

Ordinance for Enforcement of the Food Sanitation Act

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

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

Chapter I Food, Additives, Apparatus and Containers and Packaging

Chapter II Labeling

Chapter III Plans for Monitoring and Guidance

Chapter IV Product Inspections

Chapter V Import Notification

Chapter VI Food Sanitation Inspection Facilities and Food Sanitation

Inspectors

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Supplementary Provisions

Chapter I Food, Additives, Apparatus and Containers and Packaging

Article 1 Cases involving no risk to human health pursuant to the provisions of the proviso of Article 6, item (ii) of the Food Sanitation Act (Act No. 233 of 1947; hereinafter referred to as "the Act") shall be as follows:

- (i) Cases where substances, though toxic or harmful, are naturally contained in or attached to food or additives and are deemed to involve no risk to human health generally at such a dose or through treatment;
- (ii) Cases where it is inevitable to mix or add toxic or harmful substances in the process of producing food or additives and where it is found to involve no risk to human health generally.

Article 2 An application for rescission under Article 7, paragraph (4) of the Act shall be filed by submitting a written application containing the matters listed in the following items to the Minister of Health, Labour and Welfare, attaching documents to prove that there is no longer any risk of food sanitation hazards resulting from the food or articles for which said application for rescission is filed:

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

- (ii) The scope of the food or articles for which the application for rescission is filed;
- (iii) The reason that there is no longer any risk of food sanitation hazards resulting from the food or articles pertaining to said prohibition and other matters that the Minister of Health, Labour and Welfare finds necessary.

Article 3 (1) The grounds specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 8, paragraph (1) of the Act shall be as follows:

- (i) Regarding specific food or additives which are collected, produced, processed, cooked, or stored in a specific country or region, or which are collected, produced, processed, cooked, or stored by a specific person (hereinafter referred to as "specific foods, etc."), inspections under Article 26, paragraphs (1) to (3) of the Act or Article 28, paragraph (1) of the Act, or inspections conducted by a business person in accordance with administrative guidance (meaning administrative guidance provided in Article 2, item (vi) of the Administrative Procedure Act (Act No. 88 of 1993); the same shall apply in Article 17, paragraph (1), item (i)) provided by the State, prefectures, cities specified by a Cabinet Order under Article 5, paragraph (1) of the Community Health Act (Act No. 101 of 1947) (hereinafter referred to as "cities establishing health centers") or special wards show that the total number of articles falling under food or additives listed in each item of Article 8, paragraph (1) of the Act accounts for approximately 5% or more of the total number of food or additives covered by said inspections;
 - (ii) The contents of regulations and measures concerning food sanitation for specific foods, etc. in a country or region where said specific foods, etc. are collected, produced, processed, cooked, or stored, the inspection system and other systems for food sanitation management pertaining to said specific foods, etc. by the government or local public entities of said country or region, the results of inspections with regard to said specific foods, etc. conducted by the government or local public entities of said country or region, and other food sanitation management pertaining to said specific foods, etc. of said country or region;
 - (iii) Regarding specific foods, etc., food poisoning caused by said specific foods, etc. has occurred, or other health hazards caused by or suspected to have been caused by said specific foods, etc. have occurred;
 - (iv) Regarding specific foods, etc., a situation has occurred whereby said specific foods, etc. have been contaminated or are likely to be contaminated.
- (2) The provisions of the preceding paragraph shall apply mutatis mutandis to grounds specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 8, paragraph (1) of the Act which is applied mutatis

mutandis under Article 62, paragraph (1) of the Act. In this case, the term "food or additives" in item (i) of the preceding paragraph shall be deemed to be replaced with "toys," the term "specific foods, etc." in the same item and items (ii) and (iv) of the same paragraph shall be deemed to be replaced with "specific toys," the term "regarding specific foods, etc." in item (iii) of the same paragraph shall be deemed to be replaced with "specific toys," and the term "food poisoning caused by said specific foods, etc. or other health hazards caused by or suspected to have been caused by said specific foods, etc." in the same item shall be deemed to be replaced with "other health hazards caused by or suspected to have been caused by said specific toys."

Article 4 (1) The matters specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 8, paragraph (1) of the Act shall be as follows:

- (i) The level of the risk that specific foods, etc. may harm human health;
 - (ii) The matters listed in each item of paragraph (1) of the preceding Article;
 - (iii) The probability that specific foods, etc. falling under food or additives listed in each item of Article 8, paragraph (1) of the Act may continue to be sold, or collected, produced, imported, processed, used, or cooked for the purpose of marketing;
 - (iv) Effects that measures other than the prohibition under Article 8, paragraph (1) of the Act are expected to have for preventing food sanitation hazards resulting from specific foods, etc.
- (2) The provisions of the preceding paragraph shall apply mutatis mutandis to the matters specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 8, paragraph (1) of the Act which is applied mutatis mutandis under Article 62, paragraph (1) of the Act. In this case, the term "specific foods, etc." in items (i), (iii) and (iv) of the preceding paragraph shall be deemed to be replaced with "specific toys," and the term "food or additives" in item (iii) of the same paragraph shall be deemed to be replaced with "toys."

Article 5 (1) When the Minister of Health, Labour and Welfare intends to rescind the prohibition pertaining to specific foods, etc. under Article 8, paragraph (1) of the Act, based on an application from an interested person or as needed, pursuant to the provisions of paragraph (3) of the same Article, he/she shall consider the matters listed in each item of paragraph (1) of the preceding Article with regard to the specific foods, etc. pertaining to said rescission of the prohibition, when confirming that there is no risk of food sanitation hazards resulting from said specific foods, etc.

- (2) The provisions of the preceding paragraph shall apply mutatis mutandis to the case where the prohibition under Article 8, paragraph (1) of the Act is

rescinded pursuant to the provisions of paragraph (3) of the same Article which is applied mutatis mutandis under Article 62, paragraph (1) of the Act. In this case, the term "specific foods, etc." in the preceding paragraph shall be deemed to be replaced with "specific toys."

Article 6 (1) An application for rescission under Article 8, paragraph (3) of the Act shall be filed by submitting a written application containing the matters listed in the following items to the Minister of Health, Labour and Welfare, attaching documents to prove that there is no longer any risk of food sanitation hazards resulting from the food or additives for which said application for rescission is filed:

- (i) The address and name of the applicant (for a juridical person, its name, the location of its principal office, and the name of its representative);
 - (ii) The scope of the food or articles for which the application for rescission is filed;
 - (iii) Other matters that the Minister of Health, Labour and Welfare finds necessary.
- (2) The provisions of the preceding paragraph shall apply mutatis mutandis to an application for rescission under Article 8, paragraph (3) of the Act which is applied mutatis mutandis under Article 62, paragraph (1) of the Act. In this case, the term "food or additives" in the preceding paragraph shall be deemed to be replaced with "toys."

Article 7 (1) The livestock specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 9, paragraph (1) of the Act shall be buffaloes.

- (2) The cases specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 9, paragraph (1) of the Act shall be as follows:
- (i) The case where, with regard to livestock which are deemed to have had any diseases listed in the left hand columns of appended table 5 of the Ordinance for Enforcement of the Slaughterhouse Act (Ordinance of the Ministry of Health and Welfare No. 44 of 1953) or are deemed to have had any disorders listed in the same columns, the necessary measures, such as disposal, have been taken to prevent the parts listed respectively in the right hand columns of the same table from being served for human consumption;
 - (ii) The case where, with regard to diseases or disorders listed in the left hand columns of appended table 10 of the Ordinance for Enforcement of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act (Ordinance of the Ministry of Health and Welfare No. 40 of 1990), measures such as disposal of the parts listed in the right hand columns of the same table have been taken, as a result of the inspections after evisceration under Article 33, paragraph (1), item (iii) of the same Ordinance.

- (3) The case where the ministry officials find that the livestock pose no risk to human health and are edible pursuant to the provisions of the proviso of Article 9, paragraph (1) of the Act shall be when healthy livestock have been killed instantly due to an accidental disaster.

Article 8 The products specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 9, paragraph (2) of the Act shall be processed meat products.

Article 9 The matters specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 9, paragraph (2) of the Act shall be as follows:

- (i) For the meat or organs of livestock or poultry, the types of livestock or poultry, and for the products provided in the preceding Article, the names and the types of the raw meat material or organs thereof;
- (ii) The quantity and the weight;
- (iii) The address and name of the shipper (for a juridical person, its name and location);
- (iv) The address and name of the receiver (for a juridical person, its name and location);
- (v) For the meat or organs of livestock or poultry (excluding those divided or chopped), the following matters concerning the name, etc. of the agency which conducted the inspections:
 - (a) For livestock, the name of the agency which conducted the slaughtering inspections (meaning a biopsy before slaughtering and inspections before and after dressing; the same shall apply hereinafter), or the name and title of the official who conducted the slaughtering inspections;
 - (b) For poultry, the name of the agency which conducted the poultry inspections (meaning a biopsy and inspections after plucking and evisceration; the same shall apply hereinafter), or the name and title of the official who conducted the poultry inspections;
- (vi) The name and location of facilities where the following processes such as slaughtering are carried out:
 - (a) For the meat or organs of livestock (excluding those divided or chopped), the slaughterhouse where the slaughtering or dressing was carried out;
 - (b) For the meat or organs of poultry (excluding those divided or chopped), the poultry slaughterhouse where the slaughtering, plucking or evisceration was carried out;
 - (c) For the meat or organs of livestock or poultry divided or chopped, the facility where said processes were carried out;
 - (d) For the products provided in the preceding Article, the production facility

- where said products were produced;
- (vii) The fact that processing or production, such as the slaughtering, dressing, plucking, evisceration, dividing, and chopping, provided in (a) to (d) of the preceding item was carried out in a sanitary manner based on equal or better criteria than those of Japan;
 - (viii) The date when any of the following processes such as slaughtering were carried out:
 - (a) For the meat or organs of livestock (excluding those divided or chopped), the slaughtering and slaughtering inspections;
 - (b) For the meat or organs of poultry (excluding those divided or chopped), the slaughtering and poultry slaughtering inspections;
 - (c) For the meat or organs of livestock or poultry divided or chopped, said processes;
 - (d) For the products provided in the preceding Article, the production of said products.

Article 10 When certificates set forth in Article 9, paragraph (2) of the Act are for the meat or organs of livestock or poultry whose slaughtering inspections or poultry slaughtering inspections have been conducted in a country other than the exporting country, a transcript of the certificates containing the matters provided in the preceding Article which have been issued by a governmental organization of the country that conducted said slaughtering inspections or poultry slaughtering inspections shall be attached to the certificates set forth in the same paragraph.

Article 11 The countries specified by an Ordinance of the Ministry of Health, Labour and Welfare under the proviso of Article 9, paragraph (2) of the Act shall be the United States of America, Australia, and New Zealand.

Article 12 Additives involving no risk to human health under Article 10 of the Act shall be as listed in appended table 1.

Article 13 The criteria specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 13, paragraph (2) of the Act (including cases where it is applied mutatis mutandis under Article 13, paragraph (4) or Article 14, paragraph (2) of the Act) shall be as follows:

- (i) The following documents have been prepared for the comprehensive sanitation management and production process of the products:
 - (a) Product descriptions containing the name, type, raw materials and other necessary matters of the products;
 - (b) Documents concerning the processes of the production or processing that

- contain the performance and other necessary matters of machines and implements used for the production or processing;
- (c) Drawings of the facility showing structures of facilities and equipment, traveling routes of products, etc. and other necessary matters;
- (ii) Documents have been prepared, indicating the matters as provided as follows concerning the comprehensive sanitation management and production process of the products:
 - (a) Measures for the prevention of all food sanitation hazards that may occur to the products shall be specified by each substance that may cause said hazards and by each process where said hazards may occur, and in the case where substances pertaining to said measures do not contain substances that may cause any of the hazards listed in the right hand columns of appended table 2 regarding food listed in the left hand columns of the same table, the reasons shall be clarified;
 - (b) Among the measures set forth in (a), measures that require sequential or frequent checking shall be specified in order to prevent food sanitation hazards pertaining to the products;
 - (c) Methods for the checking set forth in (b) shall be specified;
- (iii) Documents have been prepared, indicating the methods of improvement measures to be taken when the checking set forth in (b) of the preceding item shows that the measures set forth in (b) of the same item have not been taken appropriately;
- (iv) Documents have been prepared, indicating the methods concerning the sanitation management in facilities and equipment, sanitary education for employees, and other necessary matters, with regard to the sanitation management methods pertaining to the comprehensive sanitation management and production process of the products;
- (v) Documents have been prepared, indicating the test methods for the products, etc. and other methods for verifying that food sanitation hazards have been prevented appropriately, with regard to the comprehensive sanitation management and production process of the products;
- (vi) Documents have been prepared, indicating the methods for recording and the methods and period of time for retaining said records, with regard to the following matters:
 - (a) The matters concerning the checking set forth in item (ii), (b);
 - (b) The matters concerning the improvement measures set forth in item (iii);
 - (c) The matters concerning the sanitation management set forth in item (iv);
 - (d) The matters concerning the verification set forth in the preceding item;
- (vii) With regard to the comprehensive sanitation management and production process of the products, a person has been placed who personally carries out the following duties (excluding the duties provided in the following item) or

has another person previously appointed in accordance with the contents of the duties carry out such duties:

- (a) Monitoring that the measures and checking set forth in item (ii), (b) have been carried out appropriately and preparing the record thereof;
 - (b) Carrying out maintenance of the machines and implements used for checking set forth in item (ii), (b) (including calibration of measuring instruments) and preparing a record thereof;
 - (c) Other necessary duties;
- (viii) With regard to the verification set forth in item (v), a person has been put in place who personally carries out the following duties or has another person previously appointed in accordance with the contents of the duties carry out such duties:
- (a) Conducting tests on the products, etc.;
 - (b) Carrying out maintenance of the machines and implements used for tests set forth in (a) and preparing a record thereof;
 - (c) Other necessary duties.

Article 14 (1) An application for approval under Article 13, paragraph (1) of the Act shall be filed by submitting a written application containing the following matters to the Minister of Health, Labour and Welfare:

- (i) The address, name, and date of birth of the applicant (for a juridical person, its name, the location of its principal office, and the name of its representative);
 - (ii) Types of product;
 - (iii) The name and location of the production or processing facility;
 - (iv) The outline of the comprehensive sanitation management and production process of the products.
- (2) A written application set forth in the preceding paragraph shall be attached with the following data:
- (i) The documents provided in items (i) to (vi) of the preceding Article;
 - (ii) The data concerning the effects of the measures set forth in item (ii), (b) of the preceding Article;
 - (iii) The data concerning the record prepared and retained with regard to the matters listed in item (vi), (d) of the preceding Article, based on the documents provided in the same item.
- (3) A fiscal stamp for the amount of the fee shall be affixed to a written application set forth in paragraph (1).

Article 15 (1) An application for approval for the change under Article 13, paragraph (4) of the Act shall be filed by submitting a written application containing the matters listed in the following items to the Minister of Health,

Labour and Welfare:

- (i) The matters listed in paragraph (1), items (i) to (iv) of the preceding Article;
 - (ii) The number and the date of the approval already obtained.
- (2) A written application set forth in the preceding paragraph shall be attached with the following data:
- (i) Among the documents set forth in paragraph (2), item (i) of the preceding Article and the data set forth in item (ii) of the same paragraph, those pertaining to the matters that the applicant intends to change (for the documents set forth in item (i) of the same paragraph, the original and changed descriptions shall be clearly presented in comparison);
 - (ii) The data set forth in paragraph (2), item (iii) of the preceding Article.
- (3) A fiscal stamp for the amount of the fee shall be affixed to a written application set forth in paragraph (1).

Article 16 (1) An application for approval for the renewal under Article 14, paragraph (1) of the Act shall be filed by submitting a written application containing the matters listed in each item of paragraph (1) of the preceding Article to the Minister of Health, Labour and Welfare:

- (2) A written application set forth in the preceding paragraph shall be attached with the following data:
- (i) The documents provided in Article 13, item (i) and items (iv) to (vi) (those with no changes shall be excluded and the original and changed descriptions pertaining to changed matters shall be clearly presented in comparison);
 - (ii) The documents provided in Article 13, items (ii) and (iii);
 - (iii) The data concerning the record prepared and retained with regard to the matters listed in Article 13, item (vi), (a), (b), and (d), based on the documents provided in the same item.
- (3) A fiscal stamp for the amount of the fee shall be affixed to a written application set forth in paragraph (1).

