

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.

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Supplementary Provisions

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

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

- (i) toxic or harmful substances that are naturally contained in or attached to food or additives and are found not to generally have a risk of harming human health depending on the amount or treatment;
- (ii) when it is unavoidable to mix or add toxic or harmful substances in the process of producing food or additives, and is found not to generally have a risk of harming human health.

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

- (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 made;
- (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 give a notification under the provisions of Article 8, paragraph (1) of the Act is to give the notification by submitting a written notification to a prefectural governor, mayor of a city with public health centers, or mayor of a special ward (referred to below 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 about the person who has suffered damage to their health due to refusal to provide the information or other circumstances, statement of the matters 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 contained amount of designated ingredients, etc.;
 - (iv) the sex, age, intake status of food containing designated ingredients, etc., and the symptoms related to the health damage, of the person who has suffered health damage;
 - (v) if the person who has suffered health damage has visited a medical institution, the name and location of the medical institution;
 - (vi) the results of the diagnosis at the medical institution referred to in the preceding item;
 - (vii) if pharmaceuticals, etc. have been used when consuming food containing designated ingredients, etc., the name of the pharmaceuticals, etc.; and
 - (viii) other necessary matters.
- (2) The notification referred to in Article 8, paragraph (1) of the Act may be given 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) for specific food or additives that are collected, produced, processed, cooked, or stored in a specific country or region, or collected, produced, processed,

- cooked, or stored by a specific person (referred to below as "specified foods, 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 the administrative guidance (meaning administrative guidance defined 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) given by the national government, 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) (referred to below as "cities with public health centers") or special wards indicate that the total number of objects falling under food or additives stated 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 for which the inspections have been conducted;
- (ii) the content of regulation and measures concerning food sanitation for the specified foods, etc., in a country or a region where specified foods, etc., are collected, produced, processed, cooked, or stored, the inspection system and other systems on food sanitation management of the specified foods, etc., by the government or local governments, etc. of the country or region, the results of inspections of the specified foods, etc., conducted by the government or local governments, etc. of the country or region, and other status of food sanitation management of the specified foods, etc., in the country or the region;
 - (iii) the fact that food poisoning or other health damages caused or suspected to be caused by the specified foods, etc., has occurred for specified foods, etc.;
 - and
 - (iv) a situation in which the specified foods, etc., have been contaminated or is likely to be contaminated has occurred for specified foods, 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 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 "specified foods, etc." in that item, and items (ii) and (iv) of that paragraph is deemed to be replaced with "specified toys", the term "for specified foods, etc." in item (iii) of that paragraph is deemed to be replaced with "for specified toys", and the term "food poisoning or other health damages caused or suspected to have been caused by the specified foods, etc." in that item is deemed to be replaced with "food poisoning or other health damages caused by or suspected to have been caused by the specified toys".

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

- (i) the level of risk that specified foods, etc. have in harming human health;
 - (ii) the matters stated in each item of paragraph (1) of the preceding Article;
 - (iii) the possibility that specified foods, etc. falling under food or additives stated in each item of Article 9, paragraph (1) of the Act will continue to be sold, or collected, produced, imported, processed, used, or cooked for the purpose of selling;
 - (iv) the effects that the method other than prohibition under the provisions of Article 9, paragraph (1) of the Act are expected to have for preventing the occurrence of food sanitation hazards resulting from specified 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 "specified foods, etc." in item (i), item (iii) and item (iv) of the preceding paragraph is deemed to be replaced with "specified toys", and the term "food or additives" in item (iii) of that paragraph is deemed to be replaced with "toys".

Article 5 (1) When confirming that there is no risk of food sanitation hazards resulting from the specified foods, etc. occurring in canceling the prohibition under the provisions of Article 9, paragraph (1) of the Act for specified foods, etc., based on the provisions of Article 9, paragraph (3), an application from a person that has an interest, or as required, the Minister of Health, Labour and Welfare must take into account the matters stated in each item of paragraph (1) of the preceding Article for the specified foods, etc., related to the prohibition intended to be canceled.

- (2) The provisions of the preceding paragraph apply mutatis mutandis to the case in which the prohibition under the provisions of Article 9, paragraph (1) of the Act is to be canceled based on 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 "specified foods, etc." in the preceding paragraph is deemed to be replaced with "specified toys".

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

- (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 to be made; and
 - (iii) other matters that the Minister of Health, Labour and Welfare finds to be 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 prescribed in Article 10, paragraph (1) of the Act are water buffaloes.

- (2) The cases specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 10, paragraph (1) of the Act are as follows:
- (i) for livestock that have been found to have a diseases stated in the left-hand column of the Appended Table 5 of the Regulations for Enforcement of the Slaughterhouse Act (Order of the Ministry of Health and Welfare No. 44 of 1953) or a disorder stated in that column, when disposal or other necessary measures to prevent the parts stated respectively in the right-hand column of that Table from being served for consumption have been taken;
 - (ii) when as a result of the inspections after evisceration referred to in Article 33, paragraph (1), item (iii) of the Regulations for Enforcement of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act (Order of the Ministry of Health and Welfare No. 40 of 1990), disposal, etc. of the parts stated in the right-hand column of the Appended Table 5 have been taken for the diseases and disorders stated in the left-hand column of that Table .
- (3) The case in which the employees find that the livestock has no risk of harming human health and are suitable for eating or drinking pursuant to the provisions of the proviso to Article 10, paragraph (1) of the Act is when healthy livestock have instantly died 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) meat products;
- (ii) milk (meaning milk defined 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); the same applies in item (i), item (ix), and item (x) of the following Article) and dairy products (meaning dairy products defined in Article 2, paragraph (13) of that

Order excluding butter oil, cheese (limited to processed cheese), ice cream products, formulated milk powder, formulated milk liquid, lactic acid bacteria beverage, and milk beverage; the same applies in , items (ix) and (x) of the following Article).

Article 9 The matters 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) for the meat or organs of livestock or poultry, the type of livestock or poultry, and for the products provided for in the preceding Article, the name and the type of the meat, milk, or organs used as 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 that have been divided into portions or cut into strips, etc.), the following matters concerning the name, etc. of the organization that conducted the inspections:
 - (a) for livestock, the name of the organization that conducted the slaughtering inspections (meaning a biopsy before slaughtering and inspections before and after butchering; the same applies below), or the name of the organization and the name and government position of the employee that conducted the slaughtering inspections;
 - (b) for poultry, the name of the organization that conducted the poultry inspections (meaning a biopsy and inspections after plucking and evisceration; the same applies below), or the name and government position of the employee that conducted the poultry inspections;
- (vi) the name and location of facilities in which the following slaughtering and other processes have been conducted:
 - (a) for the meat or organs of livestock (excluding those that have been divided into portions or cut into strips, etc.), the slaughterhouse in which the slaughtering or butchering has been conducted;
 - (b) for the meat or organs of poultry (excluding those that have been divided into portions or cut into strips, etc.), the poultry slaughterhouse in which the slaughtering, plucking, and evisceration have been conducted;
 - (c) for the meat or organs of livestock or poultry that have been divided into portions or cut into strips, etc., the facility in which the processes have been conducted;
 - (d) for the products provided for in the preceding Article, the production facility in which the products have been produced;
- (vii) the fact that processing of slaughtering, butchering, plucking, evisceration,

- portioning, and cutting into strips, etc. or producing provided for in sub-items (a) through (d) of the preceding item has been conducted in a sanitary manner based on the criteria equal to or better than the criteria in Japan;
- (viii) the date on which the following slaughtering and other processes have been conducted:
- (a) for the meat or organs of livestock (excluding those that have been divided into portions or cut into strips, etc.), slaughtering and slaughtering inspections;
 - (b) for the meat or organs of poultry (excluding those that have been divided into portions or cut into strips, etc.), slaughtering and poultry slaughtering inspections;
 - (c) for the meat or organs of livestock or poultry divided into portions or cut into strips, etc., those processes;
 - (d) for the products provided for in the preceding Article, the production of the those products.
- (ix) for milk or dairy products, the fact that production was conducted in a sanitary manner based on the criteria equal to the criteria in Japan;
- (x) for milk or dairy products, the name of the governmental organization of the exporting country that issued the certificate provided for in Article 10, paragraph (2) of the Act, or the name and government position of the employee that signed the certificate.

Article 10 When the certificate referred to in 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 copy of the certificate 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 certificate referred to in that paragraph.

Article 11 The countries specified by Order of the Ministry of Health, Labour and Welfare 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 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 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 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 food to be imported has been collected;
- (iv) the date when the food to be imported has been collected;
- (v) the name and location of the facility that processed the food 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 food to be imported has been handled in a sanitary manner based on the criteria equal to or better than the criteria in Japan.

Article 12 Additives that have no risk of harming human health pursuant to the provisions of Article 12 of the Act are as referred to in the Appended Table 1.

Article 13 through Article 16 Deleted

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

- (i) for specific apparatus or containers and packages that are produced in a specific country or region, or produced by a specific person (referred to below as "specified 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 operator in accordance with administrative guidance given by the national government, prefectures, cities with public health centers or special wards, indicate that the total number of objects falling under apparatus or containers and packages stated in the items of Article 17, paragraph (1) of the Act accounts for approximately 5% or more of the total number of apparatus or containers and packages for which the inspections have been conducted;
- (ii) the content of regulation and measures concerning food sanitation for the specified apparatus, etc., in a country or region where the specified apparatus, etc., is produced, the inspection system and other systems for food sanitation management of the specified apparatus, etc., by the government of the country or region, or local governments, etc., the results of inspections for the specified apparatus, etc., by the government of the country or region, or local governments, etc., and other status of food sanitation management of the specified apparatus, etc., in the country or region;

- (iii) health damage caused by or suspected to have been caused by the specified apparatus, etc., has occurred in relation to specified apparatus, etc.; and
 - (iv) a situation in which the specified apparatus, etc. has been contaminated or is likely to be contaminated has occurred in relation to the specified 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 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 prescribed in Article 17, paragraph (1) of the Act are as follows:

- (i) the level of the risk of specific apparatus, etc. harming human health;
 - (ii) the matters stated in the items of paragraph (1) of the preceding Article;
 - (iii) the possibility that specified apparatus, etc., falling under the apparatus or containers and packages stated in the items of Article 17, paragraph (1) of the Act will continue to be sold, or produced, or imported for the purpose of selling, or used for business;
 - (iv) the effects that the method other than prohibition under the provisions of Article 17, paragraph (1) of the Act are expected to have for preventing food sanitation hazards resulting from specified apparatus, etc. occurring
- (2) The provisions of the preceding paragraph apply mutatis mutandis to the matters specified by Order of the Ministry of Health, Labour and Welfare 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 confirming that there is no risk of food sanitation hazards resulting from the specified apparatus, etc. in canceling the prohibition under the provisions of Article 17, paragraph (1) of the Act for the specified apparatus, etc., based on 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 application from a person that has an interest, or as required, the Minister of Health, Labour and Welfare must take into account the matters stated in the items of paragraph (1) of the preceding Article concerning the specified apparatus, etc., related to the prohibition to be canceled.

- (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 as applied mutatis mutandis pursuant to Article 68, paragraph (1) of the Act, is canceled based on 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.

Article 20 (1) 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 is to be made by submitting a written application stating the matters stated in the following items to the Minister of Health, Labour and Welfare, by attaching a document proving that there is no longer a risk of food sanitation hazards resulting from the apparatus or containers and packages for which the application for the cancellation is made from occurring:

- (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 packages for which the application for cancellation is to be made; 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 have for each jurisdictional district of a Regional Bureau of Health and Welfare, the Regional Bureau of Health and Welfare, and the prefectural government, the cities with public health centers and special wards, within the jurisdictional district of the Regional Bureau of Health and Welfare, as its members.

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 made 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 applied for;
- (vii) the number of small containers by their capacity; and
- (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; referred to below 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 inspections.

Article 26 The labeling specified by Order of the Ministry of Health, Labour and Welfare referred to in Article 25, paragraph (1) of the Act is to be made by sealing the container and package of the product with certificate of passing prepared by using Form No. 1.

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

- (i) the name and address of the person who is required to undergo an inspection (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 required to undergo an inspection;
- (iii) the name and location of the production or processing facility;
- (iv) the period for the production or processing of the products which are required to undergo an inspection;
- (v) specific reasons to order a person to undergo an inspection.

Article 28 (1) An application for inspections referred to in Article 26, paragraph (1) of the Act is to be made 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; and

- (v) the quantity applied for.
- (2) The written application referred to in the preceding paragraph must have a copy of a written inspection order referred to in Article 5, paragraph (1) of the Order attached; provided, however, that this does not apply if an application for inspection has already been made for the same order and a copy of a written inspection order has been submitted.

Article 29 (1) An application for inspections referred to in Article 26, paragraph (2) of the Act is to be made 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 products have arrived at the port;
 - (vi) the location of the storage site; and
 - (vii) the quantity applied for.
- (2) The written application referred to in the preceding paragraph must have a copy of a written inspection order attached (when the Minister of Health, Labour and Welfare issues 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 printed out).

