

Regulations for Enforcement of the Food Sanitation Act

(Order of the Ministry of Health and Welfare No. 23 of July 13, 1948)

The Regulations for Enforcement of the Food Sanitation Act is established as follows.

Table of Contents

Chapter I Food, Additives, Apparatus, and Containers and Packaging (Articles 1 through 20)

Chapter II Monitoring and Guidance (Article 21)

Chapter III Deleted

Chapter IV Product Inspections (Articles 24 through 31)

Chapter V Import Notification (Articles 32 through 34)

Chapter VI Food Sanitation Inspection Facilities (Articles 35 through 37)

Chapter VII Registered Inspection Bodies (Articles 38 through 47)

Chapter VIII Business (Articles 48 through 71-2)

Chapter IX Miscellaneous Provisions (Articles 72 through 79)

Supplementary Provisions

Chapter I Food, Additives, Apparatus, and Containers and Packaging

Article 1 Cases in which there is no risk of endangering human health under the provisions of the proviso to Article 6, item (ii) of the Food Sanitation Act (Act No. 233 of 1947; hereinafter referred to as "the Act") are as follows:

- (i) toxic or harmful substances that are naturally contained in or attached to food or additives and are not generally considered hazardous to human health depending on the dose or through treatment;
- (ii) when it is unavoidable to mix or add toxic or harmful substances in the process of producing food or additives and it is found to generally involve no risk to human health.

Article 2 An application for cancellation under the provisions of Article 7, paragraph (4) of the Act is to be filed by submitting a written application to the Minister of Health, Labour and Welfare stating the matters set forth in the following items, attaching documents proving that there is no longer any risk of food sanitation hazards resulting from the food or objects for which the application for the cancellation is filed:

- (i) the address and name of the applicant (for a corporation, its name, the

- location of its principal office, and the name of its representative);
- (ii) the scope of the food or objects for which the application for cancellation is filed;
- (iii) the reason that there is no risk of food sanitation hazards resulting from the food or objects related to the prohibition, and other matters that the Minister of Health, Labour and Welfare finds necessary.

Article 2-2 (1) A person who seeks to make a notification under the provisions of Article 8, paragraph (1) of the Act is to make the notification by submitting a written notification to a prefectural governor, mayor of a city establishing health centers, or director of a special ward (hereinafter referred to as "prefectural governor, etc.") stating the following matters (excluding items (iv) through (vii) in the case of making a notification when food containing designated ingredients, etc. is likely to cause harm to human health); provided, however, that when it is difficult to obtain the information on the person who has suffered damage to their health due to refusal to provide the information or other circumstances, statement of the matters set forth in items (iv) through (vii) is not required.

- (i) the date on which information that food containing designated ingredients, etc., has caused or is likely to cause harm to human health has been obtained;
 - (ii) the product name of the food containing designated ingredients, etc.;
 - (iii) the content of designated ingredients, etc.;
 - (iv) the sex, age, consumption status of food containing designated ingredients, etc., and symptoms related to the damage to the health of the person who has suffered damage;
 - (v) if the person who has suffered damage to their health is visiting a medical institution, the name and location of the medical institution;
 - (vi) the results of diagnosis at the medical institution referred to in the preceding item;
 - (vii) the names of the pharmaceuticals, etc., used when consuming food containing designated ingredients, etc., if any; and
 - (viii) other necessary matters.
- (2) The notification referred to in Article 8, paragraph (1) of the Act may be made through a person responsible for the content of the labeling of food containing designated ingredients, etc.

Article 3 (1) The grounds specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 9, paragraph (1) of the Act are as follows:

- (i) regarding specific food or additives which are collected, produced, processed, cooked, or stored in a specific country or region, or which are collected,

produced, processed, cooked, or stored by a specific person (hereinafter referred to as "specific foods, etc."), the results of inspections under Article 26, paragraphs (1) through (3) of the Act or Article 28, paragraph (1) of the Act, or inspections conducted by a business person in accordance with the administrative guidance (meaning administrative guidance provided for in Article 2, item (vi) of the Administrative Procedure Act (Act No. 88 of 1993); the same applies in Article 17, paragraph (1), item (i) provided by the State, prefectures, cities specified by Cabinet Order based on the provisions of Article 5, paragraph (1) of the Community Health Act (Act No. 101 of 1947) (hereinafter referred to as "cities establishing health centers") or special wards show that the total number of objects falling under food or additives set forth in each item of Article 9, paragraph (1) of the Act accounts for approximately 5% or more of the total number of food or additives covered by the inspections;

- (ii) the content of regulations and measures concerning food sanitation for specific foods, etc., in a country or region where the specific foods, etc., are collected, produced, processed, cooked, or stored, the inspection system and other systems for food sanitation management related to the specific foods, etc., by the government of the country or region, or local public entities, etc., the results of inspections of the specific foods, etc., conducted by the government of the country or region, or local public entities, etc., and other status of food sanitation management related to the specific foods, etc., in the country or region;
 - (iii) regarding specific foods, etc., the fact that food poisoning or other damage caused to the health or suspected to have been caused by the specific foods, etc., has occurred;
 - (iv) regarding specific foods, etc., a situation in which the specific foods, etc., have been contaminated or are likely to be contaminated has occurred.
- (2) The provisions of the preceding paragraph apply *mutatis mutandis* to the grounds specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 9, paragraph (1) of the Act as applied *mutatis mutandis* pursuant to Article 68, paragraph (1) of the Act. In such a case, the term "food or additives" in item (i) of the preceding paragraph is deemed to be replaced with "toys", the term "specific foods, etc." in that item and items (ii) and (iv) of that paragraph is deemed to be replaced with "specific toys", the term "regarding specific foods, etc." in item (iii) of that paragraph is deemed to be replaced with "regarding specific toys", and the term "food poisoning or other damage caused to the health or suspected to have been caused by the specific foods, etc." in that item is deemed to be replaced with "other damage caused by or suspected to have been caused by the specific toys".

Article 4 (1) The matters specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 9, paragraph (1) of the Act are as follows:

- (i) the level of risk that specific foods, etc. may have in harming human health;
- (ii) the matters set forth in each item of paragraph (1) of the preceding Article;
- (iii) the possibility that specific foods, etc., falling under food or additives set forth in each item of Article 9, paragraph (1) of the Act may continue to be sold, or collected, produced, imported, processed, used, or cooked for the purpose of sale; and
- (iv) the effects that methods other than the prohibition under the provisions of Article 9, paragraph (1) of the Act are expected to have for preventing food sanitation hazards resulting from specific foods, etc.

(2) The provisions of the preceding paragraph apply mutatis mutandis to the matters specified by the Ministry of Health, Labour and Welfare provided for in Article 9, paragraph (1) of the Act as applied mutatis mutandis pursuant to Article 68, paragraph (1) of the Act. In such a case, the term "specific foods, etc." in items (i), (iii) and (iv) of the preceding paragraph is deemed to be replaced with "specific toys", and the term "food or additives" in item (iii) of that paragraph is deemed to be replaced with "toys".

Article 5 (1) When the Minister of Health, Labour and Welfare is to confirm that there is no risk of food sanitation hazards resulting from the specific foods, etc. in canceling the prohibition for specific foods, etc., provided for in Article 9, paragraph (1) of the Act, based on an application from a person that has an interest or as necessary, pursuant to the provisions of paragraph (3) of that Article, the Minister must take into account the matters set forth in each item of paragraph (1) of the preceding Article with regard to the specific foods, etc., for the cancellation of the prohibition.

(2) The provisions of the preceding paragraph apply mutatis mutandis to the case in which the prohibition under Article 9, paragraph (1) of the Act is canceled pursuant to the provisions of paragraph (3) of that Article as applied mutatis mutandis pursuant to Article 68, paragraph (1) of the Act. In such a case, the term "specific foods, etc." in the preceding paragraph is deemed to be replaced with "specific toys".

Article 6 (1) An application for cancellation under the provisions of Article 9, paragraph (3) of the Act is to be filed by submitting a written application stating the matters set forth in the following items to the Minister of Health, Labour and Welfare, attaching documents proving that there is no longer any risk of food sanitation hazards resulting from the food or additives for which application for the cancellation is filed:

- (i) the address and name of the applicant (for a corporation, its name, the

- location of its principal office, and the name of its representative);
- (ii) the scope of the food or additives for which the application for cancellation is filed; and
 - (iii) other matters that the Minister of Health, Labour and Welfare finds necessary.
- (2) The provisions of the preceding paragraph apply mutatis mutandis to an application for cancellation under the provisions of Article 9, paragraph (3) of the Act as applied mutatis mutandis pursuant to Article 68, paragraph (1) of the Act. In such a case, the term "food or additives" in the preceding paragraph is deemed to be replaced with "toys".

- Article 7 (1) The livestock specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 10, paragraph (1) of the Act are buffaloes.
- (2) The cases specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 10, paragraph (1) of the Act are as follows:
- (i) if, with regard to livestock that have been found to have any diseases set forth in the left-hand column of the Appended Table 5 of the Enforcement Regulation of the Slaughterhouse Act (Order of the Ministry of Health and Welfare No. 44 of 1953) or any of the disorders set forth in that column, the necessary measures, such as disposal, have been taken to prevent the parts set forth respectively in the right-hand column of that Table from being served for consumption;
 - (ii) if, with regard to diseases or disorders referred to in the left-hand column of the Appended Table 10 of the Enforcement Regulation of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act (Order of the Ministry of Health and Welfare No. 40 of 1990), measures such as disposal of the parts set forth in the right-hand column of that Table have been taken, as a result of the inspections after evisceration referred to in Article 33, paragraph (1), item (iii) of that Order.
- (3) The case in which the relevant employees find that the livestock pose no risk to human health and are edible pursuant to the provisions of the proviso to Article 10, paragraph (1) of the Act is when healthy livestock have died instantly due to an unforeseen disaster.

- Article 8 The products specified by Order of the Ministry of Health, Labour and Welfare referred to in Article 10, paragraph (2) of the Act are as follows:
- (i) processed meat products;
 - (ii) milk (meaning milk provided for in Article 2, paragraph (1) of the Ministerial Order on Milk and Milk Products Concerning Compositional Standards, etc. (Order of the Ministry of Health and Welfare No. 52 of 1951) excluding products preservable at ordinary temperature provided for in

Subsection (1)-3 of Section (2) ingredient standards for cow milk, certified milk, sterilized goat milk, homogenized milk, low-fat milk, fat-free milk, and processed milk and the standards for production and preservation methods of the Appended Table 2 ingredient standards for milk, etc., and the standards for production, cooking, and preservation methods of that Order; the same applies in the following Article, items (i), (ix), and (x)) and milk products (meaning milk products provided for in Article 2, paragraph (12) of the same Order excluding butter oil, cheese (limited to processed cheese), ice cream, formulated milk powder, formulated milk liquid, lactic acid bacteria beverage, and milk beverage; the same applies in the following Article, items (ix) and (x)).

Article 9 The matters specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 10, paragraph (2) of the Act are as follows:

- (i) for the meat or organs of livestock or poultry, the types of livestock or poultry, and for the products provided for in the preceding Article, the names and the types of the meat, milk, or organs for raw material;
- (ii) the quantity and weight;
- (iii) the address and name of the shipper (for a corporation, its name and location);
- (iv) the address and name of the consignee (for a corporation, its name and location);
- (v) for the meat or organs of livestock or poultry (excluding those divided or chopped), the following matters concerning the name, etc. of the organization which conducted the inspections:
 - (a) for livestock, the name of the organization which conducted the slaughtering inspections (meaning a biopsy before slaughtering and inspections before and after dressing; the same applies hereinafter), or the name and government position of the employee who conducted the slaughtering inspections;
 - (b) for poultry, the name of the organization which conducted the poultry inspections (meaning a biopsy and inspections after plucking and evisceration; the same applies hereinafter), or the name and government position of the employee who conducted the poultry inspections;
- (vi) the name and location of facilities where the following processes such as slaughtering were carried out:
 - (a) for the meat or organs of livestock (excluding those divided or chopped), the slaughterhouse where the slaughtering or dressing was carried out;
 - (b) for the meat or organs of poultry (excluding those divided or chopped), the poultry slaughterhouse where the slaughtering, plucking, and evisceration was carried out;

- (c) for the meat or organs of livestock or poultry divided or chopped, the facility where the processes were carried out;
- (d) for the products provided for in the preceding Article, the production facility where the products were produced;
- (vii) the fact that processing or production, such as the slaughtering, dressing, plucking, evisceration, dividing, and chopping, provided for in (a) through (d) of the preceding item was carried out in a sanitary manner based on the criteria equal to or better than those of Japan;
- (viii) the date on which any of the following processes such as slaughtering were carried out:
 - (a) for the meat or organs of livestock (excluding those divided or chopped), the slaughtering and slaughtering inspections;
 - (b) for the meat or organs of poultry (excluding those divided or chopped), the slaughtering and poultry slaughtering inspections;
 - (c) for the meat or organs of livestock or poultry divided or chopped, those processes;
 - (d) for the products provided for in the preceding Article, the production of the relevant products.
- (ix) for milk or dairy products, the fact that production was carried out in a sanitary manner based on the criteria equal to those of Japan;
- (x) for milk or dairy products, the name of the governmental organization of the exporting country which issued the certificate provided for in Article 10, paragraph (2) of the Act or the name and government position of the employee who signed the certificate.

Article 10 When certificates set forth in Article 10, paragraph (2) of the Act are for the meat or organs of livestock or poultry whose slaughtering inspections or poultry slaughtering inspections have been conducted in a country other than the exporting country, a transcript of the certificates stating the matters provided for in the preceding Article which have been issued by a governmental organization of the country that conducted the slaughtering inspections or poultry slaughtering inspections must be attached to the certificates set forth in that paragraph.

Article 11 The countries specified by Order of the Ministry of Health, Labour and Welfare as referred to in the proviso to Article 10, paragraph (2) of the Act are the United States of America, Australia, and New Zealand.

Article 11-2 (1) Food or additives specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 11, paragraph (1) of the Act are the meat and organs of livestock and poultry.

- (2) Food or additives specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 11, paragraph (2) of the Act are oysters and pufferfish to be eaten raw.
- (3) The matters specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 11, paragraph (2) of the Act are as follows:
- (i) the name of the food to be imported (for pufferfish, including its scientific name);
 - (ii) the quantity and the weight of food to be imported;
 - (iii) the sea area from which foods to be imported were collected;
 - (iv) the date when foods to be imported were collected;
 - (v) the name and location of the facility that processed the foods to be imported;
 - (vi) the address and name of the shipper (for a corporation, its name and location);
 - (vii) the address and name of the consignee (for a corporation, its name and location);
 - (viii) the fact that foods to be imported were handled in a sanitary manner based on the criteria equal to or better than those of Japan.

Article 12 Additives involving no risk to human health under the provisions of Article 12 of the Act are as set forth in the Appended Table 1.

Articles 13 through 16 Deleted

- Article 17 (1) The grounds specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 17, paragraph (1) of the Act are as follows:
- (i) regarding specific apparatus or containers and packaging which are produced in a specific country or region, or which are produced by a specific person (hereinafter referred to as "specific apparatus, etc."), the results of inspections under the provisions of Article 26, paragraphs (1) through (3) of the Act or Article 28, paragraph (1) of the Act, or inspections conducted by a business person in accordance with administrative guidance provided by the State, prefectures, cities establishing health centers, or special wards show that the total number of objects falling under apparatus or containers and packaging set forth in each item of Article 17, paragraph (1) of the Act accounts for approximately 5% or more of the total number of apparatus or containers and packaging covered by the inspections;
 - (ii) the content of regulations and measures concerning food sanitation for specific apparatus, etc., in a country or region where the specific apparatus, etc., is produced, the inspection system and other systems for food sanitation management related to the specific apparatus, etc., by the government of the

country or region, or local public entities, etc., the results of inspections with regard to the specific apparatus, etc., by the government of the country or region, or local public entities, etc., and other status of food sanitation management related to the specific apparatus, etc., in the country or region;

(iii) regarding specific apparatus, etc., the damage to health caused by or suspected to have been caused by the specific apparatus, etc., has occurred;

(iv) regarding specific apparatus, etc., a situation that contaminates or is likely to contaminate the specific apparatus, etc. has occurred.

(2) The provisions of the preceding paragraph apply *mutatis mutandis* to the grounds specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 17, paragraph (1) of the Act as applied *mutatis mutandis* pursuant to Article 68, paragraph (1) of the Act.

Article 18 (1) The matters specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 17, paragraph (1) of the Act are as follows:

(i) the level of the risk that specific apparatus, etc., may harm human health;

(ii) the matters set forth in each item of paragraph (1) of the preceding Article;

(iii) the possibility that specific apparatus, etc., falling under the apparatus or containers and packaging set forth in each item of Article 17, paragraph (1) of the Act may continue to be sold, or produced, or imported for the purpose of sale, or used in business;

(iv) the effects that methods other than the prohibition provided for in Article 17, paragraph (1) of the Act are expected to have for preventing food sanitation hazards resulting from specific apparatus, etc.

(2) The provisions of the preceding paragraph apply *mutatis mutandis* to the grounds specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 17, paragraph (1) of the Act as applied *mutatis mutandis* pursuant to Article 68, paragraph (1) of the Act.

Article 19 (1) When the Minister of Health, Labour and Welfare is to confirm that there is no risk of food sanitation hazards resulting from the specific apparatus, etc. in canceling the prohibition related to specific apparatus, etc., provided for in Article 17, paragraph (1) of the Act, based on an application from a person that has an interest or as necessary, pursuant to the provisions of Article 9, paragraph (3) of the Act as applied *mutatis mutandis* pursuant to Article 17, paragraph (3) of the Act following the deemed replacement of terms, the Minister must take into account the matters set forth in each item of paragraph (1) of the preceding Article with regard to the specific apparatus, etc., related to the cancellation of the prohibition.

(2) The provisions of the preceding paragraph apply *mutatis mutandis* to the case in which the prohibition under the provisions of Article 17 paragraph (1) of the

Act which is applied mutatis mutandis pursuant to Article 68, paragraph (1) of the Act, is canceled pursuant to the provisions of Article 9, paragraph (3) of the Act which is applied mutatis mutandis pursuant to Article 17, paragraph (3) of the Act following the deemed replacement of terms as applied mutatis mutandis pursuant to Article 68, paragraph (1) of the Act.

Article 20 (1) An application for cancellation under the provisions of Article 9, paragraph (3) of the Act which is applied mutatis mutandis pursuant to Article 17, paragraph (3) of the Act following the deemed replacement of terms is to be filed by submitting a written application stating the matters set forth in the following items to the Minister of Health, Labour and Welfare, attaching documents proving that there is no longer any risk of food sanitation hazards resulting from the apparatus or containers and packaging for which the application for the cancellation is filed:

- (i) the address and name of the applicant (for a corporation, its name, the location of its principal office, and the name of its representative);
- (ii) the scope of the apparatus or containers and packaging for which the application for cancellation is filed; and
- (iii) other matters that the Minister of Health, Labour and Welfare finds necessary.

(2) The provisions of the preceding paragraph apply mutatis mutandis to an application for cancellation under the provisions of Article 9, paragraph (3) of the Act as applied mutatis mutandis pursuant to Article 17, paragraph (3) of the Act following the deemed replacement of terms as applied mutatis mutandis pursuant to Article 68, paragraph (1) of the Act.

Chapter II Monitoring and Guidance

Article 21 The wide-area cooperation council referred to in Article 21-3, paragraph (1) of the Act is to consist of the Regional Bureau of Health and Welfare, the prefectural government within the jurisdictional district of the Regional Bureau of Health and Welfare, and the cities and special wards which establish health centers, established for each jurisdictional district of the Regional Bureaus of Health and Welfare.

Chapter III Deleted

Articles 22 and 23 Deleted

Chapter IV Product Inspections

Article 24 An application for inspection referred to in Article 25, paragraph (1) of the Act is to be filed by submitting a written application stating the following matters for each product constituting a lot:

- (i) the name and address of the applicant (for a corporation, its name, its location, and the name of its representative);
- (ii) the names of the products;
- (iii) the name and location of the production facility;
- (iv) the name of the food sanitation supervisor;
- (v) the date of production;
- (vi) the quantity for the application.
- (vii) the number of units by capacity of each packet;
- (viii) when inspections have been conducted by the producer, the results of the inspections.

Article 25 The collection of test samples under the provisions of Article 4, paragraph (3) of the Order for Enforcement of the Food Sanitation Act (Cabinet Order No. 229 of 1953; hereinafter referred to as "the Order") is to be made for each product constituting a lot, and the amount to be collected is to be the minimum amount necessary for the inspections.

Article 26 The labeling specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 25, paragraph (1) of the Act is to be conducted by sealing the containers and packaging of the products with certificates prepared according to Form No. 1.

