Order for Enforcement of the Food Sanitation Act

(Cabinet Order No. 229 of August 31, 1953)

The Cabinet enacts this Cabinet Order based on the provisions of Article 14, paragraph (2), Article 18, paragraph (3), Article 19, paragraphs (3) and (5), Article 20, Article 27, paragraphs (2) and (3), and Article 29-2 of the Food Sanitation Act (Act No. 233 of 1947).

(Materials Referred to in Article 18, Paragraph (3) of the Act)
Article 1 The material specified by Cabinet Order referred to in Article 18,
paragraph (3) of the Food Sanitation Act (referred to below as "the Act") is
synthetic resin.

Article 2 and Article 3 Deleted

(Inspection Referred to in Article 25, Paragraph (1) of the Act)

- Article 4 (1) The additive specified by Cabinet Order referred to in Article 25, paragraph (1) of the Act is coal-tar color, and the person that conducts an inspection for that additive a registered conformity assessment body.
- (2) A person who seeks to undergo an inspection pursuant to the provisions of Article 25, paragraph (1) of the Act must submit a written application to the Minister of Health, Labour and Welfare or a prefectural governor, or a registered conformity assessment body, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (3) Having received a written application referred to in the preceding paragraph, the Minister of Health, Labour and Welfare or a prefectural governor, or a registered conformity assessment body is to collect test samples pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (4) The Minister of Health, Labour and Welfare or a prefectural governor, or a registered conformity assessment body is to conduct inspections of test samples collected pursuant to the provisions of the preceding paragraph as prescribed by the Minister of Health, Labour and Welfare, and when the samples conform to the criteria established by the Minister, consider them to have passed the inspections and affix the labeling specified by Order of the Ministry of Health, Labour and Welfare referred to in Article 25, paragraph (1) of the Act.

(Inspection Referred to in Article 26, Paragraph (1) of the Act)
Article 5 (1) An order under the provisions of Article 26, paragraph (1) of the Act is to be made, after a prefectural governor has given a notice to a person

provided in that paragraph to the effect that the person is to take necessary measures to prevent the occurrence of food sanitation hazards, by using a written inspection order stating the inspection items, the method of collecting test samples, the inspection method, and other matters specified by Order of the Ministry of Health, Labour and Welfare, concerning the food, additives, apparatus, or containers and packages that the person has produced or processed within a period not exceeding two months that is specified by the prefectural governor.

- (2) A person who seeks to undergo an inspection pursuant to the provisions of Article 26, paragraph (1) of the Act must submit a written application to a prefectural governor or a registered conformity assessment body pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (3) Having received a written application referred to in the preceding paragraph, a prefectural governor or a registered conformity assessment body is to collect test samples and conduct an inspection in accordance with what is stated in the written inspection order.

(Inspection Referred to in Article 26, Paragraph (2) of the Act)

- Article 6 (1) A person who seeks to undergo an inspection pursuant to the provisions of Article 26, paragraph (2) of the Act must submit a written application to the Minister of Health, Labour and Welfare or a registered conformity assessment body pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (2) Having received a written application referred to in the preceding paragraph, the Minister of Health, Labour and Welfare or the registered conformity assessment body is to collect test samples and conduct an inspection in accordance with what is stated in the written inspection order.

(Inspection Referred to in Article 26, Paragraph (3) of the Act)
Article 7 The provisions of the preceding Article apply mutatis mutandis to the inspection referred to in Article 26, paragraph (3) of the Act.

(Food Sanitation Inspection Facilities)

- Article 8 (1) Prefectures, cities with public health centers, or special wards (referred to as "prefectures, etc." below in this Article) must establish the criteria for the equipment and assignment of officials at food sanitation inspection facilities to be established by the prefectures, etc. based on the provisions of Article 29, paragraph (1) or (2) of the Act, by Prefectural or Municipal Ordinance.
- (2) In establishing a Prefectural or Municipal Ordinance referred to in the preceding paragraph, the prefectures, etc. are to follow the criteria specified by

Order of the Ministry of Health, Labour and Welfare in establishing the matters stated in item (i), and are to take into consideration the criteria specified by Order of the Ministry of Health, Labour and Welfare for the matters stated in item (ii):

