

Order for Enforcement of the Food Sanitation Act

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

The Cabinet hereby enacts this Cabinet Order pursuant to 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 (hereinafter referred to as the "Act") is synthetic resin.

Articles 2 and 3 Deleted

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

Article 4 (1) The additives specified by Cabinet Order referred to in Article 25, paragraph (1) of the Act are a coal-tar color, and an inspection for that additive is carried out by a registered conformity assessment body.

(2) A person who intends 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 Ministry of Health, Labour and Welfare Order.

(3) Having received a written application referred to in the preceding paragraph, the Minister of Health, Labour and Welfare or the prefectural governor, or the registered conformity assessment body is to collect test samples pursuant to the provisions of Ministry of Health, Labour and Welfare Order.

(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 specified by the Minister of Health, Labour and Welfare and, when the samples conform to the criteria established by the Minister of Health, Labour and Welfare, deem them to have passed the inspections and affix labeling specified by Ministry of Health, Labour and Welfare Order referred to in Article 25, paragraph (1) of the Act.

(Inspections Referred to in Article 26, Paragraph (1) of the Act)

Article 5 (1) An order under Article 26, paragraph (1) of the Act is to be issued,

after a prefectural governor has notified a person provided in the same paragraph to the effect that the person must take the necessary measures to prevent food sanitation hazards, through a written inspection order stating inspection items, methods for collecting test samples, inspection methods, and other matters specified by Ministry of Health, Labour and Welfare Order, with regard to the food, additives, apparatus, or containers and packaging that the person has produced or processed within a period not exceeding two months as specified by the prefectural governor.

- (2) A person who intends 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 Ministry of Health, Labour and Welfare Order.
- (3) Having received a written application referred to in the preceding paragraph, the prefectural governor or the registered conformity assessment body is to collect test samples and conduct inspections in accordance with what is stated in the written inspection order.

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

Article 6 (1) A person who intends 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 Ministry of Health, Labour and Welfare Order.

- (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 inspections in accordance with what is stated in the written inspection order.

(Inspections Referred to in Article 26, Paragraph (3) of the Act)

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

(Food Sanitation Inspection Facilities)

Article 8 (1) Prefectures, cities with health centers, or special wards (hereinafter referred to as "prefectures, etc." in this Article), by Prefectural or Municipal Ordinance, must establish the criteria for the equipment and assignment of personnel at food sanitation inspection facilities established by the prefectures, etc. pursuant to the provisions of Article 29, paragraph (1) or (2) of the Act.

- (2) When prefectures, etc. enact Prefectural or Municipal Ordinances referred to in the preceding paragraph, matters set forth in item (i) are to be determined in accordance with the criteria specified by Ministry of Health, Labour and

Welfare Order, and matters set forth in item (ii) are to be determined by taking into consideration the criteria specified by Ministry of Health, Labour and Welfare Order:

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

(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 registration from a prefectural governor;
 - (ii) a physician, dentist, pharmacist, or veterinarian;
 - (iii) a person who has graduated from a university or a college of technology under the School Education Act (Act No. 26 of 1947), a university under the old University Order (Imperial Order No. 388 of 1918), or a vocational training school under the old Vocational Training School Order (Imperial Order No. 61 of 1903) after completing a course of study in medical science, dentistry, pharmacy, veterinary medicine, animal science, fisheries science, or agricultural chemistry (including a person who has completed that course and has completed the first semester course of a professional university under the same Act);
 - (iv) a dietitian who has two or more years of experience of being engaged in affairs concerning food sanitation administration.
- (2) The provisions of Articles 14 through 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 Food and additives specified by Cabinet Order as provided in Article 48, paragraph (1) of the Act are; whole milk powder (limited to what may be put into a can with a capacity of 1,400 grams or less), sweetened milk powder, modified milk powder, processed meat products (meaning ham, sausage, bacon, and other items similar thereto), 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, the prefectural governor is to follow the criteria specified by Ministry of Health, Labour and Welfare Order with regard to matters such as the entrance qualifications, length of training, and courses 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 in which the institute is located, pursuant to the provisions of Ministry of Health, Labour and Welfare Order.