Article 27 The matters specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 5, paragraph (1) of the Order are as follows:

- (i) the name and address of the person who is to receive inspections (for a corporation, its name, the location of its principal office, and the name of its representative);
- (ii) the names of the products which are to receive inspections;
- (iii) the name and location of the production or processing facility;
- (iv) the period for the production or processing of the products which are to receive inspections;
- (v) specific reasons to order a person to receive inspections.

Article 28 (1) An application for inspections referred to in Article 26, paragraph (1) of the Act is to be filed by submitting a written application stating the following matters for each product constituting a lot:

- (i) the name and address of the applicant (for a corporation, its name, the location of its principal office, and the name of its representative);

- (ii) the names of the products;
 - (iii) the name and location of the production or processing facility;
 - (iv) the date of production or processing;
 - (v) the quantity for the application.
- (2) The written application under the preceding paragraph must have a transcript of a written inspection order referred to in Article 5, paragraph (1) of the Order attached; provided, however, that this does not apply to the case in which an application for inspections has already been filed for the same order and a copy of a written inspection order has already been submitted.

Article 29 (1) An application for inspections referred to in Article 26, paragraph (2) of the Act is to be filed by submitting a written application stating the following matters:

- (i) the name and address of the applicant (for a corporation, its name and the location of its principal office);
 - (ii) the names of the products;
 - (iii) the name and address of the producer or processor (for a corporation, its name and the location of its principal office);
 - (iv) the name and location of the production or processing facility;
 - (v) the date of arrival of the products at the port;
 - (vi) the location of the storage site; and
 - (vii) the quantity for the application.
- (2) The written application under the preceding paragraph must have a copy of a written inspection order (when the Minister of Health, Labour and Welfare has issued a notice of inspection order using an electronic data processing system pursuant to the provisions of Article 34, paragraph (1), a document on which the content of the order is output) attached.

Article 30 The provisions of the preceding Article apply mutatis mutandis to an application for inspections under Article 26, paragraph (3) of the Act. In such a case, the term "matters" in paragraph (1) of that Article is deemed to be replaced with "matters (for an application for inspections of food other than processed food, excluding the matters set forth in item (iii))", and the term "location" in item (iv) of that paragraph is deemed to be replaced with "location (for an application for inspections of food other than processed food, the place of production of the food)".

Article 31 The payment of the fee for receiving inspections by the Minister of Health, Labour and Welfare is to be made by affixing a revenue stamp for the amount specified by the Minister of Health, Labour and Welfare under Article 25, paragraph (2) of the Act or Article 26, paragraph (6) of the Act to a written

application set forth in Article 4, paragraph (2) or Article 6, paragraph (1) of the Order (including as applied mutatis mutandis pursuant to Article 7 of the Order).

Chapter V Import Notification

Article 32 (1) A person specified in Article 27 of the Act (including as applied mutatis mutandis pursuant to Article 68, paragraph (1) of the Act; the same applies in paragraph (7), paragraph (8), and the following Article) (the person is referred to as an "importer" in item (xi), the following paragraph, and paragraphs (4) and (5)) must state the following matters in a written import notification (when submitting a written import notification prior to the carrying in of cargoes to the inventory location (hereinafter referred to as "carrying in" in this paragraph), excluding the matters set forth in item (xiv)) and submit the notification to the head of a quarantine station set forth in the right-hand column of the Appended Table 11 for the places set forth in the respective left-hand column of that Table on and after seven days prior to the planned arrival date of the cargoes (when an accident concerning the cargoes is suspected to have occurred, after the carrying in), except in cases where the person seeks to import food set forth in the Appended Table 10; provided, however, that when submitting a written import notification prior to the carrying in and an accident concerning the cargoes has occurred, a written notification stating the outline of the accident must be submitted to the head of the quarantine station immediately after the carrying in:

- (i) the name and address (for a corporation, its name and the location of its principal office);
- (ii) whether the cargoes are food, additives, apparatus, containers and packaging, or toys, the names of the articles, loaded quantity, loaded weight, type of packaging, and intended use, and when the cargoes have any marks and numbers affixed, the marks and numbers;
- (iii) when the cargoes are food containing additives which are used for purposes other than for flavoring (for food which is generally served for consumption and is used as an additive, limited to those for which criteria or standards have been established pursuant to the provisions of Article 13, paragraph (1) of the Act), the name of the additives;
- (iv) when the cargoes are processed food, its raw materials and production or processing methods;
- (v) when the cargoes are those set forth in the right-hand column of the Appended Table 17 of the Food Labeling Standards (Cabinet Office Order No. 10 of 2015) as those in which recombinant DNA or the resultant protein remains even after processing procedures are taken (including processed food

- for business use provided for in Article 2, paragraph (1), item (iii) of that Cabinet Office Order), the matters provided for respectively in 1-1 through 3 of the right-hand column in accordance with the cases provided for in 1-1 through 3 of the right-hand column of the row for processed food set forth in the right-hand column of Appended Table 17 and the middle column of Appended Table 18 in the table of Article 3, paragraph (2) of that Cabinet Office Order (excluding the case in which the labeling concerning genetic recombination of the raw material provided for in 5 of that column is not required pursuant to the provisions of the main clause of 5 of that column);
- (vi) when cargoes are target agricultural products provided for in Article 2, paragraph (1), item (xiv) of the Food Labeling Standards, matters provided for respectively in 1-1-(a) or (b) of the right-hand column in accordance with the cases provided for in 1-1-(a) or (b) of the right-hand column of the row of the target agricultural products in the table of Article 18, paragraph (2) of that Cabinet Office Order;
 - (vii) when cargoes are additives, and the additives are preparations containing the additives (excluding those used for flavoring and those generally served for consumption which are used as additives), the ingredients;
 - (viii) when cargoes are apparatus, containers and packaging, or toys, the materials;
 - (ix) the name and address of the producer or processor of the cargoes (excluding food other than processed food) (for a corporation, its name and the location of its principal office);
 - (x) the name and location of the production or processing facility of the cargoes (in the case of food other than processed food, the place of production), the loading port, loading date, unloading port, and arrival date of the cargoes;
 - (xi) the name and address (for a corporation, its name and the location of its principal office) of the exporter (meaning a person who exports cargoes to the importer) of the cargoes (limited to foods other than processed foods; hereinafter the same applies in this item) and the name and address (for a corporation, its name and the location of its principal office) of the person who packages the cargoes (limited to when the cargoes are packaged);
 - (xii) the name or flight number of the ship or aircraft loaded with the cargoes;
 - (xiii) the name and location of the warehouse where the cargoes have been stored and the date of delivery;
 - (xiv) whether there have been any accidents concerning the cargoes, and the outline of the accident, if any.
- (2) An importer must, when there have been any changes to the matters set forth in items (x) through (xiii) of the preceding paragraph (for the matters set forth in item (x), limited to the unloading port and the arrival date), immediately submit a written notification to that effect to the head of the quarantine

station referred to in that paragraph.

- (3) When genetically modified agricultural products (meaning those provided for in the Food Labeling Standards Article 2, paragraph (1), item (xv); hereinafter the same applies in this paragraph) or non-genetically modified agricultural products (meaning those provided for in item (xvi) of that paragraph) have been unintentionally mixed into to a certain degree in spite of conducting identity preserved handling (meaning the handling provided for in item (xix) of that paragraph), if the confirmation under 1-1 or 3 in the right-hand column of the row of processed foods set forth in the right-hand column of Appended Table 17 and the middle-hand column of Appended Table 18 in the table of Article 3, paragraph (2) of that Order or in 1-1-(a) in the right-hand column of the row of target agricultural products in the table of Article 18, paragraph (2) has been appropriately made, the provisions of paragraph (1) are applied, deeming that identity preserved handling has been confirmed to have been conducted.
- (4) When an importer imports food, additives, apparatus, containers and packaging set forth in the middle column of the Appended Table 12 (hereinafter referred to as "food, etc." in this Article) and has submitted a written import notification stating the import plans for the same products as the food, etc. or equivalent products (hereinafter referred to as "the same food, etc.") for a period set forth in the right-hand column of that Table (the plans for the loaded weight, unloading port, and arrival date of the cargoes related to the import planned for that period; the same applies hereinafter), the submission, notwithstanding the provisions of the main clause of paragraph (1), may replace the submission of a written import notification under paragraph (1) with regard to the import of the same food, etc., planned for the period; provided, however, that this does not apply to the case in which the food, etc., related to the import falls under or is suspected to fall under any of the following items:
- (i) food or additives set forth in each item of Article 6 of the Act;
 - (ii) food or additives provided for in Article 12 of the Act;
 - (iii) food or additives which do not conform to the criteria established pursuant to the provisions of Article 13, paragraph (1) of the Act;
 - (iv) food or additives which do not conform to the standards established pursuant to the provisions of Article 13, paragraph (1) of the Act;
 - (v) food in which substances that are the ingredients of agricultural chemicals (meaning agricultural chemicals provided for in Article 2, paragraph (1) of the Agricultural Chemicals Regulation Act (Act No. 82 of 1948), the same applies hereinafter), substances that are used by being added, mixed, or infiltrated into feed (meaning feed provided for in Article 2, paragraph (2) of the Act on Safety Assurance and Quality Improvement of Feeds (Act No. 35

- of 1953)) or are used by other methods for feeds for the purpose of providing them for usage specified by Order of the Ministry of Agriculture, Forestry and Fisheries based on Article 2, paragraph (3) of that Act, and pharmaceutical products that are provided for in Article 2, paragraph (1) of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960) and that are to be used for animals (including substances chemically generated from the substances and excluding substances that are specified as clearly having no risk to human health pursuant to the provisions of Article 13, paragraph (3) of the Act) remain in a quantity exceeding the quantity specified as having no risk to human health pursuant to the provisions of Article 13, paragraph (3) of the Act (excluding cases where standards concerning the ingredients of food under Article 13, paragraph (1) of the Act have been established with regard to the residual limit of those substances in the food);
- (vi) apparatus or containers and packaging provided for in Article 16 of the Act;
- (vii) apparatus or containers and packaging which do not conform to the standards established pursuant to the provisions of Article 18, paragraph (1) of the Act;
- (5) In the case referred to in the preceding paragraph, an importer of food, etc., set forth in the middle column of paragraph (3) of the Appended Table 12 must submit a written import notification stating the import plans provided for in the preceding paragraph, by entering the past record of imports of the same food, etc., during the three years before the date of submission of the written import notification (the past record means the name of the importer related to the import carried out during that period (for a corporation, its name), the loaded weight, unloading port, and arrival date of the cargoes).
- (6) In the case referred to in the main clause of paragraph (4), the phrase "when submitting a written import notification prior to the carrying in" in the proviso to paragraph (1) is deemed to be replaced with "related to the import" and the term "the head of the quarantine station" is deemed to be replaced with "the head of a quarantine station set forth in the right-hand column of the Appended Table 11 for the places set forth in the respective left-hand column of that Table".
- (7) The Minister of Health, Labour and Welfare may have a person make a notification under the provisions of Article 27 of the Act using an electronic data processing system (meaning an electronic data processing system that connects a computer (including input-output devices; the same applies hereinafter) used by the Ministry of Health, Labour and Welfare and an input-output device used by a person who seeks to make a notification under the provisions of that Article via a telecommunications line; hereinafter the same

applies in this Chapter).

- (8) With regard to the application of the provisions of paragraphs (1) and (2) to a person who seeks to make a notification under the provisions of Article 27 of the Act using an electronic data processing system, the phrase "state the following matters in a written import notification" is deemed to be replaced with "state the following matters," the phrase "when submitting a written import notification" is deemed to be replaced with "when the person records the matters in a file by inputting them through input-output devices set forth in paragraph (7) (limited to those used by a person who seeks to make the notification; hereinafter the same applies in this paragraph and the following paragraph)", the phrase "and submit the notification to the head of a quarantine station set forth in the right-hand column of the Appended Table 11 for the places set forth in the respective left-hand column of that Table" is deemed to be replaced with "in a file by inputting them through input-output devices", the phrase "when submitting a written import notification prior to the carrying in" in the proviso to paragraph (1) is deemed to be replaced with "when recording the matters in a file by inputting them through input-output devices", and the phrase "a written notification stating the outline of the accident must be submitted to the head of the quarantine station" is deemed to be replaced with "the outline of the accident must be recorded in a file by inputting it through an input-output device", and the phrase "immediately submit a notification to that effect to the head of the quarantine station set forth in the preceding paragraph" in paragraph (2) is deemed to be replaced with "record them in a file by inputting them through an input-output device".
- (9) The provisions of paragraphs (4) through (6) do not apply to a person provided for in the preceding paragraph.

Article 33 (1) The input pursuant to the provisions of paragraphs (1) and (2) of the preceding Article which is applied pursuant to paragraph (8) of the preceding Article following the deemed replacement of terms must be made through an input-output device that has been notified to the Minister of Health, Labour and Welfare in advance.

- (2) A person who seeks to make a notification under the provisions of Article 27 of the Act using an electronic data processing system is to make a notification referred to in the provisions of the preceding paragraph by submitting a written notification stating the following matters to the Minister of Health, Labour and Welfare, with regard to the input-output device the person seeks to use:
- (i) the name and address of the notifier (for a corporation, its name and the location of its principal office);
 - (ii) a security code (limited to one using twelve Arabic numerals or Roman

- letters, or their combination);
- (iii) the place where the input-output device is located, and the name and model number of the equipment;
- (iv) when a person other than the notifier manages the input-output device, the name and address of that person (for a corporation, its name and the location of its principal office).
- (3) A person who has made a notification referred to in the preceding paragraph must, when there are any changes to the matters set forth in each item of that paragraph or when the person has stopped using the input-output device that has been notified, promptly notify the Minister of Health, Labour and Welfare.

Article 34 (1) The Minister of Health, Labour and Welfare may use an electronic data processing system when issuing a notice of an inspection order under the provisions of Article 26, paragraph (2) or (3) of the Act to a person who has made a notification using an electronic data processing system pursuant to the provisions of Article 32, paragraph (7) with regard to food, additives, apparatus, or containers and packaging related to the notification, or issuing a notice of the results of the inspection under the provisions of Article 26, paragraph (4) of the Act (hereinafter referred to as a "specific notice" in this Article).

- (2) The Minister of Health, Labour and Welfare must, when issuing a specific notice using an electronic data processing system pursuant to the provisions of the preceding paragraph, input the content of the specific notice through the input-output device referred to in Article 32, paragraph (7) (limited to one used by the Ministry of Health, Labour and Welfare) and record them in a file.
- (3) The Minister of Health, Labour and Welfare must obtain the consent of the other party in advance for issuing a specific notice using an electronic data processing system.

Chapter VI Food Sanitation Inspection Facilities

Article 35 Deleted

Article 36 (1) The criteria specified by Order of the Ministry of Health, Labour and Welfare concerning the matters set forth in Article 8, paragraph (2), item (i) of the Order are as follows; provided, however, that if implementation of a part of the affairs concerning product inspections and examinations referred to in Article 29 of the Act are ensured even in emergency by being entrusted to food sanitation inspection facilities established by other prefectures, cities establishing health centers, or special wards, or to registered inspection bodies, this does not apply to equipment related to the part of the affairs:

(i) to provide physicochemical inspection rooms, bacteriological inspection

- rooms, animal breeding rooms, office rooms, etc.; and
- (ii) to provide water purifying apparatuses, automatic ovens, deep freezers, electric furnaces, gas chromatographs, spectrophotometers, autoclaves, dry heat sterilizers, constant temperature incubators, anaerobic culture systems, constant temperature tanks, and other machinery and tools necessary for inspection or examination.
- (2) The criteria specified by Order of the Ministry of Health, Labour and Welfare related to matters set forth in Article 8, paragraph (2), item (ii) of the Order are to assign employees necessary for inspection or examination.

Article 37 The affairs concerning the inspection or examination under the provisions of Article 8, paragraph (3) of the Order (hereinafter referred to as "inspections, etc." in this Article and the Appended Table 13) are to be managed as follows:

- (i) to confirm that inspections, etc., are appropriately conducted based on the standard operation manual provided for in item (xi);
- (ii) to conduct internal checking of the management of the operation of inspections, etc., on a regular basis, based on documents set forth in item (xii);
- (iii) to conduct accuracy management (meaning maintaining the accuracy of inspections through the method of ensuring the skill levels of persons engaged in inspections or other methods; the same applies hereinafter), based on documents set forth in item (xiii);
- (iv) to receive external investigation of accuracy management (meaning investigation concerning accuracy management conducted by the State or other persons found to be appropriate; the same applies hereinafter) on a regular basis, based on documents set forth in item (xiv);
- (v) to record the results of internal checking referred to in item (ii), accuracy management referred to in item (iii), and external investigation of accuracy management referred to in the preceding item (when improvement measures are required, including the content of the improvement measures);
- (vi) to take improvement measures for the operation of inspections, etc., promptly in accordance with the records under the provisions of the preceding item;
- (vii) when any deviation from the standard operation manual provided for in item (xi) and the documents provided for in items (xii) and (xiii) has been found upon inspections, etc., to assess the content of the deviation and take the necessary measures;
- (viii) an employee who carries out the duties referred to in item (i) or the preceding two items must not conduct inspections, etc.;
- (ix) an employee who carries out the duties referred to in items (ii) through (v)

- (hereinafter referred to as "credibility ensuring duties" in this Article) must not conduct inspections, etc., nor carry out the duties referred to in item (i) or (vi);
- (x) to make credibility ensuring duties independent from the operation of inspections, etc.;
 - (xi) to prepare standard operation manuals as prescribed in the Appended Table 13;
 - (xii) to prepare documents stating the methods of the internal checking of the management of the operation of inspections, etc.;
 - (xiii) to prepare documents stating the methods of accuracy management;
 - (xiv) to prepare documents stating the plans for receiving an external investigation of accuracy management on a regular basis;
 - (xv) to prepare documents stating the training plans for employees who carry out credibility ensuring duties;
 - (xvi) to prepare the following records and preserve them for three years from the day of their preparation:
 - (a) the name and address of a person who has applied for inspections set forth in Article 25, paragraph (1) of the Act or Article 26, paragraphs (1) through (3) of the Act (hereinafter referred to as "product inspections") or a person who has had their objects removed pursuant to the provisions of Article 28, paragraph (1) of the Act (including as applied *mutatis mutandis* pursuant to Article 68, paragraph (1) of the Act; the same applies in (b)) (for a corporation, its name and the location of its principal office);
 - (b) the date on which the application for product inspections was received, or the date on which the objects were removed pursuant to the provisions of Article 28, paragraph (1) of the Act;
 - (c) the name of the products for which inspections, etc., were conducted;
 - (d) the date on which inspections, etc., were conducted;
 - (e) the items for inspections, etc.;
 - (f) the quantity of the test samples for which inspections, etc., were conducted;
 - (g) the name of the employee who conducted inspections, etc.;
 - (h) the results of inspections, etc.;
 - (i) the records pursuant to the provisions of item (v);
 - (j) the records based on the standard operation manual set forth in item (xi);
 - (k) the records concerning the training referred to in the preceding item.

Chapter VII Registered Inspection Bodies

Article 38 (1) A person who seeks to apply for registration under Article 31 of the Act must submit a written application prepared according to Form No. 5 to

the Minister of Health, Labour and Welfare, by attaching the following documents:

- (i) the articles of incorporation or articles of endowment, and certificate of registered information;
- (ii) the resume of a person who has the knowledge and experience that meet the conditions set forth in column 3 of the Appended Table of the Act (hereinafter referred to as an "inspector");
- (iii) the documents that clarify the organization of departments provided for in Article 33, paragraph (1), item (ii), (a) of the Act (hereinafter referred to as "departments conducting product inspections") and specialized departments provided for in (c) of that item (hereinafter referred to as "departments ensuring credibility");
- (iv) the standard operation manual provided for in Article 40, item (viii) and documents provided for in items (ix) through (xii) of that Article as documents provided for in Article 33, paragraph (1), item (ii), (b) of the Act;
- (v) the documents that state the following matters:
 - (a) whether the corporation falls under any item of Article 32 of the Act;
 - (b) the type of product inspection to be conducted among those set forth in column 1 of the Appended Table of the Act;
 - (c) the number and performance of the machinery, tools, and other equipment set forth in column 2 of the Appended Table of the Act, whether they are owned or leased, the place where they are located, and the type of product inspections for which they are used;
 - (d) the name of the inspector and the type of product inspections to be conducted;
 - (e) the name of the department conducting product inspections, the name of the responsible person for the department conducting product inspections provided for in Article 40, item (i), and the name of the responsible person for the inspection category provided for in item (ii) of that Article and the type of product inspections that the person manages;
 - (f) the name of the department ensuring credibility, and the name of the responsible person for the department ensuring credibility provided for in Article 40, item (iii);
 - (g) when a person has already conducted an examination business concerning food sanitation, the outline of the business;
 - (h) whether the person falls under any of Article 33, paragraph (1), item (iii), sub-items (a) through (c) of the Act;
 - (i) for a stock company, the name and address of a shareholder who holds shares exceeding five percent of the total number of issued shares or a person who has made a contribution that exceeds five percent of the total contribution, and the number of shares held by the person or the value of

- the contribution made by the person;
- (j) the names and addresses of officers (for a membership company (meaning a membership company provided for in Article 575, paragraph (1) of the Companies Act (Act No. 86 of 2005)), a member that executes its business), whether they have the representative authority, and their brief biographical outlines (including whether they fall under officers or employees of a business person subject to inspections prescribed in Article 33, paragraph (1), item (iii) of the Act (including those who have been officers or employees of the business person subject to inspections in the past two years));
 - (k) when a person conducts a business other than an examination business concerning food sanitation, the type and outline of the business.
- (2) A revenue stamp for the amount of the fee must be affixed to a written application referred to in the preceding paragraph.