- (i) equipment at food sanitation inspection facilities;
- (ii) officials assigned to food sanitation inspection facilities.
- (3) At food sanitation inspection facilities referred to in paragraph (1), the affairs concerning inspections or tests must be administered pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Qualifications of Food Sanitation Inspectors)

- Article 9 (1) A food sanitation inspector must be a person who falls under any of the following items:
 - (i) a person who has completed the prescribed course at a training institute for food sanitation inspectors that has obtained a registration from a prefectural governor;
 - (ii) a physician, dentist, pharmacist, or veterinarian;
 - (iii) a person who has graduated from a university or a technical college under the School Education Act (Act No. 26 of 1947), a university under the former University Order (Imperial Order No. 388 of 1918), or a vocational training school under the former Vocational Training School Order (Imperial Order No. 61 of 1903) after completing a course in medical science, dentistry, pharmacy, veterinary medicine, animal science, fisheries science, or agricultural chemistry (including a person who has completed the course and has completed the first semester course of a professional and vocational university under that Act); or
 - (iv) a dietitian who has two or more years of experience of engaging in affairs concerning food sanitation administration.
- (2) The provisions of Article 14 through Article 20 apply mutatis mutandis to training institutes referred to in item (i) of the preceding paragraph.

(Amount of Registration Fees for Registered Conformity Assessment Bodies)
Article 10 The amount of the fee specified by Cabinet Order referred to in Article 31 of the Act is 202,600 yen.

(Valid Period of Registration for Registered Conformity Assessment Bodies) Article 11 The period specified by Cabinet Order referred to in Article 34, paragraph (1) of the Act is five years.

(Amount of Registration Renewal Fees for Registered Conformity Assessment Bodies)

Article 12 The amount of the fee specified by Cabinet Order referred to in Article 31 of the Act as applied mutatis mutandis pursuant to Article 34, paragraph (2) of the Act, is 131,000 yen.

(Designation of Food)

Article 13 The food and additives specified by Cabinet Order prescribed in Article 48, paragraph (1) of the Act are whole milk powder (limited to powder that can be put into a can with a capacity of 1,400 grams or less), sweetened milk powder, formulated milk powder, processed meat products (meaning ham, sausage, bacon, and other items similar to them), fish meat ham, fish meat sausage, irradiated food, edible fat and oil (limited to those produced through a process of bleaching or deodorization), margarine, shortening, and additives (limited to those for which standards have been established pursuant to the provisions of Article 13, paragraph (1) of the Act).

(Registration of Training Institutes)

Article 14 When registering a training institute referred to in Article 48, paragraph (6), item (iii) of the Act, a prefectural governor is to follow the criteria specified by Order of the Ministry of Health, Labour and Welfare for matters such as qualifications for admission, length of course of study, and course subjects.

(Application for Registration)

Article 15 When seeking registration of a training institute referred to in Article 48, paragraph (6), item (iii) of the Act, the establisher of the institute must submit a written application to the governor of the prefecture where the institute is located, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Notification of Changes)

Article 16 When there has been a change to the matters specified by Order of the Ministry of Health, Labour and Welfare, the establisher of a registered training institute referred to in Article 48, paragraph (6), item (iii) of the Act (referred to below as "registered training institute") must give a notification to the governor of the prefecture where the institute is located within one month from the date of the change.

(Collection of Reports)

Article 17 If a prefectural governor finds it necessary for a registered training institute, the prefectural governor may request the establisher of the institute to submit a report.

(Revocation of Registration)

Article 18 If a prefectural governor finds that a registered training institute no longer conforms to the criteria specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 14, or has received an application under the provisions of the following Article, the prefectural governor may revoke the institute's registration.

(Application for Revocation of Registration)

Article 19 When seeking to obtain revocation of the registration of a registered training institute by a prefectural governor, the establisher of the institute must submit a written application to the governor of the prefecture where the institute is located, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Public Notice)

Article 20 In the following cases, the prefectural governor must issue public notice to that effect:

- (i) when the prefectural governor has granted the registration referred to in Article 48, paragraph (6), item (iii) of the Act;
- (ii) when a notification under the provisions of Article 16 (limited to those related to the matters specified by Order of the Ministry of Health, Labour and Welfare) gas been given; and
- (iii) when the prefectural governor has revoked the registration referred to in Article 48, paragraph (6), item (iii) of the Act, pursuant to the provisions of Article 18.

