Safety Management Accreditation under the Food Sanitation Act;

2. An institution meeting requirements for designation specified in attached Table 3.

(2) Any institution that intends to be designated as an imported food sanitation audit institution pursuant to paragraph (1) 2 shall submit an application (including an application in electronic form) for the designation as an imported food sanitation audit institution in Form 10 to the Minister of Food and Drug Safety along with the following documents (including documents in electronic form):

1. Articles of incorporation;

2. Business plan for the business year in which the application is filed and the following year;

3. Organization chart of the institution that files an application;

4. Where the institution conducts affairs, if any, as at the time it files an application, documents outlining the affairs;

5. Its own operational regulations;

6. Current status of personnel who conduct sanitation audits under subparagraph 2 (b) of attached Table 3, and documents certifying the qualifications thereof.

(3) Where the Minister of Food and Drug Safety, in receipt of an application under paragraph (2), finds that the institution filed the application meets the requirements for designation under attached Table 3 after he/she has examined documents and conducted an on - site inspection, he/she shall enter such institution in the register of designation of imported food sanitation audit institutions, and issue a written designation of an imported food sanitation audit institution in Form 12 to the applicant.

(4) Where the Minister of Food and Drug Safety issues a written designation of an imported food sanitation audit institution pursuant to paragraph (3), he/she shall



publicly announce the following matters in the Official Gazette or on the Internet website of the Ministry of Food and Drug safety:

1. Name, representative, and location of the imported food sanitation audit institution;
2. Date of designation and period of validity of designation of the imported food sanitation audit institution.

**Article 8 (Designation, etc. of Imported Food Sanitation Audit Institutions)** (1) Where an imported food sanitation audit institution changes any of the following matters, it shall submit an application for changes to designation information on an imported food sanitation audit institution (including an application in electronic form) in Form 13 to the Minister of Food and Drug Safety, along with its written designation of an imported food sanitation audit institution in Form 12 and evidentiary materials proving such change, within 30 days from the date of modification:

1. Name of the imported food sanitation audit institution;
2. Representative of the imported food sanitation audit institution;
3. Location of the imported food sanitation audit institution.

(2) The Minister of Food and Drug Safety, in receipt of an application under paragraph (1), shall confirm the content of the application, state such changed matter in a written designation of the imported food sanitation audit institution in Form 12, and issue it to the applicant. (3) Where an imported food sanitation audit institution discontinues, suspends, or resumes business concerning sanitations audits, it shall submit an application for discontinuance, suspension, or resumption of business of the imported food sanitation audit institution in Form 14 to the Minister of Food and Drug Safety, along with its written designation of imported food sanitation audit institution in Form 12, within 30 days from the date it discontinues, suspends, or resumes its business.

**Article 9 (Extension of Period of Validity of Designation of Imported Food Sanitation Audit Institutions and Re - Designation Thereof)** (1) An institution that intends to extend the period of validity of the designation as an imported food sanitation audit institution pursuant to Article 10 (3) of the Act shall submit an application (including an application in electronic form) in Form 15 to the Minister of Food and Drug

Safety, along with a written designation of an imported food sanitation audit institution in Form 12 and documents proving grounds for extension, by no later than 60 days before the period of validity thereof expires.

(2) Any person who intends to to be re - designated as an imported food sanitation audit institution pursuant to Article 10 (4) of the Act shall submit an application (including an application in electric form) for re - designation as an imported food sanitation audit institution in Form 10 to the Minister of Food and Drug Safety, along with documents (limited to documents containing items changed) under the subparagraphs of Article 7 (2), by no later than 60 days before the period of validity of the designation thereof expires.

(3) Where the Minister of Food and Drug Safety in receipt of an application pursuant to paragraphs (1) and (2) extends the period of validity or re - designates an imported food sanitation audit institution, he/she shall reissue the applicant a written designation of an imported food sanitation audit institution in Form 12.

**Article 10 (Guidelines for Dispositions, such as Revocation of Designation of Imported Food Sanitation Audit Institutions)**

Guidelines for dispoistions imposed under Article 10 (6) of the Act, such as revocating the designation of an imported food sanitation audit institution, shall be as specified in attached Table 4.

**Article 11 (Import Sanitation Assessments, etc. of Livestock Products)** (1) “ Cases prescribed by Ordinance of the Prime Minister, such as cases where the government of an exporting country requests the government of the Republic of Korea to permit the importation of livestock products, or reassessment on the sanitary control of the exporting country is deemed necessary according to changes, etc. in international standards of the Codex Alimentarius Commission, etc. ” means any of the following cases:

1. Where the government of the exporting country makes the first request for permission to import the relevant livestock products (referring to livestock products prescribed in subparagraph 2 of Article 2 of the Livestock Products Sanitary Control Act);

2. Where it is necessary to re - assess sanitation control of an exporting country due to any change in international standards after granting permission to import, newly discovered risk factor, or any change, etc. in the food sanitation system of an exporting country;

3. Other cases where the Minister of Food and Drug Safety deems it necessary to ensure the safety of livestock products.

(2) Where the Minister of Food and Drug Safety intends to conduct an on - site inspection pursuant to Article 11 (4) of the Act, he/she shall notify a person who establishes or operates a foreign establishment of an on - site inspection plan through the government of the exporting country. In such cases, he/she may consult with the government of the exporting country about an on - site inspection schedule, etc. in advance.

(3) Detailed procedures for and methods of assessing import sanitation under Article 11 (1) of the Act shall be as specified in attached Table 5.

**Article 12 (Registration, etc. of Foreign Establishment)** (1) Any person who intends to register a foreign establishment pursuant to the former part of Article 12 (1) of the Act shall submit an application for registration of a foreign establishment in Form 16 to the Minister of Food and Drug Safety through the government of an exporting country.

(2) Where it is necessary to review as to whether to accept registration, the Minister of Food and Drug Safety in receipt of an application for registration pursuant to paragraph (1) may request a person who establishes or operates a foreign establishment to submit the following data through the government of an exporting country:

1. A document evidencing that the government of the exporting country has managed and supervised the relevant foreign establishment on a regular basis, or a checklist prepared by the government of the exporting country in accordance with standards for inspection prescribed and notified by the Minister of Food and Drug Safety;

2. A copy of the authorization or permission document concerning the operation of the relevant foreign establishment recognized by the government of the exporting country;

3. Where the foreign establishment is governed by standards corresponding to the HACCP system under the Livestock Products Sanitary Control Act, a summary of a plan to implement such standards, and a copy of the work flow chart in which critical control points are indicated;
4. Where the foreign establishment is not governed by standards corresponding to the HACCP system under the Livestock Products Sanitary Control Act, a summary of standards for the sanitation control of the relevant foreign establishment, and a copy of the work flow chart;
5. Other documents the Minister of Food and Drug Safety deems necessary to ensure the safety of livestock products.

(3) The Minister of Food and Drug Safety in receipt of an application for registration pursuant to paragraph (1) shall determine whether to accept registration by examining documents or by conducting an on - site inspection, and notify the person who established or operates the foreign establishment of the results thereof through the government of an exporting country.