Article 39 (1) A person who seeks to apply for renewal of registration under Article 34, paragraph (1) of the Act must submit a written application prepared according to Form No. 6 to the Minister of Health, Labour and Welfare, by attaching the following documents:

- (i) the documents set forth in paragraph (1), items (i) through (iii) of the preceding Article;
 - (ii) the documents stating the matters set forth in paragraph (1), item (v), sub-item (a), and sub-items (c) through (k) of the preceding Article;
 - (iii) material concerning the actual results of product inspections.
- (2) A revenue stamp for the amount of the fee must be affixed to a written application referred to in the preceding paragraph.

Article 40 The criteria specified by Order of the Ministry of Health, Labour, and Welfare as referred to in Article 35, paragraph (2) of the Act are as follows:

- (i) persons who carry out the following duties are assigned to departments conducting product inspections (hereinafter referred to as "responsible persons for departments conducting product inspections"):
 - (a) supervising the duties of departments conducting product inspections;
 - (b) taking improvement measures promptly for those duties in accordance with documents with which a report was made pursuant to the provisions of item (iii), (d); and
 - (c) carrying out other necessary duties;
- (ii) at departments conducting product inspections, persons who carry out the following duties for product inspections based on the standard operation manuals provided for in item (viii) (hereinafter referred to as "responsible persons for inspection categories") are assigned for each category of

physicochemical inspections, bacteriological inspections, and inspections using animals:

- (a) when any deviation from standard operation manuals provided for in item (viii) or documents provided for in item (ix) has been found upon product inspections, assessing the content of the deviation and taking necessary measures;
- (b) confirming that product inspections are conducted appropriately based on standard operation manuals provided for in item (viii) and carrying out other necessary duties;
- (iii) persons who personally carry out the following duties or have other people previously appointed in accordance with the content of the duties carry out the duties are assigned to departments ensuring credibility (hereinafter referred to as "responsible persons for departments ensuring credibility"):
 - (a) conducting internal checking of the management of the operation of product inspections on a regular basis, based on documents set forth in item (ix);
 - (b) conducting accuracy management based on documents set forth in item (x), and when any deviation from the documents has occurred, assessing the content of the deviation and taking necessary measures;
 - (c) conducting affairs for receiving an external investigation of accuracy management on a regular basis, based on documents set forth in item (xi);
 - (d) reporting the results of internal checking referred to in (a), accuracy management referred to in (b), and external investigation of accuracy management referred to in (c) (when improvement measures are required, including the content of the improvement measures) to responsible persons for departments conducting product inspections in writing and entering the record into the books referred to in Article 44 of the Act (hereinafter referred to as the "books");
 - (e) carrying out other necessary duties;
- (iv) a department ensuring credibility is to be independent from departments conducting product inspections;
- (v) responsible persons for departments conducting product inspections and responsible persons for departments ensuring credibility are officers of a registered inspection body;
- (vi) responsible persons for departments conducting product inspections and responsible persons for inspection categories do not concurrently hold the position of inspector;
- (vii) responsible persons for departments ensuring credibility and persons appointed pursuant to the provisions of item (iii) do not concurrently hold the position of responsible persons for departments conducting product inspections, responsible persons for inspection categories, and inspectors;

- (viii) standard operation manuals have been prepared as provided for in the Appended Table 13. In such a case, in that Table, the term "Methods for keeping records" is deemed to be replaced with "Methods for entering into the book, the records," the phrase "Standard operation manual for the implementation of inspections" is deemed to be replaced with "Standard operation manual for the implementation of product inspections," and the term "inspections, etc." is deemed to be replaced with "product inspections";
- (ix) documents stating the methods for internal checking of the management of the operation of product inspections have been prepared;
- (x) documents stating the methods for accuracy management have been prepared;
- (xi) documents stating the plans for receiving external investigations of accuracy management on a regular basis have been prepared;
- (xii) documents stating the training plans for responsible persons for departments ensuring credibility and persons appointed pursuant to the provisions of item (iii) have been prepared.

Article 41 (1) A person who seeks to make a notification of the establishment or abolition of their place of business, or changes of its location pursuant to the provisions of Article 36, paragraph (1) of the Act must submit a written notification prepared according to Form No. 7 to the Minister of Health, Labour and Welfare.

(2) A person who seeks to make a notification of changes pursuant to the provisions of Article 36, paragraph (2) of the Act must submit a written notification prepared according to Form No. 8 to the Minister of Health, Labour and Welfare.

Article 42 (1) When a registered inspection body seeks to obtain authorization for rules concerning the operation of product inspections (hereinafter referred to as "operational rules") pursuant to the provisions of the first sentence of Article 37, paragraph (1) of the Act, it must submit a written notification prepared according to Form No. 9 to the Minister of Health, Labour and Welfare, by attaching the operational rules and materials concerning the calculation of the fee for product inspections.

(2) The matters to be specified in operational rules referred to in Article 37, paragraph (2) of the Act are as follows:

- (i) the types of product inspections and matters concerning the methods for the implementation and management of the operation of product inspections;
- (ii) the matters concerning the hours for conducting product inspections and holidays;
- (iii) the matters concerning the maximum number of applications for product

- inspections that may be received;
- (iv) the matters concerning places for conducting product inspections;
 - (v) the amount of fees for each inspection item of product inspections and matters concerning methods for storage;
 - (vi) the matters concerning the appointment and dismissal of responsible persons for departments conducting product inspections, responsible persons for inspection categories, inspectors, and responsible persons for departments ensuring credibility;
 - (vii) the matters concerning the assignment of responsible persons for departments conducting product inspections, responsible persons for inspection categories, and inspectors;
 - (viii) the matters concerning the preservation of written applications for product inspections and other documents concerning product inspections;
 - (ix) the matters concerning the keeping of financial statements, etc. (meaning financial statements, etc., provided for in Article 39, paragraph (1) of the Act; hereinafter the same applies in this Article) and the acceptance of requests for the inspection, etc., of financial statements, etc.; and
 - (x) beyond what is set forth in the preceding items, matters necessary for the operation of product inspections.
- (3) When a registered inspection body seeks to obtain authorization for changes to the operational rules pursuant to the provisions of the second sentence of Article 37, paragraph (1) of the Act, it must submit a written application prepared according to Form No. 10 to the Minister of Health, Labour and Welfare. In such a case, when the changes involve changes to the amount of the fee for product inspections, materials concerning its calculation must be attached.

Article 43 When a registered inspection body seeks to obtain permission for the suspension of all or part of the operations or the discontinuation of the operations of product inspections pursuant to the provisions of Article 38 of the Act, it must submit a written application prepared according to Form No. 11 to the Minister of Health, Labour and Welfare.

Article 44 The means specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 39, paragraph (2), item (iii) of the Act are the means of indicating the matters recorded on the electronic or magnetic record on paper or on the screen of an input-output device.

Article 45 The electronic or magnetic means specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 39, paragraph (2), item (iv) of the Act are either of the means set forth in the following items specified

by a registered inspection body:

- (i) the means of using an electronic data processing system that connects the computer used by a sender and the computer used by a receiver via a telecommunications line, by which information is sent via the telecommunications line and recorded in a file stored on the computer used by the receiver; or
- (ii) the means of delivering information recorded in a file prepared by a media in which certain information can be securely recorded on a magnetic disk or other equivalent means.

Article 46 (1) The matters specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 44 of the Act are as follows:

- (i) the name and address of a person who has applied for product inspections (for a corporation, its name and the location of its principal office);
 - (ii) the date on which the application for product inspections was received;
 - (iii) the name of the products for which product inspections were conducted;
 - (iv) the date on which product inspections were conducted;
 - (v) the items for product inspection;
 - (vi) the quantity of the test samples for which product inspections were conducted;
 - (vii) the name of the inspector who conducted product inspections;
 - (viii) the results of the product inspections;
 - (ix) the records required to be entered into the books pursuant to the provisions of Article 40, item (iii), (d);
 - (x) the records required to be entered into the books by the standard operation manuals prepared pursuant to the provisions of Article 40, item (viii); and
 - (xi) the records concerning the training referred to in Article 40, item (xii).
- (2) The books must be preserved for three years from the date of the final entry.

Article 47 The identification card which the employees are to carry pursuant to the provisions of Article 28, paragraph (2) of the Act as applied mutatis mutandis pursuant to Article 47, paragraph (2) of the Act is to be prepared according to Form No. 12.

Chapter VIII Business

Article 48 A person who is found to have an academic ability equivalent to or higher than a person who has graduated from a high school or secondary education school prescribed in the School Education Act (Act No. 26 of 1947) or a secondary school prescribed in the former Secondary School Order (Imperial Order No. 36 of 1943), as provided for in Article 48, paragraph (6), item (iv) of

the Act is as follows:

- (i) a person who has completed the first year of a senior course or special course at a girls' high school under the former Secondary School Order, which requires, as an entrance requirement, graduation from a four-year course of a girls' high school under that Order, which requires, as an entrance requirement, completion of a primary course at a national elementary school under the former National Elementary School Order (Imperial Order No. 148 of 1941) (hereinafter referred to as a "national elementary school");
- (ii) a person who has completed the first year of a special course at a vocational school under the former Secondary School Order, which requires, as an entrance requirement, graduation from a four-year course of a vocational school under that Order, which requires, as an entrance requirement, completion of a primary course at a national elementary school;
- (iii) a person who has completed a preparatory course at a normal school under the former Normal School Education Order (Imperial Order No. 109 of 1943);
- (iv) a person who has graduated from an affiliated secondary school or affiliated girls' high school under the former Normal School Education Order;
- (v) a person who has completed the third year of a regular course of a normal school under the former Normal School Education Order (Imperial Order No. 346 of 1897) prior to the amendment by that Order;
- (vi) a person who has graduated from a secondary school pursuant to the provisions of Article 2 or Article 5 of Order of the Ministry of Education No. 63 of 1943 (regulations concerning the entrance into and transfer to other schools of students, pupils, or graduates of schools in regions other than the mainland) or a person who is treated in the same manner as a person set forth in item (i);
- (vii) a person who has graduated from a regular course at a boys' school (excluding schools with two-year term of study) under the former Boys' School Order (Imperial Order No. 254 of 1939);
- (viii) a person who has passed examinations under the former Technical College Entrance Examination Regulations (Order of the Ministry of Education No. 22 of 1924) based on the former Technical College Order (Imperial Order No. 61 of 1903), and a person designated by the Minister of Education as having an academic ability equivalent to or higher than graduates of a secondary school or girls' high school with regard to entrance into a professional training college pursuant to the provisions of Article 11, paragraph (2) of the Regulations;
- (ix) a person who has passed examinations under the formal Vocational School Graduation Level Examination Regulations (Order of the Ministry of Education No. 30 of 1925);

- (x) a person who has passed examinations under the provisions of Article 7 of the former High School Examination Order (Imperial Order No. 15 of 1929);
- (xi) a person who has a school teacher's license set forth in the left-hand column of item (ii), item (iii), item (vi), or item (ix) of the Table for Article 1, paragraph (1) of the Act for Enforcement of the Education Personnel Certificate Act (Act No. 148 of 1949), or a person who has a qualification set forth in the left-hand column of item (ix), items (xviii) through (xx)-4, item (xxi), or item (xxiii) of the Table for Article 2, paragraph (1) of that Act;
- (xii) a person who is specified in Article 150 of the Enforcement Regulations of the School Education Act (Order of the Ministry of Education No. 11 of 1947); and
- (xiii) beyond what is set forth in the preceding items, a person certified by the Minister of Health, Labour and Welfare to have an academic ability equivalent to or higher than graduates of a high school, secondary education school, or secondary school with regard to qualifications as a food sanitation supervisor.

Article 49 (1) The notification under the provisions of Article 48, paragraph (8) of the Act is to be made by submitting a written notification stating the following matters:

- (i) the name and address of the notifier (for a corporation, its name, the location of its principal office, and the name of its representative);
 - (ii) the type of food or additives provided for in Article 13 of the Order;
 - (iii) the name and location of the facilities;
 - (iv) the name, address, and date of birth of the food sanitation supervisor;
 - (v) the title, type of job, and content of the duties of the food sanitation supervisor; and
 - (vi) the date the food sanitation supervisor was assigned or changed.
- (2) A written notification set forth in the preceding paragraph must be attached with a resume of the food sanitation supervisor, documents proving that the food sanitation supervisor falls under one of the items of Article 48, paragraph (6) of the Act, and documents proving the relations with the business person.

Article 50 The criteria specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 14 of the Order (including as applied *mutatis mutandis* pursuant to Article 9, paragraph (2) of the Order) are as follows:

- (i) the training institute is to be a university under the School Education Act or an educational facility that has courses that are recognized to provide education equivalent to that at universities or graduate schools pursuant to the provisions of Article 104, paragraph (7), item (ii) of that Act;
- (ii) for each curriculum stated in the left-hand column of the Appended Table

- 14, one or more subjects set forth in the right-hand column of that Table are to be taken, and the total number of credits is to be 22 or more;
- (iii) subjects set forth in the preceding item and subjects set forth in the Appended Table 15 are to be taken, and the total number of credits is to be 40 or more; and
- (iv) classes are to be conducted, in principle, by using the machinery and tools set forth in column 2 of the Appended Table of the Act.

Article 51 A written application referred to in Article 15 of the Order (including as applied mutatis mutandis pursuant to Article 9, paragraph (2) of the Order) must be attached with documents stating the following matters:

- (i) the name and location of the training institution;
- (ii) the name and location of the establisher of the training institution, and the date of establishment;
- (iii) the name and address of the head of the training institution;
- (iv) the name and personal history of each teacher, the subjects they teach, and whether they are full-time teachers or have other jobs;
- (v) plans of subjects to be taken each school year, the number of credits, and whether they are compulsory subjects or optional subjects;
- (vi) student quotas;
- (vii) entrance qualifications and the time of entrance;
- (viii) term of study;
- (ix) a list of machinery and tools and a library index for teaching and training;
- (x) drawings and layout of the school site and school buildings;
- (xi) school regulations; and
- (xii) other matters for reference.

Article 52 (1) The registration of a training institution under Article 48, paragraph (6), item (iii) of the Act is to be made by entering the following matters into the register:

- (i) the date of registration and registration number; and
 - (ii) the name and location of the registered training institution (meaning a registered training institution provided for in Article 16 of the Order; the same applies hereinafter), and the name of its head.
- (2) The provisions of the preceding paragraph apply mutatis mutandis to the registration of a training institution referred to in Article 9, paragraph (1), item (i) of the Order.

Article 53 The matters specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 16 of the Order (including as applied mutatis mutandis pursuant to Article 9, paragraph (2) of the Order) are to be what are

set forth in Article 51, items (i) through (iii), items (v) through (viii), item (ix) (limited to those related to machinery and tools set forth in column 2 of the Appended Table of the Act), item (x), and item (xi).

Article 54 The written application referred to in Article 19 of the Order (including as applied mutatis mutandis pursuant to Article 9, paragraph (2) of the Order) must be attached with documents stating the following matters:

- (i) the reasons for seeking to obtain revocation of the registration;
- (ii) the planned date to obtain revocation of the registration; and
- (iii) when there are students that are attending school, measures to be taken for them.

Article 55 The matters specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 20, item (ii) of the Order (including as applied mutatis mutandis pursuant to Article 9, paragraph (2) of the Order) are those set forth in Article 51, item (i).

Article 56 (1) The courses of training sessions referred to in Article 48, paragraph (6), item (iv) of the Act must satisfy all of the following requirements:

- (i) the subjects set forth in column 1 of the Appended Table 16 and the subjects set forth in any of columns 2 through 7 of that Table are taught, and the number of hours is to be equal to or more than the the number of hours set forth in that Table;
- (ii) the lecturers are persons who teach subjects equivalent to those referred to in the preceding item at a university under the School Education Act, persons who are engaged in food sanitation administration or examination business concerning food sanitation at an entity of the State, prefecture, city establishing health centers, or special ward, or persons recognized as having knowledge and experience equal to the aforementioned persons;
- (iii) qualifications for taking training sessions are to be that a person has graduated from a high school or secondary education school under the School Education Act or a secondary school under the former Secondary School Order, or falls under those set forth in each item of Article 48, and has been engaged in sanitation management of production or processing of food or additives for two years or more at a production or processing business that is required to have food sanitation supervisors pursuant to the provisions of Article 48, paragraph (1) of the Act; and
- (iv) examinations are to be conducted for participants at the end of training sessions.

(2) Notwithstanding the provisions of item (i) of the preceding paragraph,

persons set forth in the following items may be exempted from taking subjects prescribed in the respective item:

- (i) a person who has studied subjects equivalent to or higher than those set forth in column 1 of the Appended Table 16 at a university under the School Education Act, a university under the former University Order (Imperial Order No. 388 of 1918), or a professional training college under the former Professional Training College Order: those subjects; and
- (ii) a person who has completed registered training sessions: for a person who has completed subjects set forth in column 1 of the Appended Table 16 and subjects set forth in column 2 or 3 of that Table, practical training on bacteriology set forth respectively in column 3 or column 2 of that Table.

Article 57 A person who seeks to file an application for registration pursuant to the provisions of Article 21 of the Order must submit a written application to the governor of the prefecture where the training sessions related to the registration are conducted, by attaching a copy of the resident record (for a corporation, articles of incorporation or articles of endowment, and certificate of registered information) and documents stating the following matters:

- (i) the name and address of the organizer of the training sessions (for a corporation, its name, the location of its principal office, and the name of its representative);
- (ii) whether a fact that falls under any item of Article 22 of the Order exists;
- (iii) for a corporation, the names, addresses, and brief biographical outlines of its officers;
- (iv) the name and location of the venue of the training sessions;
- (v) the name and location of the place where practical training is held;
- (vi) the periods and schedules of the training sessions;
- (vii) the planned number of participants;
- (viii) the training subjects and the number of hours; and
- (ix) the names and occupations of lecturers, the training subjects they teach, and the number of hours for each training subject.

Article 58 The registration under Article 21 of the Order is to be made by entering the following matters into the register:

- (i) the date of registration and registration number;
- (ii) the name and address of the organizer of the registered training sessions (for a corporation, its name, the location of its principal office, and the name of its representative); and
- (iii) the implementation period of the registered training sessions.

Article 59 The criteria specified by Order of the Ministry of Health, Labour and

Welfare as referred to in Article 24, paragraph (2) of the Order are as follows:

- (i) to confirm that the participant meets the qualifications for taking the training sessions through their resume, documents proving their relations with the place of business they have worked for, and other documents;
- (ii) to issue a certificate for the completion of training to the person who has completed the courses of the training sessions; and
- (iii) to hold registered training sessions pursuant to the provisions of Article 56.

Article 60 The matters specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 25 of the Order are as follows:

- (i) the name and address of the organizer of the registered training sessions (for a corporation, its name, the location of its principal office, and the name of its representative); and
- (ii) the implementation period of the registered training sessions.

Article 61 When an organizer of registered training sessions seeks to suspend or discontinue the operation of the registered training sessions pursuant to the provisions of Article 26 of the Order, they must notify the governor of the prefecture where the registered training sessions are conducted of the following matters:

- (i) the reasons for the suspension or discontinuation and the scheduled date;
- (ii) when seeking to suspend the operation, the scheduled period of suspension.

Article 62 An organizer of registered training sessions must prepare the financial statements, etc. for the previous business year (meaning the financial statements, etc., provided for in Article 27, paragraph (1) of the Order; hereinafter the same applies in this Article) (when three months have not elapsed since the end of the previous business year, they may be replaced with the financial statements, etc., for the business year before the previous business year), and must keep the financial statements, etc. at the place of business from the time of registration until they terminate the registered training sessions.

Article 63 The provisions of Article 44 apply mutatis mutandis to the means specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 27, paragraph (2), item (iii) of the Order.

Article 64 The provisions of Article 45 apply mutatis mutandis to the electronic or magnetic means specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 27, paragraph (2), item (iv) of the Order.

Article 65 (1) The matters specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 31 of the Order are as follows:

- (i) the names and personal histories of the participants;
 - (ii) the number of participants; and
 - (iii) the names, dates of birth, and addresses of persons who have received certificates for the completion of training, and the names and locations of the place of business they work for.
- (2) The books set forth in Article 31 of the Order must be preserved for three years from the date of the final entry.

Article 66 The certificate which the employees are to carry pursuant to the provisions of Article 33, paragraph (2) of the Order is to be prepared according to Form No. 13.