(Registration of Training Sessions)

Article 21 When seeking to obtain registration of training sessions referred to in Article 48, paragraph (6), item (iv) of the Act, the organizer of the training session must apply for registration with the governor of the prefecture where the training sessions are to be conducted, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Disqualification Clause)

- Article 22 A person falling under any of the following items may not obtain a registration of training sessions referred to in Article 48, paragraph (6), item (iv) of the Act:
 - (i) a person who has been sentenced to a fine or a severer punishment for violation of the Act or of a disposition based on the Act, for whom two years have not passed since the person finished serving the sentence or ceased to

be subject to the sentence;

- (ii) a person whose registration was revoked pursuant to the provisions of Article 30, for whom two years have not passed since the date of the revocation; or
- (iii) a corporation that has a person falling under any of the preceding two items among the officers conducting its business.

(Criteria for Registration)

Article 23 When an organizer of a training session who has applied for registration pursuant to the provisions of Article 21 is to conduct the training session pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare referred to in Article 49 of the Act, the prefectural governor must register the training session.

(Obligation to Conduct Training Sessions)

- Article 24 (1) An organizer of a training session that has obtained the registration referred to in Article 48, paragraph (6), item (iv) of the Act (referred to below as "registered training session") must prepare a plan for conducting the registered training session and conduct the registered training session in accordance with that plan, unless there are legitimate grounds not to do so.
- (2) An organizer of a registered training session must conduct the registered training session in a fair manner, and by a method that conforms to the criteria specified by Order of the Ministry of Health, Labour and Welfare.
- (3) An organizer of a registered training session must submit a plan prepared pursuant to the provisions of paragraph (1) to the governor of the prefecture where the registered training session is be conducted, before conducting the registered training session. The same applies when the organizer intends to change the plan.

(Notification of Changes)

Article 25 When an organizer of a registered training session intends to change the matters specified by Order of the Ministry of Health, Labour and Welfare, the organizer must give a notification to the governor of the prefecture where the registered training session is to be conducted no later than two weeks before the day the change is scheduled.

(Suspension or Discontinuation of Operations)

Article 26 When seeking to suspend operations in whole or in part, or discontinue the operations related to the registered training session, the organizer of the registered training session must give a notification to that

effect to the governor of the prefecture where the registered training session is to be conducted in advance, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Keeping and Inspection of Financial Statements)

- Article 27 (1) An organizer of a registered training session must prepare an inventory of property, balance sheet, and profit and loss statement, or income and expenditure statement, and business report (including electronic or magnetic records (meaning a record that is created in electronic form, magnetic form, or other forms that cannot be perceived by the human senses which is used for information processing by computers; the same applies below in this Article) if the electronic or magnetic records are prepared in lieu of those documents; referred to as "financial statements, etc." in the following paragraph) and keep them at the office, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (2) The persons who intend to participate in a registered training session and other interested persons, may make the following requests at any time within the business hours of an organizer of the registered training sessions; provided, however, that in making a request referred to in item (ii) or (iv), the person must pay a fee specified by the organizer of the registered training session:
 - (i) when financial statements, etc. are prepared as documents, a request to inspect or copy the documents;
 - (ii) a request for a transcript or an extract of the documents referred to in the preceding item;
 - (iii) when financial statements, etc. are prepared as an electronic or a magnetic record, a request to inspect or copy the matters recorded in the media, which are displayed by the means specified by Order of the Ministry of Health, Labour and Welfare; and
 - (iv) a request for provision of the matters recorded in the electronic or magnetic records referred to in the preceding item by electronic or magnetic means specified by Order of the Ministry of Health, Labour and Welfare, or a request for delivery of the documents stating those matters.

