

Order for Enforcement of the Food Sanitation Act

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

The Order for Enforcement of the Food Sanitation Act is hereby promulgated.

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The Cabinet shall enact this Cabinet Order pursuant to 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).

(Approval of Comprehensive Sanitation Management and Production Process)

Article 1 (1) Food specified by a Cabinet Order under Article 13, paragraph (1) of the Food Sanitation Act (hereinafter referred to as "the Act") shall be as follows:

- (i) Cow's milk, goat's milk, skim milk, and processed milk;
- (ii) Cream, ice cream, unsweetened evaporated milk, unsweetened condensed milk, powdered skim milk, cultured milk, lactic acid bacteria beverages, and milk beverages;
- (iii) Carbonated drinks;
- (iv) Processed meat products (meaning ham, sausage, bacon, and the like; the same shall apply in Article 13);
- (v) Fish jelly products (including fish meat ham, fish meat sausage, whale meat bacon, and the like);
- (vi) Retort pouch food (meaning food (excluding food listed in the preceding items and whale meat products (excluding whale meat bacon)) which are packed and sealed in tight containers and packaging and are sterilized by autoclaving and heating).

(2) The amount of the fee specified by a Cabinet Order under Article 13, paragraph (7) of the Act shall be the amount specified in the following relevant items according to the classification of persons listed as follows:

- (i) A person who intends to obtain approval under Article 13, paragraph (1) of the Act - 239,700 yen;
- (ii) A person who intends to obtain approval under Article 13, paragraph (4) of the Act - 96,900 yen.

(Valid Period of Approval of Comprehensive Sanitation Management and Production Process)

Article 2 The period specified by a Cabinet Order under Article 14, paragraph (1) of the Act shall be three years.

(Fee to Renew Approval of Comprehensive Sanitation Management and Production Process)

Article 3 The amount of the fee specified by a Cabinet Order under Article 14, paragraph (5) of the Act shall be 170,200 yen.

(Inspections under Article 25, Paragraph (1) of the Act)

Article 4 (1) Additives specified by a Cabinet Order under Article 25, paragraph (1) of the Act shall be of a coal-tar color and a person to conduct inspections thereof shall be a registered conformity assessment body.

(2) A person who intends to receive inspections pursuant to the provisions of Article 25, paragraph (1) of the Act shall submit a written application to the Minister of Health, Labour and Welfare, a prefectural governor, or a registered conformity assessment body, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

(3) The Minister of Health, Labour and Welfare, a prefectural governor, or a registered conformity assessment body shall, when receiving a written application set forth in the preceding paragraph, collect test samples, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

(4) The Minister of Health, Labour and Welfare, a prefectural governor, or a registered conformity assessment body shall 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 criteria specified by the Minister of Health, Labour and Welfare, he/she shall deem them to have passed the inspections and affix labeling specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 25, paragraph (1) of the Act.

(Inspections under Article 26, Paragraph (1) of the Act)

Article 5 (1) An order under Article 26, paragraph (1) of the Act shall be issued after a prefectural governor has made a notice to a person provided in the same paragraph to the effect that the person should take the necessary measures to prevent food sanitation hazards, with a written inspection order which contains inspection items, methods for collecting test samples, inspection methods, and other matters specified by an Ordinance of the Ministry of Health, Labour and Welfare with regard to food, additives, or apparatus which the person produces or processes within a period not exceeding two months as specified by the prefectural governor.

(2) A person who intends to receive inspections pursuant to the provisions of Article 26, paragraph (1) of the Act shall submit a written application to a prefectural governor or a registered conformity assessment body, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

(3) A prefectural governor or a registered conformity assessment body shall, when receiving a written application set forth in the preceding paragraph, collect test samples and conduct inspections in accordance with what is set down in a written inspection order.

(Inspections under Article 26, Paragraph (2) of the Act)

Article 6 (1) A person who intends to receive inspections pursuant to the provisions of Article 26, paragraph (2) of the Act shall submit a written application to the Minister of Health, Labour and Welfare, or a registered conformity assessment body, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

(2) The Minister of Health, Labour and Welfare, or a registered conformity assessment body shall, when receiving a written application set forth in the preceding paragraph, collect test samples and conduct inspections in accordance with what is set down in a written inspection order.