Article 66-2 (1) The criteria specified by Order of the Ministry of Health, Labour, and Welfare as referred to in Article 51, paragraph (1) the Act (including as applied mutatis mutandis pursuant to Article 68, paragraph (3) of the Act) concerning the matters set forth in item (i) of that paragraph are as set forth in the Appended Table 17.

(2) The criteria specified by Order of the Ministry of Health, Labour, and Welfare as referred to in Article 51, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 68, paragraph (3) of the Act) concerning the matters set forth in item (ii) of that paragraph are as set forth in the Appended Table 18.

(3) A business person must provide and observe the measures necessary for public health pursuant to the provisions of Article 51, paragraph (2) of the Act (including as applied mutatis mutandis pursuant to Article 68, paragraph (3) of the Act), in accordance with the criteria referred to in the preceding two paragraphs, and pursuant to the provisions of the following items:

- (i) to prepare plans for sanitation management of facilities and handling, etc., of food or additives (hereinafter referred to as "sanitation management plan") and thoroughly inform the persons who handle food or additives and the relevant persons of the sanitation management plan, in order to prevent food sanitation hazards;
- (ii) to take into consideration the facilities and equipment, the structure and materials of machinery and tools, and the processes of producing, processing, cooking, transporting, storing, or selling food, and prepare a procedure manual for taking appropriate measures necessary for public health in these processes (hereinafter referred to as "procedure manual") as necessary;
- (iii) to record and preserve the implementation status of sanitation management. The period for preserving the records is to be reasonably

- established by taking into account the period until the food or additives handled are used or consumed; and
- (iv) to verify the effectiveness of the sanitation management plan and the procedure manual, and review their content as necessary.
- (4) For a business person prescribed in the following items, the items of the relevant paragraph is applied by replacing the term "to prepare" in item (i) of the preceding paragraph with "to prepare as necessary" and the term "to record and preserve" in item (iii) of that paragraph with "to record and preserve as necessary".
- (i) a person who conducts business of importing food or additives;
 - (ii) a person who conducts business that only stores or transports food or additives (excluding a person who is engaged in the business of freezing or refrigerating food);
 - (iii) a person who conducts business that sells food or additives packed or wrapped in containers and packaging which are unlikely to cause food sanitation hazards resulting from rotting, deterioration, or other degradation of quality when preserved by a method other than freezing or refrigerating; and
 - (iv) a person who conducts business of importing or selling apparatus, or containers and packaging.

Article 66-3 The business persons specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 34-2, item (ii) of the Order are as follows:

- (i) a person who is engaged in a restaurant business provided for in Article 35, item (i) of the Order (including a person who is engaged in a coffee shop business (meaning business that sets up coffee shops, salons, and other facilities and serves drinks other than alcoholic beverages or refreshments to customers) and an establisher or a manager of such facilities at a school, hospital, or any other facility provided for in Article 68, paragraph (3) of the Act);
- (ii) a person who conducts business that cooks food using a vending machine that has a cooking function provided for in Article 35, item (ii) of the Order and sells the cooked food;
- (iii) a person who conducts business of producing bread (limited to that consumed in a relatively short period of time) among the confectionery production business provided for in Article 35, item (xi) of the Order;
- (iv) a person who conducts side dish production business provided for in Article 35, item (xxv) of the Order; and
- (v) a person who conducts business that cooks food using a vending machine that has a cooking function and sells the cooked food (excluding a person who

conducts business provided for in item (i) or (ii)).

Article 66-4 The business persons specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 34-2, item (iv) of the Order are as follows:

- (i) a person who conducts business that divides food into small portions, places the food in containers and packaging, or wraps it in containers and packaging and sells it;
- (ii) in addition to the business persons set forth in the preceding item, among persons who conduct business of producing, processing, storing, selling, or treating food, a business person who has a workplace where less than 50 persons are engaged in handling food (hereinafter referred to as "small-scale workplace" in this item); provided, however, that if the business person has a workplace where 50 or more persons are engaged in handling food (hereinafter referred to as "large-scale workplace" in this item), the criteria specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 51, paragraph (1), item (ii) of the Act concerning the measures appropriate for the characteristics of food to be handled provided for in that paragraph apply only to a small-scale workplace owned by the business person and do not apply to a large-scale workplace owned by the business person.

Article 66-5 (1) The criteria specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 52, paragraph (1), item (i) of the Act concerning the matters set forth in that paragraph are as follows:

- (i) to assign necessary personnel, specify the content of work, and maintain facilities and equipment, etc., so that apparatus or containers and packaging will be appropriately produced;
- (ii) to perform necessary management on the maintenance of cleanliness and health conditions of the personnel engaged in production of apparatus or containers and packaging (hereinafter referred to as "workers" in this Article and the following Article) and make the workers understand the work procedures and matters necessary for sanitation management and have them conduct work in accordance with those procedures and matters;
- (iii) to make the structure of facilities or work areas capable of preventing contamination by dust and dirt, etc., as necessary, taking into account of the manner in which apparatus or containers and packaging are used, and to maintain the facilities and areas in a clean condition;
- (iv) to perform the cleaning and maintenance inspection of the facilities and the disposal of waste appropriately in order to maintain a clean working environment;

- (v) to conduct education and training for persons who manage the production of apparatus or containers and packaging and the workers, and share information and measures necessary to prevent food sanitation hazards among the persons concerned;
 - (vi) to prepare work procedures, specify matters necessary for sanitation management as well as record the results of the measures, and preserve the results so that they can be confirmed promptly as necessary; and
 - (vii) keeping records of the purchase, use, and disposal of raw materials of apparatus or containers and packaging as well as of the production, storage, shipment, and disposal of apparatus or containers and packaging, and preserve the apparatus or containers and packaging by taking into account the period of time during which the apparatus is used or the period of time until the food or additives packed or wrapped in the containers or packaging are consumed.
- (2) The requirements specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 52, paragraph (1), item (ii) of the Act concerning the matters set forth in that paragraph are as follows:
- (i) to use raw materials that conform to the provisions of Article 18, paragraph (3) of the Act for raw materials of the materials prescribed in Article 1 of the Order (hereinafter referred to as "raw materials" in this Article and the following Article);
 - (ii) to confirm that the designed product conforms to the provisions of Article 18, paragraph (3) of the Act and that the production process conforms to the standards or criteria prescribed in paragraph (1) of that Article for product design of apparatus or containers and packaging;
 - (iii) to analyze the measures to prevent food sanitation hazards or risks of the hazards occurring as necessary and specify the factors that require management;
 - (iv) with regard to the factors that require management referred to in the preceding item, to determine the level of production and management necessary for preventing food sanitation hazards (hereinafter referred to as the "management level") and the management methods, and appropriately manage the factors;
 - (v) to confirm that raw materials and apparatus or containers and packaging meet the appropriate management level;
 - (vi) for raw materials, apparatus or containers and packaging, or collected apparatus or containers and packaging that do not meet the appropriate management level, or other apparatus or containers and packaging that may cause food sanitation hazards, to specify the method of response in advance;
 - (vii) for raw materials, apparatus or containers and packaging, or collected apparatus or containers and packaging that do not meet the appropriate

management level, or other apparatus or containers and packaging that may cause food sanitation hazards, to respond in accordance with the method prescribed in the provisions of the preceding item; and
(viii) to preserve raw materials used for production and parts of apparatus or containers and packaging produced as necessary.

Article 66-6 (1) A person who sells, produces or imports for the purpose of selling, apparatus, or containers and packaging that use the raw materials of materials specified by Article 1 of the Order, must give an explanation to the counterparty of the sales of the apparatus or containers and packaging under the provisions of Article 53, paragraph 1 of the Act in accordance with the provisions of the following items:

(i) to specify the apparatus or containers and packaging that are the subject of explanation and convey information for confirming that they fall under either of Article 53, paragraph (1), item (i) of the Act or item (ii) of that paragraph;

(ii) to establish a suitable system for conveying the information provided for in the preceding item, and if there is any change to the information referred to in the preceding item, to promptly convey the information.

(2) A person who sells, produces or imports for the purpose of selling, raw materials of apparatus or containers and packaging whose materials are provided for in Article 1 of the Order, must endeavor to give an explanation under the provisions of Article 53, paragraph 2 of the Act in accordance with the provisions of the following items:

(i) to specify the raw materials that are subject of explanation and convey the information confirming that the apparatus or containers and packaging which are produced by using the raw materials fall under either of Article 53, paragraph (1), item (i) of the Act or item (ii) of that paragraph;

(ii) to establish a suitable system for conveying the information provided for in the preceding item, and if there is any change to the information referred to in the preceding item, to promptly convey the information.

Article 66-7 The criteria specified by Order of the Ministry of Health, Labour and Welfare as prescribed in Article 54 of the Act are as set forth in the Appended Table 19 for matters common to the businesses set forth in each item of Article 35 of the Order (excluding the businesses set forth in items (ii) and (vi) of that Article), the Appended Table 20 for matters related to each business set forth in the items of that Article, and the Appended Table 21 in addition to the criteria stated in the Appended Tables 19 and 20 for the criteria of facilities related to businesses that handle meat to be eaten raw or pufferfish that conform to the standards or criteria specified pursuant to the provisions of

Article 13, paragraph (1) of the Act.

Article 66-8 The methods of trade specified by Order of the Ministry of Health, Labour, and Welfare as referred to in Article 35, item (v) of the Order are as follows:

- (i) an auction;
- (ii) transactions by bidding; and
- (iii) relative transactions.

Article 66-9 Food specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 35, item (xiii) of the Order are milk products prescribed in Article 2, paragraph (13) of the Ministerial Order on Milk and Milk Products Concerning Compositional Standards, etc. (Ministry of Health and Welfare Ordinance No. 52 of 1951) (excluding ice creams prescribed in paragraph (21) of that Article) and lactic acid bacteria beverages prescribed in paragraph (41) of that Article that contain less than 3.0% of non-fat milk solids.

Article 66-10 Food specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 35, item (xxx) of the Order are brown rice, milled rice, wheat, buckwheat seed, green coffee beans, roasted coffee beans, tea, roasted barley, honey, dried shiitake mushrooms, peanuts (excluding fresh or boiled peanuts), dried and fermented fish, dried bonito shavings, toasted laver, dried bread crumbs, gelatin, toasted wheat gluten bread, granular or powdery food, food prepared by compressing and molding granular or powdery food, granular or powdery food in capsules, food prepared by mixing these food, and vinegar.

Article 67 A person who seeks to obtain a license for business under the provisions of Article 55, paragraph (1) of the Act must submit a written application stating the following matters to the prefectural governor, etc., who has jurisdiction over the location of the facility; provided, however, that if a business person has transferred the business, the transferee of the business may omit the entry of matters set forth in item (v) when there is no change to the matters set forth in that item.

- (i) the name (with phonetic transcriptions in hiragana), date of birth, and address of the applicant (for a corporation, its name (with phonetic transcriptions in hiragana), its location, and the name of its representative (with phonetic transcriptions in hiragana));
- (ii) the location of the facility (for businesses that cook food in an automobile, the registration number of the automobile) and its name, shop name, or trade name (with phonetic transcriptions in hiragana);

- (iii) the type and form of the business to be applied for and information on the food or additives mainly handled;
- (iv) the name of the food sanitation supervisor or the food sanitation manager (with phonetic transcriptions in hiragana), and the type of qualification and the training sessions that the person attended;
- (v) drawings showing the structure and equipment of the facility (when using potable water other than water supplied by the water supply business provided for in Article 3, paragraph (2) of the Water Supply Act (Act No. 177 of 1957), the dedicated water-supply system provided for in paragraph (6) of the Article, and the small water-supply system provided for in paragraph (7) of the Article (hereinafter referred to as "potable water" in the Appended Tables 17 and 19), including copies of the documents certifying the results of the water quality inspections on the water to be used conducted by an agency of a local public entity provided for in Article 20, paragraph (3) of the Act or a person designated by the Minister of Health, Labour and Welfare);
- (vi) type of measures for managing processes that are particularly important for preventing food sanitation hazards or measures in accordance with the characteristics of food handled (limited to the case in which the applicant seeks to continue to be licensed for business upon expiration of the validity period of the license for business set forth in each item of Article 35 of the Order; provided, however, that for a person who applies for a license for business set forth in item (xxvi) or (xxviii) of that Article, including the case of a new application);
- (vii) whether the person falls under any of the items of Article 55, paragraph (2) of the Act, and when the person falls under any of the items, the details of the case; and
- (viii) when the provisions of the proviso apply, the fact that the business has been transferred to the transferee.

Article 68 (1) A person who seeks to notify their succession to the status of a person who has obtained license for business under the provisions of Article 55, paragraph (1) of the Act (hereinafter referred to as a "licensed business person") through an inheritance pursuant to the provisions of Article 56, paragraph (2) of the Act must submit a written notification stating the following matters to the prefectural governor, etc., who has jurisdiction over the location of the facility:

- (i) the name (with phonetic transcriptions in hiragana), date of birth, address, of the notifier and their relationship to the decedent;
- (ii) the name (with phonetic transcriptions in hiragana) and address of the decedent;
- (iii) the date of commencement of inheritance; and

- (iv) the license number for the facility and the date on which the license was obtained.
- (2) The written notification referred to in the preceding paragraph must have the following documents attached:
 - (i) a certified copy of the family register or a copy of the statutory inheritance information chart prescribed in Article 247, paragraph (1) of the Ordinance on Real Property Registration (Order of the Ministry of Justice No. 18 of 2005) that has been issued pursuant to the provisions of paragraph (5) of that Article; and
 - (ii) for a person selected as the successor to the status of a licensed business person with the consent of all the heirs when there are two or more heirs, the written consent of all those heirs.

Article 69 (1) A person who seeks to notify their succession to the status of a licensed business person through a merger pursuant to the provisions of Article 56, paragraph (2) of the Act must submit a written notification stating the following matters to the prefectural governor, etc., who has jurisdiction over the location of the facility:

- (i) the name of the corporation succeeding to the status (with phonetic transcriptions in hiragana), its location, and the name of its representative (with phonetic transcriptions in hiragana);
 - (ii) the name of the corporation extinguished by the merger (with phonetic transcriptions in hiragana), its location, and the name of its representative (with phonetic transcriptions in hiragana);
 - (iii) the date of the merger; and
 - (iv) the license number for the facility and the date on which the license was obtained.
- (2) The written notification referred to in the preceding paragraph must be attached with the certificate of registered information of the corporation surviving the merger or the corporation established by the merger.

Article 70 (1) A person who seeks to notify their succession to the status of a licensed business person through a split pursuant to the provisions of Article 56, paragraph (2) of the Act must submit a written notification stating the following matters to the prefectural governor, etc., who has jurisdiction over the location of the facility:

- (i) the name of the corporation succeeding to the status (with phonetic transcriptions in hiragana), its location, and the name of its representative (with phonetic transcriptions in hiragana);
- (ii) the name of the corporation prior to the split (with phonetic transcriptions in hiragana), its location, and the name of its representative (with phonetic

- transcriptions in hiragana);
 - (iii) the date of the split; and
 - (iv) the license number for the facility and the date on which the license was obtained.
- (2) The written notification set forth in the preceding paragraph must be attached with the certificate of registered information of the corporation which succeeded to the business through the split.

Article 70-2 A person who seeks to make a notification of the business under the provisions of Article 57, paragraph (1) of the Act (hereinafter referred to as "notified business person") must submit a written notification stating the following matters to the prefectural governor, etc., who has jurisdiction over the location of the facility:

- (i) the name (with phonetic transcriptions in hiragana), date of birth, and address of the notifier (for a corporation, its name (with phonetic transcriptions in hiragana), its location, and the name of its representative (with phonetic transcriptions in hiragana));
- (ii) the location of the facility (when conducting business in an automobile, the registration number of the automobile) and its name, shop name, or trade name (with phonetic transcriptions in hiragana);
- (iii) the business form and information on the food, additives, apparatus, or containers and packaging mainly handled; and
- (iv) the name of the food sanitation manager (with phonetic transcriptions in hiragana; provided, however, excluding business persons who produce apparatus or containers and packaging that use materials provided for in Article 1 of the Order).

Article 71 When there are any changes to the matters set forth in Article 67, items (i) through (vi) (for item (ii), limited to the automobile registration number and its name, shop name, or trade name, and for item (iii), excluding the type of business), Article 68, paragraph (1), item (i) (excluding the date of birth), Article 69, paragraph (1), item (i), Article 70, paragraph (1), item (i), or items (i) through (iv) of the preceding Article (for item (ii), limited to the automobile registration number and its name, shop name, or trade name), a licensed business person or a notified business person must promptly notify the prefectural governor, etc., who has jurisdiction over the location of the facility of that fact.

Article 71-2 A licensed business person or a notified business person must, when they are unable to continue the business due to discontinuation of business, submit a written notification stating the following matters to the prefectural

governor, etc., who has jurisdiction over the location of the facility:

- (i) the name (with phonetic transcriptions in hiragana) and address of the notifier (for a corporation, its name (with phonetic transcriptions in hiragana), its location, and the name of its representative (with phonetic transcriptions in hiragana));
- (ii) the address of the facility (when conducting business in an automobile, the registration number of the automobile) and its name, shop name, or trade name (with phonetic transcriptions in hiragana);
- (iii) the date of discontinuation of business; and
- (iv) for a licensed business person, the license number of the facility and the date on which the license was obtained;

Chapter IX Miscellaneous Provisions

Article 72 A notification by a physician under the provisions of Article 63, paragraph (1) of the Act (including as applied *mutatis mutandis* pursuant to Article 68, paragraph (1) of the Act; the same applies hereinafter) must be made in writing, by phone, or orally within 24 hours, with regard to the following matters:

- (i) the address and name of the physician;
- (ii) the location, name, and age of the poisoned patient, the person who is suspected to have been poisoned, or the deceased (hereinafter referred to as "patients, etc.");
- (iii) the causes of the food poisoning (meaning poisoning caused by food, additives, apparatus, containers and packaging, or toys set forth in each item of Article 78 (referred to as "food, etc." in the following Article and Article 74, paragraph (1), item (iii)); the same applies hereinafter);
- (iv) the date and time the disease occurred; and
- (v) the date and time of the diagnosis or postmortem examination.

Article 73 (1) The number of persons poisoned by food, etc., specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 63, paragraph (3) of the Act (including as applied *mutatis mutandis* pursuant to Article 68, paragraph (1) of the Act; the same applies hereinafter) is 50.

- (2) The cases specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 63, paragraph (3) of the Act are as follows:
- (i) when a fatality or a severe illness has occurred due to the poisoning;
 - (ii) when the poisoning has been caused or is suspected to have been caused by imported food, etc.;
 - (iii) when the poisoning has been caused or is suspected to have been caused by any of the disease agents set forth in the Appended Table 22;

- (iv) when patients, etc., suffering from the poisoning are found in multiple prefectures;
- (v) when investigations of the causes of the poisoning are difficult in light of the status, etc., of the outbreak of the poisoning; and
- (vi) when it is difficult to render dispositions pursuant to the provisions of Articles 59 through 61 of the Act (hereinafter referred to as "dispositions") or to judge the appropriateness of the content of the dispositions in light of the status, etc., of the outbreak of the poisoning.

Article 74 The matters specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 37, paragraph (2) of the Order are as follows:

- (i) the location of the patients, etc., and the date of notification pursuant to the provisions of Article 63, paragraph (1) of the Act;
- (ii) the number of the patients, etc., and their symptoms;
- (iii) the food, etc., that caused or is suspected to have caused the poisoning (hereinafter referred to as the "food, etc., causing poisoning") and the reasons for specifying the food, etc., as the cause;
- (iv) the disease agents that caused or are suspected to have caused the poisoning and the reasons for specifying them as the cause;
- (v) the business facilities that caused or are suspected to have caused the poisoning (hereinafter referred to as "facilities causing food poisoning") and the reasons for specifying the facilities as the cause; and
- (vi) beyond what is set forth in the preceding items, matters found important in conducting investigations of the causes of the poisoning or rendering dispositions.