(Order for Conformity)

Article 28 When a prefectural governor finds that an organizer of the registered training session has ceased to conduct registered training sessions pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare referred to in Article 49 of the Act, the prefectural governor may order the organizer of the registered training session to take necessary measures to conduct the registered training session pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare referred to in that Article.

(Order for Improvement)

Article 29 When a prefectural governor finds that an organizer of a registered training session has violated the provisions of Article 24, the prefectural governor may order the organizer of the registered training session to conduct the registered training session, or to take necessary measures to improve the method of operation such as the implementation method of the registered training session.

(Revocation of Registration)

- Article 30 When an organizer of a registered training session falls under any of the following items, the prefectural governor may revoke the registration or order the suspension of operations related to the registered training session in whole or in part, by specifying a period:
 - (i) when the organizer has come to fall under Article 22, item (i) or (iii);
 - (ii) when the organizer has violated the provisions of Article 24 through Article 26, Article 27, paragraph (1), or the following Article;
 - (iii) when the organizer has refused a request under the provisions of each item of Article 27, paragraph (2), without legitimate grounds;
 - (iv) when the organizer has violated an order under the provisions of the preceding two Articles; or
 - (v) when the organizer has obtained the registration referred to in Article 48, paragraph (6), item (iv) of the Act by wrongful means.

(Entries in Books)

Article 31 An organizer of the registered training session must keep books, enter matters concerning registered training sessions which are specified by Order of the Ministry of Health, Labour and Welfare in them, and preserve them, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Collection of Reports)

Article 32 A prefectural governor may require an organizer of a registered training session to make a report on the status of operations or accounting related to the registered training sessions, to the extent necessary for the enforcement of the Act and this Cabinet Order.

(On-Site Inspections)

Article 33 (1) A prefectural governor may have prefectural officials enter places where an organizer of a registered training session conducts operations and inspect the status of operations or books, documents, and other objects to the

- extent necessary for the enforcement of the Act and this Cabinet Order.
- (2) When conducting an on-site inspection pursuant to the provisions of the preceding paragraph, an official must carry an identification card and present it to the relevant persons.
- (3) The authority to conduct on-site inspections referred to in paragraph (1) must not be construed as being granted for the purpose of criminal investigation.

(Public Notice)

- Article 34 In the following cases, a prefectural governor must issue public notice to that effect:
 - (i) when the prefectural governor has granted the registration referred to in Article 48, paragraph (6), item (iv) of the Act;
 - (ii) when a notification under the provisions of Article 25 or Article 26 has been given; and
 - (iii) when the prefectural governor has revoked the registration of a registered training session, or ordered the suspension of operations related to a registered training session, pursuant to the provisions of Article 30.

(Small Scale Business Operator)

- Article 34-2 A business operator specified by Cabinet Order referred to in Article 51, paragraph (1), item (ii) of the Act is as follows:
 - (i) a business operator that produces or processes food, who sells at retail all or most of the food produced or processed in that facility at a store attached or adjacent to a facility;
 - (ii) a business operator that cooks food in a restaurant business (meaning a business of cooking food or of having customers eat and drink by setting up facilities; the same applies in item (i) of the following Article), or by using a vending machine that has a cooking function (limited to a machine that comes into direct contact with food not packed or wrapped in containers and packages; the same applies in item (ii) of the following Article) and sells the cooked food, or a business operator that cooks other foods, who is specified by Order of the Ministry of Health, Labour and Welfare:
 - (iii) a business operator that stores, transports, or sells only food that is packed or wrapped in containers and packages; and
 - (iv) in addition to the business operators stated in the preceding three items, a business operator who divides food and packs or wraps the food in containers and packages and sells the food at retail, or a business operator who is found to be able to take necessary measures for public health through the maintenance of cleanliness and extermination of rats and insects of the interior and exterior of facilities that are prescribed in Article 51, paragraph (1), item (i) of the Act, and other general sanitation management, and

through initiatives in accordance with the characteristics of the food handled by them which are prescribed in item (ii) of that paragraph, and is specified by Order of the Ministry of Health, Labour and Welfare.