Article 17 (1) The grounds specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 17, paragraph (1) of the Act shall be as follows:

- (i) Regarding specific apparatus or containers and packaging which are produced in a specific country or region, or which are produced by a specific person (hereinafter referred to as "specific apparatuses, etc."), inspections under Article 26, paragraphs (1) to (3) of the Act or Article 28, paragraph (1) of the Act, or inspections conducted by a business person in accordance with administrative guidance provided by the State, prefectures, cities establishing health centers, or special wards show that the total number of articles falling under apparatus or containers and packaging listed in each

- item of Article 17, paragraph (1) of the Act accounts for approximately 5% or more of the total number of apparatus or containers and packaging covered by said inspections;
- (ii) The contents of regulations and measures concerning food sanitation for specific apparatuses, etc. in a country or region where said specific apparatuses, etc. are produced, the inspection system and other systems for food sanitation management pertaining to said specific apparatuses, etc. by the government or local public entities of said country or region, the results of inspections with regard to said specific apparatuses, etc. by the government or local public entities of said country or region, and other food sanitation management pertaining to said specific apparatuses, etc. at said country or region;
 - (iii) Regarding specific apparatuses, etc., health hazards caused by or suspected to have been caused by said specific apparatuses, etc. have occurred;
 - (iv) Regarding specific apparatuses, etc., a situation has occurred that contaminates or is likely to contaminate said specific apparatuses, etc.
- (2) The provisions of the preceding paragraph shall apply *mutatis mutandis* to the grounds specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 17, paragraph (1) of the Act which is applied *mutatis mutandis* under Article 62, paragraph (1) of the Act.

Article 18 (1) The matters specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 17, paragraph (1) of the Act shall be as follows:

- (i) The level of the risk that specific apparatuses, etc. may harm human health;
 - (ii) The matters listed in each item of paragraph (1) of the preceding Article;
 - (iii) The probability that specific apparatuses, etc. falling under apparatus or containers and packaging listed in each item of Article 17, paragraph (1) of the Act may continue to be sold, produced or imported for the purpose of marketing, or used in business;
 - (iv) Effects that measures other than the prohibition under Article 17, paragraph (1) of the Act are expected to have for preventing food sanitation hazards resulting from specific foods, etc.
- (2) The provisions of the preceding paragraph shall apply *mutatis mutandis* to the matters specified by an Ordinance of Health, Labour and Welfare under Article 17, paragraph (1) of the Act which is applied *mutatis mutandis* under Article 62, paragraph (1) of the Act.

Article 19 (1) When the Minister of Health, Labour and Welfare intends to rescind the prohibition pertaining to specific apparatuses, etc. under Article 17,

paragraph (1) of the Act, based on an application from an interested person or as needed, pursuant to the provisions of Article 8, paragraph (3) of the Act which is applied mutatis mutandis by replacing the terms under Article 17, paragraph (3) of the Act, he/she shall consider the matters listed in each item of paragraph (1) of the preceding Article with regard to the specific apparatuses, etc. pertaining to said rescission of the prohibition, when confirming that there is no risk of food sanitation hazards resulting from said specific apparatuses, etc.

- (2) The provisions of the preceding paragraph shall apply mutatis mutandis to the case where the prohibition under Article 17 paragraph (1) of the Act, which is applied mutatis mutandis under Article 62, paragraph (1) of the Act, is rescinded pursuant to the provisions of Article 8, paragraph (3) of the Act, which is applied mutatis mutandis by replacing the terms under Article 17, paragraph (3) of the Act which is applied mutatis mutandis under Article 62, paragraph (1) of the Act.

Article 20 (1) An application for rescission under Article 8, paragraph (3) of the Act which is applied mutatis mutandis by replacing the terms under Article 17, paragraph (3) of the Act shall be filed by submitting a written application containing the matters listed in the following items to the Minister of Health, Labour and Welfare, attaching documents to prove that there is no longer any risk of food sanitation hazards resulting from the apparatus or containers and packaging for which said application for the rescission is filed:

- (i) The address and name of the applicant (for a juridical person, its name, the location of its principal office, and the name of its representative);
 - (ii) The scope of the apparatus or containers and packaging for which the application for rescission is filed;
 - (iii) Other matters that the Minister of Health, Labour and Welfare finds necessary.
- (2) The provisions of the preceding paragraph shall apply mutatis mutandis to an application for rescission under Article 8, paragraph (3) of the Act which is applied mutatis mutandis by replacing the terms under Article 17, paragraph (3) of the Act which is applied mutatis mutandis under Article 62, paragraph (1) of the Act.

Chapter II Labeling

Article 21 (1) The criteria for the labeling of food or additives specified in appended table 3 which are served for the purpose of marketing are as follows:

- (i) The following matters shall be indicated on conspicuous parts of the containers and packaging (when the containers and packaging are wrapped

for the purpose of retailing, said wrappings; the same shall apply in paragraphs (5) to (8) and paragraphs (16) and (19)), so that they can be read without opening said containers and packaging or wrappings;

- (a) The name (for additives listed in appended table 1 (excluding those listed in appended table 4), only the names listed in appended table 1);
- (b) For food or additives whose quality may deteriorate rapidly when preserved by the specified methods: the date indicated with the letters meaning an expiration date (meaning a date showing the limit up to which said food or additives are deemed to have no hazardous risk through deterioration, rotting, or other quality degradation when preserved by the specified methods; the same shall apply hereinafter). For other food or additives: the date indicated with the letters meaning a freshness date (meaning a date showing the limit that said food or additives are deemed to maintain fully all expected qualities when preserved by the specified methods; the same shall apply hereinafter);
- (c) The location of the production or processing facility (for imported goods, the location of the importer's business office; the same shall apply hereinafter), and the name of the producer or processor (for imported goods, the name of the importer; the same shall apply hereinafter) (for a juridical person, its name; the same shall apply in paragraphs (8) and (10))
- (d) For additive preparations: the ingredients thereof (excluding those used for flavoring food), and the percentage by weight of the respective ingredients (when the ingredients are vitamin A derivatives, their percentage by weight as vitamin A);
- (e) For food containing additives (excluding those used for nutrient enrichment, processing aids (meaning substances which are added to food during the processing process and which are removed before the completion of said food or which are changed by some of the raw materials of said food into ingredients such as those generally contained in said food without causing an evident increase in the total quantity of the ingredients, or ingredients whose quantity is so small as to have little impact on said food), and carryover (meaning substances which are used in the process of producing or processing the raw materials of food but are not used in the process of producing or processing said food and whose quantity is not large enough to impact on said food); hereinafter the same shall apply in (e)) which are used as listed in the middle columns of appended table 5: the fact that said additives are contained and the labeling listed in the relevant right hand columns of the same table. For food containing other additives: the fact that said additives are contained;
- (f) For processed food made from food listed in appended table 6 (excluding milk) (including food made from said processed food and excluding those

- deemed to be nonantigenic and listed in item 2. of appended table 3): the fact that said food is contained as one of the raw materials. For processed food made from milk (including food made from said processed food and excluding those deemed to be nonantigenic and listed in item 2. of appended table 3): the fact that milk is contained as one of the raw materials as specified by the Minister of Health, Labour and Welfare;
- (g) For food containing additives derived from the food listed in appended table 6 (hereinafter referred to as "specific raw materials") (excluding those deemed to be nonantigenic and flavoring agents; the same shall apply in (j)): the fact that said additives are contained and the fact that the additives contained in said food are derived from said specific raw materials;
- (h) For food and additives for which the criteria for preservation methods (for food and additives for which the criteria for preservation methods have been established pursuant to the provisions of Article 11, paragraph (1) of the Act, the preservation methods that conform to such criteria) have been established and the criteria for methods for use have been established pursuant to the provisions of the same paragraph: the methods for use that conform to such criteria;
- (i) For additives (excluding those provided in (j)): the letters "食品添加物(food additives);"
- (j) For additives derived from specific raw materials: the letters "食品添加物 (food additives)" and the fact that the additives are derived from said specific raw materials;
- (k) For preparations of a coal-tar color: the name of the effective color with the letters "製剤(preparations);"
- (l) For additives for which the standards established under Article 11, paragraph (1) of the Act specify the amount for labeling purposes: their percentage by weight;
- (m) For vitamin A derivatives used as additives: their percentage by weight as vitamin A
- (n) For aspartame or preparations or food containing aspartame: the fact that the substance is an L-phenylalanine compound or that the product contains an L-phenylalanine compound;
- (o) For types of mineral water (meaning carbonated drinks only made of water) whose carbon dioxide tension within the containers and packaging is less than 98kPa at 20 degrees centigrade and which are not sterilized or filtered (meaning to carry out such procedures as filtration to eliminate microbes which are derived from raw water, etc., exist in said food and may develop; the same shall apply hereinafter): the fact that they are not sterilized or filtered;

- (p) For frozen fruit drinks (meaning frozen fruit juice extraction or frozen concentrated fruit juice extraction, excluding raw fruit juice): the letters "冷凍果実飲料(frozen fruit drink),"
- (q) For canned food: the names of the principal raw materials;
- (r) For processed meat: the types of poultry or livestock;
- (s) For processed meat for which any of the following processes were carried out: chopping muscle and tissue short while keeping its original shape, infiltrating seasoning into said meat, attaching other meat pieces and pulling into shape, or other processes in which contamination caused by pathogens may expand inwardly: the fact that such processes have been carried out and that the entire meat product needs to be fully heated prior to human consumption;
- (t) For food listed in item 4. of appended table 3: the names of the raw meat materials (they shall be listed in order of the amount blended; processed meat materials shall be indicated as is shown in (r) and fish meat materials shall be indicated clearly as fish meat);
- (u) Dried processed meat products (meaning processed meat products which are dried and sold as dried processed meat products; the same shall apply hereinafter): the fact that they are dried processed meat products;
- (v) For unheated processed meat products (meaning processed meat products which are smoked or dried after salting and have not been sterilized by heating the center part at 63 degrees centigrade for 30 minutes or by any other equivalent or more effective methods; excluding dried processed meat products; the same shall apply hereinafter): the fact that they are unheated processed meat products and their pH and water activity (Aw);
- (w) For specific heated processed meat products (meaning processed meat products which are sterilized by heating the center part at 63 degrees centigrade for 30 minutes or by any other equivalent or more effective methods; excluding dried processed meat products and unheated processed meat products; the same shall apply hereinafter): the fact that they are specific heated processed meat products and their water activity (Aw);
- (x) For heated processed meat products (meaning processed meat products other than dried processed meat products, unheated processed meat products and specific heated processed meat products): the fact that they are heated processed meat products and whether they were sterilized by being heated after being packaged or were packaged after heat sterilization;
- (y) For processed meat products, whale meat products, fish meat sausage, fish meat ham, or specially packaged fish paste which are packed and sealed in tight containers and packaging and are sterilized by heating the center part at 120 degrees centigrade for four minutes or by any other

- equivalent or more effective methods (excluding canned or bottled products): the methods for sterilization;
- (z) For fish meat sausage, fish meat ham, or specially packaged fish paste whose pH is 4.6 or lower and whose water activity (A_w) is 0.94 or lower (excluding canned or bottled products): said pH or A_w ;
- (aa) For produced or processed food (excluding carbonated drinks, processed meat products, whale meat products, fish jelly products, boiled octopus and boiled crabs; the same shall apply in this Article) which are frozen: whether they need to be heated or not prior to human consumption;
- (bb) For frozen food which requires heating before consumption (meaning produced or processed food which is frozen and is deemed to require heating prior to human consumption; the same shall apply hereinafter): whether they were heated before freezing or not;
- (cc) For cut or shelled fish and seafood (excluding raw oysters) which are frozen and raw oysters: whether they can be eaten in raw or not;
- (dd) For cut or shelled fresh fish and seafood (excluding raw oysters) (excluding those frozen): the fact they can be eaten raw;
- (ee) For food listed in item 8. of appended table 3: the fact that they have been irradiated;
- (ff) For food listed in item 9. of appended table 3 (excluding canned or bottled products): the fact that the food has been packed and sealed in tight containers and packaging and has been sterilized by autoclaving and heating;
- (gg) For shell eggs (limited to those to be eaten raw): the fact that they can be eaten raw, that it is preferable to preserve them at ten degrees centigrade or lower, and that they need to be heated prior to human consumption after the freshness date;
- (hh) For shell eggs (excluding those to be eaten raw): the fact that they cannot be eaten raw and that they need to be heated prior to human consumption;
- (ii) For egg liquid (meaning the liquid part of shelled eggs; the same shall apply hereinafter) which are sterilized: the methods for sterilization;
- (jj) For egg liquid other than sterilized egg liquid: the fact that it is not sterilized and that it needs to be heated prior to human consumption;
- (kk) For raw oysters (limited to those to be eaten raw): the sea, lake or marsh waters where they were collected;
- (ll) For boiled crabs: whether they need to be heated prior to human consumption or not;
- (mm) For instant noodles which were processed with fat and oil: the fact they have been processed with fat and oil;
- (nn) For farm products and processed food listed in item 12. of appended

table 3: the matters listed in 1. to 3. below according to the relevant classification set forth in 1. to 3. below:

1. Farm products applying recombinant DNA technology (meaning farm products listed in the left hand columns of appended table 7 which were produced by applying recombinant DNA technology (meaning technology to create recombinant DNA molecules by cutting and recombining DNA with enzymes and introducing them into live cells for breeding); the same shall apply hereinafter) or processed food made from farm products applying recombinant DNA technology (including food made from said processed food; the same shall apply in ii.) for which Identity Preserved Handling (meaning a management system where farm products applying recombinant DNA technology and farm products not applying recombinant DNA technology (meaning farm products listed in the left hand columns of appended table 7, excluding farm products applying recombinant DNA technology; the same shall apply hereinafter) are managed separately in each process for production, distribution, and processing with the due care of a prudent manager and such fact is clearly certified with written documents; the same shall apply hereinafter) is confirmed to have been conducted - The matters listed in i. or ii. below according to the relevant classification set forth in i. or ii below.
 - i. Food of farm products - The fact that said food of farm products is food of farm products applying recombinant DNA technology;
 - ii. Processed food - The names of the farm products listed in the left hand columns of appended table 7 which are used as raw materials for said processed food, and the fact that said farm products are farm products applying recombinant DNA technology;
2. Food of farm products, in any process where the production, distribution, and processing of farm products applying recombinant DNA technology and farm products not applying recombinant DNA technology are not separated, or processed food made from such farm products (including food made from said processed food; the same shall apply in ii.) - The matters listed in i. or ii. below according to the relevant classification set forth in i. or ii. below:
 - i. Food of farm products - The fact that farm products applying recombinant DNA technology and farm products not applying recombinant DNA technology are not separated with regard to said food of farm products;
 - ii. Processed food - The names of the farm products listed in the left hand columns of appended table 7 which are used as raw materials for said processed food, and the fact that farm products applying

recombinant DNA technology and farm products not applying recombinant DNA technology are not separated with regard to said farm products;

3. Processed food made from farm products applying recombinant DNA technology for which Identity Preserved Handling is confirmed to have been conducted (including food made from said processed food) - The names of the farm products listed in the left hand columns of appended table 7 which are used as raw materials for said processed food;
- (oo) For food for specified health use (meaning food for which permission under Article 26, paragraph (1) of the Health Promotion Act (Act No. 103 of 2002) or approval under Article 29, paragraph (1) of the same Act (hereinafter referred to as "permission or approval" in (oo)) has been obtained to indicate to persons who consume said food for specified health purposes for their daily diet that they can expect to fulfill said health purposes by consuming said food; the same shall apply hereinafter): the fact that it is food for specified health use (for food which is required, upon the issuance of permission or approval, to show clearly under what conditions the expected specified health purposes can be met (hereinafter referred to as "conditional food for specified health use"), the fact that it is a conditional food for specified health use), the contents of the labeling permitted or approved, the amount of nutrients, calories, the names of the raw materials, content weight, recommended consumption per day, consumption methods, notes for consumption, and the wording to recommend a well-balanced daily diet;
- (pp) For food with nutrient function claims (meaning food which indicates the functions of the specified nutrients it contains to persons who consume said food so as to supplement said specified nutrients in their daily diet in accordance with the criteria specified by the Minister of Health, Labour and Welfare (excluding food for special dietary uses provided in Article 26, paragraph (5) of the Health Promotion Act and perishable food (excluding eggs)); the same shall apply hereinafter): the fact that it is food with nutrient function claims, the names and functions of the nutrients intended to be indicated as those conforming to the criteria specified by the Minister of Health, Labour and Welfare, the amount of nutrients, calories, recommended consumption per day, consumption methods, notes for consumption, the wording to recommend a well-balanced daily diet, and the fact that it has not undergone case-by-case reviews by the Minister of Health, Labour and Welfare;
- (qq) For food for specified health use for which consumption criteria by gender and age (hereinafter referred to as "consumption criteria" in (qq)) with regard to nutrients that serve the objectives of healthcare are

- indicated for the purpose of maintaining and improving citizen's health, and for food for specified health use for which consumption criteria are indicated with regard to nutrients whose functions are indicated: the rates of said respective nutrients contained in recommended consumption per day against the weighted average of criterial consumption calculated by using the population by gender and age (limited to six years old or over);
- (rr) For food for specified health use or food with nutrient function claims which require special precautions with regard to the cooking or preserving methods: said precautions;
- (ii) The matters listed in the preceding item shall be indicated in Japanese and in an accurate manner with wording which is easy to read and understand for persons who generally buy or use said food or additives;
- (iii) For food with nutrient function claims, the following matters shall not be indicated:
- (a) The functions of nutrients other than those pertaining to the criteria specified by the Minister of Health, Labour and Welfare as provided in item (i), (pp);
- (b) The fact that specified objectives of healthcare can be met;
- (iv) For food other than food for specified health use and food with nutrient function claims (hereinafter referred to as "food with health claims"), names liable to be confused with food with health claims shall not be used nor shall it be indicated that nutrient functions or specified objectives of healthcare can be met;
- (v) For food other than food of farm products not applying recombinant DNA technology for which Identity Preserved Handling is confirmed to have been conducted or processed food made from farm products not applying recombinant DNA technology for which Identity Preserved Handling is confirmed to have been conducted (including food made from said processed food), it shall not be indicated that said food of farm products is food of farm products not applying recombinant DNA technology nor that the farm products listed in the left hand columns of appended table 7 which are used as raw materials for said processed food are farm products not applying recombinant DNA technology.
- (2) Notwithstanding the provisions of item (i) of the preceding paragraph, regarding shell eggs out of the food listed in item 10. of appended table 3, the food listed in item 11., (c) of the same table, and the food of farm products listed in item 12. of the same table whose names are indicated on a nearby signboard or in another conspicuous place, the names thereof do not have to be indicated.
- (3) Notwithstanding the provisions of paragraph (1), item (i), if the period between the date for production or processing and the freshness date exceeds

three months, the month indicated with the letter meaning a freshness date may replace the date indicated with the letter meaning a freshness date.