Article 75 (1) The written reports under the provisions of Article 37, paragraph (3) of the Order are those specified in the following items in accordance with the category of food poisoning cases set forth in the respective items:

- (i) food poisoning cases which prefectural governors, etc., have immediately reported to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 63, paragraph (3) of the Act: a case notification form of the food poisoning case prepared according to Form No. 14 and a detailed report of the food poisoning case;
 - (ii) food poisoning cases other than those set forth in the preceding item: a case notification form of the food poisoning case prepared according to Form No. 14.
- (2) A detailed report of the food poisoning case provided for in item (i) of the preceding paragraph are to state the following matters:
- (i) the following matters concerning the outline of the occurrence of the food poisoning:

- (a) the date of occurrence;
- (b) the place of occurrence;
- (c) the number of persons who have consumed food, etc., causing poisoning;
- (d) the number of the deceased;
- (e) the number of patients;
- (f) the food, etc., causing poisoning;
- (g) the disease agents;
- (ii) matters concerning the understanding of information on the occurrence of the food poisoning;
- (iii) the following matters concerning the situation of the patients and the deceased:
 - (a) the number of patients and the deceased by sex and age;
 - (b) the number of patients and the deceased by date and time of occurrence of the food poisoning;
 - (c) the proportion of the patients and the deceased among the persons who consumed the food, etc., causing poisoning;
 - (d) the time it took for the disease to develop from the time the patients and the deceased consumed the food, etc., causing poisoning;
 - (e) the symptoms of the patients and the deceased and the number of patients by symptom;
- (iv) the following matters concerning the food, etc., causing poisoning and its contamination route:
 - (a) the process of specifying the food, etc., causing poisoning and the reasons for specifying the food, etc., as the cause;
 - (b) the contamination route of the food, etc., causing poisoning;
- (v) matters concerning facilities causing food poisoning:
 - (a) the situation of water supply and drainage and other sanitary conditions at facilities causing food poisoning;
 - (b) the health conditions of employees at facilities causing food poisoning;
- (vi) matters concerning disease agents:
 - (a) the results of microbiological examinations, physicochemical examinations, or examinations using animals;
 - (b) the process of specifying the disease agents and the reasons for specifying the disease agents as the cause;
- (vii) the dispositions and other measures taken by prefectural governors, etc.

Article 76 (1) The written reports under the provisions of Article 37, paragraph (4) of the Order are to be written reports specified in the following items in accordance with the category of food poisoning cases set forth in the respective items:

- (i) food poisoning cases which prefectural governors, etc., have immediately

- reported to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 63, paragraph (3) of the Act: a written report on the investigation results of the food poisoning case and a detailed report on the investigation results of the food poisoning case; and
- (ii) food poisoning cases other than those set forth in the preceding item: a written report on the investigation results of the food poisoning case.
- (2) A written report on the investigation results of the food poisoning case referred to in each item of the preceding paragraph is to be prepared according to Form No. 15.
- (3) A written report on the investigation results of the food poisoning case referred to in each item of paragraph (1) must be submitted each month by the 10th of the following month, by attaching the case notification forms of food poisoning cases referred to in each item of paragraph (1) of the preceding Article that were accepted in that month.
- (4) A detailed report on the investigation results of the food poisoning case set forth in paragraph (1), item (i) is to be prepared by entering the matters set forth in each item of paragraph (2) of the preceding Article.
- (5) A detailed report on the investigation results of the food poisoning case set forth in paragraph (1), item (i) must be prepared and submitted immediately after receiving the detailed report of the food poisoning case set forth in paragraph (1), item (i) of the preceding Article, pursuant to the provisions of Article 37, paragraph (3) of the Order.

Article 77 The number of persons specified by Order of the Ministry of Health, Labour and Welfare as referred to in Article 65 of the Act is 500.

Article 78 The toys provided for in Article 68, paragraph (1) of the Act are as follows:

- (i) toys which are essentially intended for infants to bring into contact with their mouth;
- (ii) accessory toys (toys used as accessories by infants), transfer pictures, Okiagari (daruma doll made so as to right itself when knocked over), masks, origami, rattles, educational toys (limited to those that may come into contact with the mouth, excluding those set forth in this item), building blocks, toy phones, toy animals, dolls, clay, toy vehicles, balloons, blocks, balls, cooking utensils for playing house; and
- (iii) toys to be played with in combination with the toys referred to in the preceding item.

Article 79 The following authority of the Minister of Health, Labour and Welfare is delegated to the Director-Generals of the Regional Bureaus of Health and

Welfare, pursuant to the provisions of Article 80, paragraph (1) of the Act and Article 41, paragraph (1) of the Order:

- (i) the authority provided for in Article 41 of the Act;
- (ii) the authority provided for in Article 42 of the Act;
- (iii) the authority provided for in Article 46, paragraph (2) of the Act; and
- (iv) the authority provided for in Article 47, paragraph (1) of the Act.

Appended Table 1 (Re: Article 12)

1. Zinc Salts (limited to Zinc Gluconate and Zinc Sulfate)
2. Chlorous Acid Water
3. Sodium Chlorite
4. Nitrous Oxide
5. Adipic Acid
6. Sodium Nitrite
7. L-Ascorbic Acid (Vitamin C)
8. Calcium L-Ascorbate
9. L-Ascorbic Acid 2-Glucoside
10. L-Ascorbic Stearate (Vitamin C Stearate)
11. Sodium L-Ascorbate (Vitamin C Sodium)
12. L-Ascorbic Palmitate (Vitamin C Palmitate)
13. Asparaginase
14. Monosodium L-Aspartate
15. Aspartame (L- α -aspartyl-L-phenylalanine-methyl ester)
16. Acesulfame Potassium (Acesulfame K)
17. Acetylated Distarch Adipate
18. Acetylated Oxidized Starch
19. Acetylated Distarch Phosphate
20. Acetaldehyde
21. Ethyl Acetoacetate
22. Acetophenone
23. Acetone
24. Sodium Selenite
25. Azoxystrobin
26. Advantame
27. Anisaldehyde (p-Methoxybenzaldehyde)
28. β -Apo-8'-carotenal
29. (3-Amino-3-carboxypropyl) dimethylsulfonium chloride
30. Amyl alcohol
31. α -Amylcinnamaldehyde (α -amylcinnamic aldehyde)
32. DL-Alanine
33. Ammonium Hydrogen Sulfite Water
34. Sodium Sulfite
35. L-Arginine L-Glutamate
36. Ammonium Alginate
37. Potassium Alginate
38. Calcium Alginate
39. Sodium Alginate
40. Propylene Glycol Alginate

41. Argon
42. Benzoic Acid
43. Sodium Benzoate
44. Methyl Anthranilate
45. Ammonia
46. Ammonium Isovalerate
47. Ionone
48. Ion Exchange Resin
49. Isoamyl Alcohol
50. Isoeugenol
51. Isoamyl Isovalerate
52. Ethyl Isovalerate
53. Isoquinoline
54. Isothiocyanates (except those generally found to be highly toxic)
55. Allyl Isothiocyanate (Volatile Oil of Mustard)
56. Isovaleraldehyde
57. Isobutanol
58. Isobutylamine
59. Isobutyraldehyde (Isobutanal)
60. Isopropanol
61. Isopropylamine
62. Isopentylamine
63. L-Isoleucine
64. Disodium 5' -Inosinate (Sodium 5' -Inosinate)
65. Imazalil
66. Indole and its derivatives
67. Disodium 5' -Uridylate (Sodium 5' -Uridylate)
68. γ -Undecalactone (Undecalactone)
69. Ester Gum
70. Esters
71. Mixture of 2-Ethyl-3, 5-dimethylpyrazine and 2-Ethyl-3, 6-dimethylpyrazine
72. Ethylvanillin
73. 2-Ethylpyrazine
74. 3-Ethylpyridine
75. 2-Ethyl-3-methylpyrazine
76. 2-Ethyl-5-methylpyrazine
77. 2-Ethyl-6-methylpyrazine
78. 5-Ethyl-2-methylpyridine
79. Calcium Disodium Ethylenediaminetetraacetate (Calcium Disodium EDTA)
80. Disodium Ethylenediaminetetraacetate (Disodium EDTA)
81. Ethers
82. Erythorbic Acid (Isoascorbic Acid)
83. Sodium Erythorbate (Sodium Isoascorbate)
84. Ergocalciferol (Calciferol or Vitamin D₂)
85. Ammonium Chloride
86. Potassium Chloride
87. Calcium Chloride
88. Ferric Chloride

89. Magnesium Chloride
90. Hydrochloric Acid
91. Eugenol
92. Octanal (Caprylic Aldehyde or Octyl Aldehyde)
93. Octanoic Acid
94. Ethyl Octanoate (Ethyl Caprylate)
95. Starch Sodium Octenyl Succinate
96. o-Phenylphenol and Sodium o-Phenylphenate
97. Sodium Oleate
98. Peracetic Acid
99. Hydrogen Peroxide
100. Benzoyl Peroxide
101. Sodium Caseinate
102. Ammonium Persulfate
103. Calcium Carboxymethylcellulose (Calcium Cellulose Glycolate)
104. Sodium Carboxymethylcellulose (Sodium Cellulose Glycolate)
105. β -Carotene
106. Canthaxanthin
107. Isoamyl Formate
108. Geranyl Formate
109. Citronellyl Formate
110. Xylitol
111. Chitin-Glucan
112. Disodium 5' -Guanylate (Sodium 5'-Guanylate)
113. Citric Acid
114. Isopropyl Citrate
115. Triethyl Citrate
116. Monopotassium Citrate and Tripotassium Citrate
117. Calcium Citrate
118. Sodium Ferrous Citrate (Sodium Iron Citrate)
119. Ferric Citrate
120. Ferric Ammonium Citrate
121. Trisodium Citrate (Sodium Citrate)
122. Glycine
123. Glycerin (Glycerol)
124. Glycerin Fatty Acid Ester
125. Calcium Glycerophosphate
126. Disodium Glycyrrhizinate
127. Glucono- δ -Lactone (Gluconolactone)
128. Gluconic Acid
129. Potassium Gluconate
130. Calcium Gluconate
131. Ferrous Gluconate (Iron Gluconate)
132. Sodium Gluconate
133. Glutamyl-valyl-glycine
134. L-Glutamic Acid
135. Monoammonium L-Glutamate
136. Monopotassium L-Glutamate
137. Monocalcium Di-L-Glutamate
138. Monosodium L-Glutamate (Monosodium Glutamate)

139. Monomagnesium Di-L-Glutamate
140. Calcium Silicate
141. Magnesium Silicate
142. Cinnamic Acid
143. Ethyl Cinnamate
144. Methyl Cinnamate
145. Ketones
146. Geraniol
147. High-Test Bleaching Powder
148. Succinic Acid
149. Monosodium Succinate
150. Disodium Succinate
151. Cholecalciferol (Vitamin D3)
152. Sodium Chondroitin Sulfate
153. Isoamyl Acetate
154. Ethyl Acetate
155. Calcium Acetate
156. Geranyl Acetate
157. Cyclohexyl Acetate
158. Citronellyl Acetate
159. Cinnamyl Acetate
160. Terpinyl Acetate
161. Starch Acetate
162. Sodium Acetate
163. Polyvinyl Acetate
164. Phenethyl Acetate (Phenylethyl Acetate)
165. Butyl Acetate
166. Benzyl Acetate
167. l-Menthyl Acetate
168. Linalyl Acetate
169. Saccharin
170. Calcium Saccharin
171. Sodium Saccharin (Soluble Saccharin)
172. Methyl Salicylate
173. Calcium Oxide
174. Oxidized Starch
175. Magnesium Oxide
176. Iron Sesquioxide (Diiron Trioxide or Iron Oxide Red)
177. Hypochlorous Acid Water
178. Sodium Hypochlorite (Hypochlorite of Soda)
179. Hypobromous Acid Water
180. Sodium Hydrosulfite (Hydrosulfite)
181. 2,3-Diethylpyrazine
182. 2,3-Diethyl-5-methylpyrazine
183. Allyl Cyclohexylpropionate
184. L-Cystein Monohydrochloride
185. Disodium 5'-Cytidylate (Sodium 5'-Cytidylate)
186. Citral
187. Citronellal
188. Citronellol

189. 1,8-Cineole (Eucalyptol)
190. Diphenyl (Biphenyl)
191. Difenoconazole
192. Butylated Hydroxytoluene
193. Dibenzoyl Thiamine
194. Dibenzoyl Thiamine Hydrochloride
195. Fatty Acids
196. Aliphatic Higher Alcohols
197. Aliphatic Higher Aldehydes (except those generally found to be highly toxic)
198. Aliphatic Higher Hydrocarbons (except those generally found to be highly toxic)
199. 2,3-Dimethylpyrazine
200. 2,5-Dimethylpyrazine
201. 2,6-Dimethylpyrazine
202. 2,6-Dimethylpyridine
203. Oxalic Acid
204. Potassium Bromate
205. DL-Tartaric Acid (dl -Tartaric Acid)
206. L- Tartaric Acid (d -Tartaric Acid)
207. Dipotassium DL-Tartrate (Dipotassium dl -Tartrate)
208. Dipotassium L-Tartrate (Dipotassium d -Tartrate)
209. Potassium DL-Bitartrate (Potassium Hydrogen dl -Tartrate or Potassium Hydrogen DL-Tartrate)
210. Potassium L-Bitartrate (Potassium Hydrogen d -Tartrate or Potassium Hydrogen L-Tartrate)
211. Disodium DL-Tartrate (Disodium dl -Tartrate)
212. Disodium L-Tartrate (Disodium d -Tartrate)
213. Potassium Nitrate
214. Sodium Nitrate
215. Food Red No. 2 (Amaranth) and its Aluminum Lake
216. Food Red No. 3 (Erythrosine) and its Aluminum Lake
217. Food Red No. 40 (Allura Red AC) and its Aluminum Lake
218. Food Red No. 102 (New Coccine)
219. Food Red No. 104 (Phloxine)
220. Food Red No. 105 (Rose Bengal)
221. Food Red No. 106 (Acid Red)
222. Food Yellow No. 4 (Tartrazine) and its Aluminum Lake
223. Food Yellow No. 5 (Sunset Yellow FCF) and its Aluminum Lake
224. Food Green No. 3 (Fast Green FCF) and its Aluminum Lake
225. Food Blue No. 1 (Brilliant Blue FCF) and its Aluminum Lake
226. Food Blue No. 2 (Indigo Carmine) and its Aluminum Lake
227. Sucrose Fatty Acid Ester
228. Silicone Resin (Polydimethylsiloxane)
229. Cinnamyl Alcohol (Cinnamic Alcohol)
230. Cinnamaldehyde (Cinnamic Aldehyde)
231. Potassium Hydroxide (Caustic Potash)
232. Calcium Hydroxide (Slaked Lime)
233. Sodium Hydroxide (Caustic Soda)
234. Magnesium Hydroxide

235. Sucralose (Trichlorogalactosucrose)
236. Calcium Stearate
237. Magnesium Stearate
238. Calcium Stearoyl Lactylate (Calcium Stearyl Lactylate)
239. Sodium Stearoyl Lactylate
240. Sorbitan Fatty Acid Ester
241. D-Sorbitol (D-Sorbit)
242. Sorbic Acid
243. Potassium Sorbate
244. Calcium Sorbate
245. Ammonium Carbonate
246. Potassium Carbonate (anhydrous)
247. Calcium Carbonate
248. Ammonium Bicarbonate (Ammonium Hydrogen Carbonate)
249. Sodium Bicarbonate (Sodium Hydrogen Carbonate or Bicarbonate Soda)
250. Sodium Carbonate (Crystal: Carbonate Soda, Anhydrous: Soda Ash)
251. Magnesium Carbonate
252. Thiabendazole
253. Thiamine Hydrochloride (Vitamin B1 Hydrochloride)
254. Thiamine Mononitrate (Vitamin B1 Mononitrate)
255. Thiamine Dicetylsulfate (Vitamin B1 Dicetylsulfate)
256. Thiamine Thiocyanate (Vitamin B1 Thiocyanate)
257. Thiamine Naphthalene-1,5-disulfonate (Vitamin B1 Naphthalene-1,5-disulfonate)
258. Thiamine Dilaurylsulfate (Vitamin B1 Dilaurylsulfate)
259. Thioethers (except those generally found to be highly toxic)
260. Thiols (Thioalcohols) (except those generally found to be highly toxic)
261. L-Theanine
262. Decanal (Decyl Aldehyde)
263. Decanol (Decyl Alcohol)
264. Ethyl Decanoate (Ethyl Caprate)
265. Sodium Iron Chlorophyllin
266. 5,6,7,8-Tetrahydroquinoxaline
267. 2,3,5,6-Tetramethylpyrazine
268. Sodium Dehydroacetate
269. Terpeneol
270. Terpene Hydrocarbons
271. Sodium Carboxymethylstarch
272. Copper salts (limited to Copper Gluconate and Cupric Sulfate)
273. Sodium Copper Chlorophyllin
274. Copper Chlorophyll
275. dl- α -Tocopherol
276. All-rac- α -Tocopheryl Acetate
277. R,R,R - α -Tocopheryl Acetate
278. DL-Tryptophan
279. L-Tryptophan
280. Trimethylamine
281. 2,3,5-Trimethylpyrazine
282. DL-Threonine
283. L-Threonine

284. Nisin
285. Natamycin (Pimaricin)
286. Sodium Methoxide (Sodium Methylate)
287. Nicotinic Acid (Niacin)
288. Nicotinamide (Niacinamide)
289. Sulfur Dioxide (Sulfurous Acid Anhydride)
290. Chlorine Dioxide
291. Silicon Dioxide (Silica Gel)
292. Carbon Dioxide (Carbonic Acid Gas)
293. Titanium Dioxide
294. Dimethyl Dicarbonate
295. Lactic Acid
296. Potassium Lactate
297. Calcium Lactate
298. Iron Lactate
299. Sodium Lactate
300. Neotame
301. γ -Nonalactone (Nonalactone)
302. Potassium Norbixin
303. Sodium Norbixin
304. Vanillin
305. Isobutyl p-Hydroxybenzoate
306. Isopropyl p-Hydroxybenzoate
307. Ethyl p-Hydroxybenzoate
308. Butyl p-Hydroxybenzoate
309. Propyl p-Hydroxybenzoate
310. p-Methylacetophenone
311. L-Valine
312. Valeraldehyde
313. Calcium Pantothenate
314. Sodium Pantothenate
315. Biotin
316. L-Histidine Monohydrochloride
317. Bisbentiamine (Benzoylthiamine Disulfide)
318. Vitamin A (Retinol)
319. Vitamin A Fatty Acid Esther (Retinol Fatty Acid Ester)
320. 1-Hydroxyethylidene-1,1-Diphosphonic Acid
321. Hydroxycitronellal
322. Hydroxycitronellal Dimethylacetal
323. Hydroxypropyl Distarch Phosphate
324. Hydroxypropyl Cellulose
325. Hydroxypropyl Starch
326. Hydroxypropyl Methylcellulose
327. Copolymer of Vinylimidazole/Vinylpyrrolidone (PVI/PVP)
328. Piperidine
329. Piperonal (Heliotropine)
330. Piperonyl Butoxide
331. Sunflower Lecithin
332. Glacial Acetic Acid
333. Pyrazine

334. Pyridoxine Hydrochloride (Vitamin B6)
335. Primethanil
336. Potassium Pyrosulfite (Potassium Hydrogen Sulfite or Potassium Metabisulfite)
337. Sodium Pyrosulfite (Sodium Metabisulfite or Acid Sulfite of Soda)
338. Pyrrolidine
339. Potassium Pyrophosphate (Tetrapotassium Pyrophosphate)
340. Calcium Dihydrogen Pyrophosphate (Acid Calcium Pyrophosphate)
341. Disodium Dihydrogen Pyrophosphate (Acid Disodium Pyrophosphate)
342. Ferric Pyrophosphate
343. Sodium Pyrophosphate (Tetrasodium Pyrophosphate)
344. Pyrrole
345. L-Phenylalanine
346. Isoamyl Phenylacetate
347. Isobutyl Phenylacetate
348. Ethyl Phenylacetate
349. 2-(3-Phenylpropyl) pyridine
350. Phenethylamine
351. Phenol Ethers (except those generally found to be highly toxic)
352. Phenols (except those generally found to be highly toxic)
353. Ferrocyanides (limited to Potassium Ferrocyanide (Potassium Hexacyanoferrate (II)), Calcium Ferrocyanide (Calcium Hexacyanoferrate (II)) and Sodium Ferrocyanide (Sodium Hexacyanoferrate (II)))
354. Psicose Epimerase
355. Butanol
356. Butylamine
357. sec-Butylamine
358. Butyraldehyde
359. Butylated Hydroxyanisole
360. Fumaric Acid
361. Monosodium Fumarate (Sodium Fumarate)
362. Fludioxonil
363. Furfural and its derivatives (except those generally found to be highly toxic)
364. Propanol
365. Propionaldehyde
366. Propionic Acid
367. Isoamyl Propionate
368. Ethyl Propionate
369. Calcium Propionate
370. Sodium Propionate
371. Benzyl Propionate
372. Propiconazole
373. Propylamine
374. Propylene Glycol
375. Propylene Glycol Esters of Fatty Acids
376. Hexanoic Acid (Caproic Acid)
377. Allyl Hexanoate (Allyl Caproate)
378. Ethyl Hexanoate (Ethyl Caproate)
379. Hexylamine