(Notification of Changes)

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

(Collection of Reports)

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

(Rescission of Registration)

Article 18 If a prefectural governor finds that a registered training institute has ceased to conform to the criteria specified by Ministry of Health, Labour and Welfare Order as provided in Article 14, or has received an application under the following Article, the prefectural governor may rescind the institute's registration.

(Application for Rescission of Registration)

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

(Public Notice)

Article 20 In any of the following cases, the prefectural governor must issue public notice of the relevant matters:

- (i) when the prefectural governor has granted registration referred to in Article 48, paragraph (6), item (iii) of the Act;
- (ii) when there has been a notification under Article 16 (limited to those relating to matters specified by Ministry of Health, Labour and Welfare Order);
- (iii) when the prefectural governor has rescinded 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 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 in which the training sessions will be conducted, pursuant to the provisions of Ministry of Health, Labour and Welfare Order.

(Disqualification)

Article 22 A person falling under any of the following items may not obtain 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 more severe punishment for violation of the Act or of any disposition based on the Act, and 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 rescinded pursuant to the provisions of Article 30, and two years have not passed since the date of the rescission;
- (iii) a corporation that has a person falling under any of the preceding two items among the officers in charge of its business.

(Criteria for Registration)

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

(Obligation to Conduct Training Sessions)

Article 24 (1) An organizer of registered training sessions referred to in Article 48, paragraph (6), item (iv) of the Act (hereinafter referred to as "registered training sessions") must prepare a plan for conducting the registered training sessions and must conduct the registered training sessions in accordance with that plan, unless there are legitimate grounds not to do so.

(2) An organizer of registered training sessions must conduct the registered training sessions in a fair manner and by a method that conforms to the criteria specified by Ministry of Health, Labour and Welfare Order.

(3) An organizer of registered training sessions must, prior to the implementation of the registered training sessions, submit a plan prepared pursuant to the provisions of paragraph (1) to the governor of the prefecture in which the registered training sessions will be conducted. The same applies when the organizer intends to change the plan.

(Notification of Changes)

Article 25 When intending to change the matters specified by Ministry of Health, Labour and Welfare Order, the organizer of registered training sessions must notify the governor of the prefecture in which the registered training sessions are conducted no later than two weeks before the day the change is scheduled.

(Suspension or Discontinuation of Operations)

Article 26 When seeking to suspend or discontinue operations, in whole or in part, relating to registered training sessions, the organizer of the registered training sessions must submit, in advance, a notification to that effect to the governor of the prefecture in which the registered training sessions are conducted, pursuant to the provisions of Ministry of Health, Labour and Welfare Order.

(Maintenance and Inspection of Financial Statements)

Article 27 (1) An organizer of registered training sessions 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 used in computerized information processing which is created in electronic form, magnetic form, or any other form that cannot be perceived by the human senses; hereinafter the same applies in this Article) if the electronic or magnetic records are prepared instead of those paper documents; referred to as "financial statements, etc." in the following paragraph) and must maintain them at the office, pursuant to the provisions of Ministry of Health, Labour and Welfare Order.

(2) Persons who intend to participate in registered training sessions and other interested persons, may make the following requests at any time within the business hours of an organizer of registered training sessions. However, when making a request referred to in item (ii) or item (iv), they must pay a fee specified by the organizer of the registered training sessions:

- (i) when financial statements, etc. are prepared as written 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 electronic or magnetic records, a request to inspect or copy the matters recorded on the electronic or magnetic records that are displayed in means specified by Ministry of Health, Labour and Welfare Order;
- (iv) a request for provision of the matters recorded on the electronic or magnetic records referred to in the preceding item in electronic or magnetic means specified by Ministry of Health, Labour and Welfare Order, or a request for delivery of the written documents stating the matters.

(Compliance Order)

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

(Order for Improvement)

Article 29 When a prefectural governor finds that an organizer of registered training sessions has violated the provisions of Article 24, the prefectural

governor may order the organizer of the registered training sessions to conduct the registered training sessions or to take the necessary measures to improve operational methods such as the implementation method of the registered training sessions.