- (4) Notwithstanding the provisions of paragraph (1), item (i), for food listed in item 2. of appended table 3, food packed in glass bottles (excluding glass bottles with paper caps) or polyethylene containers and packaging among those listed in item 3. of the same table, food listed in item 11., (b) of the same table (excluding food which has been canned, bottled, barreled, or jarred), food listed in (c) of the same item, food of farm products listed in item 12. of the same table, and additives listed in item 14. of the same table, the date indicated with the letters meaning an expiration date or a freshness date (hereinafter referred to as the "time limit") and the preservation methods do not have to be indicated (for food or additives for which the criteria for the preservation methods have been established pursuant to the provisions of Article 11, paragraph (1) of the Act, the time limit does not have to be indicated).
- (5) Notwithstanding the provisions of paragraph (1), item (i), for food listed in item 6. of appended table 3, the date indicated with the letters meaning import date shall be indicated, in lieu of the time limit and preservation methods, on conspicuous parts of the containers and packaging or wrappings so that they can be read without opening said containers and packaging.
- (6) Notwithstanding the provisions of paragraph (1), item (i), for food listed in item 8. of appended table 3, the date indicated with the letters meaning irradiation date shall be indicated, in lieu of the time limit and preservation methods (for food for which the criteria for preservation methods have been established pursuant to the provisions of Article 11, paragraph (1) of the Act, in lieu of the time limit), on conspicuous parts of the containers and packaging or wrappings so that they can be read without opening said containers and packaging.
- (7) Notwithstanding the provisions of paragraph (1), item (i), for shell eggs (limited to those to be eaten raw) among food listed in item 10. of appended table 3, the time limit or preservation methods may be replaced with the date indicated with the letters meaning the date when the shell eggs were laid, the date when they were collected, the date when they were selected by weight and quality or the date when they were packed, on conspicuous parts of the containers and packaging or wrappings so that they can be read without opening said containers and packaging.
- (8) Notwithstanding the provisions of paragraph (1), item (i), for shell eggs among food listed in item 10. of appended table 3, the location of the facility where the shell eggs were collected or where the shell eggs were selected by weight and quality and packed (for imported goods, the location of the importer's business office) and the name of a person who collected the shell eggs or a person who selected the shell eggs by weight and quality and packed

them (for imported goods, the name of the importer) shall be indicated, in lieu of the location of the production or processing facility and the name of the producer or processor, on conspicuous parts of the containers and packaging or wrappings so that they can be read without opening said containers and packaging.

- (9) Notwithstanding the provisions of paragraph (1), item (i), labeling indicating that there is no need for refrigeration may be omitted;
- (10) Notwithstanding the provisions of paragraph (1), item (i), for food listed in item 11., (c) of appended table 3, food other than food of farm products listed in item 12. of the same table, and additives, the location of the production facility and the name of the producer may be replaced by indicating the address and name of the producer and the marks unique to the production facility which the producer has notified to the Minister of Health, Labour and Welfare (limited to marks made in Arabic numerals, Roman letters, Hiragana, Katakana, or a combination thereof; hereinafter the same shall apply in this paragraph), or the address and name of the seller, the fact that he/she is the seller, and the marks unique to the producer's production facility which the producer and the seller have notified to the Minister of Health, Labour and Welfare in their joint names. For food listed in item 11., (c) of the same table and food of farm products listed in item 12. of the same table, the location of the production or processing facility and the name of the producer or processor do not have to be indicated.
- (11) Notwithstanding the provisions of paragraph (1), item (i), for additives which have a widely used name, labeling indicating that said additives are contained may be replaced with said name. For food containing additives used as those listed in the left hand columns of appended table 8, this labeling may be replaced with labeling listed in the respective right hand columns of the same table. For food listed in item 11., (c) of appended table 3 (limited to food containing additives other than additives used as those listed in the middle columns of paragraph (8). of appended table 5) and food of farm products listed in item 12. of appended table 3, labeling indicating that said additives are contained may be omitted.
- (12) Notwithstanding the provisions of paragraph (1), item (i), in cases listed in the following items, labeling listed in the respective items may be omitted:
 - (i) When labeling indicating that the additives are contained includes the letter "色(color)" - Food coloring or artificial coloring;
 - (ii) When labeling indicating that the additives are contained includes the letters "増粘(thickening)" - Thickening agent or thickener;
 - (iii) For food listed in item 11., (c) of appended table 3, when it contains additives other than additives used as those listed in the middle columns of paragraph (8). of appended table 5 - Labeling listed in the right hand

columns of appended table 5 pertaining to said additives.

(13) Notwithstanding the provisions of paragraph (1), item (i), for processed food made from specific raw materials where it is easy to judge that specific raw materials are contained as raw materials from its name (hereinafter referred to as "specific processed food" in this paragraph), labeling indicating that said specific raw materials are contained as raw materials may be omitted. For processed food made from specific processed food (excluding that made from milk (meaning milk provided in Article 2, paragraph (1) of the Ministerial Ordinance concerning the Ingredient Standards for Milk and Dairy Products (Ordinance of the Ministry of Health and Welfare No. 52 of 1951)); the same shall apply hereinafter), labeling indicating that specific raw materials are contained as raw materials may be replaced by indicating that said specific processed food is contained as a raw material. For food containing additives derived from specific raw materials and which has labeling attached indicating that said specific raw materials or specific processed food made from said specific raw materials are contained as raw materials and where it is easy to judge that said specific raw materials are contained as raw materials from its name, labeling indicating that additives contained in said food are derived from said specific raw materials may be omitted. For additives derived from said specific raw materials where it is easy to judge that they are derived from specific raw materials from their name, labeling indicating that they are derived from said specific raw materials may be omitted.

(14) Notwithstanding the provisions of paragraph (1), item (i), labeling for the matters listed in paragraph (1), item (i), (nn), 1. to 3. may be omitted for food listed in the following items:

(i) Processed food which does not use food of farm products listed in the left hand columns of appended table 7 or processed food which uses such processed food as the principal raw materials (meaning the top three raw materials accounting for the higher rates out of the total weight of raw materials and whose rate against the total weight is 5% or more; the same shall apply hereinafter);

(ii) Processed food other than the processed food listed in the right hand columns of appended table 7 as those in which recombinant DNA or the resultant protein remains even after processing procedures;

(iii) Among the food of farm products listed in item 12. of appended table 3, those for which the matters listed in paragraph (1), item (i), (nn), 1. to 3. are indicated on a signboard close to said food of farm products or in other conspicuous places;

(iv) Among processed food listed in item 12. of appended table 3, those falling under paragraph (1), item (i), (nn), 3. which are made from any of the farm products listed in the left hand columns of appended table 7;

- (v) Food which is not sold directly to general consumers.
- (15) When farm products applying recombinant DNA technology and farm products not applying recombinant DNA technology have been unintentionally mixed up to a certain degree, in spite of conducting Identity Preserved Handling, and if the confirmation set forth in paragraph (1), item (i), (nn), 1. or 3. has been made in the correct manner, the provisions of paragraph (1), item (i) shall apply, deeming that Identity Preserved Handling has been confirmed to have been conducted.
- (16) Notwithstanding the provisions of paragraph (1), item (i), for food listed in item 11., (b) of appended table 3 and processed food listed in item 12. of the same table which are specified by the Minister of Health, Labour and Welfare as food with containers and packaging too small to have the matters listed in paragraph (1) clearly indicated, such labeling may be omitted.
- (17) Notwithstanding the provisions of paragraph (1), item (i), labeling indicating the matters listed in the same item (excluding the matters listed in (a) and (c) of the same item) on containers and packaging may be replaced by indicating such matters in an invoice for food listed in the left hand columns of appended table 9 when falling under cases listed in the respective right hand columns of the same table. In this case, the mark which can identify said food shall be indicated on conspicuous parts of the containers and packaging so that they can be read without opening said containers and packaging, and the matters listed in (a) and (c) of the same item, said mark, and the name and address of the purchaser (for a juridical person, its name and the location of its principal office) shall be indicated in said invoice.
- (18) The provisions of paragraph (3) and paragraphs (9) to (12) shall apply *mutatis mutandis* to the case where the matters listed in paragraph (1), item (i) are indicated in an invoice pursuant to the provisions of the preceding paragraph.
- (19) Notwithstanding the provisions of paragraph (1), item (i), labeling indicating that the objectives of the healthcare pertaining to food with health claims can be expected and labeling indicating the functions of the nutrients on containers and packaging may be replaced by indicating them in attached documents.

Chapter III Plans for Monitoring and Guidance

- Article 22 (1) A prefectural governor, mayor of a city establishing health centers, or head of a special ward (hereinafter referred to as "prefectural governor, etc.") shall submit prefectural plans for the monitoring of and guidance on food sanitation for each fiscal year to the Minister of Health, Labour and Welfare prior to the start of the fiscal year.
- (2) A prefectural governor, etc. shall, when intending to change the prefectural

plans for the monitoring of and guidance on food sanitation, submit the new plans to the Minister of Health, Labour and Welfare prior to implementation.

- Article 23 (1) A prefectural governor, etc. shall publicize the outline of the performance results of prefectural plans for the monitoring of and guidance on food sanitation for every fiscal year by June 30 of the next fiscal year, compile the full text of said results and publicize it promptly.
- (2) In addition to what is provided in the preceding paragraph, a prefectural governor, etc. shall prepare an outline of the performance results of the prefectural plans for the monitoring of and guidance on food sanitation for the summer time, the year-end, or other necessary periods, and publicize it promptly.
- (3) When publicizing an outline of the performance results pursuant to the provisions of the preceding two paragraphs, a prefectural governor, etc. shall endeavor to use appropriate methods such as bulletins or the official Written Reports of the prefecture, city establishing health centers, or special ward or the internet to disseminate the contents widely to the residents.

Chapter IV Product Inspections

Article 24 An application for inspections under Article 25, paragraph (1) of the Act shall be filed by submitting a written application containing the following matters by products comprising each lot:

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

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

Article 26 The labeling specified by an Ordinance of the Ministry of Health,

Labour and Welfare under Article 25, paragraph (1) of the Act shall be made by sealing the containers and packaging of the products with certificates according to form 1.

Article 27 The matters specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 5, paragraph (1) of the Order shall be as follows:

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

Article 28 (1) An application for inspections under Article 26, paragraph (1) of the Act shall be filed by submitting a written application containing the following matters by products comprising each lot:

- (i) The name and address of the applicant (for a juridical person, its name, the location of its principal office, and the name of its representative);
 - (ii) The names of the products;
 - (iii) The name and location of the production or processing facility;
 - (iv) The date of production or processing;
 - (v) The quantity for the application.
- (2) A written application set forth in the preceding paragraph shall have a transcript of a written inspection order under Article 5, paragraph (1) of the Order attached; provided, however, that this shall not apply to the case where an application for inspections has already been filed for the same order and a transcript of a written inspection order has already been submitted.

Article 29 (1) An application for inspections under Article 26, paragraph (2) of the Act shall be filed by submitting a written application containing the following matters:

- (i) The name and address of the applicant (for a juridical person, 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 juridical person, its name and the location of its principal office);
- (iv) The name and location of the production or processing facility;
- (v) The date of the arrival of the products at a port;

- (vi) The location of the product inventory;
 - (vii) The quantity for the application.
- (2) A written application set forth in the preceding paragraph shall have a transcript of a written inspection order (when the Minister of Health, Labour and Welfare has issued a notice of inspection using an electronic data processing system pursuant to the provisions of Article 34, paragraph (1), a transcript of the printout of the contents of said order) attached.

Article 30 The provisions of the preceding Article shall apply *mutatis mutandis* to an application for inspections under Article 26, paragraph (3) of the Act. In this case, the term "matters" in paragraph (1) of the same Article shall be deemed to be replaced with "matters (for an application for inspections of food other than processed food, excluding the matters listed in item (iii)), and the term "location" in item (iv) of the same paragraph shall be deemed to be replaced with "location (for an application for inspections of food other than processed food, the place of production of said food)."

Article 31 The payment of the fee for receiving inspections by the Minister of Health, Labour and Welfare shall be made by affixing a fiscal stamp for the amount specified by the Minister of Health, Labour and Welfare under Article 25, paragraph (2) of the Act or under Article 26, paragraph (6) of the Act to a written application set forth in Article 4, paragraph (2) or Article 6, paragraph (1) of the Order (including cases where it is applied *mutatis mutandis* under Article 7 of the Order).

Chapter V Import Notification

Article 32 (1) A person provided in Article 27 of the Act (including cases where it is applied *mutatis mutandis* under Article 62, paragraph (1) of the Act; the same shall apply in paragraph (7), paragraph (8), and the following Article) (such a person shall be referred to as an "importer" in the following paragraph, and paragraphs (4) and (5)) shall enter the following matters into a written import notification (when he/she submits a written import notification prior to the carrying-in of cargoes to the inventory location (hereinafter referred to as "carrying-in" in this paragraph), excluding the matters listed in item (xii)) and submit it to the head of a quarantine station listed in the right hand columns of appended table 11 for the places listed in the respective left hand columns of the same table from seven days prior to the planned arrival date of the cargoes (when an accident concerning the cargoes is suspected, after the carrying-in), except in cases where he/she intends to import food listed in appended table 10. However, when submitting a written import notification prior to the carrying-

in and when there has been an accident concerning the cargoes, a written notification containing the outline of the accident shall be submitted to the head of said quarantine station promptly after the carrying-in:

- (i) The name and address (for a juridical person, its name and the location of its principal office);
 - (ii) Whether the cargoes are food, additives, apparatus, containers and packaging, or toys, the names of the articles, loaded quantity, loaded weight, type of packaging, and usage, and when the cargoes have any marks and numbers, said marks and numbers;
 - (iii) When the cargoes are food containing additives which are used for purposes other than for flavoring (for food which is generally served for human consumption and is used as an additive, limited to food for which standards or criteria have been established pursuant to the provisions of Article 11, paragraph (1) of the Act), the name of said additives;
 - (iv) When the cargoes are processed food, the raw materials thereof and production or processing methods;
 - (v) When the cargoes are food of farm products or processed food listed in item 12. of appended table 3 (excluding those listed in Article 21, paragraph (1)4, item (i) or item (ii)), the matters listed in paragraph (1), item (i), (nn), 1. to 3. of the same Article according to the relevant classification set forth in (nn), 1. to 3. of the same item;
 - (vi) When the cargoes are additives, or preparations containing said additives (excluding those used for flavoring and those generally served for human consumption which are used as additives), the ingredients thereof;
 - (vii) When the cargoes are apparatus, containers and packaging, or toys, the materials thereof;
 - (viii) The name and address of the producer or processor of the cargoes (excluding food other than processed food) (for a juridical person, its name and the location of its principal office);
 - (ix) The name and location of the production or processing facility of the cargoes (in the case of food other than processed food, the place of production), the loading port, loading date, unloading port, and arrival date of the cargoes;
 - (x) The name or flight of the ship or airplane loaded with the cargoes;
 - (xi) The name and location of the warehouse where the cargoes have been stored and the date of carrying-in;
 - (xii) Whether there have been any accidents concerning the cargoes and the outline of the accidents if any.
- (2) An importer shall, when there have been any changes to the matters listed in items (ix) to (xi) of the preceding paragraph (for the matters listed in item (ix), limited to the unloading port, and the arrival date), submit a notification to

that effect promptly to the head of a quarantine station set forth in the preceding paragraph.