Article 30 The provisions of the preceding Article apply mutatis mutandis to an application for the inspections referred to in 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 an inspection of food other than processed food, excluding the matters stated in item (iii))", and the term "location" in item (iv) of that paragraph is deemed to be replaced with "location (for an application for an inspection of food other than processed food, the place of production of the food)".

Article 31 The payment of the fee for undergoing inspections conducted by the Minister of Health, Labour and Welfare is to be made by affixing a revenue stamp for the amount specified by the Minister which is referred to in Article 25, paragraph (2) of the Act, or for the amount equivalent to the amount specified by the Minister which is referred to in Article 26, paragraph (6) of the Act, to a written application referred to 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 before the carrying-in of cargoes to the warehouse (referred to as "carrying-in" below in this paragraph), excluding the matters stated in item (xiv)) and submit the notification to the head of a quarantine station stated in the right-hand column of the Appended Table 11 for the places stated in the respective left-hand column of that Table on and after seven days before the planned arrival date of the cargoes (when an accident concerning the cargoes is suspected to have occurred, after the carrying-in), excluding the cases in which the food stated in the Appended Table 10 is sought to be imported; provided, however, that when a written import notification has been submitted before 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 packages, or toys, the names of the articles, quantity loaded, weight loaded, type of packages, and intended use, and when the marks and numbers are affixed to the cargoes, those marks and numbers;
- (iii) when the cargoes are food and the food contains additives that are used for purposes other than 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 names of the additives;
- (iv) when the cargoes are processed food, the raw materials and production or processing method;
- (v) when the cargoes are those stated in the right-hand column of the Appended Table 17 of the Food Labeling Standards (Cabinet Office Order No. 10 of 2015) as processed food in which recombinant DNA or the resultant protein remains even after processing procedures are taken (including processed foods for commercial use defined in Article 2, paragraph (1), item (iii) of that Order), the matters specified respectively in 1-1 through 3 of the

- right-hand column in accordance with the cases provided for in 1-1 through 1-3 of the right-hand column of the row for processed food stated in the right-hand column of Appended Table 17 and the middle column of Appended Table 18 in the Table for Article 3, paragraph (2) of that Order (excluding the case in which the labeling for genetic recombination prescribed in 5 of that column is considered not required pursuant to the provisions of the main clause of 5 of that column for the raw materials);
- (vi) when cargoes are target agricultural products defined in Article 2, paragraph (1), item (xiv) of the Food Labeling Standards, the matters provided for respectively in 1-1-(a) or (b) of the right-hand column in accordance with the cases prescribed in 1-1-(a) or (b) of the right-hand column of the row for the target agricultural products in the Table for Article 18, paragraph (2) of that Order;
 - (vii) when cargoes are additives, and the additives are preparations containing additives (excluding those used for flavoring and those generally served for consumption that are used as additives), their ingredients;
 - (viii) when cargoes are apparatus, containers and packages, or toys, their 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 (for food other than processed food, the place of production), the port of loading, date of loading, port of unloading, 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 food other than processed food; the same applies below 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 in which the cargoes have been stored and the date of carrying-in of cargoes; and
 - (xiv) whether there have been accidents concerning the cargoes, and if there has been an accident, the outline of the accident.
- (2) When there is any change to the matters stated in items (x) through (xiii) of the preceding paragraph (for the matters stated in item (x), limited to the port of unloading and the arrival date), an importer must immediately submit a written notification to that effect to the head of the quarantine station referred to in that paragraph.
- (3) Despite conducting identity preserved handling (meaning the handling

defined in Article 2, paragraph (1), item (xix) of the Food Labeling Standards; the same applies below in this paragraph), there has been a certain amount of unintentional mixing of genetically modified agricultural products (meaning those defined in item (xv) of that paragraph) or non-genetically modified agricultural products (meaning those defined in item (xvi) of that paragraph), if the confirmation under 1-1 or 3 in the right-hand column of the row for processed foods stated in the right-hand column of Appended Table 17 and the middle-hand column of Appended Table 18 in the Table for 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 for Article 18, paragraph (2) has been appropriately made, the provisions of paragraph (1) are applied by deeming that identity preserved handling has been conducted has been confirmed.

(4) When an importer has imported food, additives, apparatus, containers and packages stated in the middle column of the Appended Table 12 (referred to as "food, etc." below in this Article) and has submitted a written import notification stating the import plan for the same product or equivalent product as the food, etc. (referred to below as "the same food, etc.") for the period stated in the right-hand column of that Table (meaning the plan for the weight loaded, the port of unloading, and the arrival date of the cargoes related to the import planned for that period; the same applies below), that submission may be substituted for the submission of a written import notification referred to in paragraph (1) for the import of the same food, etc., sought to be imported during that period, notwithstanding the provisions of the main clause of paragraph (1); provided, however, that this does not apply when the food, etc., related to the import falls under or is suspected to fall under any of the following items:

- (i) food or additives stated in the items of Article 6 of the Act;
- (ii) food or additives prescribed in Article 12 of the Act;
- (iii) food or additives that do not conform to the criteria established pursuant to the provisions of Article 13, paragraph (1) of the Act;
- (iv) food or additives that do not conform to the standards established pursuant to the provisions of Article 13, paragraph (1) of the Act;
- (v) food in which agricultural chemicals (meaning agricultural chemicals defined in Article 2, paragraph (1) of the Agricultural Chemicals Regulation Act (Act No. 82 of 1948), the same applies below), substances that are used by the methods such as adding to, mixing or infiltrating into feed (meaning feed defined in Article 2, paragraph (2) of the Act on Safety Assurance and Quality Improvement of Feeds (Act No. 35 of 1953)) 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 defined 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) whose purpose are to be used for animals (including substances generated by chemical change of those substances and excluding substances specified as those that clearly have no risk of harming 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 of harming human health pursuant to the provisions of Article 13, paragraph (3) of the Act (excluding cases in which standards on the ingredients of food referred to in Article 13, paragraph (1) of the Act have been established for the residual limit of those substances in the food);
- (vi) apparatus or containers and packages specified in Article 16 of the Act; and
 - (vii) apparatus or containers and packages that 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. stated in the middle column of paragraph (3) of the Appended Table 12 must submit a written import notification stating the import plan provided for in the preceding paragraph by entering the import record of the same food, etc. for the three years before the date of submission of the written import notification (meaning the name of the importer related to the import made during that period (for a corporation, its name), the weight loaded, the port of unloading, and the 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 before the carrying-in" and the term "the head of the quarantine station" in the proviso to paragraph (1) are deemed to be replaced with "related to the import" and "the head of a quarantine station stated in the right-hand column of the Appended Table 11 for the places stated in the respective left-hand column of that Table", respectively.
- (7) For a notification under the provisions of Article 27 of the Act, the Minister of Health, Labour and Welfare may have a person give the notification by using an electronic data processing system (meaning an electronic data processing system that connects a computer (including an input/output device; the same applies below) used by the Ministry and an input/output device used by the person who seeks to give a notification under the provisions of that Article via a telecommunications line; the same applies below in this Chapter).
- (8) To apply the provisions of paragraphs (1) and (2) to a person who seeks to give a notification under the provisions of Article 27 of the Act using an electronic data processing system, the phrases "state the following matters in a written import notification", "when submitting a written import notification", "state the following matters... (when... excluding...)", and "and submit the

notification to the head of a quarantine station stated in the right-hand column of the Appended Table 11 for the places stated in the respective left-hand column of that Table" in paragraph (1) are deemed to be replaced with "state the following matters", "when the person records the matters in a file by inputting them through an input/output device referred to in paragraph (7) (limited to the device used by a person who seeks to give the notification; the same applies below in this paragraph and the following paragraph)", "when... excluding...)", " must be recorded in a file by inputting them through an input/output device", respectively; the phrases "when a written import notification has been submitted" and "stating the outline of the accident must be submitted to the head of the quarantine station" in the proviso to paragraph (1) are deemed to be replaced with "when a written notification has been recorded in a file by inputting it through an input/output device" and "must be recorded in a file by inputting it through an input/output device", respectively; the phrase "must immediately submit a notification to that effect to the head of the quarantine station referred to 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 specified in the preceding paragraph.

Article 33 (1) The input under 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 by using an input /output device that has been notified to the Minister of Health, Labour and Welfare in advance.

- (2) The notification under the provisions of the preceding paragraph is to be given by a person who seeks to give a notification under the provisions of Article 27 of the Act using an electronic data processing system submitting a written notification stating the following matters to the Minister of Health, Labour and Welfare, for 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 password (limited to one that uses twelve Arabic numerals or Roman letters, or their combination);
 - (iii) the place where the input/output device is installed, and the name and model number of the equipment;
 - (iv) when a person other than the notifier is in charge of the input/output device, the name and address of that person (for a corporation, its name and the location of its principal office).
- (3) When there are any changes to the matters stated in the item of that

paragraph, or when the person who has given a notification referred to in the preceding paragraph has stopped using the input/output device that has been notified, the person must 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 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) concerning food, additives, apparatus, or containers and packages related to the notification, or a notice of the results of the inspection under the provisions of Article 26, paragraph (4) of the Act (referred to as a "specified notice" below in this Article).

(2) When issuing a specified notice using an electronic data processing system pursuant to the provisions of the preceding paragraph, the Minister of Health, Labour and Welfare must input the content of the specified notice through the input/output device referred to in Article 32, paragraph (7) (limited to a device used by the Ministry of Health, Labour and Welfare) and record the content in a file.

(3) The Minister of Health, Labour and Welfare must obtain the consent of the other party in advance, when issuing a specified 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 stated in Article 8, paragraph (2), item (i) of the Order are as follows; provided, however, that if implementation of a part of the affairs on product inspections and examinations referred to in Article 29 of the Act are ensured even in emergencies by entrusting the implementation to food sanitation inspection facilities established by other prefectures or cities with public health centers, or special wards, or to registered conformity assessment 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.;
- (ii) to provide water purifying apparatus, 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 inspections or examinations.

- (2) The criteria specified by Order of the Ministry of Health, Labour and Welfare related to matters stated in Article 8, paragraph (2), item (ii) of the Order are to be the assignment of 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 (referred to as "inspections, etc." below in this Article and the Appended Table 13) are to be administered as follows:

- (i) to confirm that inspections, etc. are appropriately conducted based on the standard operation manual provided for in item (xi);
- (ii) to periodically conduct internal checking of the administration of the operation of inspections, etc., based on documents referred to in item (xii);
- (iii) to conduct accuracy management (meaning maintaining the accuracy of inspections through the method of ensuring the technical skill level of persons engaged in inspections or other methods; the same applies below), based on documents referred to in item (xiii);
- (iv) to periodically undergo external investigation of accuracy management (meaning investigation of accuracy management conducted by the national government or other persons found to be appropriate; the same applies below) based on documents referred to 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 promptly take improvement measures for the operation of inspections, etc. in accordance with the records under the provisions of the preceding item;
- (vii) when a deviation occurs from the standard operation manual provided for in item (xi) and the documents provided for in items (xii) and (xiii) in conducting inspections, etc., to assess the content of the deviation and take necessary measures;
- (viii) an employee who carries out the duties referred to in item (i) or the preceding two items is not to conduct inspections, etc.;
- (ix) an employee who performs the operations referred to in items (ii) through (v) (referred to as "operations to ensure reliability" below in this Article) is not to conduct inspections, etc. or perform the operations referred to in item (i) or (vi);
- (x) to make the operations to ensure reliability independent from the operation of inspections, etc.;

- (xi) to prepare a standard operation manual as provided for in the Appended Table 13;
- (xii) to prepare documents stating the method of internal checking for administering the operation of inspections, etc.;
- (xiii) to prepare documents stating the method of accuracy management;
- (xiv) to prepare documents stating the plans for periodically undergoing an external investigation of accuracy management;
- (xv) to prepare documents stating the plans for training employees who perform operations to ensure reliability; and
- (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 made an application for inspections referred to in Article 25, paragraph (1) of the Act or Article 26, paragraphs (1) through (3) of the Act (referred to below as "product inspections"), or a person who has had food and additives, etc. collected and 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 sub-item (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 food, additives, etc. have been collected and removed pursuant to the provisions of Article 28, paragraph (1) of the Act;
 - (c) the name of the products for which inspections, etc. have been conducted;
 - (d) the date on which inspections, etc. have been conducted;
 - (e) the items for inspections, etc.;
 - (f) the quantity of the test samples for which inspections, etc. have been conducted;
 - (g) the name of the employee who has conducted inspections, etc.;
 - (h) the results of inspections, etc.;
 - (i) the records under the provisions of item (v);
 - (j) the records based on the standard operation manual referred to in item (xi); and
 - (k) the records concerning the training referred to in the preceding item.