(Rescission of Registration)

Article 30 When an organizer of registered training sessions falls under any of the following items, the prefectural governor may rescind the registration of the training sessions or order the suspension of operations relating to the registered training sessions, in whole or in part, for a specified period:

- (i) when an organizer of registered training sessions has come to fall under Article 22, item (i) or item (iii);
- (ii) when an organizer of registered training sessions has violated the provisions of Articles 24 through 26, Article 27, paragraph (1), or the following Article;
- (iii) when an organizer of registered training sessions has rejected a request under each item of Article 27, paragraph (2), without legitimate grounds;
- (iv) when an organizer of registered training sessions has violated an order under the preceding two Articles;
- (v) when an organizer of registered training sessions has obtained registration referred to in Article 48, paragraph (6), item (iv) of the Act by wrongful means.

(Bookkeeping)

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

(Collection of Reports)

Article 32 A prefectural governor may require an organizer of registered training sessions to make a report on the status of operations or accounting relating 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 registered training sessions conducts operations to inspect the status of operations or objects such as books and documents, 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 identification 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 purposes of criminal investigation.

(Public Notice)

Article 34 In any of the following cases, the prefectural governor must issue public notice of the relevant matters:

- (i) when the prefectural governor has granted registration referred to in Article 48, paragraph (6), item (iv) of the Act;
- (ii) when there has been a notification under Article 25 or Article 26;
- (iii) when the prefectural governor has rescinded the registration of registered training sessions or ordered the suspension of operations relating to registered training sessions, pursuant to the provisions of Article 30.

(A Small Business)

Article 34-2 A business specified by Cabinet Order referred to in Article 51, paragraph (1), item (ii) of the Act is as follows:

- (i) a business that produces or processes food and retails, in a store attached or adjacent to a food producing or processing facility, all or most of the food produced or processed in that facility;
- (ii) a business that cooks food and is specified by Ministry of Health, Labour and Welfare Order, such as a person engaged in restaurant business (meaning business that cooks food or sets up facilities for customers to eat and drink; the same applies to item (i) of the following Article), or a person engaged in business that cooks food using a vending machine capable of cooking food (limited to a machine that comes into direct contact with foods not packed or wrapped in containers and packaging; the same applies to item (ii) of the following Article) and sells the cooked food;
- (iii) a business that stores, transports, or sells only foods that are packed or wrapped in containers and packaging;
- (iv) in addition to the businesses set forth in the preceding three items, a business that is found to be able to take measures necessary for public health through the maintenance of cleanliness of the interior and exterior of facilities, extermination of rats and insects, and other general sanitation management as provided in Article 51, paragraph (1), item (i) of the Act and through the measures appropriate for the characteristics of the food handled as provided in item (ii) of the same paragraph, and is specified by Ministry of Health, Labour and Welfare Order, such as a business that divides up food , and packs or wraps that food in containers and packaging , and sells it at retail.

(Designation of Businesses)

Article 35 Pursuant to the provisions of Article 54 of the Act, prefectures must establish criteria for the facilities for the following businesses:

- (i) restaurant business;
- (ii) business that cooks food using a vending machine capable of cooking food(excluding those equipped with devices necessary to prevent food sanitation hazards, such as devices to automatically clean the parts that come into direct contact with foods not packed or wrapped in containers and packaging) and sells the cooked food;
- (iii) processed meat sales business (excluding business that solely purchases processed meat packed in containers and packaging and sells it as it is);
- (iv) fish and seafood sales business (meaning business that sets up stores to sell fresh fish and seafood (including frozen items; hereinafter the same applies to this item and the following item), except for business that sells live fish and seafood, business that solely purchases fresh fish and seafood packed in containers and packaging and sells them as it is, and business that falls under the following item);
- (v) fish and seafood auction business (meaning business that sells fresh fish and seafood by trading methods specified by Ministry of Health, Labour and Welfare Order, such as through auctions at a fish and seafood market);
- (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 served for drinking (including packaging thereof; hereinafter the same applies to this item), or business that processes raw milk or produces milk served for drinking and also produces dairy products (limited to beverages) or nonalcoholic beverages);
- (viii) special milking and processing business (meaning business that milks cow milk and processes it into milk meeting ingredient standards specified by Ministry of Health, Labour and Welfare Order without undergoing a sterilization process or by undergoing a pasteurization process);
- (ix) meat processing business (meaning business that slaughters or dresses birds other than poultry provided 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 provided in Article 3, paragraph (1) of the Slaughterhouse Act (Act No. 114 of 1953), or divides or chops meat, organs, etc. of dressed birds or livestock for the purpose of serving them for human consumption, except for businesses that fall under item (xxvi) or item (xxviii));
- (x) food irradiation business;