(Designation of Business)

- Article 35 The business for which prefectures must establish criteria for facilities pursuant to the provisions of Article 54 of the Act are as follows:
 - (i) a restaurant business;
 - (ii) a business that cooks food using a vending machine that has a cooking function (excluding vending machines equipped with devices necessary to prevent occurrence of food sanitation hazards, such as devices for automatically washing the parts that come into direct contact with food not packed or wrapped in containers and packaging) and sells the cooked food;
 - (iii) meat retail business (excluding business that exclusively purchases processed meat packed in containers and packages and sells the meat as is);
 - (iv) seafood sales business (meaning business that sets up a store to sell fresh seafood (including frozen seafood items; the same applies below in this item and the following item), excluding business that sells live seafood, that exclusively purchases fresh seafood packed in containers and packages and sells the seafood using those containers and packages, and that falls under the following item);
 - (v) seafood auction business (meaning business that sells fresh seafood by method of trading specified by Order of the Ministry of Health, Labour and Welfare, such as auctions at seafood markets);
 - (vi) milk collection business (meaning business that collects and preserves raw milk);
 - (vii) milk processing business (meaning business that processes raw milk or produces milk for drinking (including dividing milk into small quantities; the same applies below in this item), or business that processes raw milk or produces milk for drinking and together with dairy products (limited to beverages) or soft drink);
 - (viii) special milking and processing business (meaning business of milking cows and processing the raw into milk that meets the compositional standards specified by Order of the Ministry of Health, Labour and Welfare without sterilizing the milk or by using the low-temperature pasteurization method);
 - (ix) meat processing business (meaning business of slaughtering or butchering birds other than poultry defined in Article 2, item (i) of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act (Act No. 70 of 1990) or livestock other than livestock defined in Article 3, paragraph (1) of the Slaughterhouse Act (Act No. 114 of 1953), or dividing or chopping the

- meat, organs, etc. of butchered birds and livestock for the purpose of human consumption, excluding business that falls under item (xxvi) or (xxviii));
- (x) food irradiation business;
- (xi) confectionery business (meaning business of producing confectionery (including bread and bean jam products), excluding business that falls under item (xxvi) or (xxviii));
- (xii) ice cream production business (meaning business of producing ice cream, sherbet, popsicle, and other food that are made by freezing liquid food or a mixture of liquid food and other foods);
- (xiii) dairy product production business (meaning business of producing foods made primarily from milk that are specified by Order of the Ministry of Health, Labour and Welfare, such as powdered milk, condensed milk, fermented milk, cream, butter, cheese, and lactic acid bacteria beverages (including dividing them into small quantities (excluding dividing solid products into small quantities)));
- (xiv) soft drink production business (meaning business of producing soft drink that does not use raw milk, or dairy products that does not use raw milk (limited to beverages) (including dividing them into small quantities));
- (xv) meat product production business (meaning business of producing ham, sausage, bacon, and other products similar to them (referred to as "meat products" below in this item), or business of producing ready-made dishes using meat or meat products together with meat products);
- (xvi) fishery product production business (meaning business of producing food made primarily from seafood and other aquatic animals or their eggs (referred to as "aquatic animals, etc." below in this item), or business of producing ready-made dishes using the foods or aquatic animals, etc. together with the food; excluding business that falls under item (xxvi) or (xxviii));
- (xvii) ice production business;
- (xviii) liquid egg production business (meaning business of producing liquid eggs by removing eggshells from chicken eggs (including dividing them into small portions));
- (xix) edible fat and oil production business (including margarine or shortening production business);
- (xx) miso or soy sauce production business (meaning business of producing miso or soy sauce, or business of producing food using miso or soy sauce as the main ingredients together with miso or soy sauce);
- (xxi) alcoholic beverage production business (meaning business that produces alcoholic beverages (including dividing them into small portions));
- (xxii) tofu production business (meaning business of producing tofu, or business of producing food using tofu or by-products of tofu production as

main ingredients together with tofu);

(xxiii) natto (fermented soybeans) production business;

(xxiv) noodle production business (meaning business of producing noodles, excluding business that falls under item (xxvi) or (xxviii));