- (3) When farm products applying recombinant DNA technology and farm products not applying recombinant DNA technology have been unintentionally mixed up to a certain degree, in spite of conducting Identity Preserved Handling, and if the confirmation set forth in Article 21, paragraph (1), item (i), (nn), 1. or 3. has been made in the correct manner, the provisions of paragraph (1) shall apply, deeming that Identity Preserved Handling has been confirmed to have been conducted.
- (4) When an importer imports the food, additives, apparatus, containers and packaging listed in the middle columns of appended table 12 (hereinafter referred to as "food, etc." in this Article) and when he/she has submitted a written import notification containing the import plans for the same products as said food or the equivalent thereto (hereinafter referred to as the "same food, etc.") for a period listed in the right hand columns of the same table (such plans shall mean the loaded weight, unloading port, and arrival date of the cargoes pertaining to the import planned for said period; the same shall apply hereinafter), said submission may, notwithstanding the provisions of the main clause of paragraph (1), replace the submission of a written import notification under paragraph (1) with regard to the import of the same food, etc. planned for said period; provided, however, that this shall not apply to the case where the food, etc. pertaining to said import falls under or is suspected of falling under any of the following items:
- (i) Food or additives listed in each item of Article 6 of the Act;
 - (ii) Food or additives provided in Article 10 of the Act;
 - (iii) Food or additives which do not conform to the criteria established pursuant to the provisions of Article 11, paragraph (1) of the Act;
 - (iv) Food or additives which do not conform to the standards established pursuant to the provisions of Article 11, paragraph (1) of the Act;
 - (v) Food in which substances that are the ingredients of agricultural chemicals (meaning agricultural chemicals provided in Article 1-2, paragraph (1) of the Agricultural Chemicals Control Act (Act No. 82 of 1948), the same shall apply hereinafter), substances that are used by being added, mixed or infiltrated into feed (meaning feed provided in Article 2, paragraph (2) of the Act on Safety Assurance and Quality Improvement of Feed (Act No. 35 of 1953)) or are used by other methods for feed for the purpose of providing it for usage specified by an Ordinance of the Ministry of Agriculture, Forestry and Fisheries based on Article 2, paragraph (3) of the same Act, and pharmaceutical products that are provided in Article 2, paragraph (1) of the Pharmaceutical Affairs Act (Act No. 145 of 1960) and that are to be used for animals (including substances chemically generated from such substances

- and excluding substances that are specified as clearly having no risk to human health pursuant to the provisions of Article 11, paragraph (3) of the Act) remain in a quantity exceeding the quantity specified as having no risk to human health pursuant to the provisions of Article 11, paragraph (3) of the Act (except in cases where standards concerning the ingredients of food under Article 11, paragraph (1) of the Act have been established with regard to the residual limit of said substances in said food);
- (vi) Apparatus or containers and packaging provided in Article 16 of the Act;
 - (vii) Apparatus or containers and packaging which do not conform to the standards established pursuant to the provisions of Article 18, paragraph (1) of the Act;
- (5) In the case set forth in the preceding paragraph, an importer of food, etc. listed in the middle columns of paragraph (3) of appended table 12 shall submit a written import notification containing the import plans provided in the preceding paragraph, by entering the past record of imports of the same food, etc. during the three years before the date of submission of said written import notification (such past record shall mean the name of the importer pertaining to the import which took place during said period (for a juridical person, its name), the loaded weight, unloading port, and arrival date of the cargoes).
- (6) In the case set forth in the main clause of paragraph (4), the term "when a written import notification has been submitted prior to the carrying-in and there has been an accident concerning the cargoes" in the proviso of paragraph (1) shall be deemed to be replaced with "when there has been an accident concerning the cargoes pertaining to said import" and the term "the head of said quarantine station" shall be deemed to be replaced with "the head of a quarantine station listed in the right hand columns of appended table 11 for the places listed in the respective left hand columns of the same table." 1
- (7) The Minister of Health, Labour and Welfare may have a person make a notification under Article 27 of the Act using an electronic data processing system (meaning an electronic data processing system connecting a computer (including input-output devices; the same shall apply hereinafter) used by the Ministry of Health, Labour and Welfare and input-output devices used by a person who intends to make a notification under the same Article through a telecommunications line; hereinafter the same shall apply in this Chapter).
- (8) With regard to the application of the provisions of paragraphs (1) and (2) to a person who intends to make a notification under Article 27 of the Act using an electronic data processing system, the term "enter the following matters into a written import notification" shall be deemed to be replaced with "record the following matters," the term "when he/she submits a written import notification" shall be deemed to be replaced with "when he/she records said matters in a file by inputting them through input-output devices set forth in

paragraph (7) (limited to those used by a person who intends to make said notification; hereinafter the same shall apply in this paragraph and the following paragraph)," the term "and submit it to the head of a quarantine station listed in the right hand columns of appended table 11 for the places listed in the respective left hand columns of the same table" shall be deemed to be replaced with "in a file by inputting them through input-output devices," the term "when submitting a written import notification prior to the carrying-in" in the proviso of paragraph (1) shall be deemed to be replaced with "when recording the matters in a file by inputting them through input-output devices," and the term "a written notification containing the outline of the accident shall be submitted to the head of said quarantine station" shall be deemed to be replaced with "the outline of the accident shall be recorded in a file by inputting it through input-output devices," and the term "submit a notification to that effect promptly to the head of a quarantine station set forth in the preceding paragraph" in paragraph (2) shall be deemed to be replaced with "record them in a file by inputting them through input-output devices." 2

(9) The provisions of paragraphs (4) to (6) shall not apply to a person provided in the preceding paragraph.

- Article 33 (1) The input under paragraphs (1) and (2) of the preceding Article which is applied mutatis mutandis by replacing terms under paragraph (8) of the preceding Article shall be entered through input-output devices of which a person has notified the Minister of Health, Labour and Welfare in advance.
- (2) A person who intends to make a notification under Article 27 of the Act using an electronic data processing system shall make a notification set forth in the preceding paragraph by way of submitting a written notification containing the following matters to the Minister of Health, Labour and Welfare, with regard to the input-output devices he/she intends to use:
- (i) The name and address of the notifier (for a juridical person, its name and the location of its principal office);
 - (ii) A security code (limited to 12-character Arabic numerals or Roman letters or a combination thereof)
 - (iii) The places where the input-output devices are located, the names and model numbers of the equipment;
 - (iv) When a person other than the notifier manages the input-output devices, the name and address of said person (for a juridical person, its name and the location of its principal office).
- (3) A person who has made a notification set forth in the preceding paragraph shall, when there are any changes to the matters listed in each item of the same paragraph or when he/she has stopped using the notified input-output devices, notify the Minister of Health, Labour and Welfare promptly.

- Article 34 (1) The Minister of Health, Labour and Welfare may use an electronic data processing system when issuing a notice of an inspection order under Article 26, paragraph (2) or paragraph (3) of the Act to a person who has made a notification using an electronic data processing system pursuant to the provisions of Article 32, paragraph (7) with regard to food, additives, apparatus, or containers and packaging pertaining to said notification or issuing a notice of the results of said inspections under Article 26, paragraph (4) of the Act (hereinafter such notice shall be referred to as a "specific notice" in this Article).
- (2) The Minister of Health, Labour and Welfare shall, when issuing a specific notice using an electronic data processing system pursuant to the provisions of the preceding paragraph, input the contents of the specific notice through the input-output devices set forth in Article 32, paragraph (7) (limited to those used by the Ministry of Health, Labour and Welfare) and record them in a file.
- (3) The Minister of Health, Labour and Welfare shall obtain the consent of the other party in advance for issuing a specific notice using an electronic data processing system.

Chapter VI Food Sanitation Inspection Facilities and Food Sanitation Inspectors

- Article 35 (1) When a food sanitation inspector intends to remove food, additives, apparatus, containers and packaging, or toys listed in each item of Article 78 (hereinafter referred to as "food, etc.") pursuant to the provisions of Article 28, paragraph (1) of the Act (including cases where it is applied mutatis mutandis under Article 62, paragraphs (1) and (3) of the Act), he/she shall issue a certificate for removal according to form 2 to a person whose articles are removed.
- (2) The identification to be carried by a food sanitation inspector when carrying out his/her duties shall conform to form 3, and the emblem to show that the person is a food sanitation inspector shall conform to form 4.
- (3) The Minister of Health, Labour and Welfare and a prefectural governor, etc. shall, when entrusting the affairs concerning the examination to a registered conformity assessment body pursuant to the provisions of Article 28, paragraph (4) of the Act, have an inspector of said registered conformity assessment body (meaning an inspector provided in Article 38, paragraph (1), item (ii)) conduct said examination at a level equal to or higher than the criteria listed in each item of Article 40.

Article 36 The machines and implements specified by an Ordinance of the

Ministry of Health, Labour and Welfare under Article 8, paragraph (1) of the Order shall be water purifying apparatuses, automatic ovens, deep freezers, electric furnaces, gas chromatographs, spectrophotometers, autoclaves, dry heat sterilizers, constant temperature incubators, anaerobic culture systems, constant temperature tanks, and other necessary machines and implements.

Article 37 The affairs concerning the inspections or examination under Article 8, paragraph (2) of the Order (hereinafter referred to as "inspections, etc." in this Article and appended table 13) shall be managed as follows:

- (i) Confirming that inspections, etc. are conducted appropriately based on standard operation manuals provided in item (xi);
- (ii) Conducting internal checking of the management of the operation of inspections, etc. on a regular basis, based on documents set forth in item (xii);
- (iii) Conducting accuracy control (meaning maintaining the accuracy of inspections through such methods as ensuring the skill levels of persons engaged in inspections; the same shall apply hereinafter), based on documents set forth in item (xiii);
- (iv) Receiving external investigation of accuracy control (meaning investigation concerning accuracy control conducted by the State or other persons deemed to be appropriate; the same shall apply hereinafter) on a regular basis, based on documents set forth in item (xiv);
- (v) Recording the results of internal checking set forth in item (ii), accuracy control set forth in item (iii), and external investigation of accuracy control set forth in the preceding item (when improvement measures are required, including the contents of said improvement measures);
- (vi) Taking improvement measures for the operation of inspections, etc. promptly in accordance with the records under the preceding item;
- (vii) When there has been any deviation from the standard operation manuals provided in item (xi) and the documents provided in items (xii) and (xiii) upon inspections, etc., assessing the contents of the deviation and taking the necessary measures;
- (viii) An employee who carries out the duties set forth in item (i) or the preceding two items shall not conduct inspections, etc.;
- (ix) An employee who carries out the duties set forth in items (ii) to (v) (hereinafter referred to as "credibility ensuring duties" in this Article) shall not conduct inspections, etc. nor carry out the duties set forth in item (i) or item (vi);
- (x) Making credibility ensuring duties independent from the operation of inspections, etc.;
- (xi) Preparing standard operation manuals as provided in appended table 13;

- (xii) Preparing documents containing the methods for the internal checking of the management of the operation of inspections, etc.;
- (xiii) Preparing documents containing the methods for accuracy control;
- (xiv) Preparing documents containing the plans for receiving an external investigation of accuracy control on a regular basis;
- (xv) Preparing documents containing the training plans for employees who carry out credibility ensuring duties;
- (xvi) Preparing the following records and retaining them for three years from the day on which the records are prepared:
 - (a) The name and address of a person who has applied for inspections set forth in Article 25, paragraph (1) of the Act or Article 26, paragraphs (1) to (3) of the Act (hereinafter referred to as "product inspections") or a person who has had his/her articles removed pursuant to the provisions of Article 28, paragraph (1) of the Act (including cases where it is applied mutatis mutandis under Article 62, paragraph (1) of the Act; the same shall apply in (b)) (for a juridical person, its name and the location of its principal office);
 - (b) The date on which the application for product inspections was received, or the date on which the articles were removed pursuant to the provisions of Article 28, paragraph (1) of the Act;
 - (c) The name of the products for which inspections, etc. were conducted;
 - (d) The date on which inspections, etc. were conducted;
 - (e) Inspection items;
 - (f) The quantity of the test samples for which inspections, etc. were conducted;
 - (g) The name of the employee who conducted inspections, etc.;
 - (h) The results of inspections, etc.;
 - (i) Records under item (v);
 - (j) Records based on standard operation manuals set forth in item (xi);
 - (k) Records concerning the training set forth in the preceding item.

Chapter VII Registered Conformity Assessment Bodies

- Article 38 (1) A person who intends to apply for registration under Article 31 of the Act shall submit a written application according to form 5 to the Minister of Health, Labour and Welfare, by attaching the following documents:
- (i) The articles of incorporation or certificates of an act of endowment and registered matters;
 - (ii) The resume of a person who has the knowledge and experience that meet the conditions listed in column 3 of the appended table of the Act (hereinafter referred to as an "inspector");

- (iii) Documents to clarify the organization of departments provided in Article 33, paragraph (1), item (ii), (a) of the Act (hereinafter referred to as "departments conducting product inspections") and specialized departments provided in (c) of the same item (hereinafter referred to as "departments ensuring credibility");
- (iv) A standard operation manual provided in Article 40, item (viii) and documents provided in items (ix) to (xii) of the same Article as documents provided in Article 33, paragraph (1), item (ii), (b) of the Act;
- (v) Documents containing the following matters:
 - (a) Whether the juridical person falls under any item of Article 32 of the Act;
 - (b) The type of product inspections to be conducted among those listed in column 1 of the appended table of the Act;
 - (c) The number and performance of machines, implements, and other equipment listed in column 2 of the appended table of the Act, whether such machines, etc. are owned or leased, the place where such machines, etc. are located, and the type of product inspections for which such machines, etc. are used;
 - (d) The name of the inspector and the type of product inspections to be conducted;
 - (e) The name of the department conducting product inspections, the name of the responsible person for the department conducting product inspections provided in Article 40, item (i), and the name of the responsible person for the inspection category provided in item (ii) of the same Article and the type of product inspections that he/she supervises;
 - (f) The name of the department ensuring credibility, and the name of the responsible person for the department ensuring credibility provided in Article 40, item (iii);
 - (g) When a person has already conducted an examination business concerning food sanitation, the outline of the business;
 - (h) Whether the person falls under any of Article 33, paragraph (1), item (iii), (a) to (c) of the Act;
 - (i) For a stock company, the name and address of a shareholder who holds shares in excess of 5% of the total number of issued shares or a person who has contributed in excess of five percent of the total contribution, and the number of shares held by such person or the value of the contribution made by such person;
 - (j) The names and addresses of officers (for a membership company (meaning a membership company provided in Article 575, paragraph (1) of the Companies Act (Act No. 86 of 2005)), the personnel in charge of its business), whether they have authority of representation, and their brief biographical outlines (including whether they fall under officers or

employees of a business person subject to inspections provided in Article 33, paragraph (1), item (iii) of the Act (including those who have been officers or employees of said business person subject to inspections in the past two years));

(k) When a person conducts a business other than an examination business concerning food sanitation, the type and outline of the business.

(2) A fiscal stamp for the amount of the fee shall be affixed to a written application set forth in the preceding paragraph.

Article 39 (1) A person who intends to apply for registration under Article 34, paragraph (1) of the Act shall submit a written application according to form 6 to the Minister of Health, Labour and Welfare, by attaching the following documents:

(i) Documents listed in paragraph (1), items (i) to (iii) of the preceding Article;

(ii) Documents containing the matters listed in paragraph (1), item (v), (a), and (c) to (k) of the preceding Article;

(iii) Data concerning the actual performance of product inspections.

(2) A fiscal stamp for the amount of the fee shall be affixed to a written application set forth in the preceding paragraph.

Article 40 The criteria specified by an Ordinance of the Ministry of Health, Labour, and Welfare under Article 35, paragraph (2) of the Act shall be as follows:

(i) Persons who carry out the following duties shall be placed in departments conducting product inspections (hereinafter such persons shall be referred to as "persons responsible for departments conducting product inspections"):

(a) Supervising the duties of departments conducting product inspections

(b) Taking improvement measures promptly for said duties in accordance with documents with which a report was made pursuant to the provisions of item (iii), (d)

(c) Other necessary duties;

(ii) At departments conducting product inspections, persons who carry out the following duties for product inspections based on standard operation manuals provided in item (viii) (hereinafter referred to as "persons responsible for inspection categories") shall be placed for each category of physicochemical inspections, bacteriological inspections, and Inspections using animals:

(a) When there has been any deviation from standard operation manuals provided in item (viii) and documents provided in item (ix) upon product inspections, assessing the contents of the deviation and taking necessary measures;

- (b) Confirming that product inspections are conducted appropriately based on standard operation manuals provided in item (viii) and carrying out other necessary duties;
- (iii) Persons who personally carry out the following duties or have other people previously appointed in accordance with the contents of the duties carry out such duties shall be placed in departments ensuring credibility (hereinafter such persons shall be referred to as "persons responsible for departments ensuring credibility"):
 - (a) Conducting internal checking of the management of the operation of product inspections on a regular basis, based on documents set forth in item (ix);
 - (b) Conducting accuracy control based on documents set forth in item (x), and when there has been any deviation from said documents, assessing the contents of the deviation and taking necessary measures;
 - (c) Conducting affairs for receiving an external investigation of accuracy control on a regular basis, based on documents set forth in item (xi);
 - (d) Reporting the results of internal checking set forth in (a), accuracy control set forth in (b), and external investigation of accuracy control set forth in (c) (when improvement measures are required, including the contents of said improvement measures) to persons responsible for departments conducting product inspections in writing and entering the record in the books set forth in Article 44 of the Act (hereinafter referred to as the "books");
 - (e) Carrying out other necessary duties;
- (iv) A department ensuring credibility shall be independent from departments conducting inspections.
- (v) Persons responsible for departments conducting product inspections and persons responsible for departments ensuring credibility shall be officers of a registered conformity assessment body;
- (vi) Persons responsible for departments conducting product inspections and persons responsible for inspection categories shall not hold the position of inspector concurrently;
- (vii) Persons responsible for departments ensuring credibility and persons appointed pursuant to the provisions of item (iii) shall not hold the position of persons responsible for departments conducting product inspections, persons responsible for inspection categories and inspectors concurrently;
- (viii) Standard operation manuals have been prepared as provided in appended table 13. In this case, the term "Methods for keeping records" in the same table shall be deemed to be replaced with "Methods for entering, into the books, the records," the term "Standard operation manual for the implementation of inspections" shall be deemed to be replaced with

"Standard operation manual for the implementation of product inspections," and the term "inspections, etc." shall be deemed to be replaced with "product inspections";

- (ix) Documents containing the methods for internal checking of the management of the operation of product inspections have been prepared;
- (x) Documents containing the methods for accuracy control have been prepared;
- (xi) Documents containing plans for receiving external investigations of accuracy control on a regular basis have been prepared;
- (xii) Documents containing training plans for persons responsible for departments ensuring credibility and persons appointed pursuant to the provisions of item (iii) have been prepared;

Article 41 (1) A person who intends to notify the establishment, abolition, or changes of the locations of his/her office pursuant to the provisions of Article 36, paragraph (1) of the Act shall submit a written notification according to form 7 to the Minister of Health, Labour and Welfare.