Chapter VII Registered Conformity Assessment Bodies

Article 38 (1) A person who seeks to make an application for the registration referred to in Article 31 of the Act must submit a written application prepared by using 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 a certificate of

- registered information;
- (ii) the resume of a person who has the knowledge and experience that conform to the conditions stated in column 3 of the Appended Table of the Act (referred to below as an "inspector");
 - (iii) the documents that disclose the organization of the department provided for in Article 33, paragraph (1), item (ii), (a) of the Act (referred to below as the "department conducting product inspections") and the specialized department provided for in sub-item (c) of that item (referred to below as the "department to ensure reliability");
 - (iv) the standard operation manual provided for in Article 40, item (viii) and the documents provided for in items (ix) through (xii) of that Article as the documents provided for in Article 33, paragraph (1), item (ii), (b) of the Act;
 - (v) the documents that state the following matters:
 - (a) whether or not the corporation falls under any item of Article 32 of the Act;
 - (b) the type of product inspection to be conducted among product inspections stated in column 1 of the Appended Table of the Act;
 - (c) the number and functions of the machinery, tools, and other equipment stated in column 2 of the Appended Table of the Act, and distinction of whether they are owned or leased, the place where they are located, and the type of product inspection to be used;
 - (d) the name of the inspector and the type of product inspection to be conducted;
 - (e) the name of the department conducting product inspections, the name of the responsible person of the department conducting product inspections provided for in Article 40, item (i), and the name of the responsible persons of inspection categories provided for in item (ii) of that Article and the type of product inspection that the person administers;
 - (f) the name of the department to ensure reliability, and the name of the responsible person of the department to ensure reliability specified in Article 40, item (iii);
 - (g) when a person is conducting an examination business concerning food sanitation, the outline of that business;
 - (h) whether or not 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 and the number of shares held by the shareholder, or the name and address of a person who has made a contribution that exceeds five percent of the total contribution and 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 personal record (including whether they fall under officers or employees of a business operator subject to inspections prescribed in Article 33, paragraph (1), item (iii) of the Act (including those who were officers or employees of the business person subject to inspections in the past two years)); and
 - (k) when a person conducts a business other than an examination business concerning food sanitation, the type and outline of that business.
- (2) A revenue stamp for the amount of the fee must be affixed to the written application referred to in the preceding paragraph.

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

- (i) the documents stated in paragraph (1), items (i) through (iii) of the preceding Article;
 - (ii) the document stating the matters stated in paragraph (1), item (v), sub-item (a), and sub-items (c) through (k) of the preceding Article; and
 - (iii) materials 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 referred to in Article 35, paragraph (2) of the Act are as follows:

- (i) persons who perform the following operations are assigned to departments conducting product inspections (referred to below as "responsible persons of departments conducting product inspections"):
 - (a) to supervise the operations of departments conducting product inspections;
 - (b) to promptly take improvement measures for those operations in accordance with documents for which report has been made pursuant to the provisions of item (iii), (d); and
 - (c) to conduct other necessary operations;
- (ii) at departments conducting product inspections, persons who perform the following operations for product inspections based on the standard operation manuals prescribed in item (viii) (referred to below as "responsible persons for inspection categories") are assigned to each category of physicochemical inspection, bacteriological inspection, and inspection using animals:
 - (a) when a deviation from the standard operation manuals provided for in

- item (viii) or documents provided for in item (ix) has been found when conducting product inspections, to assess the content of the deviation and take necessary measures;
- (b) to confirm that product inspections are appropriately conducted based on the standard operation manual provided for in item (viii) and to conduct other necessary operations;
- (iii) a person who personally performs the following operations or a person who has another person appointed in advance in accordance with the content of the operations perform those operations is assigned to the department to ensure reliability (referred to below as "responsible person of the department to ensure reliability"):
- (a) periodically conducting internal checking of administering the operation of product inspections, based on documents referred to in item (ix);
- (b) conducting accuracy management based on documents referred to 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 periodically undergoing an external investigation of accuracy management, based on documents referred to in item (xi);
- (d) reporting the results of internal checking referred to in sub-item (a), accuracy management referred to in sub-item (b), and external investigation of accuracy management referred to in sub-item (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 (referred to below as the "books");
- (e) performing other necessary operations;
- (iv) a department ensuring credibility is to be independent from departments conducting product inspections;
- (v) responsible persons for departments conducting product inspections and a responsible person for the department to ensure reliability are officers of a registered conformity assessment body;
- (vi) responsible persons for departments conducting product inspections and responsible persons for inspection categories do not concurrently hold the position of inspector;
- (vii) the responsible person of the department to ensure reliability and persons appointed pursuant to the provisions of item (iii) are not to concurrently hold the position of the responsible person of the departments conducting product inspections, responsible persons for inspection categories, and inspectors;
- (viii) standard operation manual has been prepared as provided for in the Appended Table 13. In such a case, the phrases "Method for preparing records" and "Standard operation manual for implementing inspections", and

- the term "inspections, etc.", in that Table are deemed to be replaced with "Methods for making entries into the books", "Standard operation manual for implementing product inspections", and "product inspections", respectively.
- (ix) a document stating the method of internal checking for managing the operation of product inspections has been prepared;
 - (x) a document stating the method of accuracy management has been prepared;
 - (xi) a document stating the plan for periodically undergoing external investigation of accuracy management has been prepared; and
 - (xii) a document stating the training plans for responsible persons of departments to ensure reliability and persons appointed pursuant to the provisions of item (iii) has been prepared.

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

(2) A person who intends to give a notification of change pursuant to the provisions of Article 36, paragraph (2) of the Act must submit a written notification prepared using Form No. 8 to the Minister of Health, Labour and Welfare.

Article 42 (1) When a registered conformity assessment body seeks to obtain authorization for the rules concerning the operation of product inspections (referred to below 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 using 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 provided for in the operational rules referred to in Article 37, paragraph (2) of the Act are as follows:

- (i) the types of product inspections and the matters concerning the method of implementing and managing the operation of product inspections;
- (ii) the matters concerning the time product inspections are conducted and holidays;
- (iii) the matters concerning the maximum number of applications for product inspections that may be received;
- (iv) the matters concerning the place for conducting product inspections;
- (v) the amount of fees for each inspection item of product inspections and matters concerning the method of 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 person for the department to ensure reliability;
- (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; the same applies below in this Article) and the acceptance of requests for inspection, etc. of financial statements, etc.; and
 - (x) beyond what is stated in the preceding items, necessary matters for the operation of product inspections.
- (3) When a registered conformity assessment 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 using Form No. 10 to the Minister of Health, Labour and Welfare. In such a case, when the changes involve change of the amount of the fee for product inspections, materials concerning its calculation must be attached.

Article 43 When a registered conformity assessment 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 using 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 prescribed in Article 39, paragraph (2), item (iii) of the Act are the means of indicating the matters recorded in the electronic or magnetic record on paper or the screen of an output device.

Article 45 The electronic or magnetic means specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 39, paragraph (2), item (iv) of the Act are either of the following means that is specified by a registered conformity assessment 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 is 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 disc or by other equivalent means.

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

- (i) the name and address of a person who has applied for product inspection (for a corporation, its name and the location of its principal office);
 - (ii) the date on which the application for product inspection has been received;
 - (iii) the name of the products for which product inspection has been conducted;
 - (iv) the date on which product inspection has been conducted;
 - (v) the items for product inspection;
 - (vi) the quantity of the test samples for which product inspection has been conducted;
 - (vii) the name of the inspector who has conducted the product inspection;
 - (viii) the results of the product inspection;
 - (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 manual 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 using 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), 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 the senior course or advanced course of a girls' high school under the former Secondary School Order, which has an entrance requirement of graduating from a girls' high school under that Order with a course term of 4 years, which has an entrance requirement

- of completion of an elementary course of a national elementary school under the former National Elementary School Order (Imperial Order No. 148 of 1941) (referred to below as a "national elementary school");
- (ii) a person who has completed the first year of an advanced course of a vocational school under the former Secondary School Order which has an entrance requirement of graduating from a vocational school under that Order with a course term of 4 years, which has an entrance requirement of completion of an elementary course at a national elementary school;
 - (iii) a person who has completed a preparatory course of 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 the first division of the regular course of a normal school under the former Normal School Education Order (Imperial Order No. 346 of 1897) before 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 on the entrance into and transfer to other schools for 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 stated in item (i);
 - (vii) a person who has graduated from a regular course at a boys' school (excluding courses with a course term for two years) 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 a person having an academic ability equivalent to or higher than graduates of a middle school or girls' high school concerning entrance into a professional training college pursuant to the provisions of Article 11, paragraph (2) of those 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-Ranking Officials Examination Order (Imperial Order No. 15 of 1929);
 - (xi) a person who has a teacher's license stated 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 qualifications stated 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 stated in the preceding items, a person certified by the Minister of Health, Labour and Welfare as having an academic ability equivalent to or higher than graduates of a high school or secondary education school, or secondary school, concerning 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 distinction of 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 referred to in the preceding paragraph must be attached with a resume of the food sanitation supervisor, a document proving that the food sanitation supervisor falls under one of the items of Article 48, paragraph (6) of the Act, and a document proving the relations with the business operator.

Article 50 The criteria specified by Order of the Ministry of Health, Labour and Welfare 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) that the training institute is a university under the School Education Act or an educational facility that has courses acknowledged 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) that for each curriculum referred to in the left-hand column of the Appended Table 14, one or more subjects stated in the right-hand column of that Table have to be taken, and the total number of credits is 22 or more;
- (iii) that the subjects stated in the preceding item and subjects stated in the Appended Table 15 have to be taken, and the total number of credits is 40 or

- more; and
- (iv) that in principle, classes are to be conducted by using the machinery and tools stated 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 a document 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 the teachers, the subjects they teach, and whether they are full-time teachers or hold another job;
- (v) plans of subjects to be taken each school year, the number of credits, and distinction between compulsory subjects and optional subjects;
- (vi) quota of students;
- (vii) entrance qualifications and the time of entrance;
- (viii) length of study;
- (ix) a list of machinery and tools for teaching and practical training, and a library index;
- (x) drawings and layout of the school site and school buildings;
- (xi) school regulations; and
- (xii) other matters that should serve as reference.

Article 52 (1) The registration of a training institution referred to in 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 below), 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 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 the matters stated in Article 51, items (i) through (iii), items (v) through (viii), item (ix) (limited to those related to machinery and tools stated 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 a document 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, the measures to be taken for them.

Article 55 The matters specified by Order of the Ministry of Health, Labour and Welfare 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 stated 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) that the subjects stated in column 1 of the Appended Table 16 and the subjects stated in any of the columns 2 through 7 of that Table are taught, and the number of hours taught is to be equal to or more than the number of hours stated in that Table;
 - (ii) that 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 the national government, a prefecture, a city with public health centers, or a special ward, or persons recognized as having knowledge and experience equal to those persons;
 - (iii) that qualifications for taking the training sessions are 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 a person who falls under the items of Article 48, who has been engaged in sanitation management of production or processing of food or additives for two years or more in a production or processing industry 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 stated in the following items may be exempted from taking subjects prescribed in each of those items:
- (i) a person who has studied subjects equivalent to or higher than those stated

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 technical college under the former Technical College Order: those subjects; and

- (ii) a person who has completed registered training sessions: for a person who has completed subjects stated in column 1 of the Appended Table 16 and column 2 or 3 of that Table, practical training on bacteriology stated in column 3 or column 2 of that Table, respectively.

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

- (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 or not a fact that falls under any item of Article 22 of the Order exists;
- (iii) for a corporation, the names, addresses, and brief personal records 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 trainings are held;
- (vi) the period of the training sessions and their schedule;
- (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 referred to in 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 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 of completion of the training session 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 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 and the scheduled date for the suspension or discontinuation; and
- (ii) when seeking to suspend the operation, the scheduled period of the 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; the same applies below in this Article) (when three months have not passed 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 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 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 referred to in Article 31 of the Order are as follows:

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

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

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

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

(3) A business operator must specify the necessary measures for public health based on 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, and abide by those measures:

- (i) to prepare plans for sanitation management of facilities and handling, etc. of food or additives (referred to below 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 the occurrence of 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 appropriately taking necessary measures for public health in those processes (referred to below as "procedure manual") as required;
- (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 to be used or consumed; and
 - (iv) to verify the effectiveness of the sanitation management plan and the procedure manual, and review their content as required.
- (4) For a business operator stated in the following items, the provisions of the preceding paragraph are applied by the deemed replacement of the term "to prepare" in item (i) of the preceding paragraph with "to prepare as required" and the term "to record and preserve" in item (iii) of that paragraph with "to record and preserve as required".
- (i) a person who conducts business of importing food or additives;
 - (ii) a person who conducts business of only storing or transporting food or additives (excluding a person who is engaged in the business of freezing or refrigerating food);
 - (iii) a person who conducts business of selling among food or additives packed or wrapped in containers and packages, food or additives that 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;
 - (iv) a person who conducts business of importing or selling apparatus, or containers and packages.
- (5) The provisions of the preceding paragraph (limited to the part on specifying the necessary measures for public health in accordance with the criteria referred to in the Appended Table 17, item (ix), (c)) do not apply to the persons stated in the following items among business operators:
- (i) a person who received the permission referred to in Article 43, paragraph (1) of the Health Promotion Act (Act No. 103 of 2002) related to food for specified health uses (meaning food for specified health uses defined in Article 2, paragraph (1), item (v) of the Cabinet Office Order on Permission to Make Representations About a Special Use Prescribed in the Health Promotion Act (Cabinet Office Order No. 57 of 2009)); the same applies below);
 - (ii) a notifier prescribed in Article 2, paragraph (1), item (x), (b) of the Food Labeling Standards.