- (xi) confectionery production business (meaning business that produces confectionery (including bread and bean jam), except for businesses that fall under item (xxvi) or item (xxviii));
- (xii) ice cream production business (meaning business that produces ice cream, ice sherbet, ice pop, and other foods that are made by freezing liquid foods or a mixture of liquid foods and other foods);
- (xiii) dairy product production business (meaning business that produces foods (including packaging thereof (excluding packaging solid products)) made primarily from milk that are specified by Ministry of Health, Labour and Welfare Order, such as powdered milk, condensed milk, cultured milk, cream, butter, cheese, and lactic acid bacteria beverages);
- (xiv) nonalcoholic beverage production business (meaning business that produces nonalcoholic beverages not using raw milk or dairy products (limited to beverages) not using raw milk (including packaging thereof));
- (xv) processed meat product production business (meaning business that produces ham, sausage, bacon, and other items similar thereto (hereinafter referred to as "processed meat products" in this item) or business that produces, together with processed meat products, side dishes using processed meat or processed meat products);
- (xvi) fishery product production business (meaning business that produces foods made primarily from aquatic animals, such as fish and seafood, or their eggs (hereinafter referred to as "aquatic animals, etc." in this item), or business that produces, together with those foods, side dishes using those foods or aquatic animals, etc., except for businesses that fall under item (xxvi) or item (xxviii));
- (xvii) ice production business;
- (xviii) liquid egg production business (meaning business that produces chicken eggs removed from the shell (including packaging thereof));
- (xix) edible fat and oil production business (including margarine or shortening production business);
- (xx) miso or soy sauce production business (meaning business that produces miso or soy sauce, or business that produces, together with these items, foods made primarily from miso or soy sauce);
- (xxi) alcoholic beverage production business (meaning business that produces alcoholic beverages (including packaging thereof));
- (xxii) tofu production business (meaning business that produces tofu or business that produces, together with tofu, foods made primarily from tofu or from by-products of tofu production);
- (xxiii) natto production business;
- (xxiv) noodle production business (meaning business that produces noodles, except for businesses that fall under item (xxvi) or item (xxviii));

- (xxv) side dish production business (meaning business that produces simmered dishes (including food boiled down in soy sauce), roast dishes (including stir-fried dishes), deep-fried dishes, steamed dishes, vinegared dishes, or dishes dressed with sauce generally served as side dishes, or foods prepared by combining these dishes with food generally considered staples such as cooked rice, except for businesses that fall under item (xv), item (xvi), or item (xxii), or items (xxvi) through (xxviii));
- (xxvi) multi side dish items production business (meaning business that, together with the business provided in the preceding item, conducts meat processing operations relating to the business provided in item (ix) (limited to when measures are taken to control processes that are particularly important to prevent food sanitation hazards as provided in Article 51, paragraph (1), item (ii) of the Act (hereinafter referred to as "critical process control" in this item); the same applies to item (xxviii)), or business that produces food relating to the business provided in item (xi), item (xvi) (excluding business relating to the production of fish paste products (including fish meat ham, fish meat sausage, whale meat bacon, and other items similar thereto); the same applies to item (xxviii)), or item (xxiv) (limited to when critical process control is undertaken; the same applies to item (xxviii)));
- (xxvii) frozen food production business (meaning business that produces food relating to the business provided in item (xxv) and uses the produced food to produce frozen foods, except for business that falls under the following item);
- (xxviii) multi frozen food items production business (meaning business that, together with the business provided in the preceding item, conducts meat processing operations relating to the business provided in item (ix), or business that produces food (limited to frozen food) relating to the business provided in item (xi), item (xvi), or item (xxiv));
- (xxix) pickle production business (meaning business that produces pickles or business that produces, together with pickles, foods made primarily from pickles);
- (xxx) sealed food production business (meaning business (excluding those that fall under any of the preceding items) that produces sealed food (meaning food sealed in containers and packaging, 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 clearly unlikely that anaerobic spore-forming bacteria resistant to heat, such as *Clostridium botulinum*, will grow when preserved by a method other than freezing or refrigeration and that are specified by Ministry of Health, Labour and Welfare Order));
- (xxxi) food packaging business (meaning business that solely divides the food produced by business falling under item (xi), item (xiii) (limited to business