(2) A person who intends to notify changes pursuant to the provisions of Article 36, paragraph (2) of the Act shall submit a written notification according to form 8 to the Minister of Health, Labour and Welfare.

Article 42 (1) When a registered conformity assessment body intends to obtain approval for rules concerning the operation of product inspections (hereinafter referred to as "operational rules") pursuant to the provisions of the first sentence of Article 37, paragraph (1) of the Act, it shall submit a written notification according to form 9 to the Minister of Health, Labour and Welfare, by attaching the operational rules and data concerning the calculation of the fee for product inspections.

- (2) The matters to be provided in operational rules set forth in Article 37, paragraph (2) of the Act shall be as follows:
- (i) Types of product inspections and matters concerning the methods for the implementation and management of the operation of product inspections;
 - (ii) Matters concerning the hours for conducting product inspections and holidays;
 - (iii) Matters concerning the upper time limit for receiving applications for product inspections;
 - (iv) Matters concerning places for conducting product inspections;
 - (v) The fee for each inspection item of product inspections and matters concerning methods for storage;
 - (vi) Matters concerning the appointment and dismissal of persons responsible for departments conducting inspections, persons responsible for inspection categories, inspectors, and persons responsible for departments ensuring

- credibility;
- (vii) Matters concerning the allocation of persons responsible for departments conducting inspections, persons responsible for inspection categories, and inspectors;
 - (viii) Matters concerning the retention of written applications for product inspections and other documents concerning product inspections;
 - (ix) Matters concerning the keeping of financial statements, etc. (meaning financial statements, etc. provided in Article 39, paragraph (1) of the Act; hereinafter the same shall apply in this Article) and the acceptance of requests for the inspection, etc. of financial statements, etc.;
 - (x) In addition to what are listed in the preceding items, matters necessary for the operation of product inspections.
- (3) When a conformity assessment body intends to obtain approval for changes to the operational rules pursuant to the provisions of the second sentence of Article 37, paragraph (1) of the Act, it shall submit a written application according to form 10 to the Minister of Health, Labour and Welfare. In this case, when said changes are accompanied with changes to the amount of the fee for product inspections, data concerning the calculation thereof shall be attached.

Article 43 When a registered conformity assessment body intends to obtain approval for the suspension, in whole or in part, of the operation of product inspections or the abolition of the operation of product inspections pursuant to the provisions of Article 38 of the Act, it shall submit a written application according to form 11 to the Minister of Health, Labour and Welfare.

Article 44 The means specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 39, paragraph (2), item (iii) of the Act shall be the means of indicating the matters recorded on said electromagnetic records on paper or the screen of an input-output device.

Article 45 The electromagnetic means specified by an Ordinance of the Ministry of Health, Labour and Welfare provided in Article 39, paragraph (2), item (iv) of the Act shall be either of those listed in the following items specified by a registered conformity assessment body:

- (i) Means of using an electronic data processing system connecting the computer used by a sender and the computer used by a receiver through a telecommunications line, by which information is sent through said telecommunications line and recorded in a file stored on the computer used by the receiver;
- (ii) Means of delivering information recorded in a file which is prepared in the

form of a magnetic disk or other equivalent means that may record or reliably store certain matters.

Article 46 (1) The matters specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 44 of the Act shall be as follows:

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

Article 47 The identification which the officials are to carry pursuant to the provisions of Article 28, paragraph (2) of the Act which is applied *mutatis mutandis* under Article 47, paragraph (2) of the Act shall conform to form 12.

Chapter VIII Business

Article 48 A person who is deemed to have an equal or greater academic ability than a person who has graduated from a high school or secondary education school under the School Education Act (Act No. 26 of 1947) or a secondary school under the old Secondary School Ordinance (Imperial Ordinance No. 36 of 1943) as provided in Article 48, paragraph (6), item (iv) of the Act shall be as follows:

- (i) A person who has completed the first year of a higher course or special course at a girls' high school under the old Secondary School Ordinance, which requires, as an entrance requirement, graduation from a four-year course of a girls' high school under the same Ordinance, which requires, as an entrance requirement, completion of a primary course at a national elementary school under the Old National Elementary School Ordinance (Imperial Ordinance No. 148 of 1941) (hereinafter referred to as a "national

- elementary school");
- (ii) A person who has completed the first year of a special course at a vocational school under the old Secondary School Ordinance, which requires, as an entrance requirement, graduation from a four-year course of a vocational school under the same Ordinance, which requires, as an entrance requirement, completion of a primary course at a national elementary school;
 - (iii) A person who has completed a preparatory course at a normal school under the old Normal School Education Ordinance (Imperial Ordinance No. 109 of 1943);
 - (iv) A person who has graduated from an attached secondary school or attached girls' high school under the old Normal School Education Ordinance;
 - (v) A person who has completed the third year of a regular course of a normal school under the old Normal School Education Ordinance prior to the revision by the same Ordinance (Imperial Ordinance No. 346 of 1897);
 - (vi) A person who has graduated from a secondary school pursuant to the provisions of Article 2 or Article 5 of the Ordinance of the Ministry of Education No. 63 of 1943 (regulations concerning the entrance into and transfer to other schools of students, pupils, or graduates of schools in regions other than the mainland) or a person who is treated in the same way as a person listed in item (i);
 - (vii) A person who has graduated from a regular course at a boys' school (excluding schools of two-year courses) under the old Boys' School Ordinance (Imperial Ordinance No. 254 of 1939);
 - (viii) A person who has passed examinations under the old Vocational Training School Entrance Examination Regulations (Ordinance of the Ministry of Education No. 22 of 1924) based on the old Vocational Training School Ordinance (Imperial Ordinance No. 61 of 1903), and a person designated by the Minister of Education as having an equal or greater academic ability than graduates of a secondary school or girls' high school with regard to entrance into a vocational training school pursuant to the provisions of Article 11, paragraph (2) of the same Regulations;
 - (ix) A person who has passed examinations under the old Vocational School Graduation Level Examination Regulations (Ordinance of the Ministry of Education No. 30 of 1925);
 - (x) A person who has passed examinations under Article 7 of the old High School Examination Ordinance (Imperial Ordinance No. 15 of 1929);
 - (xi) A person who has a school teacher's license listed in the left hand columns of item (ii), item (iii), item (vi), or item (ix) of the table of Article 1, paragraph (1) of the Act for Enforcement of the School Teacher's License Act (Act No. 148 of 1949), or a person who has a qualification listed in the left hand columns of item (ix), items (xviii) to (xx)-4, item (xxi), or item (xxiii) of

- the table of Article 2, paragraph (1) of the same Act;
- (xii) In addition to what are listed in the preceding items, a person deemed by the Minister of Health, Labour and Welfare to have an equal or greater academic ability than graduates of a high school, secondary education school, or secondary school with regard to qualifications as a food sanitation supervisor.

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

- (i) The name and address of the notifier (for a juridical person, its name, the location of its principal office, and the name of its representative);
 - (ii) The type of food or additives provided 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 contents of the duties of the food sanitation supervisor;
 - (vi) The date for putting the food sanitation supervisor in place or changing the food sanitation supervisor.
- (2) A written notification set forth in the preceding paragraph shall be attached with a resume of the food sanitation supervisor, documents certifying that he/she falls under any of the items of Article 48, paragraph (6) of the Act and documents certifying his/her relations with the business person.

Article 50 The criteria specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 14 of the Order (including cases where it is applied *mutatis mutandis* under Article 9, paragraph (2) of the Order) shall be as follows:

- (i) The training institute shall be a university under the School Education Act or an educational facility that has courses deemed to provide education equivalent to that at universities or graduate schools pursuant to the provisions of Article 68-2, paragraph (4), item (ii) of the same Act;
- (ii) For each curriculum listed in the left hand columns of appended table 14, one or more subjects listed in the right hand columns of the same table shall be taken, and the total credits shall be 22 or more;
- (iii) Subjects listed in the preceding item and subjects listed in appended table 15 shall be taken, and the total credits shall be 40 or more;
- (iv) Classes shall be conducted, in principle, by using the machines and implements listed in column 2 of the appended table of the Act.

Article 51 A written application set forth in Article 15 of the Order (including cases where it is applied *mutatis mutandis* under Article 9, paragraph (2) of

the Order) shall be attached with documents containing the following matters:

- (i) The name and location of the training institute;
- (ii) The name and location of the founder of the training institute, and the date of foundation;
- (iii) The name and address of the head of the training institute;
- (iv) The name and personal history of the teachers, their specialist subjects, and whether they are full-time workers or have other jobs;
- (v) Plans for taking subjects in each year, the number of credits, and whether they are compulsory subjects or optional subjects;
- (vi) Student quotas;
- (vii) Entrance requirements and the season for entrance;
- (viii) Course terms;
- (ix) A list of machines and implements and a library index for teaching and training;
- (x) Drawings and layout of the school site and school buildings;
- (xi) School regulations;
- (xii) Other referential matters.

Article 52 (1) Registration of a training institute under Article 48, paragraph (6), item (iii) of the Act shall be made by entering the following matters in the registry:

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

Article 53 The matters specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 16 of the Order (including cases where it is applied mutatis mutandis under Article 9, paragraph (2) of the Order) shall be what are listed in Article 51, items (i) to (iii), items (v) to (viii), item (ix) (limited to those pertaining to machines and implements listed in column 2 of the appended table of the Act), item (x) and item (xi).

Article 54 A written application set forth in Article 19 of the Order (including cases where it is applied mutatis mutandis under Article 9, paragraph (2) of the Order) shall be attached with documents containing the following matters:

- (i) The reasons for intending to receive rescission of the registration;
- (ii) The planned date to receive rescission of the registration;

(iii) When there are students still in school, measures to be taken for them.

Article 55 The matters specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 20, item (ii) of the Order (including cases where it is applied *mutatis mutandis* under Article 9, paragraph (2) of the Order) shall be those listed in Article 51, item (i).

Article 56 (1) Courses of training sessions set forth in Article 48, paragraph (6), item (iv) of the Act shall conform to all the following requirements:

- (i) Subjects listed in 1. of appended table 16 and subjects listed in any of 2. to 7. of the same table shall be taught, and the number of hours shall be those listed in the same table or more;
 - (ii) Lecturers shall be persons who teach subjects equivalent to those set forth 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 any body of the State, prefecture, city establishing health centers, or special ward, or persons deemed to have equal knowledge and experience as those mentioned above;
 - (iii) Requirements for taking training sessions shall be that a person shall have graduated from a high school or secondary education school under the School Education Act or a secondary school under the old Secondary School Ordinance or fall under those listed in each item of Article 48 and who shall have been engaged in sanitation management of the production or processing of food or additives for two years or more at production or processing businesses for which food sanitation supervisors are required under Article 48, paragraph (1) of the Act;
 - (iv) Examinations shall be held for participants at the end of training sessions.
- (2) Notwithstanding the provisions of item (i) of the preceding paragraph, persons listed in the following items may be exempted from taking subjects provided in said respective items:
- (i) A person who has studied subjects at levels equal to or higher than those listed in 1. of appended table 16 at a university under the School Education Act, university under the old University Ordinance (Imperial Ordinance No. 388 of 1918), or vocational training school under the old Vocational Training School Ordinance - Said subjects;
 - (ii) A person who has completed registered training sessions - For a person who has completed subjects listed in 1. of appended table 16 and subjects listed in 2. or 3. of the same table, practical training on bacteriology listed respectively in 3. or 2. of the same table.

Article 57 A person who intends to apply for registration under Article 21 of the

Order shall submit a written application to the Minister of Health, Labour and Welfare, by attaching a transcript of the certificate of residence (for a juridical person, articles of incorporation or certificates of an act of endowment and registered matters) and documents containing the following matters:

- (i) The name and address of the organizer of the training sessions (for a juridical person, its name, the location of its principal office, and the name of its representative);
- (ii) Whether the person falls under any item of Article 22 of the Order;
- (iii) For a juridical person, the names, addresses, and brief biographical outlines of its officers;
- (iv) The name and location of the site for the training sessions;
- (v) The name and location of the place where practical training is held;
- (vi) The periods and schedules of the training sessions;
- (vii) The number of planned participants;
- (viii) The training subjects and the number of hours;
- (ix) The names and occupations of lecturers, their specialist training subjects, and the number of hours for each of said training subjects.

Article 58 Registration under Article 21 of the Order shall be made by entering the following matters in the registry:

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

Article 59 The criteria specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 24, paragraph (2) of the Order shall be as follows:

- (i) Confirming that the participant meets the requirements for taking training sessions by checking his/her resume, the documents certifying his/her relations with the business entity he/she has worked for, and other necessary documents;
- (ii) Issuing a certificate for the completion of training to the person who has completed the courses of the training sessions;
- (iii) Holding registered training sessions as provided in Article 56.

Article 60 The matters specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 25 of the Order shall be as follows:

- (i) The name and address of the organizer of the registered training sessions (for a juridical person, its name, the location of its principal office, and the

- name of its representative);
- (ii) The period of the registered training sessions.

Article 61 When an organizer of registered training sessions intends to suspend or abolish the operation pertaining to registered training sessions pursuant to the provisions of Article 26 of the Order, he/she shall notify the Minister of Health, Labour and Welfare of the following matters:

- (i) The reasons for the suspension or abolition and the planned date therefor;
- (ii) When intending to suspend the operation, the planned period of time.

Article 62 An organizer of registered training sessions shall prepare the financial statements, etc. (meaning the financial statements, etc. provided in Article 27, paragraph (1) of the Order; hereinafter the same shall apply in this Article) for the previous business year (when three months have not yet elapsed after 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 shall keep them at the office from the time of registration up to the end of the registered training sessions.

Article 63 The provisions of Article 44 shall apply *mutatis mutandis* to the means specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 27, paragraph (2), item (iii) of the Order.

Article 64 The provisions of Article 45 shall apply *mutatis mutandis* to the electromagnetic means specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 27, paragraph (2), item (iv) of the Order.

Article 65 (1) The matters specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 31 of the Order shall be as follows:

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

Article 66 The identification which the officials are to carry pursuant to the provisions of Article 33, paragraph (2) of the Order shall conform to form 13.

Article 67 (1) A person who intends to obtain approval for business pursuant to

the provisions of Article 52, paragraph (1) of the Act shall submit a written application containing the following matters, with drawings showing the structures of business facilities, to the prefectural governor governing the location of his/her business office with regard to businesses requiring the approval of the prefectural governor (for designated cities set forth in Article 252-19, paragraph (1) of the Local Autonomy Act (Act No. 67 of 1947) and core cities set forth in Article 252-22, paragraph (1) of the same Act, the approval of the mayor of said designated city or core city; the same shall apply hereinafter), and to the city mayor or ward mayor governing the location of his/her business office with regard to businesses requiring the approval of the city mayor of a city establishing health centers or ward mayor of a special ward:

- (i) The name, address, and date of birth of the applicant (for a juridical person, its name, the location of its principal office, and the name of its representative);
 - (ii) The location of the business office;
 - (iii) The name, shop name, or trade name of the business office;
 - (iv) The type of business;
 - (v) An outline of the business equipment;
 - (vi) Whether the person falls under any of the items of Article 52, paragraph (2) of the Act, and when he/she falls under any of them, the contents thereof.
- (2) When a person who has obtained approval for business under Article 52, paragraph (1) of the Act (referred to as an "approved business person" in the following Article to Article 71) intends to obtain approval for the same business continuously upon expiration of the valid period of the former approval, he/she shall enter the following matters in a written application, notwithstanding the provisions of each item of the preceding paragraph:
- (i) The matters listed in items (i), (ii), (iv), and (vi) of the preceding paragraph;
 - (ii) The number of approvals for business already obtained and the dates the approvals were granted.