(Inspections under Article 26, Paragraph (3) of the Act)

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

(Food Sanitation Inspection Facilities)

Article 8 (1) At food sanitation inspection facilities which prefectures, cities establishing health centers, or special wards establish pursuant to the provisions of Article 29, paragraph (1) or paragraph (2) of the Act, officials necessary for inspections or examination shall be placed, physicochemical laboratories, microorganism laboratories, animal rooms, and office rooms shall be set up, and machines and implements necessary for inspections or examination as specified by an Ordinance of the Ministry of Health, Labour and Welfare shall be installed.

(2) At food sanitation inspection facilities set forth in the preceding paragraph, affairs concerning inspections or examination shall be managed pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

(Qualifications of a Food Sanitation Inspector)

Article 9 (1) A food sanitation inspector shall be any person who falls under any of the following

(i) A person who has completed prescribed courses at training institutes for food sanitation supervisors registered by the Minister of Health, Labour and

Welfare;

(ii) A physician, dentist, pharmacist, or veterinarian;

(iii) A person who has graduated from a university or a vocational high school under the School Education Act (Act No. 26 of 1947), a university under the old University Ordinance (Imperial Ordinance No. 388 of 1918) or a vocational training school under the old Vocational Training School Ordinance (Imperial Ordinance No. 61 of 1903) after completing a course in medical science, dentistry, pharmacy, veterinary medicine, animal science, fisheries science, or agricultural chemistry;

(iv) A dietitian who has experience of being engaged in affairs concerning food sanitation administration for two years or more.

(2) The provisions of Articles 14 to 20 shall apply mutatis mutandis to training institutes set forth in item (i) of the preceding paragraph.

(Fee to Register as a Registered Conformity Assessment Body)

Article 10 The amount of the fee specified by a Cabinet Order under Article 31 of the Act shall be 202,600 yen.

(Valid Period of Registration as a Registered Conformity Assessment Body)

Article 11 The period specified by a Cabinet Order under Article 34, paragraph (1) of the Act shall be five years.

(Fee to Renew Registration as a Registered Conformity Assessment Body)

Article 12 The amount of the fee specified by a Cabinet Order under Article 31 of the Act which is applied mutatis mutandis under Article 34, paragraph (2) of the Act shall be 131,000 yen.

(Designation of Food, etc.)

Article 13 Food and additives specified by a Cabinet Order provided in Article 48, paragraph (1) of the Act shall be whole milk powder (limited to what may be put into a can whose capacity is 1,400 grams or less), sweetened milk powder, modified milk powder, processed meat products, fish meat sausage, irradiated food, edible fat and oil (limited to what is 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 11, paragraph (1) of the Act).

(Registration of a Training Institute)

Article 14 When the Minister of Health, Labour and Welfare registers a training institute under Article 48, paragraph (6), item (iii) of the Act, he/she shall follow

the criteria specified by an Ordinance of the Ministry of Health, Labour and Welfare with regard to the eligibility of entrance, training terms, subjects and other matters.

(Application for Registration)

Article 15 When intending to obtain registration of a training institute under Article 48, paragraph (6), item (iii) of the Act, the establisher thereof shall submit a written application to the Minister of Health, Labour and Welfare, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

(Notification of Changes)

Article 16 An establisher of a training institute for which registration under Article 48, paragraph (6), item (iii) of the Act has been obtained (hereinafter referred to as registered training institute") shall, when there are any changes to matters specified by an Ordinance of the Ministry of Health, Labour and Welfare, notify the Minister of Health, Labour and Welfare within one month since the date of the changes.

(Collection of Reports)

Article 17 The Minister of Health, Labour and Welfare may, when finding it necessary with regard to a registered training institute, request the establisher thereof to make a report.

(Rescission of Registration)

Article 18 When the Minister of Health, Labour and Welfare finds that a registered training institute has become unconfirmable to the criteria specified by an Ordinance of the Ministry of Health, Labour and Welfare under Article 14, or when there has been an application pursuant to the provisions of the following Article, he/she may rescind the registration thereof.