Article 66-3 The business operators specified by Order of the Ministry of Health, Labour and Welfare 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 of setting up coffee shops, salons, and other facilities and serving drinks other than alcoholic beverages or refreshments to customers) and a proprietor or an administrator of those facilities at a school, hospital, or other facilities provided for in Article 68, paragraph (3) of

- the Act);
- (ii) a person who conducts business of cooking food using a vending machine that has a cooking function provided for in Article 35, item (ii) of the Order and selling the cooked food;
 - (iii) a person who conducts business of producing bread (limited to bread 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 business of producing ready-made dishes provided for in Article 35, item (xxv) of the Order; and
 - (v) a person who conducts business of cooking food using a vending machine that has a cooking function and selling the cooked food (excluding a person who conducts business provided for in item (i) or (ii)).

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

- (i) a person who conducts business of dividing food into small portions, putting the food in containers and packages, or wrapping it in containers and packages, and selling it;
- (ii) in addition to the business operators stated in the preceding item, among the persons who conduct the business of producing, processing, storing, selling, or treating food, business operators who have a workplace in which less than 50 persons are engaged in handling of food (referred to as "small-scale workplace" below in this item); provided, however, that if the business operator has a workplace in which 50 or more persons are engaged in handling of food (referred to as "large-scale workplace" below in this item), the criteria specified by Order of the Ministry of Health, Labour and Welfare referred to in Article 51, paragraph (1), item (ii) of the Act concerning the initiatives in accordance with the characteristics of food handled which is provided for in that paragraph apply only to a small-scale workplace owned by the business operator and do not apply to a large-scale workplace owned by the business operator.

Article 66-5 (1) The criteria specified by Order of the Ministry of Health, Labour and Welfare referred to in Article 52, paragraph (1), item (i) of the Act concerning the matters stated 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 packages will be appropriately produced;
- (ii) to perform necessary management of the maintenance of cleanliness and health conditions for the personnel engaged in production of apparatus or

- containers and packages (hereinafter referred to as "workers" below in this Article and the following Article) and make the workers understand the work procedures and necessary matters 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 in which contamination by dust and dirt, etc. may be prevented as required, by taking into account the method, etc. of using apparatus or containers and packages, and maintain the facilities and work areas in a clean condition;
 - (iv) to appropriately perform the cleaning and maintenance inspection of the facilities and the disposal of waste in order to maintain a clean working environment;
 - (v) to conduct education and training for persons who administer the production of apparatus or containers and packages and the workers, and share necessary information and initiatives to prevent the occurrence of food sanitation hazards among the persons concerned;
 - (vi) to prepare work procedures, specify necessary matters for sanitation management, and record the results of the initiatives, and preserve the results so that they can be promptly confirmed as required;
 - (vii) to prepare records of the purchase, use, and disposal of raw materials of apparatus or containers and packages and the production, storage, shipment, and disposal of apparatus or containers and packages, and preserve the apparatus or containers and packages 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 packages are consumed.
- (2) The requirements specified by Order of the Ministry of Health, Labour and Welfare referred to in Article 52, paragraph (1), item (ii) of the Act concerning the matters stated 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 (referred to as "raw materials" below in this Article and the following Article);
 - (ii) for product design of apparatus or containers and packages, 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 referred to in paragraph (1) of that Article;
 - (iii) to analyze the measures to prevent occurrence of food sanitation hazards or risks of the hazards occurring as required, and specify the factors that require control;
 - (iv) for the factors that require control referred to in the preceding item, to determine the level of production and control necessary for preventing occurrence of food sanitation hazards (referred to below as the "control level")

- and the control method, and appropriately control those factors;
- (v) to confirm that raw materials and apparatus or containers and packages meet the appropriate control level;
- (vi) for raw materials, apparatus or containers and packages, or apparatus or containers and packages collected that do not meet the appropriate control level, or other apparatus or containers and packages that may cause food sanitation hazards, to specify the method of response in advance;
- (vii) for raw materials, apparatus or containers and packages, or apparatus or containers and packages collected that do not meet the appropriate control level, or other apparatus or containers and packages that may cause food sanitation hazards, to handle them 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 packages produced, as required.

Article 66-6 (1) A person who sells, or produces or imports for the purpose of selling apparatus, or containers and packages 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 packages under the provisions of Article 53, paragraph 1 of the Act as prescribed in the provisions of the following items:

- (i) to specify the apparatus or containers and packages that are the subject of the explanation, and convey information that enables to confirm that they fall under either of Article 53, paragraph (1), item (i) of the Act or item (ii) of that paragraph; and
 - (ii) to develop a 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 that information.
- (2) A person who sells, or produces or imports for the purpose of selling, raw materials of apparatus or containers and packages 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 as prescribed in the provisions of the following items:
- (i) to specify the raw materials that are subject of the explanation, and convey the information that enables to confirm that the apparatus or containers and packages that 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 develop a 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 that information.

Article 66-7 The criteria specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 54 of the Act are as provided for in the Appended Table 19 for matters common to the businesses stated in each item of Article 35 of the Order (excluding the business stated in items (ii) and (vi) of that Article), the Appended Table 20 for matters concerning each business stated 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 business that handles meat to be eaten raw or pufferfish that conform to the standards or criteria specified based on the provisions of Article 13, paragraph (1) of the Act.

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

- (i) an auction;
- (ii) transactions by bidding; and
- (iii) over-the-counter transactions.

Article 66-9 Foods specified by Order of the Ministry of Health, Labour and Welfare referred to in Article 35, item (xiii) of the Order are milk products defined in Article 2, paragraph (13) of the Order on Milk and Milk Products Concerning Compositional Standards, etc. (excluding ice cream products prescribed in paragraph (21) of that Article) and lactic acid bacteria beverages prescribed in paragraph (41) of that Article, which contain less than 3.0% of non-fat milk solids.

Article 66-10 Foods specified by Order of the Ministry of Health, Labour and Welfare 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, tea substitutes (limited to dried products), dried mushrooms, dried cereals, dried seeds, dried pulses, honey, dried sweet potato, peanuts (excluding fresh or boiled peanuts), dried seaweed, dried and fermented fish, dried bonito shavings, liquid sugar, processed sesame seeds, dried kudzu starch noodles, dried soup products, dried spices, dried tapioca, dried herbs, dried breadcrumbs, salt, gelatin, cooking roux, 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 those foods, and vinegar.

Article 67 A person who seeks to obtain an approval 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.

- (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 business 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 to be 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 has attended;
- (v) drawings showing the structure and equipment of the facility (when using potable water other than water supplied by the water supply services provided for in Article 3, paragraph (2) of the Water Supply Act (Act No. 177 of 1957), the specified privately owned water supply systems provided for in paragraph (6) of the Article, and the specified building water supply systems with tank storage provided for in paragraph (7) of the Article (referred to as "potable water" below in the Appended Tables 17 and 19), including copies of the documents certifying the results of the water quality testing of the water to be used conducted by an agency of a local government provided for in Article 20, paragraph (3) of that Act or a person designated by the Minister of Land, Infrastructure, Transport and Tourism and the Minister of the Environment);
- (vi) classification of initiatives for managing processes that are particularly important for preventing occurrence of food sanitation hazards or initiatives implemented in accordance with the characteristics of food handled (limited to the cases in which the applicant seeks to continue to be licensed for business upon expiration of the validity period of the license for business stated in the items of Article 35 of the Order; provided, however, that for a person who applies for a license for business stated in item (xxvi) or (xxviii) of that Article, including when making a new application);
- (vii) whether or not 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 content of the case.

Article 67-2 (1) A person who seeks to notify their succession to the status of a person who has obtained a business license under the provisions of Article 55, paragraph (1) of the Act (referred to below as a "licensed business operator")

through the transfer of business 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, 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 name of the person who has transferred the business (with phonetic transcriptions in hiragana) and the address of that person (for a corporation, its name (with phonetic transcriptions in hiragana), its location, and the name of its representative (with phonetic transcriptions in hiragana));
 - (iii) the date of the transfer of business; and
 - (iv) the license number for the facility and the date on which the license has been obtained.
- (2) The written notification referred to in the preceding paragraph must have documents proving the transfer of business attached.

Article 68 (1) A person who intends to notify their succession to the status of a licensed business operator 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 the opening of inheritance; and
 - (iv) the license number of 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 Regulations on Real Property Registration (Order of the Ministry of Justice No. 18 of 2005) which has been issued pursuant to the provisions of paragraph (5) of that Article; and
 - (ii) for a person who is selected as the successor to the status of the licensed business operator with the consent of all the heirs in the case there are two or more heirs, the written consent of all those heirs.

Article 69 (1) A person who intends to notify their succession to the status of a licensed business operator 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 that disappeared in 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 the registered matters of the corporation surviving the merger or the corporation established by the merger.

Article 70 (1) A person who intends to notify their succession to the status of a licensed business operator 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 before 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 has been obtained.
- (2) The written notification referred to in the preceding paragraph must be attached with the certificate of registered information of the corporation that succeeded to the business through the split.

Article 70-2 (1) A person who intends to give a notification under the provisions of Article 57, paragraph (1) of the Act (including as applied mutatis mutandis pursuant to Article 68, paragraphs (1) and (3) of the Act; the same applies in the following paragraph) 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 type of business (including those prescribed in Article 68, paragraph (3) of the Act; the same applies in Article 71-2) and information on the food, additives, apparatus, or containers and packages mainly handled;
 - (iv) the name of the food sanitation manager (with phonetic transcriptions in hiragana; provided, however, that this excludes business operators who produce apparatus or containers and packages that use materials provided for in Article 1 of the Order).
- (2) The provisions of the preceding four Articles apply *mutatis mutandis* to a person who intends to notify their succession to the status of a person who has given a notification under the provisions of Article 57, paragraph (1) of the Act (referred to below as a "notifying business operator") pursuant to the provisions of Article 56, paragraph (2) of the Act as applied *mutatis mutandis* pursuant to Article 57, paragraph (2) of the Act (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (3) of the Act) following the deemed replacement of terms. In such a case, the phrases "business pursuant to" and "a person who has obtained a business license under the provisions of Article 55, paragraph (1) of the Act (referred to below as a "licensed business operator")" in Article 67-2, paragraph (1) of the Act are deemed to be replaced with "business pursuant to... (including cases prescribed in Article 68, paragraph (3) of the Act; the same applies below)" and "a person who has given a notification under the provisions of Article 57, paragraph (1) of the Act (including as applied *mutatis mutandis* pursuant to Article 68, paragraphs (1) and (3) of the Act) (referred to below as "notifying business operator")", respectively; the phrase "the license number for the facility and the date on which the license was obtained" in item (iv) of that paragraph is deemed to be replaced with "the location of the facility related to the succession to the status (for business conducted in an automobile, the registration number of the automobile) and its name, shop name, or trade name (with phonetic transcriptions in hiragana)"; the term "licensed business operator" in Article 68, paragraph (1) is deemed to be replaced with "notifying business operator"; the phrase "the license number for the facility and the date on which the license was obtained" in item (iv) of that paragraph is deemed to be replaced with "the location of the facility related to the succession to the status (for business

conducted in an automobile, the registration number of the automobile) and its name, shop name, or trade name (with phonetic transcriptions in hiragana)"; the term "licensed business operator" in paragraph (2), item (ii) of that Article is deemed to be replaced with "notifying business operator"; the term "licensed business person" in Article 69, paragraph (1) is deemed to be replaced with "notifying business operator"; the phrase "the license number for the facility and the date on which the license was obtained" in item (iv) of that paragraph is deemed to be replaced with "the location of the facility related to the succession to the status (for business conducted in an automobile, the registration number of the automobile) and its name, shop name, or trade name (with phonetic transcriptions in hiragana)"; the term "licensed business operator" in paragraph (1) of the preceding Article is deemed to be replaced with "notifying business operator"; the phrase "the license number for the facility and the date on which the license was obtained" in item (iv) of that paragraph is deemed to be replaced with "the location of the facility related to the succession to the status (for business conducted in an automobile, the registration number of the automobile) and its name, shop name, or trade name (with phonetic transcriptions in hiragana)".