(4) Where the Minister of Food and Drug Safety intends to conduct an on - site inspection pursuant to Article 12 (2) of the Act, he/she shall notify the person who established or operates the workplaceforeign establishment of an on - site inspection plan through the government of an exporting country. In such cases, the Minister of Food and Drug Safety may pre - consult with the government of an exporting country about an on - site inspection schedule, etc.

(5) Detailed matters necessary for on - site inspections referred to in Article 12 of the Act shall be prescribed and notified by the Minister of Food and Drug Safety.

(6) Where an agreement exists concerning procedures for and methods of registration of a foreign establishment under paragraphs (1) through (5) between countries, the Minister of Food and Drug Safety may comply with such agreement.

**Article 13 ( Changes to Foreign Establishment Registration Information)** (1) Any person who intends to register any change pursuant to the latter part of Article 12 (1) of the Act shall submit an application for changes to foreign establishment registration information in Form 16 to the Minister of Food and Drug Safety through the government of an exporting country before he/she makes an import declaration under Article 20 of the Act from the date on which any of the following matters is

changed:

1. Name of the foreign establishment;
2. Registration number of the foreign establishment;
3. Location of the foreign establishment (including where the name of the administrative district is changed);
4. Type of industry.

(2) The Minister of Food and Drug Safety in receipt of an application for registration of any change pursuant to paragraph (1) shall determine whether to approve the registration of such change by examining documents or by conducting an on - site inspection, and notify the person who established or operates the foreign establishment of the results thereof through the government of an exporting country.

**Article 14 (Revocation, etc. of Registration of Foreign Establishment)** (1) Criteria for the revocation, etc. of registration of a foreign establishment under Article 13 (1) of the Act shall be as specified as attached Table 6.

(2) Where the Minister of Food and Drug suspends the importation of livestock products or revokes the registration of a foreign establishment under article 13 (1) of the Act, he/she shall give written notice to the person who established or operates a foreign establishment of reasons for taking the relevant measures and the date of commencement of import suspension (including documents in electronic form; hereafter the same shall apply in this Article) through the government of an exporting country. In such cases, the date of commencement of import suspension shall be based on the date of shipment from the exporting country.

(3) Where the Minister of Food and Drug Safety removes an import suspension or requires re - registration pursuant to Article 13 (2) of the Act, he/she shall give written notice to the person who established or operates the relevant foreign establishment of the aforesaid matters through the government of an exporting country.

**Article 15 (Facility Standards, etc. by Business Type)** (1) Facility standards by business type under Article 14 (1) of the Act shall be as specified in attached Table 7.

(2) “ Facility or place prescribed by Ordinance of the Prime Minister in subparagraph 4 of Article 2 of the Enforcement Decree of the Special Act on Imported Food Safety Control (hereinafter referred to as the “ Decree ” ) means any of the following facilities or places:

1. A bonded warehouse located in a specially - permitted bonded area or general bonded area under Article 154 of the Customs Act: Provided, That the foregoing shall not apply to a bonded warehouse for containers only;
2. A storage facility of a person who obtains permission to occupy pursuant to Article 11 of the Act on Designation and Management of Free Trade Zones.

**Article 16 (Registration, etc. of Business )** (1) Any person who intends to register his/her business pursuant to the main sentence of Article 15 (1) of the Act shall submit an application for business registration in Form 17 to the head of a Regional Office of Food and Drug Safety, along with the following documents (including documents in electronic form) after he/she has facilities necessary for business operations. In such cases, the head of a Regional Office of Food and Drug Safety shall verify the written confirmation of the land use plan and the building register through the common use of administrative information under Article 36 (1) of the Electronic Government Act:

1. A certificate of completion of education (only applicable where the person has received education in advance pursuant to the main sentence of Article 17 (1) of the Act);
2. A contract for lease of a storage facility (only applicable where a storage facility is leased);
3. Details of facilities in the place of business and the layout thereof (only applicable to the business of storing imported food, etc.);
4. Documents concerning license, reporting, or permission under the Customs Act and the Act on Designation and Management of Free Trade Zones for bonded warehouses and storage facilities prescribed in Article 15 (2) (only applicable to the business of storing imported food, etc.);
5. A permit to use State property under Article 14 (3) of the Enforcement Rule of the State Property Act (only applicable where the person intends to engage in the business of importing and selling imported food, etc. at facilities within urban

railway stations);

6. Documents concerning a contract for use of urban railroad facilities, concluded with an urban railroad operator under the Urban Railroad Act (only applicable where the person intends to engage in the business of importing and selling imported food, etc. at facilities within urban railway stations).

(2) Where the head of a Regional Office of Food and Drug Safety is unable to internally verify whether an applicant falls under Article 15 (7) 5 of the Act, he/she may require the applicant to submit data necessary for identification (including data in electronic form) in addition to documents under the subparagraphs of paragraph (1). In such cases, where the applicant is a foreigner, the head of a Regional Office of Food and Drug Safety may require him/her to submit a document issued by the government or other authoritative agency of the relevant country, or document confirmed by a consulate of the Republic of Korea being stationed in the relevant country pursuant to the Act on Notarial Acts Done at Overseas Diplomatic and Consular Missions, being a written statement of the applicant notarized by a notary public.

(3) Where the head of a Regional Office of Food and Drug Safety receives an application for registration under paragraph (1), he/she shall issue a certificate of business registration in Form 18 after he/she examines accompanying documents for application, etc. In such cases, with regard to an application for registration of the business of storing imported food, etc., he/she shall verify facilities of the relevant place of business before he/she approves the relevant registration.

(4) The head of a Regional Office of Food and Drug Safety shall prepare and keep matters registered pursuant to paragraph (3) in the business register in Form 19, or manage such matters by entering them in a computer network.

(5) Where a business entity intends to obtain a certificate of business registration because it is lost or defaced, he/she shall submit an application for re - issuance of a certificate of business registration (including an application in electronic form; where a certificate of business registration is defaced, he/she shall also submit the relevant certificate of business registration) in Form 20 to the head of a Regional Office of Food and Drug Safety.

**Article 17 (Changes in Registered Matters)** (1) Any person who intends to register any change pursuant to the latter part of Article 15 (1) of the Act shall submit an application for changes to business registration information (including an application in electronic form) in Form 21 to the head of a Regional Office of Food and Drug Safety at the seat of the new location along with a certificate of business registration and relevant documents under Article 16 (1) 2 through 6. In such cases, the head of the Regional Office of Food and Drug Safety shall check a written confirmation of land use plan and the building register through the common use of administrative information under Article 36 (1) of the Electronic Government Act.

(2) Where any person who has registered his/her business under the main sentence of Article 15 (1) of the Act changes any matter other than the location of his/her place of business under Article 3 of the Decree, he/she shall file a report on changes to business registration information in Form 21 (including a report in electronic form) to the head of a Regional Office of Food and Drug Safety in accordance with Article 15 (3), along with a certificate of business registration and other documents (including documents in electronic form) that may verify such change:: Provided, That the foregoing shall not apply to any change due to the succession to the position of a business entity under Article 16 of the Act.