380. Ethyl Heptanoate (Ethyl Enanthate)
381. l-Perillaldehyde
382. Benzyl Alcohol
383. Benzaldehyde
384. 2-Pentanol (sec-Amyl alcohol)
385. Pentylamine
386. trans-2-Pentenal
387. 1-Penten-3-ol
388. Aromatic Alcohols
389. Aromatic Aldehydes (except those generally found to be highly toxic)
390. Propyl Gallate
391. Sodium Polyacrylate
392. Polyisobutylene (Butyl Rubber)
393. Polysorbate 20
394. Polysorbate 60
395. Polysorbate 65
396. Polysorbate 80
397. Polyvinylpyrrolidone
398. Polyvinylpolypyrrolidone
399. Polybutene (Polybutylene)
400. Potassium Polyphosphate
401. Sodium Polyphosphate
402. d-Borneol
403. Maltol
404. D-Mannitol (D-Mannite)
405. Metatartaric Acid
406. Potassium Metaphosphate
407. Sodium Metaphosphate
408. DL-Methionine
409. L-Methionine
410. Methyl N-Methylantranilate
411. 5-Methylquinoxaline
412. 6-Methylquinoline
413. 5-Methyl-6,7-dihydro-5H-cyclopentapyrazine
414. Methyl Cellulose
415. 1-Methylnaphthalene
416. Methyl β -Naphthyl Ketone
417. 2-Methylpyrazine
418. 2-Methylbutanol
419. 3-Methyl-2-butanol
420. 2-Methylbutylamine
421. 2-Methylbutyraldehyde
422. trans-2-Methyl-2-butenal
423. 3-Methyl-2-butenal
424. 3-Methyl-2-butenol
425. Methyl Hesperidin (Soluble Vitamin P)
426. DL-Menthol (dl-Peppermint Camphor)
427. l-Menthol (Peppermint Camphor)
428. Morpholine Fatty Acid Salt
429. Folic Acid

430. Butyric Acid
431. Isoamyl Butyrate
432. Ethyl Butyrate
433. Cyclohexyl Butyrate
434. Butyl Butyrate
435. Lactones (except those generally found to be highly toxic)
436. L-Lysine L-Aspartate
437. L-Lysine Monohydrochloride
438. L-Lysine L-Glutamate
439. Linalool
440. Calcium 5'-Ribonucleotide
441. Disodium 5'-Ribonucleotide (Sodium 5'-Ribonucleotide)
442. Riboflavin (Vitamin B2)
443. Riboflavin Tetrabutyrates (Vitamin B2 Tetrabutyrates)
444. Riboflavin 5'-Phosphate Sodium (Sodium Riboflavin Phosphate or Sodium Vitamin B2 Phosphate)
445. Sulfuric Acid
446. Aluminum Ammonium Sulfate (Crystal: Ammonium Alum, Dried: Burnt Ammonium Alum)
447. Aluminum Potassium Sulfate (Crystal: Alum or Potassium Alum, Dried: Burnt Alum)
448. Ammonium Sulfate
449. Potassium Sulfate
450. Calcium Sulfate
451. Ferrous Sulfate
452. Sodium Sulfate
453. Magnesium Sulfate
454. DL-Malic Acid (dl -Malic Acid)
455. Sodium DL-Malate (Sodium dl -Malate)
456. Phosphoric Acid
457. Distarch Phosphate
458. Monostarch Phosphate
459. Tripotassium Phosphate (Potassium Tertiary Phosphate)
460. Tricalcium Phosphate (Calcium Tertiary Phosphate)
461. Trimagnesium Phosphate (Magnesium Tertiary Phosphate)
462. Diammonium Hydrogen Phosphate (Di-Ammonium Phosphate)
463. Ammonium Dihydrogen Phosphate (Monoammonium Phosphate)
464. Dipotassium Hydrogen Phosphate (Dipotassium Phosphate)
465. Potassium Dihydrogen Phosphate (Monopotassium Phosphate)
466. Calcium Monohydrogen Phosphate (Dibasic Calcium Phosphate)
467. Calcium Dihydrogen Phosphate (Monocalcium Phosphate)
468. Disodium Hydrogen Phosphate (Disodium Phosphate)
469. Sodium Dihydrogen Phosphate (Monosodium Phosphate)
470. Magnesium Monohydrogen Phosphate
471. Trisodium Phosphate (Tribasic Sodium Phosphate)
472. Phosphated Distarch Phosphate

Appended Tables 2 through 9

Deleted

Appended Table 10 (Re: Article 32)

Raw salt
 Copra
 Oils and fats of animal origin or plant origin used for producing edible oils and fats
 Raw sugar
 Crude alcohol
 Molasses
 Malt
 Hops

Appended Table 11 (Re: Article 32)

Places for Customs Clearance of Cargoes	Names of Quarantine Stations
Hokkaido	Otaru
Aomori Prefecture, Iwate Prefecture, Miyagi Prefecture, Akita Prefecture, Yamagata Prefecture, and Fukushima Prefecture	Sendai
Chiba Prefecture (limited to Narita City; Taiei-machi, Katori-gun; Tako-machi, Katori-gun; and Shibayama-machi, Sanbu-gun)	Narita Airport
Ibaraki Prefecture, Tochigi Prefecture, Gunma Prefecture, Saitama Prefecture, Chiba Prefecture (excluding areas under the jurisdiction of the Narita Airport Quarantine Station), Tokyo Metropolis, Kanagawa Prefecture (limited to Kawasaki City), Yamanashi Prefecture, and Nagano Prefecture	Tokyo
Kanagawa Prefecture (excluding areas under the jurisdiction of the Tokyo Quarantine Station)	Yokohama
Niigata Prefecture, Toyama Prefecture, and Ishikawa Prefecture	Niigata
Shizuoka Prefecture, Gifu Prefecture, Aichi Prefecture, Mie Prefecture, and Wakayama Prefecture (limited to Shingu City and Higashimuro-gun)	Nagoya
Fukui Prefecture, Shiga Prefecture, Kyoto Prefecture, Osaka Prefecture (excluding areas under the jurisdiction of the Kansai Airport Quarantine Station), Nara Prefecture, and Wakayama Prefecture (excluding areas under the jurisdiction of the Nagoya Quarantine Station)	Osaka
Osaka Prefecture (limited to the Kansai International Airport)	Kansai Airport
Hyogo Prefecture, Okayama Prefecture, Tokushima Prefecture, and Kagawa Prefecture	Kobe
Tottori Prefecture, Shimane Prefecture, Hiroshima Prefecture, Ehime Prefecture, and Kochi Prefecture	Hiroshima

Yamaguchi Prefecture, Fukuoka Prefecture, Saga Prefecture, Nagasaki Prefecture, Kumamoto Prefecture, Oita Prefecture, Miyazaki Prefecture, and Kagoshima Prefecture	Fukuoka
Okinawa Prefecture	Naha
Remarks: The areas set forth in this Table are designated by administrative districts and other areas as of September 1, 1991.	

Appended Table 12 (Re: Article 32)

1	<p>Machines used for producing foods</p> <p>Apparatus or containers and packaging made of aluminum</p> <p>Apparatus or containers and packaging made of stainless steel</p> <p>Apparatus or containers and packaging made of colorless glass</p>	<p>Three years from the date of the submission of the written import notification</p>
2	<p>Alphanized rice</p> <p>Ethyl alcohol</p> <p>Barley</p> <p>Canned food or bottled food (excluding processed meat products or wine)</p> <p>Unprocessed sake (excluding unprocessed wine)</p> <p>Kaoliang</p> <p>Sesame</p> <p>Wheat</p> <p>Rice</p> <p>Safflower seeds</p> <p>Distilled alcohol</p> <p>Food (excluding processed meat products) which are packed and sealed in airtight containers and packaging and are sterilized by autoclaving and heating (excluding canned food and bottled food)</p> <p>Vegetable protein</p> <p>Buckwheat</p> <p>Soybean</p> <p>Starch (excluding tapioca starch)</p> <p>Animal oil and fat (excluding fish and marine mammal oil and fat)</p> <p>Rapeseed</p>	<p>One year from the date of the submission of the written import notification</p>

	<p>Sunflower seeds Indian millet Rye Apparatus or containers and packaging made of materials other than aluminum, stainless steel, colorless glass, or synthetic resins</p>	
3	<p>The following food, additives, apparatus, or containers and packaging which has been continuously imported since before the submission of the written import notification stating the import plans provided for in Article 32, paragraph (4) and which has not fallen under any of the items of that paragraph for three years prior to the submission of the notification</p> <p>Sweet bean jam Fruits and fruit peel temporarily stored Roasted coffee beans or ground coffee beans Locusts boiled in water Fish roes (limited to those dried) Fish Tsukudani (preservable food boiled in soy sauce) Fish or marine mammal oil and fat Oatmeal Seaweeds Cacao beans (excluding those roasted) Unprocessed wine Frozen food which requires heating before consumption (meaning produced or processed food which is frozen and is required to be heated for consumption) Gymnema tea Raw fruit juice Flours of cereals, beans, or potatoes Cocoa products (excluding powdered carbonated drinks) Coffee extract Coffee beans (excluding those roasted) Corn flakes Konnyaku (jelly made from devil's-tongue starch) Salt Vegetable creaming powders Vegetable oil and fat Shortening Sake (rice wine) Tea Chocolate Sugar Tochu tea Nimame (cooked beans) Hachinoko (hornet larva) boiled in water</p>	<p>One year from the date of the submission of the written import notification</p>

<p>Honey containing honeycomb</p> <p>Bread</p> <p>Pre-mixed flour for bread</p> <p>Beer</p> <p>Margarine</p> <p>Mate tea</p> <p>Mirin (a type of sake with low alcohol content and high sugar content)</p> <p>Noodles</p> <p>Vegetables boiled in water</p> <p>Vegetable puree or paste</p> <p>Frozen fruits (excluding frozen fruits produced or processed)</p> <p>Frozen vegetables (excluding frozen vegetables produced or processed)</p> <p>Additives other than those set forth in the Appended Table 1 (excluding those for which criteria or standards have been established pursuant to the provisions of Article 13, paragraph (1) of the Act)</p> <p>Apparatus or containers and packaging made of synthetic resin</p>	
---	--

Appended Table 13 (Re: Article 37 and Article 40)

Type of Standard Operation Manual to be Prepared	Matters to be Entered
Standard operation manual for maintenance and management of machinery and tools	<ol style="list-style-type: none"> 1. The names of the machinery and tools 2. Methods for routine maintenance (including calibration for gauges) 3. A plan for regular maintenance 4. Measures to be taken if a breakdown occurs (including how to handle test samples if a breakdown occurs during testing) 5. Methods for keeping records concerning maintenance of machinery and tools 6. Dates for preparing and revising the standard operation manual
Standard operation manual for management of reagents, etc.	<ol style="list-style-type: none"> 1. Methods for labeling the containers used for reagents, test solutions, culture media, reference standards, standard solutions, and standard microorganism strains (hereinafter referred to as "reagents, etc.") 2. Precautions concerning the management of reagents, etc. 3. Methods for keeping records concerning the management of reagents, etc.

	4. Date of preparation and date of amendment of the standard operation manual
Standard operation manual for animal husbandry management	<ol style="list-style-type: none"> 1. Methods for managing animal rooms 2. Precautions for receiving animals 3. Methods for animal husbandry 4. Methods for observing animal health conditions 5. Methods for handling animals that have or are suspected to have diseases 6. Methods for keeping records concerning animal husbandry 7. Date of preparation and date of amendment of the standard operation manual
Standard operation manual for handling of test samples	<ol style="list-style-type: none"> 1. Precautions for collecting, transporting, and receiving test samples 2. Methods for managing test samples 3. Methods for keeping records concerning the management of test samples 4. Date of preparation and date of amendment of the standard operation manual
Standard operation manual for the implementation of inspections	<ol style="list-style-type: none"> 1. Items of inspections, etc.; 2. Name of the products; 3. Methods for conducting inspections, etc.; 4. Methods for selecting and preparing reagents; 5. Methods for handling standard microbe strains, for bacteriological inspections; 6. Methods for preparing samples; 7. Methods for operating machinery and tools used for inspections, etc.; 8. Precautions for conducting inspections, etc. 9. Methods for processing data obtained by inspections, etc. 10. Methods for keeping records concerning inspections, etc. 11. Date of preparation and date of amending the standard operation manual

Remarks

- (i) The standard operation manual for animal husbandry management is to be prepared only by a person who conducts inspections using animals.
- (ii) The standard operation manual for the implementation of inspections is to be prepared for each item of inspections, etc.

Appended Table 14 (Re: Article 50)

Curriculum	Subjects
Chemistry	Analytical chemistry, Organic chemistry, Inorganic chemistry
Biological chemistry	Biological chemistry, Food chemistry, Physiology, Food analysis, Toxicology
Microbiology	Microbiology, Food microbiology, Food preservation, Food manufacturing
Public health	Public health, Food hygiene, Environmental hygiene, Health administration, Epidemiology

Appended Table 15 (Re: Article 50)

Fishery chemistry, Livestock chemistry, Radiation chemistry, Dairy chemistry, Meat chemistry, Polymer chemistry, Biological organic chemistry, Analysis of environmental pollutants, Enzyme chemistry, Food physics and chemistry, Fisheries physiology, Livestock physiology, Plant physiology, Environmental biology, Applied microbiology, Dairy microbiology, Pathology, Introduction to medical science, Anatomy, Medical chemistry, Occupational medicine, Hematology, Serology, Genetics, Parasitology, Veterinary medicine, Nutritional chemistry, Sanitary statistics, Nutritional science, Environmental health science, Hygiene management, Fisheries manufacturing, Livestock products manufacturing, Agricultural products manufacturing, Brewed food manufacturing, Dairy products manufacturing, Distilled liquor manufacturing, Canned product engineering, Food engineering, Food preservation, Freezing and refrigeration studies, Quality control studies, and other similar subjects related to food sanitation

Appended Table 16 (Re: Article 56)

	Classification	Subjects	Hours
1	General common subjects	1. Overview of public health	9
		2. Food Sanitation Act and related laws and regulations	18
		3. Standards for foods and additives, etc.	18
		4. Introduction to chemistry	18
		5. Introduction to bacteriology	18
		6. Toxicology	9
		7. Food toxicology	15
		8. Food science (including Nutritional science)	18
		9. Sanitation management in facilities	9
2	Subjects related to dairy products	1. Standards for dairy products	12
		2. Practical training on bacteriology	18
		3. Inspection methods for dairy products	6

		4. Practical training on dairy product inspections	18
		5. Visits to facilities and on-site training	15
3	Subjects related to processed meat products	1. Standards for processed meat products	12
		2. Practical training on bacteriology	18
		3. Inspection methods for processed meat products	6
		4. Practical training on processed meat product inspections	18
		5. Visits to facilities and on-site training	15
4	Subjects related to fish meat ham and fish meat sausages	1. Related laws and regulations and standards concerning fish meat ham and fish meat sausages	15
		2. Practical training on bacteriology	18
		3. Inspection methods for fish meat ham and fish meat sausages	9
		4. Practical training on inspections of fish meat ham and fish meat sausages	15
		5. Visits to facilities and on-site training	15
5	Subjects related to edible oil and fat	1. Overview of oil and fat chemistry	10
		2. Usage criteria for food and food additives	14
		3. Duties of food sanitation supervisors	4
		4. Responsibilities of food sanitation supervisors	3
		5. Theory of and practical training on inspection methods for oil and fat	28
		6. Visits to facilities and on-site training	10
6	Subjects related to margarine and shortening	1. Nutritional science and analytical methods	6
		2. Sanitation management in the production process	6
		3. Sanitation standards in the production process	3
		4. Method of assessment of food additives	6
		5. Practical training on analysis methods	16
		6. Practical training on assessment of food additives	15
		7. Visits to facilities and on-site training	21
7	Subjects related to food additives	1. Overview of analysis methods for additives	9
		2. Method of assessment of food additives	9
		3. Practical training on assessment of food additives	24
		4. Visits to facilities and on-site training	15

Appended Table 17 (Re: Article 66-2, paragraph (1))

(i) Appointment of a food sanitation manager

(a) A person who conducts business prescribed in Article 51, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 68, paragraph (3) of the Act; hereinafter referred to as the "business person" in this Table) is to appoint a food sanitation manager; provided, however, that this does not apply to a business person specified in each item of Article 66-2, paragraph (4). The food sanitation supervisor specified in Article 48 of the Act may also serve as the food sanitation manager.

(b) A food sanitation manager is to be a person who falls under any of the following cases.

1. A person who satisfies the qualification requirements for food sanitation inspector provided for in Article 30 of the Act or food sanitation supervisor provided for in Article 48 of the Act.
2. A licensed cook, confectionery hygienist, nutritionist, ship cook, or sanitation manager prescribed in Article 7 of the Slaughterhouse Act (Act No. 114 of 1953), work sanitation manager prescribed in Article 10 of the Slaughterhouse Act, or poultry slaughtering sanitation manager prescribed in Article 12 of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act (Act No. 70 of 1990).
3. A person who has taken training sessions provided by a prefectural governor, etc., or training sessions found appropriate by a prefectural governor, etc.

(c) A food sanitation manager is to observe the following matters.

1. To take training sessions provided by prefectural governors, etc., or training sessions approved by prefectural governors, etc., on a regular basis, and endeavor to acquire new knowledge on food sanitation (limited to businesses set forth in Article 54 of the Act (including as applied mutatis mutandis pursuant to Article 68, paragraph (3) of the Act)).
2. To manage sanitation by following the instructions of the business person.

(d) A business person is to respect the opinions of the food sanitation manager.

(e) A food sanitation manager is to exercise necessary care as well as endeavor to state any necessary opinions to the business person, in order to comply with the measures provided for in Article 66-2, paragraph (3).

(f) A business person who processes pufferfish must have a person who is certified by a prefectural governor, etc. to have the knowledge of distinguishing the type of pufferfish and skills for removing toxic parts,

etc., process the pufferfish, or have another person process the pufferfish in the presence of that person.

(ii) Sanitation management of facilities:

- (a) The facility and its surroundings are to be cleaned on a regular basis and kept clean while the facility is in operation, in order to prevent food sanitation hazards.
- (b) Unnecessary articles, etc., must not be placed at places where food or additives are produced, processed, cooked, stored, or sold.
- (c) The inner walls, ceiling, and floor of the facility are to be kept clean.
- (d) Adequate lighting, illumination, and ventilation are to be secured and temperature and humidity are to be managed appropriately as necessary, in the facility.
- (e) Windows and entrances must not be left open in principle. Measures to prevent the intrusion of dust, rodents, insects, etc., are to be taken when the windows and entrances are left open.
- (f) The drain gutters are to be cleaned to prevent the inflow of solid matter and to ensure proper drainage, and repairs are to be promptly made if they are damaged.
- (g) The toilets are to be kept clean, and cleaning and sterilization are to be performed on a regular basis.
- (h) Animals are not to be raised in areas where food or additives are handled or preserved.

(iii) Sanitation management of equipment, etc.:

- (a) Machinery and tools are to be appropriately used according to their purpose in order to maintain sanitation.
- (b) Cleansing and sterilization of machinery and tools and their parts are to be performed and they are to be stored in a sanitary manner in designated places in order to prevent metal pieces, foreign substances, or chemical substances from being mixed into food or additives. In the event of any malfunction or damage, repairs are to be promptly made, and maintenance is to be made so that they can be properly used.
- (c) Detergents are to be used in an appropriate manner when detergents are used for cleansing machinery and tools and their parts.
- (d) For measuring instruments such as thermometers, pressure gauges, and flowmeters, and devices used for sterilization, disinfection, sanitization, or water purification, their functions are to be inspected on a regular basis and the results of the inspections are to be recorded.
- (e) The items that may come into contact with food or additives such as tools, cleaning equipment, and protective equipment are to be sterilized with hot water, steam, or a disinfectant, etc., and dried after each instance of contamination or each time work is finished.