Article 71 When changes are made to the matters stated 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), the matters stated in Article 67-2, paragraph (1), item (i) (excluding the date of birth), Article 68, paragraph (1), item (i) (excluding the date of birth), Article 69, paragraph (1), item (i), or Article 70, paragraph (1), item (i) (each including as applied *mutatis mutandis* pursuant to paragraph (2) of the preceding Article), or the matters stated in paragraph (1), 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 operator or a notifying business operator must promptly notify the prefectural governor, etc. who has jurisdiction over the location of the facility of that fact.

Article 71-2 When it becomes no longer possible to continue the business due to discontinuation of business, a licensed business operator or a notified business operator 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) 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 operator, 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 below) must be made in writing, by phone, or orally within 24 hours for the following matters:

- (i) the address and name of the physician;
- (ii) the location, name, and age of the poisoned patient or the person who is suspected to have been poisoned, or the deceased persons (referred to below as "patients, etc.");
- (iii) the causes of the food poisoning (meaning poisoning caused by food, additives, apparatus, containers and packages, or toys stated in the items of Article 78 (referred to as "food, etc." in the following Article and Article 74, paragraph (1), item (iii)); the same applies below);
- (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 specified by Order of the Ministry of Health, Labour and Welfare 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 below) is 50.

(2) The cases specified by Order of the Ministry of Health, Labour and Welfare 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 the disease agents stated in the Appended Table 22;
- (iv) when poisoned patients, etc. are found in multiple prefectures;
- (v) when investigations of the causes of the poisoning are difficult in consideration of the circumstances, etc. of the outbreak of the poisoning; and
- (vi) when it is difficult to render dispositions under the provisions of Article 59 through Article 61 of the Act (referred to below as "dispositions") or to determine the appropriateness of the content of the dispositions in

consideration of the circumstances, etc., of the outbreak of the poisoning.

Article 74 The matters specified by Order of the Ministry of Health, Labour and Welfare 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 under the provisions of Article 63, paragraph (1) of the Act;
- (ii) the number of patients, etc., and their symptoms;
- (iii) the food, etc., that caused or is suspected to have caused the poisoning (referred to below 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 or other facilities that caused or are suspected to have caused the poisoning (referred to below as "facilities of origin") and the reasons for specifying the facilities as the cause; and
- (vi) beyond what is stated in the preceding items, the matters found to be 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 stated in each of those 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 for the food poisoning case prepared using Form No. 14 and a detailed report of the food poisoning case; and
 - (ii) food poisoning cases other than those stated in the preceding item: a case notification form for the food poisoning case prepared using Form No. 14.
- (2) A detailed report of the food poisoning case provided for in item (i) of the preceding paragraph is to state the following matters:
- (i) the following matters concerning the outline of the occurrence of 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 deceased persons;
 - (e) the number of patients;
 - (f) the food, etc., causing poisoning;
 - (g) the disease agents;
 - (ii) the matters concerning the understanding of information on the occurrence

- of food poisoning;
- (iii) the following matters concerning the situation of the patients and the deceased persons:
 - (a) the number of patients and deceased persons by sex and age;
 - (b) the number of patients and deceased persons by date and time of occurrence of the food poisoning;
 - (c) the ratio of patients and deceased persons among the persons who consumed the food, etc. causing poisoning;
 - (d) the circumstances during 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 persons 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) the 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) the 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 written reports specified in the following items in accordance with the category of food poisoning cases stated in each of those items:

- (i) food poisoning cases that 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 stated 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 cases

referred to in the items of the preceding paragraph is to be prepared using Form No. 15.

- (3) A written report on the investigation results of the food poisoning cases referred to in the items of paragraph (1) must be submitted each month by the tenth of the following month, by attaching the case notification forms of food poisoning cases referred to in the items of paragraph (1) of the preceding Article which were accepted in that month.
- (4) A detailed report on the investigation results of the food poisoning case referred to in paragraph (1), item (i) is to be prepared by entering the matters set forth in the items of paragraph (2) of the preceding Article.
- (5) A detailed report on the investigation results of the food poisoning case referred to in paragraph (1), item (i) must be prepared and submitted immediately after receiving the detailed report of the food poisoning case referred to 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 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 that are essentially intended for infants to bring into contact with their mouth;
- (ii) accessory toys (toys used as accessories by infants), transfer pictures, tumbler dolls (daruma-shaped dolls 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 stated 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 a Director-General of a Regional Bureau 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-Ascorbyl Palmitate (Vitamin C Palmitate)
13. Asparaginase
14. Monosodium L-Aspartate
15. Aspartame (L-alpha-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. 6-Apo-8' -carotenal
29. (3-Amino-3-carboxypropyl) dimethylsulfonium chloride
30. Amylalccohol
31. alpha-Amylcinnamaldehyde (alpha-Amylcinnamic Aldehyde)
32. DL-Alanine
33. Ammonium Hydrogen Sulfite Water
34. Sodium Sulfite (Disodium 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 (excluding substances generally accepted as 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 derivatives thereof
67. Disodium 5' -Uridylate (Sodium 5' -Uridylate)
68. gamma-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 (Octyl Aldehyde or Caprylic 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. beta-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. Glycerol Esters of Fatty Acids
125. Calcium Glycerophosphate
126. Disodium Glycyrrhizinate
127. Glucono-delta-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 Hypochlorite
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-Cysteine Monohydrochloride
185. Disodium 5' -Cytidylate (Sodium 5' -Cytidylate)
186. Citral
187. Citronellal
188. Citronellol
189. 1,8-Cineole (Eucalyptol)

190. Diphenyl (Biphenyl)
191. Difenconazole
192. Butylated Hydroxytoluene
193. Dibenzoyl Thiamine
194. Dibenzoyl Thiamine Hydrochloride
195. Fatty Acids
196. Aliphatic Higher Alcohols
197. Aliphatic Higher Aldehydes (excluding substances generally accepted as highly toxic)
198. Aliphatic Higher Hydrocarbons (excluding substances generally accepted as 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. Calcium L-Tartrate (Calcium d-Tartrate)
210. Potassium DL-Bitartrate (Potassium Hydrogen dl-Tartrate or Potassium Hydrogen DL-Tartrate)
211. Potassium L-Bitartrate (Potassium Hydrogen d-Tartrate or Potassium Hydrogen L-Tartrate)
212. Disodium DL-Tartrate (Disodium dl-Tartrate)
213. Disodium L-Tartrate (Disodium d-Tartrate)
214. Potassium Nitrate
215. Sodium Nitrate
216. Food Red No. 2 (Amaranth) and Food Red No. 2 Aluminum Lake
217. Food Red No. 3 (Erythrosine) and Food Red No. 3 Aluminum Lake
218. Food Red No. 40 (Allura Red AC) and Food Red No. 40 Aluminum Lake
219. Food Red No. 102 (New Coccine)
220. Food Red No. 104 (Phloxine)
221. Food Red No. 105 (Rose Bengal)
222. Food Red No. 106 (Acid Red)
223. Food Yellow No. 4 (Tartrazine) and Food Yellow No. 4 Aluminum Lake
224. Food Yellow No. 5 (Sunset Yellow FCF) and Food Yellow No. 5 Aluminum Lake
225. Food Green No. 3 (Fast Green FCF) and Food Green No. 3 Aluminum Lake
226. Food Blue No. 1 (Brilliant Blue FCF) and Food Blue No. 1 Aluminum Lake
227. Food Blue No. 2 (Indigo Carmine) and Food Blue No. 2 Aluminum Lake
228. Sucrose Esters of Fatty Acids
229. Silicone Resin (Polydimethylsiloxane)
230. Cinnamyl Alcohol (Cinnamic Alcohol)
231. Cinnamaldehyde (Cinnamic Aldehyde)

232. Potassium Hydroxide (Caustic Potash)
233. Calcium Hydroxide (Slaked Lime)
234. Sodium Hydroxide (Caustic Soda)
235. Magnesium Hydroxide
236. Sucralose (Trichlorogalactosucrose)
237. Calcium Stearate
238. Magnesium Stearate
239. Calcium Stearoyl Lactylate (Calcium Stearyl Lactylate)
240. Sodium Stearoyl Lactylate
241. Sorbitan Esters of Fatty Acids
242. D-Sorbitol (D-Sorbit)
243. Sorbic Acid
244. Potassium Sorbate
245. Calcium Sorbate
246. Ammonium Carbonate
247. Potassium Carbonate (anhydrous)
248. Calcium Carbonate
249. Ammonium Bicarbonate (Ammonium Hydrogen Carbonate)
250. Potassium Hydrogen Carbonate (Potassium Bicarbonate or Potassium Acid Carbonate)
251. Sodium Bicarbonate (Sodium Hydrogen Carbonate or Bicarbonate Soda)
252. Sodium Carbonate (Crystal: Carbonate Soda, Anhydrous: Soda Ash)
253. Magnesium Carbonate
254. Thiabendazole
255. Thiamine Hydrochloride (Vitamin B1 Hydrochloride)
256. Thiamine Mononitrate (Vitamin B1 Mononitrate)
257. Thiamine Dicetylsulfate (Vitamin B1 Dicetylsulfate)
258. Thiamine Thiocyanate (Vitamin B1 Rodanate)
259. Thiamine Naphthalene-1,5-disulfonate (Vitamin B1 Naphthalene-1,5-disulfonate)
260. Thiamine Dilaurylsulfate (Vitamin B1 Dilaurylsulfate)
261. Thioethers (excluding substances generally accepted as highly toxic)
262. Thiols (Thioalcohols) (excluding substances generally accepted as highly toxic)
263. L-Theanine
264. Decanal (Decyl Aldehyde)
265. Decanol (Decyl Alcohol)
266. Ethyl Decanoate (Ethyl Caprate)
267. Sodium Iron Chlorophyllin
268. 5, 6, 7, 8-Tetrahydroquinoxaline
269. 2, 3, 5, 6-Tetramethylpyrazine
270. Sodium Dehydroacetate
271. Terpeneol
272. Terpene Hydrocarbons
273. Sodium Carboxymethylstarch
274. Copper salts (limited to Copper Gluconate and Cupric Sulfate)
275. Sodium Copper Chlorophyllin
276. Copper Chlorophyll
277. dl-alpha-Tocopherol

278. All-rac-alpha-Tocopheryl Acetate
279. d-alpha-Tocopheryl Acetate
280. DL-Tryptophan
281. L-Tryptophan
282. Trimethylamine
283. 2, 3, 5-Trimethylpyrazine
284. DL-Threonine
285. L-Threonine
286. Nisin
287. Natamycin (Pimaricin)
288. Sodium Methoxide (Sodium Methylate)
289. Nicotinic Acid (Niacin)
290. Nicotinamide (Niacinamide)
291. Sulfur Dioxide (Sulfurous Acid Anhydride)
292. Chlorine Dioxide
293. Silicon Dioxide (Silica Gel)
294. Carbon Dioxide (Carbonic Acid Gas)
295. Titanium Dioxide
296. Dimethyl Dicarbonate
297. Lactic Acid
298. Potassium Lactate
299. Calcium Lactate
300. Iron Lactate
301. Sodium Lactate
302. Neotame
303. gamma-Nonalactone (Nonalactone)
304. Potassium Norbixin
305. Sodium Norbixin
306. Vanillin
307. Isobutyl p-Hydroxybenzoate
308. Isopropyl p-Hydroxybenzoate
309. Ethyl p-Hydroxybenzoate
310. Butyl p-Hydroxybenzoate
311. Propyl p-Hydroxybenzoate
312. p-Methylacetophenone
313. L-Valine
314. Valeraldehyde
315. Calcium Pantothenate
316. Sodium Pantothenate
317. Biotin
318. L-Histidine Monohydrochloride
319. Bisbentiamine (Benzoylthiamine Disulfide)
320. Vitamin A (Retinol)
321. Vitamin A Esters of Fatty Acids (Retinol Fatty Acids Esters)
322. 1-Hydroxyethylidene-1,1-Diphosphonic Acid
323. Hydroxycitronellal
324. Hydroxycitronellal Dimethylacetal
325. Hydroxypropyl Distarch Phosphate