Article 68 (1) A person who intends to notify his/her succession to the status of approved business person through an inheritance pursuant to the provisions of Article 53, paragraph (2) of the Act shall submit a written notification containing the following matters to the prefectural governor governing the location of his/her business office with regard to businesses for which the approval of the prefectural governor has been obtained, and to the city mayor or ward mayor governing the location of his/her business office with regard to businesses for which the approval of the city mayor of a city establishing health centers or ward mayor of a special ward has been obtained:

- (i) The name, address, and date of birth of the notifier and his/her relationship to the decedent;

- (ii) The name and address of the decedent;
 - (iii) The date of the start of the inheritance;
 - (iv) The location of the business office;
 - (v) The type of business;
 - (vi) The number of approvals for business already obtained and the date the approvals were granted.
- (2) A written notification set forth in the preceding paragraph shall have the following documents attached:
- (i) A transcript of the family register;
 - (ii) For a person selected as the successor to the status of approved business person with the consent of all the heirs when there are two or more heirs, the written consent of all those heirs.

Article 69 (1) A person who intends to notify his/her succession to the status of approved business person through a merger pursuant to the provisions of Article 53, paragraph (2) of the Act shall submit a written notification containing the following matters to the prefectural governor governing the location of his/her business office with regard to businesses for which the approval of the prefectural governor has been obtained and to the city mayor or ward mayor governing the location of his/her business office with regard to businesses for which the approval of the city mayor of a city establishing health centers or ward mayor of a special ward has been obtained:

- (i) The name of the notifier, the location of his/her principal office, and the name of his/her representative;
 - (ii) The name of the juridical person extinguished by the merger, the location of its principal office, and the name of its representative;
 - (iii) The date of the merger;
 - (iv) The location of the business office;
 - (v) The type of business;
 - (vi) The number of approvals for business already obtained and the date the approvals were granted.
- (2) A written notification set forth in the preceding paragraph shall have attached certificates of the registered matters of the juridical person surviving the merger or the juridical person established by the merger.

Article 70 (1) A person who intends to notify his/her succession to the status of approved business person through a split pursuant to the provisions of Article 53, paragraph (2) of the Act shall submit a written notification containing the following matters to the prefectural governor governing the location of his/her business office with regard to businesses for which the approval of the prefectural governor has been obtained and to the city mayor or ward mayor

governing the location of his/her business office with regard to businesses for which the approval of the city mayor of a city establishing health centers or ward mayor of a special ward has been obtained:

- (i) The name of the notifier, the location of his/her principal office, and the name of his/her representative;
 - (ii) The name of the juridical person prior to the split, the location of its principal office, and the name of its representative;
 - (iii) The date of the split;
 - (iv) The location of the business office;
 - (v) The type of business;
 - (vi) The number of approvals for business already obtained and the date the approvals were granted.
- (2) A written notification set forth in the preceding paragraph shall be attached with certificates of the registered matters of the juridical person which succeeded to the business through the split.

Article 71 When there are any changes to the matters set forth in Article 67, paragraph (1), item (i), item (iii), or item (v), Article 68, paragraph (1), item (i), Article 69, paragraph (1), item (i) or paragraph (1), item (i) of the preceding Article, an approved business person shall make a notification promptly to the prefectural governor governing the location of his/her business office with regard to businesses for which the approval of the prefectural governor has been obtained and to the city mayor or ward mayor governing the location of his/her business office with regard to businesses for which the approval of the city mayor of a city establishing health centers or ward mayor of a special ward has been obtained.

Chapter IX Miscellaneous Provisions

Article 72 A notification by a physician under Article 58, paragraph (1) of the Act (including cases where it is applied mutatis mutandis under Article 62, paragraph (1) of the Act; the same shall apply hereinafter) shall be made in writing, by phone, or orally within 24 hours, with regard to the following matters:

- (i) The address and name of the physician;
- (ii) The location, name, and age of the poisoned patient, the person who is suspected to have been poisoned, or the person who has died (hereinafter referred to as a "patient, etc.");
- (iii) The causes of the food poisoning (meaning poisoning caused by food, etc.; the same shall apply hereinafter);
- (iv) The date and time that the disease occurred;

- (v) The date and time of the diagnosis or examination.

Article 73 (1) The number of persons poisoned by food, etc. specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 58, paragraph (3) of the Act (including cases where it is applied *mutatis mutandis* under Article 62, paragraph (1) of the Act; the same shall apply hereinafter) shall be 50.

- (2) The cases specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 58, paragraph (3) of the Act shall be as follows:
 - (i) When a fatality has occurred due to said poisoning;
 - (ii) When said poisoning has been caused or is suspected to have been caused by imported food, etc.;
 - (iii) When said poisoning has been caused or is suspected to have been caused by any of the disease agents listed in appended table 17;
 - (iv) When patients, etc. suffering from said poisoning are found in multiple prefectures;
 - (v) When investigations of the causes of said poisoning are difficult in light of the actual situation of said poisoning;
 - (vi) When it is difficult to take countermeasures pursuant to the provisions of Articles 54 to 56 of the Act (hereinafter referred to as "countermeasures") or to judge the appropriateness of the contents thereof in light of the actual situation of said poisoning.

Article 74 The matters specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 37, paragraph (2) of the Order shall be as follows:

- (i) The location of the patients, etc. and the date of notification under Article 58, paragraph (1) of the Act;
- (ii) The number of the patients, etc. and their symptoms;
- (iii) The food, etc. that caused or is suspected to have caused the poisoning (hereinafter referred to as the "food, etc. causing poisoning") and the reasons for identifying it as the cause;
- (iv) The disease agents that caused or are suspected to have caused the poisoning and the reasons for identifying them as the cause;
- (v) The business facilities that caused or are suspected to have caused the poisoning (hereinafter referred to as "facilities causing poisoning") and the reasons for identifying them as the cause;
- (vi) In addition to what are listed in the preceding items, matters deemed important in carrying out investigations of the causes of the poisoning and taking countermeasures.

Article 75 (1) Written Reports under Article 37, paragraph (3) of the Order shall be Written Reports specified in the following items according to the classification of food poisoning cases listed in said respective items:

- (i) Food poisoning cases which prefectural governors, etc. have promptly reported to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 58, paragraph (3) of the Act - A report of the food poisoning case according to form 14 and written details of the food poisoning case;
 - (ii) Food poisoning cases other than those listed in the preceding item - A report of the food poisoning case according to form 14.
- (2) Written details of the food poisoning case provided in item (i) of the preceding paragraph shall contain the following matters:
- (i) The following matters concerning the outline of the occurrence of the food poisoning:
 - (a) The date of occurrence;
 - (b) The place of occurrence;
 - (c) The number of persons who have consumed food, etc. causing poisoning;
 - (d) The number of the dead;
 - (e) The number of patients;
 - (f) The food, etc. causing poisoning;
 - (g) The disease agents.
 - (ii) Matters concerning the gathering of information on the occurrence of the food poisoning;
 - (iii) The following matters concerning the situation of the patients and the dead:
 - (a) The number of patients and the dead by gender and age;
 - (b) The number of patients and the dead by date and time;
 - (c) The ratio of patients and the dead among those who have consumed the food, etc. causing poisoning;
 - (d) The time taken for the disease to develop from the time the patients and the dead consumed the food, etc. causing poisoning;
 - (e) The symptoms of the patients and the dead and their number by symptom;
 - (iv) The following matters concerning the food, etc. causing poisoning and its contamination routes:
 - (a) The process of identifying the food, etc. causing poisoning and the reasons for identifying it as the cause;
 - (b) The contamination routes of the food, etc. causing poisoning;
 - (v) Matters concerning facilities causing poisoning:
 - (a) The situation of water supply and drainage and other sanitary conditions at facilities causing poisoning;

- (b) The health conditions of workers at facilities causing poisoning;
- (vi) Matters concerning disease agents:
 - (a) The results of microbiological investigations, physicochemical investigations, or investigations using animals;
 - (b) The process of identifying the disease agents and the reasons for identifying them as the cause of the disease;
- (vii) Countermeasures and other measures taken by prefectural governors, etc.

Article 76 (1) Written Reports under Article 37, paragraph (4) of the Order shall be Written Reports specified in the following items according to the classification of food poisoning cases listed in said respective items:

- (i) Food poisoning cases which prefectural governors, etc. have reported promptly to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 58, paragraph (3) of the Act - A report on the investigation results of the food poisoning case and written details of thereof;
 - (ii) Food poisoning cases other than those listed in the preceding item - A report on the investigation results of the food poisoning case.
- (2) A report on the investigation results of the food poisoning case set forth in each item of the preceding paragraph shall be prepared according to form 15.
- (3) A report on the investigation results of the food poisoning case set forth in each item of paragraph (1) shall be submitted monthly by the 10th of the following month, by attaching all Written Reports of food poisoning cases set forth in each item of paragraph (1) of the preceding Article which were accepted in said month.
- (4) Written details of the investigation results of the food poisoning case set forth in paragraph (1), item (i) shall be prepared by entering the matters listed in each item of paragraph (2) of the preceding Article.
- (5) Written details of the investigation results of the food poisoning case set forth in paragraph (1), item (i) shall be prepared and submitted promptly after receiving written details of the food poisoning case set forth in paragraph (1), item (i) of the preceding Article pursuant to the provisions of Article 37, paragraph (3) of the Order.

Article 77 The number of persons poisoned by food, etc. specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 60 of the Act shall be 500.

Article 78 The toys provided in Article 62, paragraph (1) of the Act shall be as follows:

- (i) Toys made of paper, wood, bamboo, rubber, leather, celluloid, synthetic resins, metals, or ceramics, which are used by infants principally by putting

- them in their mouth;
- (ii) Ground cherries;
- (iii) Transfer pictures, origami, and building blocks;
- (iv) The following toys made of rubber, synthetic resins, or metals:
 - Okiagari (daruma doll made so as to right itself when knocked over), masks, rattles, toy phones, toy animals, dolls, clay, toy vehicles (excluding those clockwork-driven and electrically-driven), balloons, blocks, balls, toys for playing house.

Article 79 (1) The following authority of the Minister of Health, Labour and Welfare shall be delegated to the directors of the Local Bureaus of Health and Welfare, pursuant to the provisions of Article 70, paragraph (1) of the Act and Article 41, paragraph (1) of the Order; provided, however, that it shall not prevent the Minister of Health, Labour and Welfare from personally exercising the authority listed in item (vi) (limited to the authority pertaining to Article 18 of the Order (including cases where it is applied *mutatis mutandis* under Article 9, paragraph (2) of the Order)):

- (i) The authority provided in Article 41 of the Act;
 - (ii) The authority provided in Article 42 of the Act;
 - (iii) The authority provided in Article 46, paragraph (2) of the Act;
 - (iv) The authority provided in Article 47, paragraph (1) of the Act;
 - (v) The authority provided in Article 48, paragraph (6), item (iii) of the Act;
 - (vi) The authority provided in Articles 15 to 19 of the Order (including cases where these provisions are applied *mutatis mutandis* under Article 9, paragraph (2) of the Order);
 - (vii) The authority provided in Article 28 of the Order;
 - (viii) The authority provided in Article 29 of the Order;
 - (ix) The authority provided in Article 32 of the Order;
 - (x) The authority provided in Article 33 of the Order.
- (2) The authority listed in items (v) and (vi) of the preceding paragraph shall be delegated to the chiefs of the Local Welfare Bureau Branches, pursuant to the provisions of Article 70, paragraph (2) of the Act and Article 41, paragraph (2) of the Order; provided, however, that it shall not prevent the directors of the Local Bureaus of Health and Welfare from personally exercising said authority.

Appended Table 1 (Re: Art. 12 and Art. 21)

1. Zinc Salts (limited to Zinc Gluconate and Zinc Sulfate)
2. Sodium Chlorite
3. Nitrous Oxide
4. Adipic Acid
5. Sodium Nitrite
6. L-Ascorbic Acid (Vitamin C)

7. L-Ascorbic Acid 2-Glucoside
8. L-Ascorbic Stearate (Vitamin C Stearate)
9. Sodium L-Ascorbate (Vitamin C Sodium)
10. L-Ascorbyl Palminate (Vitamin C Palminate)
11. Monosodium L-Aspartate
12. Aspartame (L-alpha-Aspartyl-L-Phenylalanine-Methyl Ester)
13. Acesulfame Potassium (Acesulfame K)
14. Acetaldehyde
15. Ethyl Acetoacetate
16. Acetophenone
17. Acetone
18. Anisaldehyde (p-Methoxybenzaldehyde)
19. Amyl alcohol
20. alpha-Amylcinnamaldehyde (alpha-Amylcinnamic Aldehyde)
21. DL-Alanine
22. Sodium Sulfite (Disodium Sulfite)
23. L-Arginine L-Glutamate
24. Ammonium Alginate
25. Potassium Alginate
26. Calcium Alginate
27. Sodium Alginate
28. Propylene Glycol Alginate
29. Benzoic Acid
30. Sodium Benzoate
31. Methyl Anthranilate
32. Ammonia
33. Ionone
34. Ion Exchange Resin
35. Isoamyl alcohol
36. Isoeugenol
37. Isoamyl Isovalerate
38. Ethyl Isovalerate
39. Isothiocyanate (excluding substances generally accepted as highly toxic)
40. Allyl Isothiocyanate (Volatile Oil of Mustard)
41. Isobutanol
42. Isopropanol
43. L-Isoleucine
44. Disodium 5' -Inosinate (Sodium 5' -Inosinate)
45. Imazalil
46. Indole and derivatives thereof
47. Disodium 5' -Uridilate (Sodium 5' -Uridilate)
48. gamma-Undecalactone (Undecalactone)
49. Ester Gum
50. Esters
51. Mixture of 2-Ethyl-3, 5-Dimethylpyrazine and 2-Ethyl-3, 6-Dimethylpyrazine
52. Ethylvanillin
53. 2-Ethyl-3-Methylpyrazine
54. Calcium Disodium Ethylenediaminetetraacetate (Calcium Disodium EDTA)

55. Disodium Ethylenediaminetetraacetate (Disodium EDTA)
56. Ethers
57. Erythorbic Acid (Isoascorbic Acid)
58. Sodium Erythorbate (Sodium Isoascorbate)
59. Ergocalciferol (Vitamin D2)
60. Ammonium Chloride
61. Potassium Chloride
62. Calcium Chloride
63. Ferric Chloride
64. Magnesium Chloride
65. Hydrochloric Acid
66. Eugenol
67. Octanal (Octyl Aldehyde, Caprylic Aldehyde)
68. Ethyl Octanoate (Ethyl Caprylate)
69. o-Phenylphenol and Sodium o-Phenylphenate
70. Sodium Oleate
71. Hydrogen Peroxide
72. Benzoyl Peroxide
73. Sodium Caseinate
74. Ammonium Persulfate
75. Calcium Carboxymethylcellulose (Calcium Cellulose Glycolate)
76. Sodium Carboxymethylcellulose (Sodium Cellulose Glycolate)
77. beta-Carotene
78. Isoamyl Formate
79. Geranyl Formate
80. Citrinellyl Formate
81. Xylitol
82. Disodium 5' -Guanylate (Disodium Guanosine 5'-Monophosphate)
83. Citric Acid
84. Isopropyl Citrate
85. Potassium Dihydrogen Citrate, Tripotassium Citrate
86. Calcium Citrate
87. Sodium Ferrous Citrate
88. Ferric Citrate
89. Ferric Ammonium Citrate
90. Trisodium Citrate
91. Glycine
92. Glycerol (Glycerine)
93. Glycerol Esters of Fatty Acids
94. Calcium Glycerophosphate
95. Disodium Glycyrrhizinate
96. Glucono-delta-Lactone (Gluconolactone)
97. Gluconic Acid
98. Potassium Gluconate
99. Calcium Gluconate
100. Ferrous Gluconate (Iron (II) Di-D-Gluconate Dihydrate)
101. Sodium Gluconate
102. L-Glutamic Acid
103. Monopotassium L-Glutamate
104. Monocalcium Di- L-Glutamate

105. Monosodium L-Glutamate
106. Monomagnesium Di- L-Glutamate
107. Cinnamic Acid
108. Ethyl Cinnamate
109. Methyl Cinnamate
110. Ketone
111. Geraniol
112. High-Test Hypochlorite
113. Succinic Acid
114. Monosodium Succinate
115. Disodium Succinate
116. Cholecalciferol (Vitamin D3)
117. Sodium Chondroitin Sulfate
118. Isoamyl Acetate
119. Ethyl Acetate
120. Geranyl Acetate
121. Cyclohexyl Acetate
122. Citronellyl Acetate
123. Cinnamyl Acetate
124. Terpinyl Acetate
125. Sodium Acetate
126. Polyvinyl Acetate
127. Phenethyl Acetate (2-Phenethyl Acetate)
128. Butyl Acetate
129. Benzyl Acetate
130. l-Menthyl Acetate (p-Menthan-3-yl Acetate)
131. Linalyl Acetate
132. Saccharin
133. Sodium Saccharin (Soluble Saccharin)
134. Methyl Salicylate
135. Magnesium Oxide
136. Iron Sesquioxide (Anhydrous Ferric Oxide or Anhydrous iron (III) Oxide)
137. Hypochlorous acid water
138. Sodium Hypochlorite
139. Sodium Hydrosulfite
140. Allyl Cyclohexylpropionate
141. L-Cysteine Monohydrochloride
142. Disodium 5' -Cytidylate
143. Cytral
144. Cytronellal
145. Cytronellol
146. 1, 8-Cineole (Eucalyptol)
147. Diphenyl (Phenylbenzene)
148. Butylated Hydroxytoluene
149. Dibenzoyl Thiamine
150. Dibenzoyl Thiamine Hydrochloride
151. Fatty Acids
152. Aliphatic Higher Alcohols
153. Aliphatic Higher Aldehydes (excluding substances generally accepted as highly toxic)