(3) The head of a Regional Office of Food and Drug Safety in receipt of an application filed under paragraph (1) for registering changes or a report on changes filed under paragraph (2) shall issue a certificate of business registration containing such changed matters: Provided, That where a person engaged in the business of storing imported food, etc. intends to register the change of the location of his/her place of business in accordance with paragraph (1), he/she shall verify such change before the issuance of the certificate of business registration containing such changed matter.

**Article 18 (Reporting of Cessation of Business)** (1) Any person who intends to report cessation of business pursuant to Article 15 (3) of the Act shall submit a report of cessation of business (including a report in electronic form) in Form 22 to the head of a Regional Office of Food and Drug Safety, along with a certificate of business registration.



(2) Where any person who intends to report cessation of business pursuant to paragraph (1) intends to report cessation of business under Article 8 (6) of the Value - Added Tax Act at the same time, he/she shall submit a report of cessation of business as required under paragraph (1), along with a report of cessation of business in Form 9 of the Enforcement Rule of the Value - Added Tax Act. In such cases, the head of a Regional Office of Food and Drug Safety shall immediately send (including via the information and telecommunications network; hereafter the same shall apply in this Article) a report of cessation of business which he/she receives simultaneously to the head of the competent tax office.

(3) Where the head of the competent tax office sends a report of cessation of business under paragraph (1) to the head of a Regional Office of Food and Drug Safety after he/she receives it pursuant to Article 13 (5) of the Enforcement Decree of the Value - Added Tax Act, a report of cessation of business under paragraph (1) shall be deemed submitted.

**Article 19 (Procedures for Cancellation of Registered Matters of Business by Inherent Jurisdiction)**

Where the head of a Regional Office of Food and Drug Safety intends to cancel registered matters by inherent jurisdiction pursuant to Article 15 (4) of the Act, he/she shall follow the following procedures:

1. He/she shall pre - notify the relevant business entity of the fact that he/she plans to cancel registered matters;
2. He/she shall preannounce the fact that he/she plans to cancel registered matters on the bulletin board of the relevant Regional Office of Food and Drug Safety and the web site for at least ten days.

**Article 20 (Reporting of Registration of Business)**

Where the head of a Regional Office of Food and Drug Safety approves registration of business under Article 15 (1) of the Act, he/she shall report his/her approval of the registration of business in Form 23 to the Minister of Food and Drug Safety within 20 days after each quarter ends.

**Article 21 (Reporting of Succession to Position of Business Entity) (1)** Any person who intends to report succession to the position of a business entity pursuant to

Article 16 (3) of the Act shall submit a report of succession to the position of business entity (including a report in electronic form) in Form 24 to the head of a Regional Office of Food and Drug Safety along with the following documents (including documents in electronic form): Provided, That where the head of a Regional Office of Food and Drug Safety may confirm the transfer and acquisition by other methods, in which case the person is unable to submit the relevant documents due to the unknown whereabouts, etc. of a transferor, the person need not submit the relevant documents:

1. A certificate of business registration;
2. Documents that evidence the transfer of the following rights (including documents in electronic form):
  - (a) In cases of transfer, a copy of documents that may evidence the transfer and acquisition;
  - (b) In cases of inheritance, a certificate of family relations under Article 15 (1) 1 of the Act on the Registration, etc. of Family Relationship and a document evidencing that he/she is a successor;
  - (c) Other documents that may evidence the fact that he/she has succeeded to the position of business entity for each relevant reason;
3. A certificate of completion of education (only applicable where he/she has received education in advance pursuant to the main body of Article 17 (1) of the Act);
4. A copy of an identification card and a power of attorney (only applicable where a transferor or transferee delegates the reporting of succession to the position of business entity) of a person who delegates the reporting signed by him/her in his/her own handwriting.

(2) Where the head of a Regional Office of Food and Drug Safety is unable to internally verify whether a reporter falls under Article 15 (7) 5 of the Act, he/she may require the reporter to submit data (including documents in electronic form) necessary for identification in addition to documents under the subparagraphs of paragraph (1). .

(3) Where a person who reports succession to the position of a business entity pursuant to paragraph (1) intends to change the name of his/her place of business or

the trade name pursuant to Article 17, he/she may report such change simultaneously.

- Article 22 (Institutions, etc. Conducting Sanitation Education)** (1) Institutions that conduct education concerning sanitation control, etc. (hereinafter referred to as “ sanitation education ” ) under Article 17 (1) and (2) of the Act shall be institutions designated and notified by the Minister of Food and Drug Safety (hereinafter referred to as “ institution conducting sanitation education ” ).
- (2) The curriculum of sanitation education shall include relevant Acts and subordinate legislation, systems, sanitation control, the maintenance of the quality, labeling, and advertising of imported food, etc..
- (3) Each institution conducting sanitation education shall produce teaching materials and provide persons subject to education with teaching materials.
- (4) Each institution conducting sanitation education shall issue a certificate of completion to persons who have received education, and keep and manage records concerning education, such as the book of issuance of certificates of completion, for three years.
- (5) Each institution conducting sanitation education shall report the results of education to the head of a Regional Office of Food and Drug Safety within one month after the completion of education, and report the aforesaid results to the Minister of Food and Drug Safety within one month after the relevant year ends.
- (6) Each institution conducting sanitation education may receive actual expenses incurred in conducting education from persons who receive education, such as tuition payments, expenses incurred in producing teaching materials, and expenses incurred in purchasing office supplies related to education.
- (7) Detailed matters concerning educational operation and accounting of institutions conducting sanitation education shall be prescribed by the Minister of Food and Drug Safety.

- Article 23 (Hours, etc. of Sanitation Education)** (1) Hours of sanitation education which any person who intends to conduct business should receive in advance pursuant to Article 17 (1) of the Act shall be four hours.

(2) Hours of sanitation education which any business entity should receive every year pursuant to Article 17 (2) of the Act shall be three hours.

(3) Where any person who receives sanitation education pursuant to paragraph (1) less than two years ago or who has received sanitation education under paragraph (2) in the relevant year intends to engage in the business under the subparagraphs of Article 14 (1) of the Act, he/she shall be deemed to have received sanitation education under paragraph (1) regarding the relevant business.

(4) Where any person who has received sanitation education under paragraph (2) in the relevant year engages in other business under the subparagraphs of Article 14 (1) of the Act, he/she shall be deemed to have received sanitation education under paragraph (2) regarding the relevant business.

(5) Among persons subject to sanitation education under Article 17 (1) and (2) of the Act, the distribution of teaching materials under Article 22 (3) to business entities and persons in charge of management on islands, remote rural areas, etc. for whom the Minister of Food and Drug Safety finds impracticable to attend sanitation education so that they can learn and utilize teaching materials may be conducted in lieu of sanitation education under paragraphs (1) and (2).

**Article 24 (Cases Where Person in Charge of Management May Receive Sanitation Education on Behalf of Business Entity)**

“ Unavoidable reasons prescribed by Ordinance of the Prime Minister ” in the proviso to Article 17 (2) of the Act means any of the following cases:

1. Where a business entity is unable to receive sanitation education due to a natural disaster, his/her disease, accident or for reasons, such as his/her overseas business trip;
2. Where a business entity is not directly engaged in business;
3. Where the same business entity conducts business at least two places;
4. Where a business entity is a foreign entity.