326. Hydroxypropyl Cellulose
327. Hydroxypropyl Starch
328. Hydroxypropyl Methylcellulose
329. Copolymer of Vinylimidazole/Vinylpyrrolidone (PVI/PVP)
330. Piperidine
331. Piperonal (Heliotropine)
332. Piperonyl Butoxide
333. Sunflower Lecithin
334. Glacial Acetic Acid
335. Pyrazine
336. Pyridoxine Hydrochloride (Vitamin B6)
337. Pyrimethanil
338. Potassium Pyrosulfite (Potassium Hydrogen Sulfite or Potassium Metabisulfite)
339. Sodium Pyrosulfite (Sodium Metabisulfite or Acid Sulfite of Soda)
340. Pyrrolidine
341. Potassium Pyrophosphate (Tetrapotassium Pyrophosphate)
342. Calcium Dihydrogen Pyrophosphate (Acid Calcium Pyrophosphate)
343. Disodium Dihydrogen Pyrophosphate (Acid Sodium Pyrophosphate)
344. Ferric Pyrophosphate
345. Tetrasodium Pyrophosphate (Sodium Pyrophosphate)
346. Pyrrole
347. Calcium Phytate
348. L-Phenylalanine
349. Isoamyl Phenylacetate
350. Isobutyl Phenylacetate
351. Ethyl Phenylacetate
352. 2-(3-Phenylpropyl)pyridine
353. Phenethylamine
354. Phenol Ethers (excluding substances generally accepted as highly toxic)
355. Phenols (excluding substances generally accepted as highly toxic)
356. Ferrocyanides (limited to Potassium Ferrocyanide (Potassium Hexacyanoferrate(II)), Calcium Ferrocyanide (Calcium Hexacyanoferrate(II)), and Sodium Ferrocyanide (Sodium Hexacyanoferrate(II)))
357. Psicose Epimerase
358. Butanol
359. Butylamine
360. sec-Butylamine
361. Butyraldehyde
362. Butylated Hydroxyanisole
363. Fumaric Acid
364. Monosodium Fumarate (Sodium Fumarate)
365. Fludioxonil
366. Furfurals and derivatives thereof (excluding substances generally accepted as highly toxic)
367. Propanol
368. Propionaldehyde
369. Propionic Acid
370. Isoamyl Propionate

371. Ethyl Propionate
372. Calcium Propionate
373. Sodium Propionate
374. Benzyl Propionate
375. Propiconazole
376. Propylamine
377. Propylene Glycol
378. Propylene Glycol Esters of Fatty Acids
379. Hexanoic Acid (Caproic Acid)
380. Allyl Hexanoate (Allyl Caproate)
381. Ethyl Hexanoate (Ethyl Caproate)
382. Hexylamine
383. Ethyl Heptanoate (Ethyl Enanthate)
384. l-Perillaldehyde
385. Benzyl Alcohol
386. Benzaldehyde
387. 2-Pentanol (sec-Amyl alcohol)
388. Pentylamine
389. trans-2-Pentenal
390. 1-Penten-3-ol
391. Aromatic Alcohols
392. Aromatic Aldehydes (excluding substances generally accepted as highly toxic)
393. Propyl Gallate
394. Sodium Polyacrylate
395. Polyisobutylene (Butyl Rubber)
396. Polysorbate 20
397. Polysorbate 60
398. Polysorbate 65
399. Polysorbate 80
400. Polyvinyl Alcohol (Vinyl Alcohol Polymer)
401. Polyvinylpyrrolidone
402. Polyvinylpolypyrrolidone
403. Polybutene (Polybutylene)
404. Potassium Polyphosphate
405. Sodium Polyphosphate
406. d-Borneol
407. Maltol
408. D-Mannitol (D-Mannite)
409. Metatartaric Acid
410. Potassium Metaphosphate
411. Sodium Metaphosphate
412. DL-Methionine
413. L-Methionine
414. Methyl N-Methylantranilate
415. 5-Methylquinoxaline
416. 6-Methylquinoline
417. 5-Methyl-6,7-dihydro-5H-cyclopentapyrazine

418. Methyl Cellulose
419. 1-Methylnaphthalene
420. Methyl β -Naphthyl Ketone
421. 2-Methylpyrazine
422. 2-Methylbutanol
423. 3-Methyl-2-butanol
424. 2-Methylbutylamine
425. 2-Methylbutyraldehyde
426. trans-2-Methyl-2-butenal
427. 3-Methyl-2-butenal
428. 3-Methyl-2-butenol
429. Methyl Hesperidin (Soluble Vitamin P)
430. dl-Menthol (dl-Peppermint Camphor)
431. l-Menthol (Peppermint Camphor)
432. Morpholine Salts of Fatty Acids
433. Folic Acid
434. Butyric Acid
435. Isoamyl Butyrate
436. Ethyl Butyrate
437. Cyclohexyl Butyrate
438. Butyl Butyrate
439. Lactones (excluding substances generally accepted as highly toxic)
440. L-Lysine L-Aspartate
441. L-Lysine Monohydrochloride
442. L-Lysine L-Glutamate
443. Linalool
444. Calcium 5' -Ribonucleotide
445. Disodium 5' -Ribonucleotide (Sodium 5' -Ribonucleotide)
446. Riboflavin (Vitamin B2)
447. Riboflavin Tetrabutyrates (Vitamin B2 Tetrabutyrates)
448. Riboflavin 5' -Phosphate Sodium (Sodium Riboflavin Phosphate or Sodium Vitamin B2 Phosphate)
449. Sulfuric Acid
450. Aluminum Ammonium Sulfate (Crystal: Ammonium Alum, Dried: Burnt Ammonium Alum)
451. Aluminum Potassium Sulfate (Crystal: Alum or Potassium Alum, Dried: Burnt Alum)
452. Ammonium Sulfate
453. Potassium Sulfate
454. Calcium Sulfate
455. Ferrous Sulfate
456. Sodium Sulfate
457. Magnesium Sulfate
458. DL-Malic Acid (dl-Malic Acid)
459. Sodium DL-Malate (Sodium dl-Malate)
460. Phosphoric Acid
461. Distarch Phosphate
462. Monostarch Phosphate
463. Tripotassium Phosphate (Potassium Phosphate, Tribasic)

464. Tricalcium Phosphate (Calcium Phosphate, Tribasic)
465. Trimagnesium Phosphate (Magnesium Phosphate, Tribasic)
466. Diammonium Hydrogen Phosphate (Ammonium Phosphate, Dibasic)
467. Ammonium Dihydrogen Phosphate (Ammonium Phosphate, Monobasic)
468. Dipotassium Hydrogen Phosphate (Potassium Phosphate, Dibasic)
469. Potassium Dihydrogen Phosphate (Potassium Phosphate, Monobasic)
470. Calcium Monohydrogen Phosphate (Calcium Phosphate, Dibasic)
471. Calcium Dihydrogen Phosphate (Calcium Phosphate, Monobasic)
472. Disodium Hydrogen Phosphate (Disodium Phosphate)
473. Sodium Dihydrogen Phosphate (Sodium Phosphate, Monobasic)
474. Magnesium Monohydrogen Phosphate
475. Trisodium Phosphate (Sodium Phosphate, Tribasic)
476. 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; Takomachi, 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 Shizuoka Prefecture, Gifu Prefecture, Aichi Prefecture, Mie Prefecture, and Wakayama Prefecture (limited to Shingu City and Higashimuro-gun)	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.	
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Appended Table 12 (Re: Article 32)

1	Machines used for producing foods Apparatus or containers and packagesing made of aluminum Apparatus or containers and packagesing made of stainless steel Apparatus or containers and packagesing made of colorless glass	Three years from the date of the submission of the written import notification
2	Alphanized rice Ethyl alcohol Barley Canned food or bottled food (excluding processed meat products or wine) Unprocessed sake (excluding unprocessed wine) Kaoliang Sesame Wheat Rice Safflower seeds Distilled alcohol 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) Vegetable protein Buckwheat Soybean Starch (excluding tapioca starch)	One year from the date of the submission of the written import notification

	<p>Animal oil and fat (excluding fish and marine mammal oil and fat)</p> <p>Rapeseed</p> <p>Sunflower seeds</p> <p>Indian millet</p> <p>Rye</p> <p>Apparatus or containers and packagesing made of materials other than aluminum, stainless steel, colorless glass, or synthetic resins</p>	
3	<p>The following food, additives, apparatus, or containers and packagesing which that 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 for which the same food, etc. 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</p> <p>Fruits and fruit peel temporarily stored</p> <p>Roasted coffee beans or ground coffee beans</p> <p>Locusts boiled in water</p> <p>Fish roes (limited to those dried)</p> <p>Fish Ttsukudani (preservedable food made by boiledsimmering in soy sauce)</p> <p>Fish or marine mammal oil and fat</p> <p>Oatmeal</p> <p>Seaweeds</p>	<p>One year from the date of the submission of the written import notification</p>

	Cacao beans (excluding those roasted) Unprocessed wine Frozen food which requires heating before consumption (meaning food 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 Honey containing honeycomb Bread Pre-mixed flour for bread Beer Margarine Mate tea Mirin (a type of sake with low alcohol content and high sugar content)	
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	<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 stated 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 packages made of synthetic resin</p>	
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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	<p>1. The names of the machinery and tools</p> <p>2. Methods for routine maintenance (including calibration for gauges)</p> <p>3. A plan for regular maintenance</p> <p>4. Measures to be taken if a breakdown occurs (including how to handle the handling of test samples if a breakdown occurs during testing)</p>

	<p>5. Guidelines Methods for preparing keeping records concerning maintenance of machinery and tools</p> <p>6. Dates for preparing and revising the standard operation manual</p>
Standard operation manual for management of reagents, etc.	<p>1. Methods for of labeling the containers used for reagents, test solutions, culture media, reference standards, standard solutions, and standard microorganism strains (hereinafter referred to below as "reagents, etc.")</p> <p>2. Precautions concerning the management of reagents, etc.</p> <p>3. Guidelines Methods for keeping preparing records concerning the management of reagents, etc.</p> <p>4. Date of preparation and date of amendment of the standard operation manual</p>
Standard operation manual for animal husbandry management	<p>1. Methods for of managing animal rooms</p> <p>2. Precautions for receiving animals</p> <p>3. Methods for of animal husbandry</p> <p>4. Methods for of observing animal health conditions of animals</p>

	<p>5. Methods for handling animals that have or are suspected to have diseases</p> <p>6. Guidelines Methods for keeping preparing records concerning animal husbandry</p> <p>7. Date of preparation and date of amendment of the standard operation manual</p>
Standard operation manual for handling of test samples	<p>1. Precautions for collecting, transporting, and receiving test samples</p> <p>2. Methods for of managing test samples</p> <p>3. Guidelines Methods for keeping preparing records concerning the management of test samples</p> <p>4. Date of preparation and date of amendment of the standard operation manual</p>
Standard operation manual for the implementation of inspections	<p>1. Items of inspections, etc.</p> <p>2. Name of the products</p> <p>3. Methods for of conducting inspections, etc.;</p> <p>4. Methods for of selecting and preparing reagents;</p> <p>5. Methods for of handling standard microbe strains, for in conducting bacteriological inspections;</p>

	6. Methods for preparing samples; 7. Methods for of operating machinery and tools used for inspections, etc.; 8. Precautions for conducting inspections, etc. 9. Methods for of processing data obtained by inspections, etc. 10. Guidelines Methods for preparing keeping records concerning inspections, etc. 11. Date of preparation and date of amending the standard operation manual
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Remarks

- (i) The standard operation manual for animal husbandry 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 2. Food Sanitation Act and related laws and regulations 3. Standards and criteria for concerning foods and additives, etc. 4. Introduction to chemistry 5. Introduction to bacteriology 6. Toxicology 7. Food toxicology 8. Food science (including Nutritional science) 9. Sanitation management in facilities	9 18 18 18 18 9 15 18 9
2	Subjects related to dairy products	1. Standards for dairy products 2. Practical training on bacteriology 3. Inspection methods for of dairy products 4. Practical training on dairy product inspections 5. Visits to facilities and on-site training	12 18 6 18 15
3	Subjects related to processed meat products	1. Standards and for criteria concerning processed meat products	12
		2. Practical training on bacteriology	18
		3. Inspection methods for of 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 and criteria concerning fish meat ham and fish meat sausages 2. Practical training on bacteriology 3. Inspection methods for fish meat ham and fish meat sausages 4. Practical training on inspections of fish meat ham and fish meat sausages 5. Visits to facilities and on-site training	15 18 9 15 15
5	Subjects related to edible oil and fat	1. Overview of oil and fat chemistry 2. Usage criteria for food and food additives 3. Duties of food sanitation supervisors 4. Responsibilities of food sanitation supervisors 5. Theory of and practical training on inspection methods for oil and fat 6. Visits to facilities and on-site training	10 14 4 3 28 10
6	Subjects related to margarine and shortening	1. Nutritional science and analytical methods 2. Sanitation management in the production process 3. Sanitation standards criteria in the production process 4. Method of assessment of food additives 5. Practical training on analytical methods 6. Practical training on assessment of food additives 7. Visits to facilities and on-site training	6 6 3 6 16 15 21
7	Subjects related to food additives	1. Overview of analytical methods for additives 2. Method of assessment of food additives 3. Practical training on assessment of food additives	9 9 24

		4. Visits to facilities and on-site training	15
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Appended Table 17 (Re: Article 66-2, paragraph (1))

- (i) Appointment of food sanitation manager, etc.
 - (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; referred to as the "business operator" below in this Table) is to appoint a food sanitation manager; provided, however, that this does not apply to a business operator specified in the items 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 inspectors 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 managers prescribed in Article 7 of the Slaughterhouse Act (Act No. 114 of 1953) or work sanitation manager prescribed in Article 10 of the Slaughterhouse Act, or poultry slaughtering sanitation managers 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 conducted 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 periodically take training sessions provided by prefectural governors, etc., or training sessions approved by prefectural governors, etc., and endeavor to acquire new knowledge on food sanitation (limited to business referred to 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 operator.
 - (d) A business operator is to respect the opinions of a food sanitation manager.
 - (e) A food sanitation manager is to exercise necessary care and also endeavor to state necessary opinions to the business operator, in order to comply with the measures provided for in Article 66-2, paragraph (3).
 - (f) The business operator 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 pufferfish, or have another person process pufferfish in the presence of that person.