154. Aliphatic Higher Hydrocarbons (excluding substances generally accepted as highly toxic)
155. Oxalic Acid
156. Potassium Bromate
157. DL-Tartaric Acid (2, 3-Dihydroxysuccinic Acid)
158. L- Tartaric Acid (2, 3-Dihydroxybutanedioic Acid)
159. Potassium DL-Bitartrate
160. Potassium L-Bitartrate
161. Disodium DL-Tartrate (Sodium dl-Tartrate)
162. Disodium L-Tartrate (Sodium Dextro-tartrate)
163. Potassium Nitrate
164. Sodium Nitrate
165. Food Red No. 2 (Amaranth) and Food Red No. 2 Aluminium Lake
166. Food Red No. 3 (Erythrosine) and Food Red No. 3 Aluminium Lake
167. Food Red No. 40 (Allura Red AC) and Food Red No. 40 Aluminium Lake
168. Food Red No. 102 (New Coccine)
169. Food Red No. 104 (Phloxine)
170. Food Red No. 105 (Rose Bengal)
171. Food Red No. 106 (Acid Red 52, C.I. 45100)
172. Food Yellow No. 4 (Tartrazine) and Food Yellow No. 4 Aluminium Lake
173. Food Yellow No. 5 (Sunset Yellow FCF) and Food Yellow No. 5 Aluminium Lake
174. Food Green No. 3 (Fast Green FCF) and Food Green No. 3 Aluminium Lake
175. Food Blue No. 1 (Brilliant Blue FCF) and Food Blue No. 1 Aluminium Lake
176. Food Blue No. 2 (Indigo Carmine) and Food Blue No. 2 Aluminium Lake
177. Sucrose Esters of Fatty Acids
178. Silicone Resin (Polydimethylsiloxane)
179. Cinnamyl Alcohol (Cinnamic Alcohol)
180. Cinnamaldehyde (Cinnamic Aldehyde)
181. Potassium Hydroxide (Potassium Hydrate)
182. Calcium Hydroxide (Slaked Lime)
183. Sodium Hydroxide (Sodium Hydrate)
184. Sucralose (4, 1' , 6' -Trichlorogalactosucrose)
185. Calcium Stearate
186. Magnesium Stearate
187. Calcium Stearoyl Lactylate (Calcium Stearoyl Lactate)
188. Sorbitan Esters of Fatty Acids
189. D-Sorbitol (Sorbit)
190. Sorbic Acid
191. Potassium Sorbate
192. Ammonium Carbonate
193. Potassium Carbonate, Anhydrous
194. Calcium Carbonate
195. Ammonium Bicarbonate (Ammonium Bicarbonate)
196. Sodium Bicarbonate (Sodium Acid Carbonate, Baking Soda or Sodium Bicarbonate)
197. Sodium Carbonate (crystal: Carbonate of Soda, anhydrous; Soda Ash)
198. Magnesium Carbonate

199. Tiabendazole
200. Thiamine Hydrochloride (Vitamin B1 Hydrochloride)
201. Thiamine Mononitrate (Vitamin B1 Mononitrate)
202. Thiamine Dicetylsulfate (Vitamin B1 Dicetylsulfate)
203. Thiamine Thiocyanate (Vitamin B1 Rodanate)
204. Thiamine Naphthalene-1, 5-Disulfonate (Thiamine Naphthalene-1, 5-Disulfonate or Vitamin B1-1, 5-Disulfonate)
205. Thiamine Dilaurylsulfate (Vitamin B1 Dilaurylsulfate)
206. Thioethers (excluding substances generally accepted as highly toxic)
207. Thiols (Thioalcohols) (excluding substances generally accepted as highly toxic)
208. L-Theanine
209. Decanal (Decyl Aldehyde)
210. Decanol (Decyl Alcohol)
211. Ethyl Decanoate (Ethyl Caprate)
212. Sodium Iron Chlorophyllin
213. 2, 3, 5,6-Tetramethylpyrazine
214. Sodium Dehydroacetate
215. Terpeneol
216. Terpene Hydrocarbon
217. Sodium Carboxymethylstarch
218. Sodium Starch Phosphate
219. Copper Salts (limited to Copper Gluconate and Copric Sulfate)
220. Sodium Copper Chlorophyllin
221. Copper Chlorophyll
222. dl-alpha-Tocopherol
223. all-rac-alpha-Tocopheryl Acetate
224. d-alpha-Tocopheryl Acetate
225. DL-Tryptophan
226. L-Tryptophan
227. 2, 3, 5-Trimethylpyrazine
228. DL-Threonine (DL-Threonine)
229. L-Threonine
230. Natamycin (Pimaricin)
231. Sodium Methoxide (Sodium Methylate)
232. Nicotinic Acid (Niacin)
233. Nicotinamide (Niacinamide)
234. Sulfur Dioxide
235. Chlorine Dioxide
236. Silicon Dioxide
237. Carbon Dioxide
238. Titanium Dioxide
239. Lactic Acid
240. Calcium Lactate
241. Iron Lactate
242. Sodium Lactate
243. gamma-Nonalactone (4-Nonanolide)
244. Potassium Norbixin
245. Sodium Norbixin
246. Vanillin

- 247. Isobutyl p-Hydroxybenzoate
- 248. Isopropyl p-Hydroxybenzoate
- 249. Isopropyl p-Hydroxybenzoate
- 250. Butyl p-Hydroxybenzoate
- 251. Propyl p-Hydroxybenzoate
- 252. p-Methylacetophenone
- 253. L-Valine
- 254. Calcium Pantothenate
- 255. Sodium Pantothenate
- 256. Biotin
- 257. L-Histidine Monohydrochloride
- 258. Bisbentiamine
- 259. Vitamin A (Retinol)
- 260. Vitamin A Fatty Acid Ester
- 261. Hydroxycitronellal
- 262. Hydroxycitronellal Dimethyl Acetal
- 263. Hydroxypropyl Cellulose
- 264. Hydroxypropylmethyl Cellulose
- 265. Piperonal (Heliotropin)
- 266. Piperonyl Butoxide (Piperonyl Butoxide)
- 267. Glacial Acetic Acid
- 268. Pyridoxine Hydrochloride (Vitamin B6)
- 269. Potassium Pyrosulfite (Potassium Pentaoxodisulfate or Potassium Metabisulfite)
- 270. Disodium Pyrosulfite (Disodium Pentaoxadisulfite, Sodium Metabisulfite or Sodium Disulfite)
- 271. Potassium Pyrophosphate
- 272. Calcium Dihydrogen Pyrophosphate (Acid Calcium Pyrophosphate)
- 273. Disodium Dihydrogen Pyrophosphate (Acid Sodium Pyrophosphate)
- 274. Ferric Pyrophosphate
- 275. Sodium Pyrophosphate
- 276. L-Phenylalanine
- 277. Isoamyl Phenylacetate
- 278. Isobutyl Phenylacetate
- 279. Ethyl Phenylacetate
- 280. Phenol Ethers (excluding substances generally accepted as highly toxic)
- 281. Phenols (excluding substances generally accepted as highly toxic)
- 282. Ferrocyanides (limited to Potassium Ferrocyanide (Potassium Hexacyanoferrate (II)), Calcium Ferrocyanide (Calcium Hexacyanoferrate (II)) and Sodium Ferrocyanide (Sodium Hexacyanoferrate (II)))
- 283. Butanol
- 284. Butylated Hydroxyanisole
- 285. Fumaric Acid
- 286. Monosodium Fumarate (Sodium Fumarate)
- 287. Furfural and derivatives thereof (excluding substances generally accepted as highly toxic)
- 288. Propanol
- 289. Propionic Acid
- 290. Isoamyl Propionate
- 291. Ethyl Propionate

- 292. Calcium Propionate
- 293. Sodium Propionate
- 294. Benxyl Propionate
- 295. Propylene Glycol
- 296. Propylene Glycol Esters of Fatty Acids
- 297. Hexanoic Acid (Caproic Acid)
- 298. Allyl Hexanoate (Allyl Caproate)
- 299. Ethyl Hexanoate (Ethyl Caproate)
- 300. Ethyl Heptanoate (Ethyl Oenanthate)
- 301. l-Perillaldehyde
- 302. Benzyl Alcohol
- 303. Benzaldehyde
- 304. Aromatic Alcohols
- 305. Aromatic Aldehydes (excluding substances generally accepted as highly toxic)
- 306. Propyl Gallate
- 307. Sodium Polyacrylate
- 308. Polyisobutylene (Butyl Rubber)
- 309. Polyvinylpyrrolidone
- 310. Polybutene (Polybutylene)
- 311. Potassium Polyphosphate
- 312. Sodium Polyphosphate
- 313. d-Borneol
- 314. Maltol
- 315. D- Mannitol (D-Mannite)
- 316. Potassium Metaphosphate
- 317. Sodium Metaphosphate
- 318. DL-Methionine
- 319. L-Methionine
- 320. Methyl N-Methylanthranilate
- 321. 5-Methylquinoxaline
- 322. Methylcellulose
- 323. Methyl beta-Naphthyl Ketone
- 324. Methyl Hesperidin (Soluble Vitamin P)
- 325. dl-Menthol
- 326. l-Menthol
- 327. Morpholine Salts of Fatty Acids
- 328. Folic Acid
- 329. Butyric Acid
- 330. Isoamyl Butyrate
- 331. Ethyl Butyrate
- 332. Cyclohexyl Butyrate
- 333. Butyl Butyrate
- 334. Lactones (excluding substances generally accepted as highly toxic)
- 335. L-Lysine L-Aspartate
- 336. L-Lysine Monohydrochloride
- 337. L-Lysine L-Glutamate
- 338. Linalool
- 339. Calcium 5' -Ribonucleotide
- 340. Disodium 5' -Ribonucleotide (Sodium 5' -Ribo-nucleotide)

341. Riboflavin (Vitamin B2)
342. Riboflavin Tetrabutyrate (Vitamin B2 Tetrabutyrate)
343. Riboflavin 5' -Phosphate Sodium (Sodium Riboflavin Phosphate, Sodium Vitamin B2 Phosphate)
344. Sulfuric Acid
345. Aluminium Ammonium Sulfate (crystal: Ammonium Alum, exsiccated: Ammonium Alum, Exsiccated)
346. Aluminium Potassium Sulfate (crystal: Alum, Potassium Alum, exsiccated: Alum, Exsiccated)
347. Ammonium Sulfate
348. Calcium Sulfate
349. Ferrous Sulfate
350. Sodium Sulfate
351. Magnesium Sulfate
352. DL-Malic Acid (dl-Malic Acid)
353. Sodium DL-Malate (Sodium dl-Malate)
354. Phosphoric Acid
355. Tripotassium Phosphate (Tripotassium Monophosphate)
356. Tricalcium Phosphate (Calcium Phosphate Tribasic)
357. Trimagnesium Phosphate (Magnesium Phosphate, Tribasic)
358. Diammonium Hydrogen Phosphate (Diammonium Hydrogen Tetraoxophosphate)
359. Ammonium Dihydrogen Phosphate (Ammonium Dihydrogen Tetraoxophosphate)
360. Dipotassium Hydrogen Phosphate (Dipotassium Hydrogen Monophosphate)
361. Potassium Dihydrogen Phosphate (Monopotassium Dihydrogen Monophosphate)
362. Calcium Hydrogen Phosphate (Secondary Calcium Phosphate)
363. Calcium Dihydrogen Phosphate (Monocalcium Phosphate)
364. Disodium Hydrogen Phosphate (Disodium Hydrogen Monophosphate)
365. Sodium Dihydrogen Phosphate (Monosodium Dihydrogen Monophosphate)
366. Trisodium Phosphate (Trisodium Monophosphate)

Appended Table 2 (Re: Article 13)

Category of food	Substances which may cause food sanitation hazards
Carbonated drinks	<ol style="list-style-type: none"> 1. Foreign contaminants 2. Yersinia enterocolitica 3. Staphylococcus aureus 4. Campylobacter jejuni 5. Campylobacter coli 6. Clostridium genus

7. Antimicrobial substances (limited to chemically synthesized compounds (meaning substances obtained by causing a chemical reaction other than a degradation reaction to elements or compounds by chemical means; the same shall apply hereinafter) contained in milk, etc. used as raw materials (meaning milk, etc. specified by a Ministerial Ordinance concerning the ingredient standards for milk and dairy products; hereinafter the same shall apply in this table) or in processed products thereof)
8. Antibiotics
9. Bactericides
10. Salmonellae genus
11. Heavy metals and compounds thereof (limited to heavy metals and compounds thereof for which standards have been established with regard to food ingredients pursuant to the provisions of Article 11, paragraph 1 of the Act and which are contained in raw materials; hereinafter the same shall apply in this table)
12. Bacillus cereus
13. Detergents
14. Food additives (limited to food additives for which standards have been established with regard to usage pursuant to the provisions of Article 11, paragraph 1 of the Act and excluding bactericides; hereinafter the same shall apply in this table)
15. Substances which are ingredients of anti-parasite medicine (including those chemically generated from such substances, excluding those specified as clearly having no risk to human health pursuant to the provisions of Article 11, paragraph 3 of the Act, and limited to those contained in raw materials; hereinafter the same shall apply in this table)
16. Substances which are ingredients of agricultural chemicals (including those chemically generated from such substances, excluding those specified as clearly having no risk to human health pursuant to the provisions of Article 11, paragraph 3 of the Act, and limited to those contained in raw materials; hereinafter the same shall apply in this table)
17. Enteropathogenic Escherichia coli
18. Putrefactive microbe (bacteria)

	19. <i>Listeria monocytogenes</i>
Processed meat products	1. Aflatoxin (limited to aflatoxin contained in spices used as raw materials; hereinafter the same shall apply in this table) 2. Foreign contaminants 3. <i>Staphylococcus aureus</i> 4. <i>Campylobacter jejuni</i> 5. <i>Campylobacter coli</i> 6. <i>Clostridium</i> genes 7. Antimicrobial substances (limited to chemically synthesized compounds contained in milk, etc., meat, poultry eggs or fish and seafood used as raw materials or in processed products thereof; hereinafter the same shall apply in this table) 8. Antibiotics 9. Bactericides 10. <i>Salmonellae</i> genus 11. <i>Bacillus cereus</i> 12. Detergents 13. <i>Trichina</i> worm 14. <i>Vibrio parahaemolyticus</i> (limited to <i>vibrio parahaemolyticus</i> contained in fish and seafood or whale meat used as raw materials or in processed products thereof; hereinafter the same shall apply in this table) 15. Food additives 16. Substances which are ingredients of anti-parasite medicine 17. Enteropathogenic <i>Escherichia coli</i> 18. Putrefactive microbe (bacteria) 19. Substances which are ingredients of hormones (including those chemically generated from such substances, excluding those specified as clearly having no risk to human health pursuant to the provisions of Article 11, paragraph 3 of the Act, and limited to those contained in raw materials; hereinafter the same shall apply in this table)
Fish jelly products	1. Anisaks 2. Aflatoxin 3. Foreign contaminants 4. <i>Staphylococcus aureus</i> 5. <i>Clostridium</i> genus 6. Bactericides 7. <i>Salmonellae</i> genus 8. <i>Pseudoterranova</i> 9. <i>Bacillus cereus</i> 10. Detergents 11. <i>Diplogonoporous grandis</i>

	12. <i>Vibrio parahaemolyticus</i> 13. Foods additives 14. Histamine (limited to histamine contained in fish and seafood used as raw materials or in processed products thereof; hereinafter the same shall apply in this table) 15. Enteropathogenic <i>Escherichia coli</i> 16. Putrefactive microbe (bacteria)
Retort pouch food	1. Aflatoxin 2. Foreign contaminants 3. <i>Staphylococcus aureus</i> 4. <i>Clostridium</i> genus 5. Diarrheal and paralytic shellfish poison (limited to diarrheal and paralytic shellfish poison contained in shellfish used as raw materials or in processed products thereof) 6. Antimicrobial substances 7. Antibiotics 8. Bactericides 9. Heavy metals and compounds thereof 10. <i>Bacillus cereus</i> 11. Detergents 12. Food additives 13. Substances which are ingredients of anti-parasite medicine 14. Substances which are ingredients of agricultural chemicals 15. Histamine 16. Putrefactive microbes (bacteria) 17. Substances which are ingredients of hormones

Appended Table 3 (Re: Article 21)

1. Margarine
2. Alcoholic liquor (meaning alcoholic liquor which contains 1% or more alcohol by volume (including drinking products in powder form which contain 1% or more alcohol by volume when dissolved))
3. Carbonated drinks
4. Processed meat products
5. Fish meat ham, fish meat sausage, whale meat bacon, and the like
6. Pulses which contain cyanide compounds
7. Frozen food (meaning produced or processed food (excluding carbonated drinks, processed meat products, whale meat products, fish jelly products, boiled octopus and boiled crabs) and cut or shelled fresh fish and seafood (excluding raw oysters) which are frozen and packed in containers and packaging.)
8. Irradiated food
9. Retort pouch food
10. Poultry eggs

11. Food packed in containers and packaging (excluding those listed in the preceding items) which are listed below:

(a) Processed meat, raw oysters, fresh noodles (including boiled noodles), instant noodles, ready-made lunches, prepared bread, daily dish, fish jelly products, moist confectioneries, cut or shelled fresh fish and seafood (excluding raw oysters) (excluding those frozen), and boiled crabs.