**Article 25 (Matters with which Business Entities Should Comply)**

Matters with which business entities should comply pursuant to Article 18 (1) of the Act shall be as specified in attached Table 8.

**Article 26 (Management by Classifying Business Entities)** (1) The Minister of Food and Drug Safety may differentially manage business entities importing and selling imported food, etc. by classifying them as follows, pursuant to Article 19 (1) of the Act:

1. Good importers: Persons registered as good importers pursuant to Article 7 of the Act (excluding those falling under subparagraph 3);
2. Ordinary importers: Persons who do not fall under subparagraph 1 or 3;
3. Importers under special management: Any of the following business entities:
  - (a) A business entity against whom administrative disposition was effective less than one year ago (where a penalty surcharge is imposed in lieu of the suspension of business, the date on which he/she is subject to such penalty surcharge) after he/she was subject to administrative disposition pursuant to subparagraph 3 (b) of individual standards in attached Table 13 II;
  - (b) A business entity in whose case one year has not passed after he/she violates any measure falling under any of the subparagraphs of Article 34 (1).

(2) The area of application of differential management based on the classification under the subparagraphs of paragraph (1) shall be import inspection under Article 21 of the Act and access, inspection, collection, etc. under Article 25 of the Act.

**Article 27 (Import Declaration of Imported Food, etc.)** (1) Any person who intends to make an import declaration (excluding a business entity engaged in the business of online purchasing of imported food, etc. by proxy) pursuant to Article 20 (1) of the Act shall submit an import declaration of imported food, etc. (including an import declaration in electronic form) in Form 25 to the head of a Regional Office of Food and Drug Safety having jurisdiction over the place of the clearing of imported food, etc. through customs, along with the following documents (including documents in electronic form). In such cases, he/she may make an import declaration in advance up to five days before the scheduled date of arrival of imported food, etc., and where important matters, such as the port of arrival reported in advance, the scheduled date of arrival, the place in which goods are brought and the scheduled date of bringing goods in, are changed, he/she shall immediately report the details thereof in writing (including documents in electronic form):

1. A wrapper printed in Korean (including wrappers to which a label printed in Korean is attached) or a document mentioning content in Korean;
2. A test or inspection report issued by an overseas testing or inspection agency under Article 8 of the Act on Testing and Inspection in the Food and Drug Industry through a detailed inspection (only applicable to imported food, etc. subject to detailed inspection under subparagraph 2 (c) of attached Table 9);
3. A certificate of separate distribution [referring to a document proving that imported food, etc. has been managed separately from genetically modified foods (referring to foods which have undergone safety assessment, which are agricultural products, livestock products and fishery products cultivated or raised by using genetic engineering techniques, or foods manufactured or processed with such products as raw materials) in the handling processes, such as the purchase of seeds, production, manufacturing, storage, sorting, transportation and shipment] or a certificate recognized by the government of a producing country as having the same effect as a certificate of separate distribution (only applicable to where foods are subject to GMO labeling, but are not GMO - food labeled);
4. A statement of reasons for setting the expiration date under Article 20 (4) of the Act or a statement of reasons for the expiration date (only applicable to OEM - branded imported food, etc. prescribed in Article 18 (2) of the Act) under Article 29;
5. An exporting plan (a specific plan after bringing imported food, etc. in the Republic of Korea shall be stated; only applicable to where imported food, etc. is imported to acquire foreign currency pursuant to the Foreign Trade Act );
6. A copy of the approval or permission document, such as a business permit, or a copy of a report of manufacturing items (only applicable to where imported food, etc. is imported as raw materials to acquire foreign currency or as raw materials for manufacturing the importer ' s products; excluding where such documents are verified through a computer);
7. A health certificate or inspection certificate (only applicable to fishery products imported from an exporting country with which the Republic of Korea has concluded an agreement, etc. concerning the attachment of a certificate pursuant to Article 37 of the Act or Article 88 (1) 1 of the Agricultural and Fishery Products

Quality Control Act);

8. An export health certificate (only applicable to livestock products) under Article 11 (5) of the Act;
9. A copy of a certificate of attestation (only applicable to the labeling or advertising of halal - certified food or halal - certified livestock products) of halal - certified food (referring to food certified by an agency under Article 8 (1) 6 (d) of the Enforcement Rule of the Food Sanitation Act as being permitted for Muslims ' consumption; hereinafter the same shall apply) or halal - certified livestock products (referring to livestock products certified by an agency under Article 52 (1) 8 (d) of the Enforcement Rule of the Livestock Products Sanitary Control Act as being permitted for Muslims ' consumption; hereinafter the same shall apply);
10. In addition to documents under subparagraphs 1 through 9, documents which the Minister of Food and Drug Safety deems necessary to secure the safety of imported food, etc. in accordance with hazard information, such as an inspection report on dioxin residue, a certificate issued by the government of a producing country certifying that a raw material from a healthy ruminant not infected by bovine spongiform encephalopathy is used, and an approval document related to the safety of genetic recombination.

(2) Where a business entity engaged in the business of online purchasing of imported food, etc. by proxy intends to make an import declaration pursuant to Article 20 (1) of the Act, it shall submit an import declaration (including an import declaration in electronic form) of imported food, etc. purchased on the Internet by proxy in Form 26 to the head of a Regional Office of Food and Drug Safety having jurisdiction over the place where imported food, etc. is cleared through customs. In such cases, an import declaration shall be made before the clearance of imported food, etc. through customs.

(3) Imported food, etc. declared (hereinafter referred to as " imported food, etc. purchased by proxy) pursuant to paragraph (2) may be exempted from the labeling of food, etc. under Article 10 of the Food Sanitation Act, the nutrition labeling of food under Article 11 of the aforesaid Act, the labeling of GMO food under Article 12 - 2 of the aforesaid Act, the labeling of health functional food under Article 17 of the Health Functional foods Act or the labeling of livestock products under Article 6 of

the Livestock Products Sanitary Control Act.

(4) The head of a Regional Office of Food and Drug Safety may request documents necessary for import declaration of imported food, etc. under paragraphs (1) and (2) in electronic form, and enter declared matters, etc. of imported food, etc. in a computer network and manage them accordingly.

(5) In cases of imported food, etc. seized or confiscated pursuant to other Acts, such as the Customs Act, the submission of an import declaration of imported food, etc. under paragraphs (1) and (2), and its accompanying documents may be omitted.

(6) Where imported food, etc. arrives later than the scheduled date of arrival declared in advance pursuant to the latter part of paragraph (1), the delay period shall not be counted in the period of handling civil petitions under Article 13 of the Enforcement Decree of the Civil Petitions Treatment Act.

**Article 28 (Approval for Change of Purposes of Raw Materials for Manufacturing**

**Products)** (1) Where a business entity who has made an import declaration of imported food, etc. (excluding health functional foods and imported grain subject to restrictions pursuant to subparagraph 2 of Article 13 of the Grain Management Act; hereinafter the same shall apply in this Article) as raw materials for manufacturing products intends to sell such imported food, etc. to other manufacturing or processing businesses because he/she is unable to use the imported food, etc. as raw materials for manufacturing products for reasons of the cessation of business, bankruptcy, or the discontinuance of the use of the relevant raw materials, he/she may obtain approval for any change of purpose pursuant to the proviso to Article 20 (2) 2 of the Act.