relating to the production of solid products), item (xv), item (xvi), item (xix), or item (xx), or items (xxii) through (xxix) into small portions, and pack or wrap those portions in containers and packaging);

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

(Businesses that Have a Minor Impact on Public Health)

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

- (i) business that imports food or additives;
- (ii) business that only stores or transports food or additives (excluding food freezing or refrigeration business);
- (iii) business that sells food or additives packed or wrapped in containers and packaging that, when preserved by a method other than freezing or refrigeration, are unlikely to cause food sanitation hazards resulting from quality degradation such as rotting or deterioration;
- (iv) business that produces apparatus, or containers and packaging (limited to apparatus, or containers and packaging in which raw materials other than the materials provided in Article 1 are used);
- (v) business that imports or sells apparatus, or containers and packaging.

(Investigation of the Causes of Poisoning)

Article 36 Investigations that the director of a 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 to paragraph (1) of the following Article) are as follows:

- (i) epidemiological investigations necessary to search for food, additives, apparatus, containers and packaging, or toys (hereinafter referred to as "food, etc." in this Article and in paragraph (2) of the following Article) that have caused poisoning and disease agents;
- (ii) investigations through microbiological or physicochemical tests or tests using animals on substances such as blood, feces, urine, or vomit from a poisoned patient, a person suspected of being poisoned, or a corpse thereof, or on food, etc. that may have caused poisoning.

(Reports on Poisoning)

Article 37 (1) With regard to investigations conducted under Article 63, paragraph (2) of the Act (hereinafter referred to as "food poisoning investigations" in this Article), the director of a health center must report

sequentially on the implementation status of the investigations set forth in each item of the preceding Article to a prefectural governor, a city mayor of a city with health centers or a ward mayor of a special ward (hereinafter referred to as a "prefectural governor, etc." in this Article) .

- (2) When a report under 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 report sequentially to the Minister of Health, Labour and Welfare on the matters specified by Ministry of Health, Labour and Welfare Order, such as the number of poisoned patients and the food, etc. that has caused poisoning, from among the matters reported pursuant to the provisions of the preceding paragraph.
- (3) After the food poisoning investigations have finished, the director of a health center must promptly prepare a written report and submit it to a prefectural governor, etc. pursuant to the provisions of Ministry of Health, Labour and Welfare Order.
- (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 Ministry of Health, Labour and Welfare Order.

(Special Measures for Large Cities)

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

(2) In core cities referred to in Article 252-22, paragraph (1) of the Local Autonomy Act (hereinafter referred to as "core cities" in this Article), affairs to be handled by core cities pursuant to the provisions of Article 77 of the Act are specified by 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 Businesses specified by Cabinet Order referred to in Article 79, paragraphs (1) and (2) of the Act are businesses set forth 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 is the authority under the provisions of Article 19, paragraphs (1) (including as applied mutatis mutandis pursuant to Article 68, paragraph (1) of the Act), Article 72, paragraphs (2) and (3), and Article 78 of the Act.

(Classification of Affairs)

Article 41 Affairs to be handled by prefectures, cities with health centers, or special wards pursuant to the provisions of Article 37 are type 1 statutory entrusted functions provided 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 provided in this Cabinet Order may be delegated to the Director-Generals of the Regional Bureaus of Health and Welfare pursuant to the provisions of Ministry of Health, Labour and Welfare Order.

(2) The authority delegated to the Director-Generals of the Regional Bureaus of Health and Welfare pursuant to the provisions of the preceding paragraph may be delegated to the head of the Regional Branch of Health and Welfare pursuant to the provisions of Ministry of Health, Labour and Welfare Order.