- (f) Careful attention is to be paid when handling detergents, disinfectants, and other chemical substances, and measures are to be taken to prevent them from being mixed into food or additives, such as labelling the names of the contents on the containers and packaging in which they are contained as necessary.
- (g) Equipment for cleaning facilities and equipment is to be used in an appropriate manner according to the purpose, and cleaned, dried, and stored in a designated place each time it is used.
- (h) Equipment for washing hands is to be equipped with soap, paper towels, etc., and disinfectants, and maintained in a condition that cleansing and drying of the fingers can be appropriately carried out.
- (i) Cleansing equipment is to be kept clean.
- (j) If hand washing equipment is to be also used as cleansing equipment with the confirmation of the prefecture, etc., it is to be cleansed after each instance of contamination.
- (k) For food irradiation business, the absorbed dose is to be confirmed using a chemical dosimeter at least once each business day, and the records of the results are to be preserved for two years.
- (iv) Management of water used, etc.
 - (a) The water to be used for producing, processing, or cooking food or additives is to be water supplied by a water supply business provided for in Article 3, paragraph (2) of the Water Supply Act (Act No. 177 of 1957), the dedicated water-supply system provided for in paragraph (6) of that Article, or the small water-supply system provided for in paragraph (7) of that Article (referred to as "water supplied by water supply businesses, etc." in item (iii), (f) of the Appended Table 19) or potable water; provided, however, that this does not apply to use of water for refrigeration or other processes that do not affect the safety of food or additives.
 - (b) If potable water is used, water quality inspection is to be conducted at least once a year and the certificate of the results is to be preserved for one year (or for the period until the food or additives to be handled are used or consumed if the period is one year or longer); provided, however, that if there is a risk that the water source, etc., has been contaminated due to an unexpected disaster, water quality inspection is to be conducted each time.
 - (c) To immediately suspend the use when it is found that the conditions set forth in (a) are not satisfied as a result of the inspection referred to in (b).
 - (d) Water tanks are to be cleaned on a regular basis and kept clean when they are used.
 - (e) If potable water is used and a sterilizer or water purifier is installed, it is to be confirmed on a regular basis that the device is operating properly, and the results are to be recorded;

- (f) Ice that comes into direct contact with food is to be made from water that meets the conditions under (a) supplied by properly managed water supply equipment. Ice is to be handled and stored in a sanitary manner.
- (g) When reusing used water, necessary treatment is to be conducted so as not to affect the safety of food or additives.
- (v) Measures against rodents and insects
 - (a) The facilities and their surroundings are to be maintained in a condition that maintenance and management can be appropriately conducted, the breeding sites of rodents and insects are to be eliminated, and rodents and insects are to be prevented from intruding the facilities by installing screens for windows, doors, suction and exhaust ports, traps, drain ditch covers, etc.
 - (b) The extermination work of rodents and insects is to be conducted at least twice a year and the records of the work are to be preserved for one year; provided, however, that if the purpose can be achieved by taking necessary measures based on the results of the investigation conducted periodically and in a unified manner on the locations, and habitats, and invasion routes of rodents and insects, and the status of damage, the work may be conducted in a method and at a frequency appropriate for the situation of the facility.
 - (c) When using rodenticides or insecticides, sufficient care is to be taken so as not to contaminate food or additives.
 - (d) Raw materials, products, and packaging materials, etc., are to be preserved in containers away from floors and walls in order to prevent contamination by rodents and insects. For items that have been opened once, measures are to be taken to prevent contamination, such as preserving them in containers with covers.
- (vi) Handling of waste and wastewater
 - (a) Procedures for the storage and disposal of waste are to be established.
 - (b) To make waste containers clearly distinguishable from other containers, and to keep them clean to prevent the leakage of dirty liquids or foul odors.
 - (c) Wastes must not be stored in areas where food or additives are handled or preserved (including adjacent areas), excluding cases in which it is found that food sanitation hazards can be prevented.
 - (d) Storage sites for wastes are to be sites where they can be managed appropriately so as not to adversely affect the surrounding environment.
 - (e) Wastes and wastewater are to be treated appropriately.
- (vii) Sanitation management for persons who handle food or additives:
 - (a) Medical examinations for a person who handles food or additives (hereinafter referred to as "food handler") are to be conducted for the purpose of ascertaining the health conditions necessary to prevent food

- sanitation hazards.
- (b) When a prefectural governor, etc., gives an instruction to have a food handler to undergo a feces examination, to instruct the food handler to undergo the feces examination.
 - (c) When a food handler exhibits the following symptoms, efforts are to be made to ascertain the details of the symptoms and determine whether the symptoms require medical examination by a physician and discontinuation of operations of handling food or additives.
 - 1. Jaundice
 - 2. Diarrhea
 - 3. Abdominal pain
 - 4. Fever
 - 5. Suppurative disease of the skin, etc.
 - 6. Secretion from the ears, eyes, or nose (limited to those that have risks of catching an infectious diseases, etc.)
 - 7. Nausea and vomiting
 - (d) When making a person with a skin injury engage in work, the injured part is to be covered with a water-resistant covering material. In addition, food or additives that may have been contaminated by vomitus, etc., are to be disposed of. If vomiting occurred in a facility, the facility is to be immediately disinfected appropriately with a disinfectant.
 - (e) Food handlers are to wear exclusive work clothes appropriate for the purpose and wear hats and masks as necessary when they engage in the work of handling food or additives. In addition, they are to use exclusive footwear in the workplace and must not leave the designated area wearing the footwear used in the workplace.
 - (f) Food handlers must not bring decorative items, etc., that may interfere with hand washing and cause foreign substance getting mixed into facilities handling food, etc.
 - (g) When food handlers use gloves, they are to use those that use water-resistant materials for the parts that come into direct contact with raw materials, etc., in principle.
 - (h) Food handlers are to cut their nails short as well as wash their hands to keep their fingers clean to avoid food sanitation hazards.
 - (i) When food handlers have finished defecation, or finished handling fresh raw materials or handling unheated raw materials, they are to wash and disinfect their hands sufficiently. When disposable gloves are used to handle fresh or unheated raw materials, the gloves are to be replaced after finishing the work.
 - (j) A food handler must not conduct the following acts while handling food or additives, from the viewpoint of preventing food sanitation hazards.

1. Act of unnecessarily contaminating the fingers, tools, or containers and packaging.
 2. Coughing out phlegm or spitting.
 3. Contaminating food or additives with droplets from coughing or sneezing, or causing the risk.
- (k) A food handler must not change clothes, smoke, eat, or drink in places other than designated areas.
- (l) When persons other than food handlers enter the facilities, they are to change to clean and exclusive work clothes, and comply with the provisions of sanitation management of food handlers indicated in this paragraph.
- (viii) Implementation of food inspection
- (a) For a business person who cooks and provides the same 300 meals at a time or 750 meals or more per day, the food is to be preserved for an appropriate period of time for each raw material and cooked food. Raw materials are to be preserved in the state at the time of purchase without cleansing, sterilization, etc.
 - (b) In the case referred to in (a), information of the recipient of the cooked food, the time of serving the cooked food (in the case of transporting and providing cooked food, the time when the food was carried out), and the quantity of cooked food provided are to be recorded and preserved.
- (ix) Provision of information
- (a) A business person is to endeavor to provide consumers with information necessary for consumers to safely eat food or additives which are collected, produced, imported, processed, cooked, stored, transported, or sold (hereinafter referred to as "products" in this Table).
 - (b) When a business person has received from a customer information on damage to health related to the products (limited to those that have been diagnosed by a physician and has been diagnosed that the symptoms are caused by or suspected to be caused by the food or additives; hereinafter the same applies in this item) and information in violation of laws, the business person is to endeavor to provide the information to the prefectural governor, etc.
 - (c) When a business person has received from a consumer or those who handle products information on abnormal tastes or odors, on contamination with foreign substances, or other information for which the risk of leading to damage to health is undeniable, the business person is to endeavor to provide the information to the prefectural governor, etc.
- (x) Recall and disposal
- (a) In the case food sanitation hazards resulting from products have occurred or there is a risk of such a hazard to occur, from the perspective of preventing the damage to health of consumers, a business person is to

specify a responsibility system related to recall, a method to alert consumers, a specific recall method, and procedures for making a report to the prefectural governor, etc., who has jurisdiction over the location where the facility that handles the food or additives is located, so that the food or additives can be promptly and appropriately recalled.

(b) When recalling products, the products recalled are to be stored by separating them from products not subject to recall, and are to be disposed of appropriately.

(xi) Transportation

(a) Vehicles, containers, etc. used for transporting food or additives are to be cleansed and disinfected as necessary to prevent contamination of food, additives, or their containers and packaging.

(b) Vehicles, containers, etc., are to be maintained in a clean condition as well as maintained in an appropriate condition by making repairs, etc.

(c) When food or additives and cargoes other than food or additives are loaded together, food or additives are to be separated by storing them into appropriate containers as necessary, in order to prevent contamination from cargoes other than food or additives.

(d) Food or additives are to be managed so as not to become contaminated with dust and exhaust gas, etc. during transportation.

(e) When using vehicles, containers, etc., used for transporting different items of food or additives, and cargoes other than food or additives, they are to be cleansed by effective methods and disinfected as necessary.

(f) In the case of food or additives loaded in bulk, vehicles, containers, etc., exclusive for food or additives are to be used as necessary and the fact that they are exclusive for food or additives is to be clearly indicated.

(g) Temperature and humidity are to be managed carefully during transportation.

(h) Delivery time is to be set based on temperature and humidity during transportation and appropriately managed so as not to exceed the prescribed delivery time.

(i) When cooked food is delivered and provided, the time is to be managed appropriately taking into consideration the time until it is served for consumption.

(xii) Sales

(a) An appropriate quantity is to be purchased in anticipation of sales volume.

(b) Products are to be managed so that they are not sold at an inappropriate temperature such as those kept in direct exposure to sunlight.

(xiii) Education and training

(a) Food handlers are to be provided with education necessary for sanitation management.

- (b) The persons who handle chemical substances are to be provided with education and training so that they can safely handle the chemical substances they use.
- (c) The effects of the education and training referred to in (a) and (b) are to be verified on a regular basis and the content of the education are to be reviewed as necessary.
- (xiv) Others
 - (a) Effort is to be made to make and preserve records concerning suppliers, conditions of production or processing, etc., shipping or sales destinations, and other necessary matters concerning food or additives handled, within the extent necessary for preventing food sanitation hazards.
 - (b) When a self-inspection is conducted on produced or processed products, effort is to be made to preserve its records.

Appended Table 18 (Re: Article 66-2, paragraph (2))

(i) Analysis of hazard factors

A list of factors that may cause food sanitation hazards (hereinafter referred to as "hazard factors" in this table) are to be prepared for each process of production, processing, cooking, transportation, storage, and sales of food or additives, and measures to control these hazards (hereinafter referred to as "control measures" in this Table) are to be specified.

(ii) Determination of critical control point

To determine the process for which it is essential to take control measures to prevent, eliminate, or reduce to acceptable levels the hazards specified in the preceding item (hereinafter referred to as "critical control point" in this Table);

(iii) Establishment of control criteria

To establish the criteria to prevent, eliminate, or reduce to acceptable levels the hazard factors at each critical control point (hereinafter referred to as "control criteria" in this table).

(iv) Establishment of monitoring methods

To establish a method for monitoring the implementation status of the control on critical control points continuously or by a reasonable frequency (hereinafter referred to as "monitoring" in this Table).

(v) Establishment of improvement measures

To establish improvement measures for cases in which deviation from the control criteria is found as the result of monitoring at each critical control point.

(vi) Specifying a verification method

To establish procedures to verify the effectiveness of the measures provided for in the preceding items on a regular basis.

(vii) Preparation of records

To prepare documents concerning the content of the measures provided for in the preceding items and records of their implementation, according to the scale and type of business.

(viii) A business person provided for in Article 34-2 of the Order

A business person provided for in Article 34-2 of the Order (including a business person whose scale of business is provided for in Article 66-4, item (ii) that produces additives) may simplify the matters set forth in the preceding items in accordance with the characteristics of the food the person handles or the scale of the business to take necessary measures for public health.

Appended Table 19 (Re: Article 66-7)

- (i) The facility is to have the structure or equipment or the arrangement of machinery and tools necessary for preventing contamination from outdoors and for continuously performing the work in a sanitary manner, and sufficient space in accordance with the amount of food or additives handled.
- (ii) Taking into account of contamination of food or additives, containers and packaging, machinery and tools, or other objects that may come into contact with food or additives (hereinafter referred to as "food, etc."), and in order to prevent public health hazards, necessary sections are provided by partitions, etc., in accordance with the category of work, and facilities and equipment are appropriately arranged based on the process, or equipment to manage the flow of air is installed; provided, however, that this does not apply to cases in which necessary sanitation management measures have been taken by establishing the routes of food, etc., or employees engaged in work, or by appropriately implementing cleansing and disinfection when the same section is alternately used for different types of work. When residences and other rooms or places not intended for handling food, etc., are located in the same building, the places that handle food, etc., are partitioned from the residences and the rooms or places.
- (iii) Structure and equipment of the facility
 - (a) The facility is to have a structure or equipment capable of preventing contamination by dust, wastewater, and wastes, and equipment capable of preventing the intrusion of rodents and insects.
 - (b) The facility is to have a structure or equipment capable of preventing condensation and occurrence of mold due to condensation and providing appropriate ventilation so as not to contaminate food, etc., with water drops due to condensation at the place directly above the place where the handling of food, etc., is carried out.
 - (c) The floor surface, inner walls, and ceiling are to be made of materials that are easy to clean, cleanse, and disinfect (hereinafter referred to as "clean, etc." in this Table) and has a structure that is easy to clean, etc.

- (d) For facilities that require water to clean, etc., the floor surface and inner walls, the floor surface is made of impermeable materials and has good drainage. The inner walls are covered with impermeable material from the floor surface to the height that will be easily contaminated.
- (e) Lighting equipment is to have a function to secure necessary illumination to enable adequate work, inspection, and cleaning, etc.
- (f) The facility is to have water supply equipment capable of supplying water supplied by a water supply business, etc., or potable water in a sufficient quantity at an appropriate temperature to the places of the facilities that require such water. When using water other than that supplied by a water supply business, etc., the facility is to have a disinfection device and a water purifying device as necessary and the water source is to have a structure that prevents contamination from the outside. When using a water storage tank, it is to have a structure that does not hinder food sanitation.
- (g) With regard to the application of (f) for a business that handles food for which the use of water for food production is specified in the standards or requirements separately established pursuant to the provisions of Article 13, paragraph (1) of the Act, the term "potable water" is deemed to be replaced with "water for food production", and with regard to the application of (f) for a business that handles food for which there are provisions specifying that water for food or sterilized seawater may be used, the term "potable water" is deemed to be replaced with "water for food production or sterilized seawater".
- (h) The facility has the necessary number of water-flow type hand washing equipment with a device for cleansing and disinfecting the fingers of employees. The faucet is structured to prevent re-contamination of fingers after cleansing.
- (i) The drainage equipment meets the following requirements
 1. The equipment has adequate drainability and is installed on the floor surface of sections cleansed with water and sections where wastewater and liquid waste, etc., flows.
 2. The equipment has piping to prevent food or additives from being contaminated by backflow of sewage and has the function to appropriately discharge it outside the facility.
 3. The piping has sufficient capacity and is placed in an appropriate position.
- (j) The facility has refrigeration or freezing equipment that has the functions necessary for handling food or additives in a sanitary manner as necessary. For refrigeration or freezing during production and preservation, for a business that handles food for which refrigeration or freezing is specified

- in the standards or criteria separately prescribed pursuant to Article 13, paragraph (1) of the Act, the facility is to have the necessary equipment in accordance with what is specified.
- (k) The facility has an equipment to prevent intrusion of rodents, insects, etc., and equipment to exterminate them when they intrude into the facility, as necessary.
 - (l) The facility has toilets that satisfy the following requirements in accordance with the number of employees.
 - 1. The toilet has a structure that does not to affect the workplace with contamination.
 - 2. The toilet has exclusive water-flow type hand washing equipment.
 - (m) The facility has equipment of sufficient size that can store raw materials at temperatures appropriate for the type and characteristics of the raw materials and in a condition that can prevent contamination. In addition, the facility has equipment for separately storing detergents, disinfectants, and other chemicals used in facilities from food, etc.
 - (n) Containers for storing wastes or equipment for storing wastes are to be impermeable, have sufficient capacity, are easy to clean, and have a structure that prevents dirty liquids and foul odors from leaking.
 - (o) For a business that packages products, the facility has a place where the products can be put into containers and packaging in a sanitary manner.
 - (p) The changing room has enough space in accordance with the number of workers and is located in a place that is easily accessible from the workplace.
 - (q) In order to cleanse food, etc., the facility has cleansing equipment of the size and number appropriate for the purpose of use and capable of supplying hot water, steam, etc., as necessary.
 - (r) A facility that uses additives has equipment or place that can exclusively store them, as well as measuring instruments.
- (iv) Machinery and tools
- (a) Machinery, tools, containers, and any other equipment (hereinafter referred to as "machinery and tools, etc." in this Appended Table) in workplaces where food or additives are produced or food is cooked have a structure that can properly be cleansed, maintained, and inspected.
 - (b) The facility is equipped with machinery and tools, etc., and containers appropriate for the work.
 - (c) Machinery and tools, etc., that come into direct contact with food or additives are made of water-resistant materials, are easy to cleanse, and are able to be disinfected with hot water, steam, or disinfectants.
 - (d) Fixed machinery and tools, etc., or those that are difficult to move are placed at positions convenient for work and easy to clean and cleanse.

Assembly-type machinery and tools, etc., have a structure that is easy to disassemble and clean, and that can be cleansed and disinfected as necessary.

- (e) When transporting food or additives, exclusive containers that can prevent contamination are used.
- (f) Equipment for refrigeration, freezing, sterilization, heating, etc., is equipped with a thermometer, and equipped with a pressure gauge, a flowmeter, and other measuring instruments as necessary.
- (g) The facility is equipped with the necessary number of tools exclusive for cleaning, etc., of the workplace and has the storage site for them and equipment to post the contents of the work to help workers understand the work.
- (v) Others
 - (a) The criteria referred to in item (iii), (o) do not apply to restaurant businesses provided for in Article 35, item (i) of the Order.
 - (b) Among the restaurant businesses provided for in Article 35, item (i) of the Order, in conducting simple businesses (meaning simple food business such as serving food that can be consumed as it is on dishes or heating semi-processed side dishes and including coffee shop business (coffee shops, salons and other businesses that set up equipment to serve drinks other than alcoholic beverages or refreshments to customers); hereinafter the same applies in the Appended Table 20, item (i), (1)), the businesses may be conducted pursuant to the following criteria, in addition to the provisions of (a).
 1. For the floor surface and inner walls, materials other than impermeable materials may be used if it is found to have no adverse effect on food sanitation in light of the food handled and the type of business.
 2. Drainage equipment may not have to be installed on the floor surface if it is found to have no adverse effect on food sanitation in light of the food handled and the type of business.
 3. Refrigeration or freezing equipment may be installed outside the facility if it is found to have no adverse effect on food sanitation in light of the food handled and the type of business.
 4. In areas where food is handled, if the structure is such that persons other than employees cannot easily enter, the areas are not required to be partitioned.
 - (c) Among the restaurant businesses provided for in Article 35, item (i) of the Order, in the case of cooking in an automobile, the criteria referred to in item (iii), (d), (i), (l), and (p) do not apply.
 - (d) Among the meat processing businesses provided for in Article 35, item (ix) of the Order, in the case of processing a living body or carcass in an

automobile, the criteria set forth in item (iii), (l), (m), and (p), and item (iv), (e) do not apply.

(e) When producing frozen food in a business other than those set forth in Article 35, item (xxvii) and item (xxviii) of the Order, the following requirements are satisfied in addition to those set forth in items (i) through (iv).

1. The facility has a room or place for storing and preprocessing raw materials and for producing, freezing, packaging, and storing products. If a room is to be used as a place, it is partitioned in accordance with the category of work.
2. The facility is to have refrigeration or freezing equipment in the room or place for the storage of raw materials.
3. The room or place for the producing products has equipment necessary for heating, sterilizing, cooling, and refrigerating in accordance with the items produced.
4. The facility has a freezing room and storage room with the function to control the temperature of the products at minus 15 degrees centigrade or less.

(f) When producing hermetically sealed food in a business other than those set forth in Article 35, item (xxx) of the Order, the structure satisfies the following criteria, in addition to those set forth in items (i) through (iv).

1. The facility has a room or place for the storing, preprocessing, or mixing raw materials, and for producing and storing products, and cleansing equipment for containers and packaging as necessary. If a room is to be used as a place, it is partitioned in accordance with the category of work.
2. The facility has refrigerating or freezing equipment in the room or place for storing raw materials.
3. The room or place where the products are produced has equipment necessary for thawing, heating, filling, hermetically sealing, sterilization, and refrigeration in accordance with the items produced.

Appended Table 20 (Re: Article 66-7)

(i) Restaurant business provided for in Article 35, item (i) of the Order

In the case of cooking in an automobile, the following requirements are satisfied.

1. For a simple business, water storage equipment that can supply approximately 40 liters of water for one day of business and that can store wastewater is installed.
2. For a business that does not require a relatively large amount of water, water storage equipment that can supply approximately 80 liters of water for

one day of business and that can store wastewater is installed.

3. For a business that requires a relatively large amount of water, water storage equipment that can supply approximately 200 liters of water for one day of business and that can store wastewater is installed.

(ii) A business that cooks food using a vending machine capable of cooking food prescribed in Article 35, item (ii) of the Order (excluding those installed indoors and equipped with devices necessary to prevent food sanitation hazards, such as devices to automatically clean the parts that come into direct contact with food not packed or wrapped in containers and packaging) and sells the cooked food.

(a) Equipment capable of preventing intrusion of rain water such as eaves and roofs are installed; provided, however, that this does not apply to the case in which a vending machine is installed at a place which is found not to be affected by rainwater.

(b) Floor surfaces are made of impermeable materials that are easy to clean, cleanse, and disinfect.

(iii) Processed meat sales business prescribed in Article 35, item (iii) of the Order:

(a) The facility has a processing room.

(b) The processing room has equipment necessary for cutting up meat, internal organs, and other meat parts of the dressed birds or livestock.

(c) The facility has refrigerating or freezing equipment with the function to control the temperature of products at 10 degrees centigrade or less when the product requires refrigeration storage and refrigeration or freezing equipment with the function to control the temperature at minus 15 degrees centigrade or less when the product requires freezing storage, at a scale appropriate for the amount of products processed.