(2) Any person who intends to obtain approval for any change of purpose of imported food, etc. pursuant to paragraph (1) shall submit an application for approval for any change of purpose of raw materials for manufacturing products in Form 27, to the head of a Regional Office of Food and Drug Safety to whom he/she has made an import declaration of such imported food, etc., along with the following documents, and obtain his/her approval thereof:

1. A copy of a contract for the quantity which he/she intends to sell to a business entity manufacturing or processing foods, manufacturing food additives, or manufacturing containers or packages under Food Sanitation Act, business entity



manufacturing health functional foods under the Health Functional foods Act, business entity processing livestock products or packaging and handling meat under the Livestock Products Sanitary Control Act;

2. A copy of the authorization or permission document, such as a business permission, and a report on manufacturing items of a person who uses the relevant raw material pursuant to subparagraph 1 (excluding where such documents are confirmed through a computer network);
3. A test or inspection report (limited to a test or inspection report issued by a livestock product testing or inspection agency, or testing or inspection agency specializing in food designated by the Minister of Food and Drug Safety pursuant to Article 6 of the Act on Testing and Inspection in Food and Drug Industry, or testing or inspection agency prescribed by Ordinance of the Prime Minister pursuant to the proviso to paragraph (4) of the aforesaid Article);
4. A copy of a consignment agreement (only applicable where imported food, etc. is imported under a consignment agreement).

(3) Where the head of a Regional Office of Food and Drug Safety approves any change of purpose pursuant to paragraph (2), he/she shall notify the head of an agency authorized to issue business permissions, approve registration or receive reports at the seat of a place of business in which the use of imported food, etc. is approved, and the head of an agency authorized to issue business permissions, approve registration, or receive reports, who have received notification, shall manage the distribution thereof.

(4) Where imported food, etc. falls under any of the following, such imported food, etc. shall not be deemed subject to approval for any change of purpose of the raw material for manufacturing products under paragraph (1):

1. Where he/she uses the raw material he/she has imported for use in manufacturing another producing item or newly developed product;
2. Where he/she supplies the raw material to several manufacturing or processing factories within the same corporation;
3. Where he/she uses the raw material as a raw material for acquiring foreign currency or re - exports the raw material;

4. Where he/she converts the raw material for use other than food.

**Article 29 (Import Declaration of OEM - branded Imported Food, etc.)**

“ Where he/she changes important matters prescribed by Ordinance of the Prime Minister ” in the latter part of Article 20 (4) of the Act means where he/she extends the expiration date.

**Article 30 (Inspection, etc. of Imported Food, etc.)** (1) Where the head of a Regional Office of Food and Drug Safety receives an import declaration pursuant to Article 27 (1), he/she shall conduct an inspection of the relevant imported food, etc. in accordance with methods of inspection prescribed in attached Table 9, and where he/she deems the results of inspection appropriate, he/she shall issue a certificate of confirmation of an import declaration of imported food, etc. (including such certificate of confirmation in electronic form) in Form 28 to a person who has made an import declaration (hereinafter referred to as “ person who has made an import declaration ” ).

(2) Where the head of a Regional Office of Food and Drug Safety receives an import declaration pursuant to Article 27 (2), he/she shall conduct an inspection of the relevant imported food, etc. in accordance with methods of inspection prescribed in attached Table 9, and where he/she deems the results of inspection appropriate, he/she shall issue a certificate of confirmation of an import declaration of imported food, etc. purchased on the Internet by proxy (including such certificate of confirmation in electronic form) in Form 29 to a person who has made an import declaration (hereinafter referred to as “ person who has made an import declaration for purchasing by proxy ” ) .

**Article 31 (Conditional Import Inspection)** (1) The head of a Regional Office of Food and Drug Safety may issue a certificate of confirmation of an import declaration of any of the following imported food, etc. (excluding health functional foods; hereinafter the same shall apply in this Article), by attaching necessary conditions pursuant to the latter part of Article 21 (1) of the Act:

1. Fresh foods:

(a) Live, fresh or refrigerated fishery products;

- (b) Fresh or refrigerated agricultural products or forest products (including where some products have gone bad or rotten, but they can be sorted out).
2. Imported food, etc. urgently imported to coordinate the supply and demand of raw materials or to regulate prices;
  3. Imported food, etc. in which case the Minister of Food and Drug Safety deems the degree of violation of standards for labeling of foods, etc. under Article 10 of the Food Sanitation Act or standards for labeling of livestock products under Article 6 of the Livestock Products Sanitary Control Act insignificant, and such violation may be rectified before imported food, etc. is distributed or sold in markets after customs clearance;
  4. Imported food, etc. subject to random sampling inspection under subparagraph 2 (d) of attached Table 9.
- (2) Any person who makes an import declaration who intends to obtain a certificate of confirmation of an import declaration issued with conditions attached pursuant to paragraph (1) shall submit documents containing the following matters related to the implementation of the relevant conditions, to the head of a Regional Office of Food and Drug Safety, and shall not distribute or sell the relevant imported food, etc. before he/she is notified of the results of inspection or he/she obtains confirmation as to whether he/she has implemented any rectification:
1. Scheduled date of delivery from a bonded warehouse;
  2. The following matters concerning the workplace or storage warehouse for the implementation of conditions:
    - (a) Scheduled date of warehousing;
    - (b) Location;
    - (c) Person in charge of storage.
- (3) Where the head of a Regional Office of Food and Drug Safety in receipt of documents pursuant to paragraph (2) issues a certificate of confirmation of an import declaration with conditions attached, to the relevant person who has made an import declaration, he/she shall immediately send such documents to the head of a Regional Office of Food and Drug Safety having jurisdiction over the workplace or storage warehouse under paragraph (2) 2, or the Mayor of the Metropolitan Autonomous City Mayor, the Governor of the Special Self - Governing Province, or the head of a

Si/Gun/Gu (the head of a Gu refers to the head of an autonomous Gu; hereinafter the same shall apply) and request him/her to perform follow - up management.

(4) The head of a Regional Office of Food and Drug Safety shall conduct inspections of any of the following imported food, etc. pursuant to Article 30 (1), which is subject to declaration for import with conditions attached under paragraph (1), and where it is found adequate as a result of inspection, he/she shall issue a certificate of confirmation of an import declaration of imported food, etc. in Form 28:

1. Imported food, etc. imported by a business entity who has violated conditions of an import declaration;
2. Imported food, etc. notified as inadequate pursuant to Article 34 (1) within the last two years;
3. Imported food, etc. being particularly inspected because information about hazardous food is confirmed.

**Article 32 (Criteria for Classification of Imported Food, etc.)**

Criteria for classification of imported food, etc. under Article 21 (2) of the Act shall be as specified in attached Table 10.

**Article 33 (Disclosure of Results, etc. of Inspections)** (1) The Minister of Food and Drug Safety may disclose the following matters on the website of the Ministry of Food and Drug Safety pursuant to Article 21 (4) of the Act:

1. Information about good importers under Article 26 (1) 1;
2. Information about inspection of imported food, etc. found inadequate as a result of inspection under Article 30 (1): Provided, That the period of disclosure shall be up to six months.