(xxv) ready-made dish production business (meaning the business of producing simmered dishes (including food boiled in soy sauce), grilled dishes (including stir-fried dishes), deep-fried dishes, steamed dishes, pickled dishes or food dressed with miso, sesame, or vinegar, usually served as food other than staple food, or food prepared by combining those food with cooked rice and other food acknowledged to be staple food, excluding business that falls under item (xv), item (xvi), or item (xxii), or the following item through item (xxviii));

(xxvi) combined ready-made dish production business (meaning the business of processing meat related to the business provided for in item (ix) together with the business provided for in the preceding item (limited to cases in which initiatives are taken to control steps that are particularly important for preventing occurrence of food sanitation hazards prescribed in Article 51, paragraph (1), item (ii) of the Act (referred to as "control of important steps" below in this item); the same applies in item (xxviii), or business of producing food related to the business prescribed in item (xi), item (xvi) (excluding business related to the production of fish paste products (including fish meat ham, fish meat sausage, whale meat bacon, and other products similar to them); the same applies in item (xxviii), or item (xxiv) (limited to cases in which control of important steps is taken; the same applies in item (xxviii));

(xxvii) frozen food production business (meaning the business of producing food related to the business prescribed in item (xxv) and producing frozen products of those produced food, excluding business that falls under the following item);

(xxviii) combined frozen food production business (meaning the business of processing meat related to the business prescribed in item (ix) together with the business prescribed in the preceding item, or business of producing food related to the business prescribed in item (xi), item (xvi), or item (xxiv) (limited to frozen food));

(xxix) pickle production business (meaning business of producing pickles, or business of producing foods that uses pickles as the main ingredients together with pickles);

(xxx) hermetically sealed food production business (meaning business of producing hermetically sealed food (meaning food hermetically sealed in containers and packages, such as retort pouch food, canned food, and bottled food) that does not require freezing or refrigeration for preservation

(excluding foods for which it is clear that there is no risk of anaerobic sporeforming bacteria resistant to heat, such as Clostridium botulinum growing when preserved by a method other than freezing or refrigeration, and are specified by Order of the Ministry of Health, Labour and Welfare) (excluding business that falls under any of the preceding items));

(xxxi) business of packaging food in small portions (meaning the business of exclusively dividing the food produced by business falling under item (xi), item (xiii) (limited to business related to the production of solid products), item (xv), item (xvi), item (xix), or item (xx), or items (xxii) through (xxix) into small portions, and packing or wrapping them in containers and packages); and

(xxxii) additive production business (meaning the business of producing the additives for which standards have been established pursuant to the provisions of Article 13, paragraph (1) of the Act (including packaging the additives in small portions)).

(Businesses that Have Minor Impact on Public Health)

Article 35-2 The businesses specified by Cabinet Order as those having a minor impact on public health which are prescribed in Article 57, paragraph (1) of the Act are as follows:

- (i) business of importing food or additives;
- (ii) business of exclusively storing or transporting food or additives (excluding food freezing business or food refrigeration business);
- (iii) business of selling food or additives packed or wrapped in containers and packages that are unlikely to cause food sanitation hazards resulting from degradation of quality, such as decomposition or deterioration;
- (iv) business of producing apparatus, or containers and packages (limited to apparatus, or containers and packages that use raw materials other than the materials prescribed in Article 1); and
- (v) business of importing or selling apparatus, or containers and packages.

(Investigation of Causes of Poisoning)

Article 36 The investigations that the director of a public health center must conduct pursuant to the provisions of Article 63, paragraph (2) of the Act (including as applied mutatis mutandis pursuant to Article 68, paragraph (1) of the Act; the same applies in paragraph (1) of the following Article) are as follows:

(i) epidemiological investigation necessary to pursue the food, additives, apparatus, containers and packages, or toys (referred to as "food, etc." below in this Article and paragraph (2) of the following Article) that caused poisoning and the disease agents; and

(ii) investigation by microbiological or physicochemical tests or tests using animals on things such as blood, feces, urine, or vomit from a poisoned patient, a person suspected of being poisoned, or a corpse of that person, or on food, etc. considered to be the cause of poisoning.