(ii) Sanitation management of facilities:

- (a) The facility and its surroundings are to be periodically cleaned and maintain a clean condition while the facility is in operation, in order to prevent occurrence of 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 in the facility are to be secured and the temperature and humidity are to be appropriately managed as required.
- (e) Windows and entrances must not be left open in principle. Measures to prevent the intrusion of dust, rodents, and 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 periodically performed.
- (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) Washing 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. If there is any malfunction or damage, to promptly make repairs, and keep them maintained so that they can be properly used.
- (c) When detergents are used for washing machinery and tools and their parts, they are to be used in an appropriate manner.
- (d) For measuring instruments such as thermometers, pressure gauges, and flowmeters, and devices used for sterilization, disinfection, sanitization, or water purification, to periodically inspect their functions and record the results of the inspections.
- (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 packages in which they are contained as required.
 - (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 in which cleansing and drying of the hands and fingers can be appropriately carried out.
 - (i) Cleaning equipment is to be kept clean.
 - (j) If hand washing equipment is to be also used as cleaning equipment by obtaining confirmation of the prefecture, etc., it is to be washed 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 the water supply services provided for in Article 3, paragraph (2) of the Water Supply Act (Act No. 177 of 1957), the specified privately owned water supply systems provided for in paragraph (6) of that Article, or the specified building water supply systems with tank storage provided for in paragraph (7) of that Article (referred to as "water supplied by water supply services, 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 (if the period until the food or additives handled is used or consumed is one year or longer, that period); provided, however, that if there is a risk of the water source, etc. being contaminated due to an unexpected disaster, water quality inspection is to be conducted each time there is a disaster.
 - (c) When it is found that the conditions referred to in (a) are not satisfied as a result of the inspection referred to in (b), to immediately suspend the use of water.
 - (d) When using water tanks, the water tanks are to be periodically cleaned and kept clean.

- (e) If potable water is used and a sterilizing device or water purification device is installed, to periodically confirm that the device is properly operating, and to record its results;
- (f) Ice that comes into direct contact with food is to be made from water that is supplied by properly managed water supply equipment and that meets the conditions referred to in (a). Ice is to be handled and stored in a sanitary manner.
- (g) When reusing used water, to conduct necessary treatment so as not to affect the safety of food or additives.
- (v) Measures against rodents and insects
 - (a) To maintain the facilities and their surroundings in a condition in which maintenance and management can be appropriately conducted, to eliminate the breeding sites of rodents and insects, and prevent intrusion of rodents and insects into the facilities by installing screens for windows, doors, suction and exhaust ports, traps, drain ditch covers, etc.
 - (b) To conduct extermination work of rodents and insects at least twice a year and preserve the records of the work for one year; provided, however, that if it is a method in which by conducting an investigation periodically and in a unified manner on the locations, and habitats, and invasion routes of rodents and insects, and the state of damage, and taking necessary measures based on the results of the investigation, the purpose may be achieved, the work may be conducted by the 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 and away from floors and walls in order to prevent contamination by rodents and insects. For items that have been opened once, measures to prevent contamination are to be taken, 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 the occurrence of food sanitation hazards can be prevented.
 - (d) Storage sites for wastes are to be places where wastes can be appropriately managed so as not to adversely affect the surrounding environment.
 - (e) Wastes and wastewater are to be appropriately disposed.

- (vii) Sanitation management for persons who handle food or additives
 - (a) Medical examination for a person who handles food or additives (referred to below as a "food handler") are to be conducted for the purpose of understanding the health conditions necessary to prevent the occurrence of food sanitation hazards.
 - (b) When a prefectural governor, etc. gives an instruction to have a food handler undergo a feces examination, to instruct the food handler to undergo the feces examination.
 - (c) When a food handler exhibits the following symptoms, to endeavor to grasp the details of the symptoms and judge whether the symptoms require medical examination by a physician or 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 secretion that is likely to result in infecting an infectious disease, etc.)
 - 7. Nausea and vomiting
 - (d) When having a person with a skin injury engage in work, to cover the injured part with a water-resistant covering material. In addition, to dispose of food or additives that may have been contaminated by vomitus, etc. 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 required when engaging 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 and also wash their hands to keep their hands and fingers clean to prevent occurrence of food sanitation hazards.
 - (i) When food handlers have finished defecation, or finished handling fresh raw materials or handling unheated raw materials, they are to sufficiently

wash and disinfect their hands and fingers. 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 the occurrence of food sanitation hazards.

1. Act of unnecessarily contaminating hand and fingers, or tools or containers and packages.
2. Coughing out phlegm or spitting.
3. Contaminating food or additives with droplets from coughing or sneezing, or causing that 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, to have them change to clean, 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 operator who cooks the same food and serves 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 condition they were purchased without cleansing or sterilizing them.

(b) In the case referred to in (a), information of the recipient of the cooked food, the time of serving the cooked food (when transporting and providing cooked food, the time when the food was taken out), and the quantity of cooked food provided are to be recorded and preserved.

(ix) Provision of information

(a) A business operator is to endeavor to provide consumers with necessary information for consumers to safely eat food or additives that are collected, produced, imported, processed, cooked, stored, transported, or sold (referred to as "products" below in this Table).

(b) When a business operator has received information on health damage 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; the same applies below in (c)) and information on violation of laws, the business operator is to endeavor to provide the information to a prefectural governor, etc.

(c) A business operator (limited to a person stated in the items of Article 66-2, paragraph (5)) is to collect information on health damage related to the food for specified health uses, and the foods with functional claims defined in Article 2, paragraph (1), item (x) of the Food Labeling Standards

(excluding cases in which the food containing designated ingredients), and when the business operator obtains information that there is a risk of occurrence or spread of health damage related to the food, they are to promptly provide the information to a prefectural governor, etc., notwithstanding the provision of (b).

- (d) When a business operator has obtained information on abnormal tastes or odors, mixing in of foreign substances, or other information from which the risk of leading to health damage is undeniable for products, the business operator is to endeavor to provide the information to a prefectural governor, etc.

(x) Recall and disposal

- (a) In the case in which food sanitation hazards resulting from products have occurred or there is a risk of such a hazard to occur, from the perspective of preventing health damage of consumers, a business operator is to specify a responsibility system related to recall, a method to alert consumers, 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 may be promptly and appropriately recalled.
- (b) When recalling products, the products recalled are to be stored by separating them from products not subject to the recall, and are to be appropriately disposed of.

(xi) Transportation

- (a) Vehicles, containers, etc. to be used for transporting food or additives are to be washed and disinfected as required to prevent contamination of food, additives, or their containers and packages.
- (b) Vehicles, containers, etc., are to be maintained in a clean condition, and also 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 in appropriate containers as required, in order to prevent contamination from cargoes other than food or additives.
- (d) Food or additives are to be managed so that they will not to be contaminated with dust and exhaust gas, etc. during transportation.
- (e) When using vehicles, containers, etc. that has been used for transporting different items of food or additives, and cargoes other than food or additives, they are to be washed by effective methods and disinfected as required.
- (f) For food or additives loaded in bulk, vehicles, containers, etc., exclusive for food or additives are to be used as required, and the fact that they are exclusive for food or additives is to be clearly indicated.

- (g) Temperature and humidity are to be carefully controlled during transportation.
- (h) To set the delivery time based on temperature and humidity during transportation, and appropriately control the time so as not to exceed the prescribed delivery time.
- (i) When cooked food is delivered and served, the food is to be appropriately managed by taking into consideration the time until it is served for consumption.
- (xii) Sales
 - (a) To purchase an appropriate quantity based on the anticipated sales volume.
 - (b) Products are to be managed so that they are not sold at an inappropriate temperature such as selling them under direct exposure to sunlight.
- (xiii) Education and training
 - (a) To provide necessary education for sanitation management to food handlers.
 - (b) To provide the persons who handle chemical substances with education and training to enable them to safely handle the chemical substances they use.
 - (c) To periodically verify the effects of the education and training referred to in (a) and (b), and review the content of the education as required.
- (xiv) Others
 - (a) To endeavor to prepare and preserve records on suppliers, conditions of production or processing, etc., shipping or sales destinations, and other necessary matters concerning food or additives handled, to the extent necessary for preventing occurrence of food sanitation hazards.
 - (b) When self-inspection is conducted on produced or processed products, to endeavor to preserve its records.

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

(i) Analysis of hazard factors

To prepare a list of factors that may cause food sanitation hazards (referred to as "hazard factors" below in this Table) for each process of production, processing, cooking, transportation, storage, or sales of food or additives, and specify measures to control those hazard factors (referred to as "control measures" below in this Table).

(ii) Decision of critical control point

To decide the essential processes to take control measures to prevent, eliminate, or reduce the occurrence of hazard factors specified in the preceding item (referred to as "essential control point" below in this Table) to an acceptable level;

(iii) Establishment of control criteria

To establish the criteria to prevent, eliminate, or reduce the occurrence of hazard factors at individual essential control points (referred to as "control criteria" below in this Table) to an acceptable level.

(iv) Establishment of monitoring method

To establish a method for understanding the implementation status of the control of essential control points continuously or at a considerable frequency (referred to as "monitoring" below in this Table).

(v) Establishment of improvement measures

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

(vi) Establishment of verification method

To establish procedures to periodically verify the effectiveness of the content of the measures provided for in the preceding items.

(vii) Preparation of records

To prepare documents concerning the content of the measures provided for in the preceding items and records of their implementation, in accordance with the size and type of business.

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

A business operator provided for in Article 34-2 of the Order (including a business operator who engages in business of a size that is provided for in Article 66-4, item (ii) which produces additives) may simplify the matters stated in the preceding items in accordance with the characteristics of the food they handle or the size of their business and 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 continuously performing work in a sanitary manner, and have sufficient space in accordance with the amount of food or additives handled.

(ii) Taking into account the contamination of food or additives, containers and packages, machinery and tools, or other objects that may come into contact with food or additives (referred to below as "food, etc."), and to prevent occurrence of public health hazards, necessary division of sections are made by partitions, etc., in accordance with the category of work, and facilities and equipment are appropriately arranged based on the processes, or equipment to control the flow of air is installed; provided, however, that this does not apply if necessary sanitation management measures have been taken by establishing the routes for food, etc., or employees engaged in work, or appropriately implementing washing and disinfection when the same section

is used alternately for different 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 has a structure or equipment capable of preventing contamination by dust, wastewater, and wastes, and equipment capable of preventing intrusion of rodents and insects.
- (b) The facility has a structure or equipment that may be properly ventilated so that condensation is less likely to appear, generation of mold due to water condensation is prevented, and water drops from condensation do not contaminate food, etc. at the place directly above the place where the work of handling food, etc. is conducted.
- (c) The floor surface, inner walls, and ceiling are to be made of materials that are easy to clean, wash, and disinfect (referred to as "clean, etc." below 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 that enables to secure necessary illumination to sufficiently conduct work, inspection, and cleaning, etc.
- (f) The facility is to have water supply equipment capable of supplying water provided by a water supply services, etc. or potable water, to the places of the facilities that require the water in a sufficient quantity at an appropriate temperature. When using water other than water supplied by a water supply services, etc., the facility is to have a disinfection device and a water purifying device as required, and the water source is to have a structure that prevents contamination from outside. When using a water storage tank, the tank is to have a structure that does not hinder food sanitation activities.
- (g) For applying (f) to 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 for applying (f) to a business that handles food for which there are provisions prescribing 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 hand washing facilities with running water which are equipped with a device for cleansing and

disinfecting the hands and fingers of employees. The faucet is to have a structure that prevents re-contamination of hands and fingers after cleansing.

- (i) The drainage equipment meets the following requirements
 - 1. The equipment has adequate draining function, and, it is installed on the floor surface of the sections washed with water and the 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 the sewage 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 required. 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 has the necessary equipment in accordance with what is specified concerning refrigeration or freezing during production and preservation.
- (k) The facility has equipment to prevent intrusion of rodents, insects, etc., and equipment to exterminate them when they intrude into the facility, as required.
- (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 hand washing equipment with running water.
- (m) The facility has an equipment with a size sufficient to store raw materials at temperatures appropriate for their type and characteristics and in a condition that is possible to prevent contamination. In addition, the facility has an 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 impermeable, have sufficient capacity, and a structure that is easy to clean and in which dirty liquids and foul odors do not leak.
- (o) For a business that packages products, the facility has a place where the products can be put into containers and packages 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) The facility has cleaning equipment of the size and number appropriate

for the purpose of use and capable of supplying hot water, steam, etc., as required, in order to wash food, etc.

- (r) A facility that uses additives has equipment or a place that can exclusively store them, and is equipped with measuring instruments.