(2) The scope of information to be disclosed under paragraph (1) shall be as follows:

1. In cases falling under paragraph (1) 1: Product name, type of product, importer, foreign food facility, manufacturing country, and the date of registration;
2. In cases falling under paragraph (1) 2: Product name, type of product, foreign food facility, foreign establishment, exporter, manufacturing country, producing country, inadequacy, and the date of determination on inadequacy.

**Article 34 (Follow - up Management of Imported Food, etc.)** (1) The head of a Regional Office of Food and Drug Safety shall issue a notification of inadequacy (including in electronic form) in Forms 30 and 31 on imported food, etc. found inadequate as a result of inspection under Article 30 (1) and (2) to the relevant person who has made an import declaration (where a person who has made an import declaration is a business entity who makes an import declaration of imported food, etc. by proxy, referring to an importer or dealer of imported food, etc. who has entrusted the importation of imported food, etc. by proxy; hereafter the same shall apply in this Article) or a person who has made an import declaration for purchasing imported food, etc. by proxy, respectively, and immediately inform a business entity storing imported food, etc. and the superintendent of the relevant customs of the fact. In such cases, a person who has made an import declaration or person who has made an import declaration for purchasing by proxy in receipt of notification of inadequacy shall take any of the following measures:

1. Returning goods to an exporting country or taking out to other country;
2. Converting for a use as animal feed after obtaining approval from the Minister of Agriculture, Food and Rural Affairs (limited to where imported food, etc. is grain or beans under standards and specifications of food, etc. under Article 7 of the Food Sanitation Act, which may be used as animal feed pursuant to the Control of Livestock and Fish Food Act);
3. Discarding the goods.

(2) The Minister of Food and Drug safety may designate and manage imported food, etc. deemed likely to be converted to other purposes among imported food, etc. whose import declaration has been made pursuant to Article 27 (1) as imported food, etc. subject to distribution management.

(3) Where the head of a Regional Office of Food and Drug Safety receives an import declaration of imported food, etc. subject to distribution management under paragraph (2), he/she shall notify the head of a Regional Office of Food and Drug Safety having jurisdiction over the location of the place of business of a person who has made an import declaration, or the Mayor of the Metropolitan Autonomous City Mayor, the Governor of the Special Self - Governing Province, or the head of a Si/Gun/Gu of the details of such import declaration.

(4) Detailed matters concerning methods, etc. of designating and notifying imported food, etc. subject to distribution management under paragraphs (2) and (3) shall be prescribed and notified by the Minister of Food and Drug Safety.

**Article 35 (Imported Food, etc. Subject to Traceability)** (1) Imported food, etc. subject to traceability under Article 23 (1) of the Act shall be as follows:

1. Baby food (referring to manufactured baby food, manufactured baby food for the growth period, grain - based manufactured baby food, and other baby food);
2. Health functional foods;
3. Manufactured milk products;
4. Imported food, etc. for which a business entity intends to register traceability.

(2) “ Business entities prescribed by Ordinance of the Prime Minister, such as business entities who import infant formula and business entities who import health functional foods which reach a certain amount of sales ” in the proviso to Article 23 (1) of the Act means the following business entities, who import and sell imported food, etc. under paragraph (1) 1 through 3, and the following business entities shall register the traceability of imported food, etc. on the following relevant date:

1. Business entities whose sales of each type of baby food in 2013 is at least one billion won: February 4, 2016;
2. Business entities whose sales of each type of baby food in 2013 is not less than 100 million won nor more than one billion won: December 1, 2016;
3. Business entities whose sales of each type of baby food in 2013 is less than 100 million won, and a business entity who commenced business in 2014: December 1, 2017;
4. Business entities whose sales of each item of health functional foods in 2013 is at least five billion won: February 4, 2016;
5. Business entities whose sales of each item of health functional foods in 2014 is at least one billion won: June 1 2016;
6. Business entities whose annual sales of each item of health functional foods after 2015 is at least one billion won: June 1 of the following year;
7. Business entities whose sales of manufactured milk products in 2015 is at least five billion won: December 1, 2016;

8. Business entities whose sales of manufactured milk products in 2015 is not less than one billion won nor more than five billion won: June 1, 2017;
  9. Business entities whose sales of manufactured milk products in 2015 is not less than 100 million won nor more than one billion won: December 1, 2017;
  10. Business entities whose sales of manufactured milk products in 2015 is less than 100 million won, and business entities who commenced business in 2016: June 1, 2018.
- (3) Detailed standards, etc. for the management of imported food, etc. subject to traceability shall be prescribed and notified by the Minister of Food and Drug Safety.

**Article 36 (Application, etc. for Registration of Traceability)** (1) Any person who intends to register the traceability of imported food, etc. pursuant to Article 23 (1) of the Act shall submit an application for registration of the traceability of imported food, etc. (including in electronic form) in Form 32 to the head of a Regional Office of Food and Drug Safety, along with the following documents (including in electronic form):

1. A copy of a certificate of confirmation of an import declaration of imported food, etc. in Form 28;
2. A plan for traceability of imported food, etc. including matters prescribed and notified by the Minister of Food and Drug Safety.

(2) The items of imported food, etc. subject to registration of traceability shall meet the following requirements:

1. Items of imported food, etc. shall be managed so that information on the history of imported food, etc. at each step from importation to sale thereof may be traced and provided;
2. A follow - up management system concerning the recall, etc. of imported food, etc. at each step from importation to sale thereof shall be established.

(3) The head of a Regional Office of Food and Drug Safety in receipt of an application for registration under paragraph (1) shall examine whether an applicant has a computer system for traceability and items submitted for registration are appropriate for registration under paragraph (2), and where he/she deems imported food, etc. appropriate as a result of the examination thereof, he/she shall register the relevant imported food, etc. item by item and issue a certificate of registration of

traceability of Imported Food, etc. in Form 33.

(4) Any person who has registered traceability (hereinafter referred to as “ person who has registered traceability ” ) pursuant to paragraph (3) shall comply with criteria for the traceability of imported food, etc. prescribed and notified by the Minister of Food and Drug Safety.

**Article 37 (Matters, etc. Registered for Traceability)** (1) Matters to be registered for the traceability of imported food, etc. under Article 23 (1) of the Act shall be as follows:

1. Name and location of the place of business;
2. Product name;
3. Manufacturing country or producing country;
4. Good foreign food facility, foreign establishment, or exporting company.

(2) Any person who intends to report any change in registered matters under paragraph (1) shall report (including in electronic form) any change in matters registered for the traceability of imported food, etc. in Form 34 to the head of a Regional Office of Food and Drug Safety, along with a certificate of registration of the traceability of imported food, etc., within one month from the date a reason for change occurs.

(3) The head of a Regional Office of Food and Drug Safety in receipt of a report of any change pursuant to paragraph (2) shall state any changed matters in a certificate of registration of the traceability of imported food, etc. and deliver such certificate.