(Reports on Poisoning)

- Article 37 (1) The director of a public health center must report step by step the implementation status of the investigations stated in each item of the preceding Article concerning investigations conducted under Article 63, paragraph (2) of the Act (referred to as "food poisoning investigations" below in this Article) to a prefectural governor, a mayor of a city with public health centers or a mayor of a special ward (referred to as a "prefectural governor, etc." below in this Article).
- (2) When a report under the provisions of Article 63, paragraph (3) of the Act (including as applied mutatis mutandis pursuant to Article 68, paragraph (1) of the Act) has been made, the prefectural governor, etc. must sequentially report the number of poisoned patients and the food, etc. that caused poisoning, and other matters specified by Order of the Ministry of Health, Labour and Welfare, from among the matters the governor has received a report pursuant to the provisions of the preceding paragraph to the Minister of Health, Labour and Welfare.
- (3) After the director of a public health center has finished the food poisoning investigation, the director must promptly prepare a written report and submit it to a prefectural governor, etc. pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (4) When a prefectural governor, etc. has received a written report referred to in the preceding paragraph, the prefectural governor, etc. must prepare a written report and submit it to the Minister of Health, Labour and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Special Provisions for Large Cities)

- Article 38 (1) For designated cities referred to in Article 252-19, paragraph (1) of the Local Autonomy Act (Act No. 67 of 1947) (referred to as "designated cities" below in this Article), the affairs to be handled by designated cities pursuant to the provisions of Article 77 of the Act are as specified in Article 174-34 of the Order for Enforcement of the Local Autonomy Act (Cabinet Order No. 16 of 1947).
- (2) For core cities referred to in Article 252-22, paragraph (1) of the Local Autonomy Act (referred to as "core cities" below in this Article), the affairs to be handled by core cities pursuant to the provisions of Article 77 of the Act are as specified in Article 174-49-14 of the Order for Enforcement of the Local

Autonomy Act.

(Businesses Referred to in Article 79, Paragraphs (1) and (2) of the Act)
Article 39 The businesses prescribed in Cabinet Order referred to in Article 79,
paragraphs (1) and (2) of the Act are those stated in Article 35, items (i)
through (iv).

(Authority Not Delegated to the Commissioner of the Consumer Affairs Agency)

Article 40 The authority specified by Cabinet Order referred to in Article 80, paragraph (3) of the Act (including as applied mutatis mutandis pursuant to Article 2-2, paragraph (6) and Article 2-3, paragraph (7) of the Supplementary Provisions of the Act Partially Amending the Food Sanitation Act and the Nutrition Improvement Act (Act No. 101 of 1995); referred to as the "Amending Act of 1995" below in this Article)) is the authority under the provisions of Article 8, paragraph (1), Article 12 (including as applied mutatis mutandis pursuant to Article 68, paragraph (1) of the Act), Article 13, paragraph (1) (including as applied mutatis mutandis pursuant to Article 68, paragraph (1) of the Act) and paragraph (3), Article 14, Article 18, paragraph (1) (including as applied mutatis mutandis pursuant to Article 68, paragraph (1) of the Act) and paragraph (3), Article 19, paragraph (1) (including as applied mutatis mutandis pursuant to Article 68, paragraph (1) of the Act), Article 72, paragraphs (2) and (3) (including as applied mutatis mutandis pursuant to Article 2-2, paragraph (5) and Article 2-3, paragraph (6) of the Supplementary Provisions of the Amending Act of 1995) and paragraph (4), and Article 78, paragraph (1) of the Act, and Article 2-2, paragraph (1) of the Supplementary Provisions of the Amending Act of 1995.

(Classification of Affairs)

Article 41 The affairs to be handled by prefectures, cities with public health centers, or special wards, pursuant to the provisions of Article 37 are type 1 statutory entrusted functions defined in Article 2, paragraph (9), item (i) of the Local Autonomy Act.

(Delegation of Authority)

- Article 42 (1) The authority of the Minister of Health, Labour and Welfare prescribed in this Cabinet Order may be delegated to the Director General of a Regional Bureau of Health and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (2) The authority delegated to the Director Generals of a Regional Bureau of Health and Welfare pursuant to the provisions of the preceding paragraph may

be delegated to the Director General of a Regional Branch Bureau of Health and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.