(b) Processed food other than those listed in (a)

(c) Citrus fruits, banana

12. Food of farm products listed in the left hand columns of appended table 7, and processed food made from such food (including any food made from said processed food)

13. Food for special dietary use

14. Food additives

Appended Table 4 (Re: Article 21)

Isothocyanates

Indole and Derivatives thereof

Ethers

Esters

Ketones

Fatty Acids

Aliphatic Higher Alcohols

Aliphatic Higher Aldehydes

Aliphatic Higher Hydrocarbons

Thioethers

Thiols

Terpene Hydrocarbons

Phenol Ethers

Phenols

Furfural and Derivatives thereof

Aromatic Alcohols

Aromatic Aldehydes

Lactones

Appended Table 5 (Re: Article 21)

1	Sweetener	Sweetener, artificial sweetener, or synthetic sweeteners
2	Food color	Food coloring or artificial coloring
3	Preservative	Preservative or artificial preservative
4	Thickening agent, stabilizer, gelling agent or thickener	Thickening agent or thickener, where the substance is used mainly for thickening Stabilizer or thickener, where the substance is used mainly for stabilizing

		Gelling agent or thickener, where the substance is used mainly for gelling
5	Antioxidant	Antioxidant
6	Color fixative	Color fixative
7	Bleaching agent	Bleaching agent
8	Antimold agent	Antimold agent

Appended Table 6 (Re: Article 21)

Wheat
Buckwheat
Eggs
Milk
Peanuts

Appended Table 7 (Re: Article 21)

Farm products	Processed Food
Soybeans (including immature soybeans and bean sprout)	<ol style="list-style-type: none"> 1. Tofu (soybean curd) and Aburaage (fried soybean curd) 2. Kooridofu (frozen soybean curd), Okara (dried Tofu refuse) and Yuba (dried soybean milk membrane) 3. Natto (fermented soybeans) 4. Soybean milk 5. Miso (fermented soybean paste) 6. Soybean Nimame (cooked soybeans) 7. Canned soybeans and bottled soybeans 8. Kinako (roasted soybean flour) 9. Roasted soybeans 10. Food made mainly from ingredients listed in item 1 to item 9 11. Food made mainly from soybean for cooking 12. Food made mainly from soybean flour 13. Food made mainly from soybean protein 14. Food made mainly from immature soybean 15. Food made mainly from soybean sprouts
Corn	<ol style="list-style-type: none"> 1. Corn snack confectionery 2. Corn starch 3. Popcorn 4. Frozen corn 5. Canned corn and bottled corn 6. Food made mainly from corn flour 7. Food made mainly from corn grits (excluding corn flakes) 8. Food made mainly from corn for cooking 9. Food made mainly from ingredients listed in item 1 to item 5
Potato	<ol style="list-style-type: none"> 1. Potato snack confectionery

	2. Dried potato 3. Frozen potato 4. Potato starch 5. Food made mainly from potato for cooking 6. Food made mainly from ingredients listed in item 1 to item 4
Rapeseed	
Cottonseed	
Alfalfa	Food made mainly from alfalfa
Sugar beet	Food made mainly from sugar beet for cooking

Appended Table 8 (Re: Article 21)

Yeast food	Yeast food
Gum base	Gum base
Kansui (Alkaline preparations for Chinese noodles)	Kansui
Enzyme	Enzyme
Glazing agent	Glazing agent
Flavoring agent	Flavoring agent or synthetic flavoring agent
Acidifier	Acidifier
Softener for chewing gum	Softener
Seasoning (excluding seasoning falling under sweeteners or acidifiers)	<p>Seasoning (Amino acid), where the substance is composed exclusively of amino acids</p> <p>Seasoning (Amino acid, etc.), where the substance is composed mainly of amino acids (excluding the case where the substance is composed exclusively of amino acids)</p> <p>Seasoning (Nucleic acid), where the substance is composed exclusively of nucleic acids</p> <p>Seasoning (Nucleic acid, etc.), where the substance is composed mainly of nucleic acid (excluding the case where the substance is composed exclusively of nucleic acid)</p> <p>Seasoning (Organic acids), where the substance is composed exclusively of organic acids</p> <p>Seasoning (Organic acids, etc.), where the substance is composed mainly of organic acids (excluding the case where the substance is composed exclusively of organic acids)</p> <p>Seasoning (Inorganic salts), where the substance is composed exclusively of inorganic salts</p> <p>Seasoning (Inorganic salts, etc.), where the substance is composed mainly of inorganic salts (excluding the case where the substance is composed exclusively of inorganic salts)</p>
Coagulant for Tofu (soybean curd)	Coagulant for Tofu or coagulant

Bittering agent	Bittering agent
Emulsifier	Emulsifier
Acidity regulator	Acidity regulator
Raising agent	Raising agent, baking powder, or baking soda

Appended Table 9 (Re: Article 21)

Raw fruit juice (limited to products contained in cans with a capacity of 200 liters or more)	When a delivery unit consisting of 10 cans or more is sold to a person licensed for a carbonated drink producing business as prescribed in Article 35, item (xix) of the Order for Enforcement of the Food Sanitation Act
Concentrated coffee solution (limited to products contained in cans with a capacity of 20 liters or more)	When a delivery unit consisting of 20 cans or more is sold to a person licensed for a carbonated drink producing business as prescribed in Article 35, item (xix) of the Order for Enforcement of the Food Sanitation Act
Raw fish meat Surimi (limited to products contained in containers and packaging with a capacity of 20 kilograms or more)	When a delivery unit consisting of 10 or more of said containers and packaging is sold to a person licensed for a fish jelly product producing business as prescribed in Article 35, item (xvi) of the Order for Enforcement of the Food Sanitation Act or for a daily dish producing business as prescribed in Article 35, item (xxxii) of the Order for Enforcement of the Food Sanitation Act

Appended Table 10 (Re: Article 32)

Raw salt
 Copra
 Fat or oil of animal origin or plant origin which are used in the production of edible fat and oil
 Raw sugar
 Crude alcohol
 Molasses
 Malt
 Hops

Appended Table 11 (Re: Article 32)

Places for customs clearance	Names of quarantine stations
Hokkaido	Otaru
Aomori Pref., Iwate Pref., Akita Pref., Yamagata Pref., and Fukushima Pref.	Sendai

Chiba Pref. (limited to Narita City; Taiei-machi, Katori-gun; Tako-machi, Katori-gun; and Shibayama-machi, Sanbu-gun)	Narita Airport
Ibaraki Pref., Tochigi Pref., Gunma Pref., Saitama Pref., Chiba Pref. (excluding areas under the jurisdiction of the Narita Airport Quarantine Station), Metropolis of Tokyo, Kanagawa Pref. (limited to Kawasaki City), Yamanashi Pref., and Nagano Pref.	Tokyo
Kanagawa Pref. (excluding areas under the jurisdiction of the Tokyo Quarantine Station)	Yokohama
Niigata Pref.	Niigata
Shizuoka Pref., Gifu Pref., Aichi Pref., Mie Pref., Wakayama Pref. (confined to Singu City and Higashimuro-gun)	Nagoya
Toyama Pref., Ishikawa Pref., Fukui Pref., Shiga Pref., Kyoto Pref., Osaka Pref. (excluding areas under the jurisdiction of the Kansai Airport Quarantine Station), Nara Pref., and Wakayama Pref. (excluding areas under the jurisdiction of the Nagoya Quarantine Station)	Osaka
Osaka Pref. (limited to the Kansai International Airport)	Kansai Airport
Hyogo Pref., Okayama Pref., Tokushima Pref., and Kagawa Pref.	Kobe
Tottori Pref., Shimane Pref., Hiroshima Pref., Ehime Pref., and Kochi Pref.	Hiroshima
Yamaguchi Pref., Fukuoka Pref., Saga Pref., Nagasaki Pref., Kumamoto Pref., Oita Pref., Miyazaki Pref., and Kagoshima Pref.	Fukuoka
Okinawa Pref.	Naha

Appended Table 12 (Re: Article 32)

1	<p>Machines used for the production of foods</p> <p>Apparatus or containers and packaging made of aluminum</p> <p>Apparatus or containers and packaging made of stainless steel</p> <p>Apparatus or containers and packaging made of colorless glass</p>	Three years from the date of the submission of an import notification
2	<p>Alphanized rice</p> <p>Ethyl alcohol</p> <p>Barley</p>	One year from the date of the submission of an import notification

	<p>Canned food or bottled food (excluding processed meat products or wine)</p> <p>Original alcohol not bottled for retail sale (excluding original wine)</p> <p>Kaoliang</p> <p>Sesame</p> <p>Wheat</p> <p>Rice</p> <p>Safflower seeds</p> <p>Distilled alcohol</p> <p>Food (excluding processed meat products) which are packed and sealed in tight containers and packaging and are sterilized by autoclaving and heating (excluding canned food and bottled food)</p> <p>Vegetable protein</p> <p>Buckwheat</p> <p>Soybean</p> <p>Starch (excluding tapioca starch)</p> <p>Animal fat and oil (excluding fish and marine mammal fat and oil)</p> <p>Rapeseed</p> <p>Sunflower seeds</p> <p>Indian millet</p> <p>Rye</p> <p>Apparatus or containers and packaging made of materials other than aluminum, stainless steel, colorless glass, or synthetic resins</p>	
3	<p>The following food, additives, apparatus, or containers and packaging which had been continuously imported before the submission of an import notification containing the import plans prescribed in Article 32, paragraph 4 and which had never fallen under any of the items of the same paragraph for three years prior to said submission of the notification</p> <p>An (sweetened bean jam)</p> <p>Fruits and fruit peel for temporary storage?</p> <p>Roasted coffee beans or ground roasted coffee beans</p> <p>Locusts boiled in water</p> <p>Fish roes (limited to dried roes)</p> <p>Fish Tsukudani (preservable food boiled down in soy sauce)</p> <p>Fish or marine mammal fat and oil</p> <p>Oatmeal</p> <p>Seaweeds</p> <p>Cacao beans (excluding roasted ones)</p> <p>Original wine</p> <p>Frozen food which requires heating prior to consumption</p>	One year from the date of the submission of an import notification

Gymnema tea Raw fruit juice Flours of cereals, beans, or potatoes Cocoa products (excluding powdered carbonated drinks) Coffee extract Coffee beans (excluding roasted ones) Corn flakes Konnyaku (taro jelly) Salt Vegetable creaming powders Vegetable fat and oil Shortening Sake (rice wine) Tea Chocolate Sugar Tochu tea Nimame (cooked beans)	
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Appended Table 13 (Re: Article 37 and Article 40)

Type of standard operation manuals to be prepared	Matters to be entered
Standard operation manual for maintenance of machines and implements	1. The names of the machines and implements 2. Methods for routine maintenance (including calibration of gauges) 3. A plan for regular maintenance 4. Measures to be taken if a breakdown occurs (including how to handle test samples if a breakdown occurs during testing) 5. Methods for keeping records concerning maintenance of machines and implements 6. Dates for preparing and revising the standard operation manual
Standard operation manual for management of reagents, etc.	1. Methods for labeling the containers used for reagents, test solutions, culture media, reference standards, standard solutions, and standard microorganism strains (hereinafter referred to as "reagents, etc.") 2. Notes concerning the management of reagents, etc. 3. Methods for keeping records concerning the management of reagents, etc. 4. Dates for preparing and revising the standard operation manual

Standard operation manual for animal husbandry management	<ol style="list-style-type: none"> 1. Methods for managing animal rooms 2. Notes when receiving animals 3. Methods for animal husbandry 4. Methods for observation of animal health conditions 5. Methods for handling animals that have or are suspected to have diseases 6. Methods for keeping records concerning animal husbandry 7. Dates for preparing and revising the standard operation manual
Standard operation manual for handling of test samples	<ol style="list-style-type: none"> 1. Notes when collecting, transporting, and receiving test samples 2. Methods for managing test samples 3. Methods for keeping records concerning the management of test samples 4. Dates for preparing and revising the standard operation manual
Standard operation manual for the implementation of inspections	<ol style="list-style-type: none"> 1. Items for inspections, etc. 2. Name of the product 3. Methods for conducting inspections, etc. 4. Methods for selecting and preparing reagents 5. Methods for handling standard microbe strains for bacteriological inspections 6. Methods for preparing samples 7. Methods for operating machines and implements used for inspections, etc. 8. Notes when conducting inspections, etc. 9. Methods for processing data obtained by inspections, etc. 10. Methods for keeping records concerning inspections, etc. 11. Dates of preparing and revising the standard operation manual
<p>Remarks 1. The standard operation manual for animal husbandry management shall be prepared only by a person who conducts inspections using animals.</p>	

2. The standard operation manual for the implementation of inspections shall be prepared for the respective items 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 production
Public health	Public health, Food hygiene, Environmental hygiene, Health administration, Epidemiology

Appended Table 15 (Re: Article 50)

Fish chemistry, Livestock chemistry, Radiation chemistry, Dairy chemistry, Meat chemistry, Polymer chemistry, Biological organic chemistry, Analysis of environmental pollution substances, Enzyme chemistry, Physical and chemical study of food, Fishery physiology, Livestock physiology, Plant physiology, Environmental biology, Applied microbiology, Dairy microbiology, Pathology, Outline of medical science, Anatomy, Medical chemistry, Industrial medical science, Blood science, Serology, Genetics, Parasite science, Veterinary medicine, Nutritional chemistry, Health statistics, Nutritional science, Environmental health, Health supervision, Fishery production, Production of livestock products, Production of agricultural products, Production of brewery products and seasoning products, Production of dairy products, Production of distilled wine, Canned product engineering, Food engineering, Food preservation, Freezing and cold storage, Quality control, and other subjects related to food sanitation

Appended Table 16 (Re: Article 56)

	Classification	Subjects	Hours
1	General common subjects	1. Overview of public health	9
		2. Food Sanitation Act and related laws and regulations	18
		3. Standards and criteria for food and food additives, etc.	18
		4. Introduction to chemistry	18
		5. Introduction to bacteriology	18
		6. Toxicology	9
		7. Food poisoning basics	15

		8. Food science (including nutritional science)	18
		9. Sanitation management in facilities	9
2	Subjects related to dairy products	1. Standards and criteria for dairy products	12
		2. Practical training on bacteriology	18
		3. Inspection methods for dairy products	6
		4. Practical training on dairy product inspections	18
		5. Visits to facilities and on-site training	15
3	Subjects related to processed meat products	1. Standards and criteria for processed meat products	12
		2. Practical training on bacteriology	18
		3. Inspection methods for processed meat products	6
		4. Practical training on processed meat product inspections	18
		5. Visits to facilities and on-site training	15
4	Subjects related to fish meat ham and fish meat sausage	1. Related laws and regulations and standards and criteria concerning fish meat ham and fish meat sausage	15
		2. Practical training on bacteriology	18
		3. Inspection methods for fish meat ham and fish meat sausage	9
		4. Practical training on fish meat ham and fish meat sausage inspections	15
		5. Visits to facilities and on-site training	15
5	Subjects related to edible fat and oil	1. Overview of fat and oil chemistry	10
		2. Utilization criteria for food and food additives	14
		3. Duties of food sanitation supervisors	4
		4. Responsibilities of food sanitation supervisors	3
		5. Theory of and practical training on inspection methods for fat and oil	28
		6. Visits to facilities and on-site training	10
6	Subjects related to margarine and shortenings	1. Nutritional science and analytical methods	6
		2. Sanitation management in the production process	6
		3. Sanitation criteria in the production process	3
		4. Introduction to judgment method for food additives	6
		5. Practice on analytical methods	16
		6. Practical training on judgment method for food additives	15

		7. Visits to facilities and on-site training	21
7	Subjects related to food additives	1. Overview of analytical methods for food additives	9
		2. Introduction to judgment method for food additives	9
		3. Practical training on judgment method for food additives	24
		4. Visits to facilities and on-site training	15

Appended Table 17 (Re: Article 73)

1. Salmonella enteritidis
2. Clostridium botulinum
3. Enterohaemorrhagic Escherichia coli
4. Yersinia enterocolitica O8
5. Campylobacter jejuni/coli
6. Vibrio cholerae
7. Shigella
8. Typhoid bacillus
9. Paratyphoid A bacillus