**Article 38 (Revocation, etc. of Registration of Traceability)** (1) Criteria for revocation, etc. of registration of the traceability of imported food, etc. under Article 23 (2) of the Act shall be as specified in attached Table 11.

(2) A person deregistered pursuant to paragraph (1) shall return his/her certificate of registration of the traceability of imported food, etc. to the head of the relevant Regional Office of Food and Drug Safety.

**Article 39 (Examinations and Evaluations)** (1) The head of a Regional Office of Food and Drug Safety shall examine and evaluate whether a person who has filed for registration of the traceability of imported food, etc. complies with criteria for traceability, every three years: Provided, That he/she shall examine and evaluate a



person who falls under the proviso to Article 23 (1) of the Act, every two years.

(2) Examinations and evaluations of the traceability of imported food, etc. shall be conducted in accordance with methods of examination of documents and on - site inspection, and examinations and evaluations shall include the following matters:

1. Whether a person who has filed for registration of the traceability of imported food, etc. establishes and operates a computer system for the traceability of imported food, etc.;
2. Whether a person who has filed for registration of the traceability of imported food, etc. complies with criteria for the traceability of imported food, etc.

(3) Detailed matters concerning matters to be examined, methods, etc. of examination and evaluation under paragraph (2) shall be prescribed and notified by the Minister of Food and Drug Safety.

**Article 40 (Recording, Storage, etc.)** (1) A person who has filed for registration of the traceability of imported food, etc. shall record and keep information on the traceability of imported food, etc. in a computer - based recording system in connection with an information system for the traceability of imported food, etc. (hereinafter referred to as “ traceability system ” ) using a food traceability system under Article 49 - 3 of the Food Sanitation Act.

(2) A person who has filed for registration of the traceability of imported food, etc. shall keep records on information on traceability under paragraph (1) for at least two years from the date on which the expiration date, etc. of the relevant product expires.

(3) A person who has filed for registration of the traceability of imported food, etc. shall provide cooperation to enable information recorded and stored pursuant to paragraph (1) to be linked to the traceability system.

**Article 41 (Disclosure of Information)** (1) The Minister of Food and Drug Safety shall enable customers, etc. to easily verify the following information connected to the traceability system on the website of the Ministry of Food and Drug Safety:

1. Traceability number of imported food, etc.;
2. Name and location of the importer;

3. Manufacturing country;
4. Name and location of the manufacturing company;
5. Manufacturing date;
6. Whether imported food, etc. is GMO food;
7. Date of importation;
8. Expiration date or best - by date;
9. Names of raw materials or ingredients;
10. Functionality (only applicable to health functional foods);
11. Whether imported food, etc. is subject to recall and grounds for recall.

(2) Information under paragraph (1) shall be available for confirmation for at least one year from the date the expiration date or best - by date expires.

(3) No person shall use information connected pursuant to paragraph (1) for any purpose other than the traceability of imported food, etc.

**Article 42 (Formulation and Implementation of Distribution Management Plan)**

A distribution management plan under Article 24 (1) of the Act shall include the following matters:

1. Matters relating to the direction - setting for and objectives of a policy for distribution management of imported food, etc.;
2. Matters relating to direction and supervision at each stage of distribution;
3. Matters relating to the collection and inspection of imported food, etc. under distribution;
4. Matters relating to the interception and recall of hazardous imported food, etc. under distribution;
5. Matters relating to sanitation education and public relations concerning imported food, etc. under distribution;
6. Other matters relating to the securing of the safety and quality of imported food, etc. under distribution.

**Article 43 (Access, Inspection, Collection, etc.)** (1) Access, inspection, collection, etc. under Article 25 of the Act shall be implemented as occasion requires where such activities are deemed necessary for public health and sanitation.

(2) Notwithstanding paragraph (1), access to, inspection of, collection from a business establishment subject to administrative disposition imposed pursuant to Article 46 shall be implemented at least once within six months from the date the relevant administrative disposition is imposed: Provided, That the foregoing shall not apply to cases where a business entity subject to administrative disposition reports the results of the implementation of such administrative disposition.

**Article 44 (Quantity of Imported Food Collected, Requests for Inspection, etc.) (1)**

Imported food, etc. that can be collected without compensation pursuant to Article 25 (1) 2 (b) of the Act and the quantity of imported food, etc. collected shall be as specified in attached Table 12.

(2) Where a relevant public official or inspection officer under Article 13 of the Livestock Products Sanitary Control Act (hereinafter referred to as “ relevant public official, etc. ” ) has collected imported food, etc. pursuant to paragraph (1), he/she shall issue a certificate of collection (including a certificate of collection in electronic form) in Form 35.

(3) A relevant public official, etc. who has collected imported food, etc. pursuant to paragraph (1) shall seal the collected imported food, etc. at the place of collection and place thereon the seal, etc. of the relevant public official, etc. and a person subject to the collection thereof.

(4) The Minister of Food and Drug Safety (including the head of a Regional Office of Food and Drug Safety) shall immediately request a livestock product testing and inspection agency or testing and inspection agency specializing in food designated by him/her pursuant to Article 6 of the Act on Testing and Inspection in the Food and Drug Industry, or testing and inspection agency prescribed by Ordinance of the Prime Minister pursuant to the proviso to paragraph (4) of the aforesaid Article to inspect imported food, etc. collected pursuant to paragraph (1).

(5) Where the Minister of Food and Drug Safety (including the head of a Regional Office of Food and Drug Safety) requires relevant public officials, etc. to have access, conduct inspections, or perform collection pursuant to Article 25 (1) of the Act, he/she shall record the details of such activities in the collection and Inspection processing log (including in electronic form) in Form 36 and keep such log.

(6) An identification certificate indicating the authority of a public official who intends to have access, conduct inspections, perform collection or make perusals under Article 25 (3) of the Act shall be as described in Form 37.

**Article 45 (Order to Receive Education concerning Safety of Imported Food, etc.) (1)**

The head of a Regional Office of Food and Drug Safety may order business entities referred to in the subparagraphs of Article 26 (1) of the Act to receive education on the safety and quality control of imported food, etc. at the following institutions or organizations (hereinafter referred to as “ institution that provides education on the safety of imported food ” ):

1. Korea Institute for Food Safety Management Accreditation established under the Food Sanitation Act;
2. Korea Livestock Products HACCP Accreditation Service established under the Livestock Products Sanitary Control Act;
3. Government - funded research institutes established under the Act on the Establishment, Operation, and Fostering of Government - Funded Research Institutes, Etc.;
4. Other institutions or organizations designated by the Minister of Food and Drug Safety.

(2) A business entity (including a person responsible for the sanitation of imported food designated by a business entity) ordered to receive education under Article 26 (1) of the Act shall receive education concerning the following matters for at least three hours at a designated institution that provides education on the safety of imported food within three months:

1. Matters concerning investigating the cause of inadequate imported food, etc. and methods of taking measures for improvement;
2. Matters concerning systems and statutes related to the sanitation of imported food, etc.

(3) An educational institution shall prepare teaching materials and provide persons subject to education with such teaching materials.

(4) An institution that provides education on the safety of imported food shall issue a certificate of completion to persons who have received education, report the results of conducting education to the head of a Regional Office of Food and Drug

Safety within one month after education, and keep and manage records concerning education including a log of certificates of completion issued during for three years.