(Application for Rescission of Registration)

Article 19 When intending to obtain the rescission of the registration of the Minister of Health, Labour and Welfare with regard to a registered training institute, the establisher thereof shall submit a written application to the Minister of Health, Labour and Welfare, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

(Public Notice)

Article 20 In any of the following cases, the Minister of Health, Labour and Welfare shall issue a public notice of the relevant matters in official gazettes:

- (i) When the Minister of Health, Labour and Welfare has granted registration under Article 48, paragraph (6), item (iii) of the Act;
- (ii) When there has been a notification under Article 16 (limited to a notification pertaining to what is specified by an Ordinance of the Ministry of Health, Labour and Welfare);
- (iii) When the Minister of Health, Labour and Welfare has rescinded registration under Article 48, paragraph (6), item (iii) of the Act pursuant to the provisions of Article 18.

(Registration of Training Sessions)

Article 21 When intending to obtain registration of training sessions set forth in Article 48, paragraph (6), item (iv) of the Act, the organizer thereof shall apply for registration with the Minister of Health, Labour and Welfare, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

(Disqualification)

Article 22 A person falling under any of the following items may not obtain registration of training sessions set forth in Article 48, paragraph (6), item (iv) of the Act:

- (i) A person who has been sentenced to a fine or severer punishment for violation of the Act or any disposition based on the Act, before the expiration of a period of two years since the person served out the sentence or ceased to be subject to the sentence;
- (ii) A person who has had his/her registration rescinded pursuant to the provisions of Article 30, before the expiration of a period of two years since the date of said rescission;
- (iii) A juridical person who has persons falling under any of the preceding two items among the officers engaged in its business.

(Criteria for Registration)

Article 23 The Minister of Health, Labour and Welfare shall register training sessions which are organized by an organizer who has applied for registration under Article 21 pursuant to an Ordinance of the Ministry of Health, Labour and Welfare under Article 49 of the Act.

(Obligation to Organize Training Sessions)

Article 24 (1) An organizer of training sessions for which registration under Article 48, paragraph (6), item (iv) of the Act has been obtained (hereinafter referred to as "registered training sessions") shall prepare plans for organizing registered training sessions and organize registered training sessions in accordance with the

plans, except where there are justifiable grounds not to do so.

(2) An organizer of registered training sessions shall organize registered training sessions fairly by a method that conforms to the criteria specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(3) An organizer of registered training sessions shall submit plans prepared pursuant to the provisions of paragraph (1) to the Minister of Health, Labour and Welfare prior to the initiation of registered training sessions. The same shall apply when he/she intends to change the plans.

(Notification of Changes)

Article 25 An organizer of registered training sessions shall, when intending to change the matters specified by an Ordinance of the Ministry of Health, Labour and Welfare, notify the Minister of Health, Labour and Welfare by two weeks prior to the day when the change is scheduled.

(Suspension or Abolition of Operation)

Article 26 An organizer of registered training sessions shall, when intending to suspend the operation pertaining to registered training sessions, in whole or in part, or abolish said operation, notify the Minister of Health, Labour and Welfare in advance, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

(Maintenance and Inspection, etc. of Financial Statements, etc.)

Article 27 (1) An organizer of registered training sessions shall prepare an inventory of property, balance sheet, profit and loss statement or income and expenditure account statement, and business report (including an electromagnetic record (any record which is prepared by electronic, magnetic, or any other means unrecognizable by natural perceptive function, and is provided information processing by a computer; hereinafter the same shall apply in this Article) in cases where electromagnetic records are prepared instead of those paper documents; referred to as "financial statements, etc." in the following paragraph), and maintain them at the office, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

(2) A person who intends to participate in registered training sessions and any other interested person may make the following requests at any time within the business hours of an organizer of registered training sessions. However, when making a request set forth in item (ii) or item (iv), he/she shall pay fees specified by the organizer of registered training sessions:

(i) When financial statements, etc. are prepared as written documents, a request for inspection or copy of said documents;

- (ii) A request for a transcript or extract of the documents set forth in the preceding item;
- (iii) When financial statements, etc. are prepared as electromagnetic records, a request for inspection or copy of matters recorded on said electromagnetic records which are indicated in means specified by an Ordinance of the Ministry of Health, Labour and Welfare;
- (iv) A request for the matters recorded on the electromagnetic records set forth in the preceding item in electromagnetic means specified by an Ordinance of the Ministry of Health, Labour and Welfare or a request for delivery of written documents containing said matters.