(iv) Machinery and tools

- (a) Machinery, tools, containers, and other equipment (referred to as "machinery and tools, etc." below in this Appended Table) in workplaces where food or additives are produced or food is cooked have a structure that can be properly washed, 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 wash, and are possible 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 are easy to clean and wash. Assembly-type machinery and tools, etc. have a structure that is easy to disassemble and clean, and that can be washed and disinfected as required.
- (e) When transporting food or additives, exclusive containers that can prevent contamination are to be 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 required.
- (g) The facility is equipped with the necessary number of tools exclusive for cleaning, etc. the workplace, and has a storage site for them and equipment to post the content of 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, those that conduct simple business (meaning business of engaging in simple cooking such as serving food that can be consumed as is on dishes or heating semi-processed 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); the same applies below in the Appended Table 20, item (i), (1)), may conduct businesses pursuant to the following criteria, in addition to the criteria referred to in 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 view of the food handled and the type of business.

2. Drainage equipment does not have to be installed on the floor surface if it is found to have no adverse effect on food sanitation in view 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 view of the food handled and the type of business.
 4. In areas where food is handled, the areas are not required to be partitioned if the structure is such that persons other than employees cannot easily enter.
- (c) Among the restaurant businesses provided for in Article 35, item (i) of the Order, when 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, when processing a living body or carcass in an automobile, the criteria referred to in item (iii), (l), (m), and (p), and item (iv), (e) do not apply.
- (e) When producing frozen food in a business other than businesses stated in Article 35, item (xxvii) and item (xxviii) of the Order, to satisfy the following requirements in addition to those stated 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 to be partitioned in accordance with the category of work.
 2. The facility is to have refrigeration or freezing equipment in the room or place for storing raw materials.
 3. The room or place for producing the products has equipment necessary for heating, sterilizing, cooling, and refrigerating the products 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 lower.
- (f) When producing hermetically sealed food in a business other than the businesses stated in Article 35, item (xxx) of the Order, the facility has the structure that satisfies the following criteria, in addition to those stated in items (i) through (iv).
1. The facility has a room or place for the storing, preprocessing, or mixing raw materials, and producing and storing products, and washing equipment for containers and packages as required. If a room is to be used as a place, it is to be 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, sterilizing, and refrigerating products 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
When 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 of cooking food using a vending machine that has a function of cooking food which is referred to in Article 35, item (ii) of the Order (excluding those installed indoors and equipped with devices necessary to prevent occurrence of food sanitation hazards, such as a device to automatically wash the parts that come into direct contact with food not packed or wrapped in containers and packages) and selling the cooked food.
 - (a) Equipment capable of preventing intrusion of rainwater such as eaves and roofs is installed; provided, however, that this does not apply when a vending machine is installed at a place that is found not to be affected by rainwater.
 - (b) Floor surfaces are made of impermeable materials that are easy to clean, wash, 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 that can control the temperature of products at 10 degrees centigrade or lower when the product requires refrigeration storage, and refrigeration or freezing equipment with the function that can control the temperature at minus 15 degrees centigrade or lower when the product requires freezing storage, and with a size appropriate for the amount of products to be 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 to be processed, are easy to disinfect, have a structure that prevents dirty liquids and foul odors from leaking, and have a lid.
- (iv) Fish and shellfish 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 shellfish.
 - (c) A facility that handles fresh fish and shellfish to be eaten raw is equipped with an exclusive instrument for processing fresh fish and shellfish.
 - (d) When processing oysters, the following requirements are satisfied.
 - 1. The facility has purification equipment as required.
 - 2. The room or place for preprocessing oysters has equipment necessary for washing oysters with shells.
 - 3. The room or place for the processing of oysters has equipment necessary for processing, washing, and packaging shelled oysters.
- (v) Fish and shellfish auction business provided for in Article 35, item (v) of the Order
 - (a) The facility has a place to receive, sort, display, temporarily store, transact, and ship fresh fish and shellfish, and is partitioned as required.
 - (b) The facility has refrigerating or freezing equipment, ice making equipment, and equipment for washing and disinfecting shoes, as required.
 - (c) In the case of washing and refrigerating fresh fish and shellfish using seawater, the facility has sterilizing equipment for seawater as required.
- (vi) Milk collection business provided for in Article 35, item (vi) of the Order
 - (a) The facility has raw milk storage equipment and acceptance inspection equipment (excluding facilities that 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 inspection, storage, and processing of raw milk, and storage of products, and a room or place for washing bottles, and container cleansing equipment as required; provided, however, that a facility that does not use raw milk is not required to have a room or place for storage and acceptance inspection, 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 filtering, sterilizing, 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 lower and a size appropriate for the volume 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, and also washing equipment, storing equipment for raw milk, and acceptance inspection equipment (excluding facilities that outsource the inspections), and has a room or place for washing bottles as required. 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 filtering, sterilizing, filling, and tight sealing. When sterilizing raw milk, the facility has sterilization equipment with a self-recording thermometer attached.
 - (c) The facility has a cooler and a refrigerating equipment with the function that can control the temperature of products at 10 degrees centigrade or lower and with a size appropriate for the amount processed.
- (ix) Meat processing business provided for in Article 35, item (ix) of the Order
- (a) The facility has a room or place for receiving and processing raw materials, and storing products. If a room is to be used as a place, it is partitioned in accordance with the category of work.
 - (b) Containers to put in non-edible parts and containers used for their 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 that can control the temperature of products at 10 degrees centigrade or lower when the product requires refrigeration storage, and refrigeration or freezing equipment with the function that can control the temperature at minus 15 degrees centigrade or lower when the product requires frozen storage, which is appropriate for the volume of products processed.
 - (d) The processing room is to have equipment necessary for cutting up meat, internal organs, and other meat parts of the butchered livestock or poultry.

- (e) When processing a living body or carcass, the following requirements are to be satisfied.
1. The facility has a slaughter and bleeding room (limited to when slaughter and bleeding are practiced), a place for skinning, and equipment for washing 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 required, and the place for carry-in and carry-out of living bodies or carcasses before processing and the place for carry-in and carry-out of the meat, etc. after processing are partitioned.
 2. The place where a carcass is skinned has hanging equipment and equipment for washing and disinfecting the hands and fingers of the workers, and tools such as knives.
 3. The hanging room is partitioned from other workplaces by partition walls and has a structure that enables the entrance door to be shut tightly.
 4. The washing and disinfection equipment has equipment capable of supplying warm water of 60 degrees centigrade or higher and hot water of 83 degrees centigrade or higher. In addition, it is to be equipped with a thermometer that can check the temperature of warm water and hot water supplied.
- (f) When processing a living body or carcass in an automobile, the following requirements are to be satisfied.
1. The processing room is partitioned from other workplaces 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 stated 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 determined 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 that temporarily prevents the contamination of carcasses by the external environment such as wind and rain, dust, and the

intrusion of insects, etc.

- (g) For a facility that processes blood, the following requirements are to be satisfied.
 - 1. The facility has a room for washing and sterilizing transportation tools, a room for storing and processing blood to be used as raw materials, equipment for refrigerating or freezing, and a room for packaging products as required; provided, however, that it is not required for a facility in which processes from blood collection to processing are consistently performed and the blood to be used as raw material is not transported from another facility to have a room for washing and sterilizing transportation tools, and a room for 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 receiving equipment to the filling equipment for blood to be used as raw material 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 the 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 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, fermenting, heating, sterilizing, cooling, and refrigerating 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 required.
 - (d) When producing raw bean jam from beans containing cyanide compounds as raw material, the facility has equipment necessary for immersing, steaming, making bean jam, and soaking bean jam in water.
- (xii) Ice cream product 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 and equipment for storing raw milk (excluding facilities that do not use raw milk), and acceptance inspection equipment (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 filtering, sterilizing, refrigerating, 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, and equipment for storing raw milk (excluding facilities that do not use raw milk) and acceptance inspection equipment (excluding facilities that outsource the inspections), and a room or place for washing bottles as required. 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 filtering, sterilizing, refrigerating, filling, and packaging products, and equipment for fermenting, concentrating, drying, emulsifying, and separating raw materials as required.
- (xiv) Soft drink 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 one for production), and has equipment for washing and producing or assembling containers as required. 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 sterilizing or disinfecting.
- (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, refrigerating, and performing other processes, as required.
- (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 required. 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 required.
 - (c) The room or place for preprocessing raw materials or producing products has equipment necessary for thawing, mixing, heating, sterilizing, drying, smoking, roasting, dehydrating, refrigerating, and performing other processes, as required.
 - (d) When handling fresh fish and shellfish to be eaten raw, the facility has an exclusive instrument for processing fresh fish and shellfish.
 - (e) When producing fish paste products, the room or place for preprocessing raw materials and producing products has equipment necessary for grinding and sterilizing (excluding when producing minced fish meat).
 - (f) When processing oysters, the following requirements are satisfied.
 - 1. To have purification equipment as required.
 - 2. The room or place for preprocessing oysters has equipment necessary for washing oysters with shells.
 - 3. The room or place for processing oysters has equipment necessary for processing, washing, 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 a room or place for preparing and packaging products as required. 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 washing of eggs, filtration, heat sterilization, and refrigeration as required.
 - (c) The facility has refrigerating or freezing equipment with the function that can control the temperature of products at 8 degrees centigrade or lower when the product requires refrigeration storage, and refrigerating or freezing equipment with the function that can control the temperature at minus 15 degrees centigrade or lower 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 required.
 - (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, sterilizing, and refrigerating as required. It also has a curing room as required.
- (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 washing and manufacturing or assembling containers as required.
 - (b) When producing soy sauce, the facility has equipment necessary for compressing, heating, mixing, filtering, and compression molding as required.
 - (c) When producing food that has miso or soy sauce as the main raw material, the facility has equipment necessary for mixing, filtering, 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 compression) 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 washing, inspecting, and producing or assembling containers as required.
 - (c) The facility has equipment necessary for washing, immersion, steaming, making koji, saccharification, boiling, fermenting, distillation, compression, heating, mixing, filtering, 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 required.
- (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 that has tofu as the main raw material, the facility has equipment for freezing, drying, oil cooking, and performing other processes, as required.
- (xxiii) Natto (fermented soybeans) production business provided for in Article 35, item (xxiii) of the Order
 - (a) The facility has a room or place for storing, preprocessing, fermenting, and maturing, 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 facility has equipment necessary for steaming, fermenting, and refrigerating raw materials and 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 required. 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 refrigerating in accordance with the items produced.
- (xxv) Ready-made dish production business provided for in Article 35, item (xxv) of the Order and combined ready-made dish production business referred to 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, sterilizing, cooling, and refrigerating 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 combined frozen food items production business referred to in item (xxviii) of that Article
- (a) The facility has a room or place for storing and preprocessing raw materials and 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, sterilizing, cooling, and refrigerating in accordance with the items produced.
 - (d) The facility has a freezing room and storage room that have the function to control the temperature of the products at minus 15 degrees centigrade or lower.
- (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 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 washing, pickling, sterilizing, etc., as required.
 - (c) When producing asazuke (lightly pickled vegetables), the facility has cooling equipment with a function that can control the temperature of the products at 10 degrees centigrade or lower.
- (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 equipment for washing container and packages as required. 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, sterilizing, and refrigerating in accordance with the items produced.
- (xxix) Business of packaging food in small portions provided for in Article 35, item (xxxi) of the Order
- (a) The facility has a room or place for storing and processing raw materials, and 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 required.
- (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, dividing into small portions, 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 required. 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 this does not apply to equipment and tools necessary for special tests among the tests and inspections, when testing and inspecting the additives on the business person's own responsibility by using another organization that has equipment necessary for the testing and it is found that there is no problem in terms of food sanitation as a result..
 - (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 referred to in 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, combined ready-made dish production business provided for in item (xxvi) of that Article, and combined frozen food 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 partitioned from other equipment.
 - (b) The facility has exclusive equipment for washing 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 lower when the meat to be eaten raw handled by the business operator requires refrigeration storage, and refrigerating or freezing equipment with the function to control the temperature at minus 15 degrees centigrade or lower 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 shellfish sales business provided for in item (iv) of that Article, fishery product production business provided for in item (xvi) of that Article, combined ready-made dish production business provided for in item (xxvi) of that Article, and combined frozen food 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 of removed ovaries, liver, etc.
 - (b) The facility has exclusive tools for processing pufferfish.
 - (c) When freezing pufferfish, the facility has freezing equipment that has the function to rapidly freeze pufferfish at minus 18 degrees centigrade or lower.

Appended Table 22 (Re: Article 73)

- (i) Salmonellae bacteria
- (ii) Clostridium botulinum
- (iii) Enterohaemorrhagic Escherichia coli
- (iv) Yersinia enterocolitica O8
- (v) Campylobacter jejuni/coli
- (vi) Cholera bacillus
- (vii) Shigella
- (viii) Salmonella Typhi
- (ix) Salmonella Paratyphi A
- (x) Chemical substances (meaning elements and chemical compounds)