(5) An institution that provides education on the safety of imported food, etc. may receive actual expenses incurred in providing education, such as tuition payments, expenses incurred in preparing teaching materials and expenses incurred in purchasing office supplies related to education, from persons who receive education.

(6) Detailed matters concerning the operation of education, accounting, etc. of institutions that provide education on the safety of imported food shall be prescribed and notified by the Minister of Food and Drug Safety.

**Article 46 (Guidelines for Administrative Dispositions)**

Guidelines for administrative dispositions imposed pursuant to Articles 27 through 29 of the Act shall be as specified in attached Table 13.

**Article 47 (Cases Exempt from Imposition of Penalty Surcharges)**

Cases exempt from the imposition of penalty surcharges under the proviso to Article 33 (1) of the Act shall be as specified in attached Table 13.

**Article 48 (Issuance of Health Certificates, etc. of Imported Food, etc.)**

Types and procedures for issuance of health certificates, etc. under Article 38 (2) of the Act shall be as specified in attached Table 14.

**Article 49 (Operation of Monitoring Personnel)** (1) The Minister of Food and Drug

Safety may appoint imported food, etc. monitoring personnel from among the following persons pursuant to Article 39 (1) of the Act:

1. Persons who specialize in food, food additives, utensils, containers, packages, health functional foods, or livestock products (hereafter referred to as “ food, etc. ” in this Article);
2. Persons who have worked in an industry related to food, etc. for at least one year;
3. Persons who reside in the relevant country that exports imported food, etc.

(2) Detailed matters necessary for the operation of imported food, etc. monitoring personnel under paragraph (1) shall be prescribed by the Minister of Food and Drug Safety.

**Article 50 (Fees)**

Fees prescribed in Article 41 of the Act shall be as specified in attached Table 15. In such cases, fees may be paid to the relevant institution authorized to approve registrations, grant designation, or conduct inspections by means of revenue stamps, cash, credit card, debit card, or electronic currency or electronic payment using an information and telecommunications network.

**Article 51 (Persons, etc. Exempt from Penalty Provisions)**

“ A person who violates any of the minor matters prescribed by Ordinance of the Prime Minister ” in the proviso to subparagraph 5 of Article 43 of the Act and “ a person who fails to observe a minor matter prescribed by Ordinance of the Prime Minister ” in Article 46 (2) of the Act mean any of the following persons:

1. A person who violates Article 18 (2) of the Act;
2. A person who violates subparagraph 1 (a) or (c), 2 (a), (c), (h), (j), (n), (p) or (q), 3 (a), 4 (a) through (c), (e), or (g) of attached Table 8.

**Article 52 (Amounts of Administrative Fines Imposed)**

“ Amounts prescribed by Ordinance of the Prime Minister ” in subparagraph 2 (b) of attached Table 2 of the Decree means amounts prescribed in attached Table 16.

**ADDENDA** <No. 1253, 04. Feb, 2016 >

**Article 1 (Enforcement Date)**

This Rule shall enter into force on February 4, 2016.

**Article 2 (Applicability to Submission of Export Health Certificate of Livestock Products at Time of Making Import Declaration)**

**Article 27 (1) 8** (only applicable to the part concerning livestock products other than those designated as products subject to quarantine under Article 31 of the Act on the Prevention of Contagious An

**Article 3 (Transitional Measures concerning Registration, etc. of Foreign Food Facilities)**

(1) Even where an importer, etc. under Article 5 (1) of the Act fails to register a foreign food facility pursuant to Article 2, he/she may make an import declaration of imported food, etc. manufactured by the relevant foreign food facility pursuant to

Article 27 for up to six months from the date this Rule enters into force.

(2) Even where a person who established and operates a foreign establishment under Article 12 (1) of the Act fails to register the foreign establishment pursuant to Article 12, an importer, etc. may make an import declaration of livestock products processed at the relevant foreign establishment pursuant to Article 27 for up to six months from the date this Rule enters into force.

**Article 4 (Transitional Measures concerning Imported Food Sanitation Audit Institutions)**

(1) Any institution or organization that conducts on - site sanitary inspection, etc. pursuant to Article 44 (5) 1 of the previous Food Sanitation Act before this Rule enters into force shall be deemed designated as an imported food sanitation audit institution pursuant to Article 7 (1): Provided, That the scope of its affairs shall be limited to sanitation audits, etc. under Article 18 (2) of the Act.

(2) Any institution or organization deemed designated as an imported food sanitation audit institution pursuant to paragraph (1) shall meet requirements for designation under Article 7 (1) 2 and attached Table 3, within one year from the date this Rule enters into force.

(3) Where any institution or organization deemed designated as an imported food sanitation audit institution pursuant to paragraph (1) meets requirements for designation pursuant to paragraph (2), the scope of its affairs shall be limited to on - site inspections under Articles 6 through 8 of the Act and sanitation audits, etc. under Article 18 (2) of the Act pursuant to Article 9 (1) of the Act.

**Article 5 (Transitional Measures concerning Facility Standards for Business Entities Importing and Selling Imported Food, etc.)**

(1) A business entity importing health functional foods under subparagraphs 2 of Article 2 of the previous Enforcement Decree of the Health Functional Foods Act who is deemed a business entity importing and selling imported food, etc. under Article 14 (1) 1 of the Act pursuant to Article 2 (1) of the Addenda to the Special Act on Imported Food Safety Control (Act No. 13201), as at the time this Rule enters into force, shall meet facility standards prescribed in Article 15 (1) and subparagraph 1 of attached Table 7, within one year from the date this Rule enters into force.

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**Article 6 (Transitional Measures concerning Educational Institutions)**

(1) The following institutions existing as at the time this Rule enters into force shall be deemed institutions that provide sanitary education designated pursuant to Article 22 (1):

1. Institutions that provide education on food sanitation under Article 51 (1) of the Enforcement Rule of the Food Sanitation Act;
2. Institutions that conduct education under Article 18 (1) of the Enforcement Rule of the Health Functional foods Act;
3. Institutions that provide sanitation education under Article 47 (1) of the Enforcement Rule of the Livestock Products Sanitary Control Act.

(2) An institution that provides education on food safety under Article 15 - 7 (1) of the former Enforcement Rule of the Food Sanitation Act as at the time this Rule enters into force shall be deemed an institution that provides education on the safety of imported food under Article 45 (1).

**Article 7 Omitted.**

**Article 8 (Relationship to Other Acts and Subordinate Legislation)**

Where the previous Enforcement Rule of the Food Sanitation Act, the previous Enforcement Rule of the Health Functional foods Act, the previous Enforcement Rule of the Livestock Products Sanitary Control Act, or any provision thereof is cited by other Acts and subordinate legislation as at the time this Rule enters into force, and also this Rule contains provision corresponding thereto, this Rule or the corresponding provision of this Rule shall be deemed cited in lieu of the previous Enforcement Rule of the Food Sanitation Act, the previous Enforcement Rule of the Health Functional foods Act, the previous Enforcement Rule of the Livestock Products Sanitary Control Act, or the relevant provision thereof.