(d) Containers for putting in non-edible parts and containers used for disposal are made of impermeable materials, have a capacity appropriate for the amount of products processed, are easy to disinfect, have a structure that prevents dirty liquids and foul odors from leaking, and have a lid.

(iv) Fish and seafood sales business provided for in Article 35, item (iv) of the Order

(a) The facility has a room or place for storing and processing raw materials and for packaging and storing products. If a room is to be used as a place, it is to be partitioned in accordance with the category of work.

(b) The room or place for processing raw materials has equipment necessary for processing fresh fish and seafood.

(c) A facility that handles fresh fish and seafood to be eaten raw is equipped with an exclusive instrument for processing fresh fish and seafood.

- (d) When processing oysters, the following requirements are satisfied.
 - 1. The facility has purification equipment as necessary.
 - 2. The room or place for preprocessing oysters has equipment necessary for cleansing oysters with shells.
 - 3. The room or place for the processing of oysters has equipment necessary for processing, cleansing, and packaging shelled oysters.
- (v) Fish and seafood auction business provided for in Article 35, item (v) of the Order
 - (a) The facility has a place to receive, sort, display, store temporarily, trade, and ship fresh fish and seafood, and is partitioned as necessary.
 - (b) The facility has refrigerating or freezing equipment, ice making equipment, and equipment for cleansing and disinfecting shoes, as necessary.
 - (c) In the case of cleansing and refrigerating fresh fish and seafood using seawater, the facility has sterilizing equipment for seawater as necessary.
- (vi) Milk collection business provided for in Article 35, item (vi) of the Order
 - (a) The facility has raw milk storage equipment and equipment for acceptance inspection (excluding facilities which outsource the inspections).
 - (b) The facility has cooling equipment or refrigeration storage equipment appropriate for the amount of raw milk handled.
- (vii) Milk processing business provided for in Article 35, item (vii) of the Order
 - (a) The facility has a room or place for acceptance inspections, storage, and processing of raw milk, and storage of products, and a room or place for cleansing bottles and container cleansing equipment as necessary; provided, however, that a facility that does not use raw milk is not required to have a room or place for storage and acceptance inspections, and a facility that outsources inspections is not required to have a room or place for acceptance inspections. If a room is to be used as a place, it is partitioned in accordance with the category of work.
 - (b) The room or place for processing raw milk has equipment necessary for filtration, sterilization, filling, and tight sealing.
 - (c) The facility has cooling equipment and refrigeration equipment with the function to control the temperature of products at 10 degrees centigrade or less at a scale appropriate for the amount of products processed or produced (excluding facilities that produce only products that can be stored at room temperature).
 - (d) The room or place where the inspection of raw milk is conducted has equipment necessary for inspecting raw milk.
- (viii) Special milking and processing business provided for in Article 35, item (viii) of the Order
 - (a) The facility has a room or place for milking, processing raw milk, and

- storing products, as well as equipment for cleansing cows' bodies, equipment for storing raw milk, and equipment for acceptance inspections (excluding facilities that outsource the inspections), and has a room or place for cleansing bottles as necessary. If a room is to be used as a place, it is partitioned in accordance with the category of work.
- (b) The room or place for processing raw milk has equipment necessary for filtration, sterilization, filling, and tight sealing. When sterilizing raw milk, the facility has sterilization equipment with a self-registering thermometer.
 - (c) The facility has a cooler and refrigerating equipment with the function to control the temperature of products at 10 degrees centigrade or less at a scale appropriate for the amount processed.
- (ix) Meat processing business provided for in Article 35, item (ix) of the Order
- (a) The facility is has a room or place for receipt and processing of raw materials and for storage of products. If a room is to be used as a place, it is partitioned in accordance with the category of work.
 - (b) Containers for putting in non-edible parts and containers used for disposal are made of impermeable materials, have a capacity appropriate for the amount processed, are easy to disinfect, have a structure that prevents dirty liquid and foul odor from leaking, and have a lid.
 - (c) The facility has refrigeration or freezing equipment with the function to control the temperature of products at 10 degrees centigrade or less when the product requires refrigeration storage, and refrigeration or freezing equipement with the function to control the temperature at minus 15 degrees centigrade or less when the product requires frozen storage, appropriate for the amount of products processed.
 - (d) The processing room is to have equipment necessary for cutting up meat, internal organs, and other meat parts of the dressed livestock or poultry.
 - (e) In the case of processing a living body or carcass, the following requirements are satisfied.
 1. The facility has a slaughtering and bleeding room (limited to cases of slaughtering and bleeding), a place for skinning, and equipment for cleansing carcass before skinning. In addition, the facility has a hanging room, a place to remove feathers, and a place to store feathers, skin, bones, etc., as necessary, and the place to carry in and out the living bodies or carcasses before processing and the place to carry in and out the meat and other meat parts after processing are partitioned.
 2. The place where a carcass is skinned has hanging equipment and equipment for cleansing and disinfecting the the fingers and knives and other tools of the workers.
 3. The hanging room is partitioned from other work places by partition walls and has a structure that enables the entrance door to be shut

tightly.

4. The cleansing and disinfection equipment has equipment capable of supplying warm water of 60 degrees centigrade or more and hot water of 83 degrees centigrade or more. In addition, it is to be equipped with a thermometer that can check the temperature of warm water and hot water supplied.
- (f) In the case of processing a living body or carcass in an automobile, the following requirements are satisfied.
1. The processing room is partitioned from other work places by partition walls and has a structure that enables the entrance door, windows, etc., to be shut tightly.
 2. The facility has water storage equipment with the function to sufficiently supply water that satisfies the matters set forth in item (iv), (a) of the Appended Table 17, in accordance with the planned number of living bodies or carcasses to be processed (meaning the number of living bodies or carcasses decided to be processed at one facility in advance). When processing deer or wild boars, the facility has water storage equipment capable of supplying approximately 100 liters of water for each full-grown animal.
 3. The facility has wastewater storage equipment. The storage equipment is made of impermeable materials, structured to prevent dirty liquids and foul odors from leaking, and has a lid.
 4. When skinning carcasses outside an automobile, there is a place for processing adjacent to the entrance of the processing room and equipment to temporarily prevent the contamination of carcasses by the external environment such as wind and rain, dust, etc., and the intrusion of insects, etc., is installed.
- (g) For a facility that processes blood, the following requirements are satisfied.
1. The facility has a room for cleansing and sterilizing transportation tools, a room for storing and processing blood to be used as raw materials, a room for refrigerating or freezing necessary; provided, however, that for a facility in which blood collection and processing are carried out consistently and the blood to be used as raw material is not transported from another facility is not required to have a room for cleansing and sterilizing transportation tools and storing the blood to be used as raw material. Each room or equipment is partitioned in accordance with the category of work.
 2. The facility has a raw material storage tank, a separator, etc., in accordance with the amount processed.
 3. All pieces of equipment from the equipment for receiving blood to be

used as raw material to the filling equipment are connected by a sanitary pipe.

- (x) Food irradiation business provided for in Article 35, item (x) of the Order
 - (a) The facility has an exclusive irradiation room.
 - (b) The facility has a belt conveyor and irradiation equipment capable of accurately adjusting an appropriate irradiation dose.
 - (c) The facility has a chemical dosimeter that can accurately measure the irradiation dose.
- (xi) Confectionery production business provided for in Article 35, item (xi) of the Order
 - (a) The facility has a room or place for storing and preprocessing raw materials and for producing, packaging, and storing products. If a room is to be used as a place, it is partitioned in accordance with the category of work.
 - (b) The room or place for preprocessing raw materials and producing products has equipment necessary for thawing, preparing, mixing, shaping, fermentation, heating, sterilizing, cooling, and refrigeration in accordance with the items produced.
 - (c) The room or place for storing raw materials and products is to have refrigerating or freezing equipment as necessary.
 - (d) When producing raw bean jam from beans containing cyanide compounds as a raw material, the facility has equipment necessary for immersion, steaming, making bean jam, and soaking bean jam in water.
- (xii) ice cream production business provided for in Article 35, item (xii) of the Order
 - (a) The facility has a room or place for storing and mixing raw materials, producing and storing products, as well as equipment for storing raw milk (excluding facilities that do not use raw milk), and equipment for acceptance inspections (excluding facilities that outsource the inspections). If a room is to be used as a place, it is partitioned in accordance with the category of work.
 - (b) The room or place for producing products has the equipment necessary for filtration, sterilization, refrigeration, filling, packaging, and freezing.
- (xiii) Dairy product production business provided for in Article 35, item (xiii) of the Order
 - (a) The facility has a room or place for storing and mixing raw materials, producing and storing products, as well as equipment for storing raw milk (excluding facilities that do not use raw milk), and equipment for acceptance inspections (excluding facilities that outsource the inspections), and a room or place for cleansing bottles as necessary. If a room is to be used as a place, it is partitioned in accordance with the category of work.

- (b) The room or place for producing products has equipment necessary for filtration, sterilization, refrigeration, filling, and packaging, and equipment for fermentation, concentration, drying, emulsification, and separation as necessary.
- (xiv) Nonalcoholic beverage production business provided for in Article 35, item (xiv) of the Order
 - (a) The facility has a room or place for storing and mixing raw materials and producing products (for a facility that produces only mineral water, limited to production), and has equipment for cleansing and producing or assembling containers as necessary. If a room is to be used as a place, it is partitioned in accordance with the category of work.
 - (b) The room or place for mixing raw materials and producing products has equipment necessary for mixing, filling, hermetically sealing, and sterilization or disinfection.
- (xv) Processed meat product production business provided for in Article 35, item (xv) of the Order
 - (a) The facility has a room or place for storing, preprocessing, and mixing raw materials and producing, packaging, and storing products. If a room is to be used as a place, it is partitioned in accordance with the category of work.
 - (b) The room or place for producing products has equipment for sterilizing, drying, smoking, salting, measuring the temperature of the center of a product, refrigeration, and other processes, as necessary.
- (xvi) Fishery product production business provided for in Article 35, item (xvi) of the Order
 - (a) The facility has a room or place for storing and preprocessing raw materials, and producing and storing products, and drying, cleansing, and thawing raw materials, as necessary. If a room is to be used as a place, it is partitioned in accordance with the category of work.
 - (b) The room or place for storing raw materials and products is to have refrigerating or freezing equipment as necessary.
 - (c) The room or place for preprocessing raw materials or producing products has equipment necessary for thawing, mixing, heating, sterilization, drying, smoking, roasting, dehydrating, refrigeration, and other processes, as necessary.
 - (d) When handling fresh fish and seafood to be eaten raw, the facility has an exclusive instrument for processing fresh fish and seafood.
 - (e) When producing fish paste products, the room or place for preprocessing raw materials and producing products has equipment necessary for grinding and sterilization (excluding the case of producing ground fish meat).

- (f) When processing oysters, the following requirements are satisfied.
 1. To have purification equipment as necessary.
 2. The room or place for preprocessing oysters has equipment necessary for cleansing oysters with shells.
 3. The room or place for processing oysters has equipment necessary for processing, cleansing, and packaging shelled oysters.
- (xvii) Ice production business provided for in Article 35, item (xvii) of the Order

The facility has a room or place for producing and storing products, and for preparing and packaging products as necessary. If a room is to be used as a place, it is partitioned in accordance with the category of work.
- (xviii) Liquid egg production business provided for in Article 35, item (xviii) of the Order
 - (a) The facility has a room or place for storing raw materials and for producing, packaging, and storing products. If a room is to be used as a place, it is partitioned in accordance with the category of work.
 - (b) The room or place for producing products has equipment necessary for cracking eggs, filling, and refrigeration, and equipment necessary for cleansing eggs, filtration, heat sterilization, and refrigeration as necessary.
 - (c) The facility has refrigerating or freezing equipment with the function to control the temperature of products at 8 degrees centigrade or less when the product requires refrigeration storage and refrigerating or freezing equipment with the function to control the temperature at minus 15 degrees centigrade or less when the product requires freezing storage.
- (xix) Edible oil and fat production business provided for in Article 35, item (xix) of the Order
 - (a) The facility has storage equipment for raw materials and a room or place for producing and storing products. If a room is to be used as a place, it is partitioned in accordance with the category of work.
 - (b) The room or a place for producing products at a facility that produces edible oil and fat has equipment necessary for refining, filling, and packaging, and equipment necessary for oil extraction and blending as necessary.
 - (c) The room or a place of a facility that produces margarine or shortening has equipment necessary for filling and packaging, and equipment necessary for kneading, sterilization, and refrigeration as necessary. It also has a curing room as necessary.
- (xx) Miso or soy sauce production business provided for in Article 35, item (xx) of the Order
 - (a) The facility has a room or place for making koji, for storing, preprocessing, preparing, and maturing raw materials, and packaging, filling, and storing products. If a room is to be used as a place, it is partitioned in

- accordance with the category of work. The room or place for packaging and filling has equipment for cleansing and manufacturing or assembling containers as necessary.
- (b) When producing soy sauce, the facility has equipment necessary for compressing, heating, mixing, filtration, and method of squeezing as necessary.
 - (c) When producing food mainly made from miso or soy sauce, the facility has equipment necessary for mixing, filtration, drying, heat sterilization, filling, and tight sealing.
- (xxi) Alcoholic beverage production business provided for in Article 35, item (xxi) of the Order
- (a) The facility has a room or place for making koji, and storing, preprocessing, preparing, and maturing (including distillation and squeezing) raw materials, and packaging, filling, and storing products in accordance with the items produced. If a room is to be used as a place, it is partitioned in accordance with the category of work.
 - (b) The room or place for packaging and filling products has equipment for cleansing, inspecting, and producing or assembling containers as necessary.
 - (c) The facility has equipment necessary for cleansing, immersion, steaming, making koji, saccharification, boiling, fermentation, distillation, squeezing, heating, mixing, filtration, filling, and tight sealing in accordance with the items produced.
- (xxii) A tofu production business provided for in Article 35, item (xxii) of the Order
- (a) The facility has a room or place for storing and preprocessing raw materials and for producing and storing products. If a room is to be used as a place, it is partitioned in accordance with the category of work.
 - (b) The room or place for producing products has equipment necessary for sterilization and refrigeration, and equipment for packaging as necessary.
 - (c) When producing aseptically-filled tofu, the facility has a heat sterilizer with continuous flow system and equipment necessary for filling and tight sealing.
 - (d) When producing food mainly made from tofu, the facility has equipment for freezing, drying, oil cooking, and other processes, as necessary.
- (xxiii) Natto production business provided for in Article 35, item (xxiii) of the Order
- (a) The facility has a room or place for storing, preprocessing, fermentation, and maturing raw materials, and for producing and storing products. If a room is to be used as a place, it is partitioned in accordance with the category of work.
 - (b) The facility has equipment necessary for steaming, fermentation, and

- refrigeration of raw materials and for packaging products.
- (xxiv) Noodle production business provided for in Article 35, item (xxiv) of the Order
- (a) The facility has a room or place for storing and preprocessing raw materials, producing, packaging, and storing products, and a room or place for drying and refrigerating or freezing raw materials and products as necessary. If a room is to be used as a place, it is partitioned in accordance with the category of work.
- (b) The room or place for preprocessing raw materials and producing products has equipment necessary for kneading, shaping, rolling, cutting, boiling, steaming, oil cooking, and refrigeration in accordance with the items produced.
- (xxv) Side dish production business provided for in Article 35, item (xxv) of the Order and multi side dish items production business provided for in item (xxvi) of that Article
- (a) The facility has a room or place for storing and preprocessing raw materials and for producing, packaging, and storing products. If a room is to be used as a place, it is partitioned in accordance with the category of work.
- (b) The room or place for producing products has equipment necessary for thawing, heating, sterilization, cooling, and refrigeration in accordance with the items produced.
- (c) The room or place for storing raw materials and products has refrigerating or freezing equipment.
- (xxvi) Frozen food production business provided for in Article 35, item (xxvii) of the Order and multi frozen food items production business provided for in item (xxviii) of that Article
- (a) The facility has a room or place for storing and preprocessing raw materials and for producing, freezing, packaging, and storing products. If a room is to be used as a place, it is partitioned in accordance with the category of work.
- (b) The room or place for storing raw materials has refrigerating or freezing equipment.
- (c) The room or place for producing products has equipment necessary for heating, sterilization, cooling, and refrigeration in accordance with the items produced.
- (d) The facility has a freezing room and storage room with the function to control the temperature of the products at minus 15 degrees centigrade or less.
- (xxvii) Pickle production business provided for in Article 35, item (xxix) of the Order

- (a) The facility has a room or place for storing and preprocessing raw materials and for producing, packaging, and storing products. If a room is to be used as a place, it is partitioned in accordance with the category of work.
 - (b) The room or place for preprocessing raw materials and producing products has equipment necessary for cleansing, pickling, sterilization, etc., as necessary.
 - (c) When producing asazuke (lightly pickled vegetables), the facility has cooling equipment with the function to control the temperature of the products at 10 degrees centigrade or less.
- (xxviii) Hermetically sealed food production business provided for in Article 35, item (xxx) of the Order
- (a) The facility has a room or place for storing, preprocessing, or mixing raw materials, and producing and storing products, and a container and packaging cleansing equipment as necessary. If a room is to be used as a place, it is partitioned in accordance with the category of work.
 - (b) The room or place for storing raw materials has refrigerating or freezing equipment.
 - (c) The room or place for producing the products has equipment necessary for thawing, heating, filling, hermetically sealing, sterilization, and refrigeration in accordance with the items produced.
- (xxix) Food packaging business provided for in Article 35, item (xxxii) of the Order
- (a) The facility has a room or place for storing and processing raw materials and for packaging and storing products. If a room is to be used as a place, it is partitioned in accordance with the category of work.
 - (b) The room or place for storing raw materials and products has refrigerating or freezing equipment as necessary.
- (xxx) Additive production business provided for in Article 35, item (xxxii) of the Order
- (a) The facility has a room or place for storing raw materials and producing, subdividing, packaging, and storing products. If a room is to be used as a place, it is partitioned in accordance with the category of work.
 - (b) The room or place for producing products has equipment necessary for extraction, reaction, mixing, filtration, sieving, refining, concentration, and other processes as necessary. When producing additive preparation, the facility has machinery and equipment to make the ingredients contained uniform.
 - (c) The facility has equipment and tools necessary for testing and inspecting raw materials or products; provided, however, that for equipment and tools necessary for special test among the tests and inspections, this does not

apply if no problem in terms of food sanitation is found as a result of testing and inspecting the additives on the business person's own responsibility by using another organization that has equipment necessary for the testing.

- (d) For a facility that produces additives and products other than additives, the machinery and tools used for producing additives are partitioned; provided, however, that this does not apply when additives and products other than additives are produced by the same process and the additives produced by using the same machinery and tools conform to the criteria and standards under Article 13, paragraph (1) of the Act.

Appended Table 21 (Re: Article 66-7)

- (i) Among the restaurant business provided for in Article 35, item (i) of the Order, processed meat sales business provided for in item (iii) of that Article, meat processing business provided for in item (ix) of that Article, multi side dish items production business provided for in item (xxvi) of that Article, and multi frozen food items production business provided for in item (xxviii) of that Article, a facility that processes or cooks meat to be eaten raw satisfies the following requirements.

- (a) The equipment for processing or cooking meat to be eaten raw is separated from other equipment.
- (b) The facility has exclusive equipment for cleansing and disinfecting tools and fingers.
- (c) The facility has exclusive machinery and tools for processing or cooking meat to be eaten raw.
- (d) The facility has refrigerating or freezing equipment with the function to control the temperature of the meat to be eaten raw at 4 degrees centigrade or less when the meat to be eaten raw handled by the business person requires refrigeration storage, and refrigerating or freezing equipment with the function to control the temperature at minus 15 degrees centigrade or less when the meat to be eaten raw requires freezing storage.
- (e) The facility that processes meat to be eaten raw has equipment for heat sterilization in accordance with the amount of meat processed.

- (ii) Among the restaurant business provided for in Article 35, item (i) of the Order, fish and seafood sales business provided for in item (iv) of that Article, fishery products production business provided for in item (xvi) of that Article, multi side dish items production business provided for in item (xxvi) of that Article, and multi frozen food items production business provided for in item (xxviii) of that Article, a facility that processes pufferfish satisfies the following requirements.

- (a) The facility has containers, etc., that can be locked for storing the

poisonous parts such as ovaries, liver, etc.

(b) The facility has exclusive tools for processing pufferfish.

(c) When freezing pufferfish, the facility has freezing equipment with the function to rapidly freeze the pufferfish at minus 18 degrees centigrade or less.

Appended Table 22 (Re: Article 73)

(i) Salmonellae genus

(ii) Clostridium botulinum

(iii) Enterohaemorrhagic Escherichia coli

(iv) Yersinia enterocolitica O8

(v) Campylobacter jejuni/coli

(vi) Vibrio cholerae

(vii) Shigella

(viii) Salmonella typhi

(ix) Salmonella paratyphi A

(x) Chemical substances (meaning elements and chemical compounds)