(Order for Conformity)

Article 28 When the Minister of Health, Labour and Welfare finds that an organizer of registered training sessions is no longer the one who organizes registered training sessions pursuant to an Ordinance of the Ministry of Health, Labour and Welfare under Article 49 of the Act, he/she may order the organizer of registered training sessions to take the measures necessary to organize registered training sessions pursuant to an Ordinance of the Ministry of Health, Labour and Welfare under the same Article.

(Order for Improvement)

Article 29 When the Minister of Health, Labour and Welfare finds that an organizer of registered training sessions has violated the provisions of Article 24, he/she may order the organizer of registered training sessions to organize registered training sessions or take the measures necessary to improve the methods of organizing registered training sessions or other operational methods.

(Rescission, etc. of Registration)

Article 30 When an organizer of registered training sessions falls under any of the following items, the Minister of Health, Labour and Welfare may rescind registration thereof or order the suspension of the operation pertaining to registered training sessions, in whole or in part, for a specified period:

- (i) When an organizer of registered training sessions now falls under Article 22, item (i) or item (iii);
- (ii) When an organizer of registered training sessions has violated the provisions of Articles 24 to 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 justifiable 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 under Article 48, paragraph (6), item (iv) of the Act by wrongful means.

(Bookkeeping)

Article 31 An organizer of registered training sessions shall keep books, record matters concerning registered training sessions specified by an Ordinance of the Ministry of Health, Labour and Welfare, and retain them, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

(Collection of Reports)

Article 32 The Minister of Health, Labour and Welfare may have an organizer of registered training sessions make a report on the operation of or financial situations pertaining to the registered training sessions, to the extent necessary for the enforcement of the Act and this Cabinet Order.

(On-site Inspection)

Article 33 (1) The Minister of Health, Labour and Welfare may have the ministry officials visit places for the operation of an organizer of registered training sessions to inspect its operational situations or books, documents and other articles, to the extent necessary for the enforcement of the Act and this Cabinet Order.

(2) An official who conducts an on-site inspection pursuant to the provisions of the preceding paragraph shall carry his/her identification and produce it to the relevant persons.

(3) The authorities for on-site inspections set forth in paragraph (1) shall not be construed as having been granted for criminal investigation.

(Public Notice)

Article 34 In any of the following cases, the Minister of Health, Labour and Welfare shall issue a public notice of the relevant matters in official gazettes:

(i) When the Minister of Health, Labour and Welfare has granted registration under 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 Minister of Health, Labour and Welfare has rescinded registration of registered training sessions or ordered the suspension of the operation pertaining to registered training sessions, pursuant to the provisions of Article 30.

(Designation of Businesses)

Article 35 Businesses for which prefectures shall establish the criteria for their

facilities pursuant to the provisions of Article 51 of the Act shall be as follows:

- (i) Restaurant businesses (meaning businesses of general eating places, cooking stores, sushi restaurants, soba noodle shops, Japanese inns, caterers, lunch box stores, restaurants, cafes, bars, and cabarets, and other businesses for cooking food or setting up facilities to serve customers, and excluding businesses falling under the following item);
- (ii) Coffee shop businesses (meaning businesses of coffee shops and salons, and other businesses for setting up facilities to serve drinks other than alcoholic beverages or refreshments to customers);
- (iii) Confectionery businesses (including bakery businesses);
- (iv) Bean jam producing businesses;
- (v) Ice cream producing businesses (meaning businesses for producing ice cream, ice sherbet, ice candy, and other fluid food, or food made by freezing a mixture of fluid food and other food);
- (vi) Milk processing businesses (meaning businesses for processing or producing cow's milk (including skim milk and other milk beverages appearing similar to cow's milk) or goat's milk);
- (vii) Special milking and processing businesses (meaning businesses for collecting cow's milk and processing it into milk that meets ingredient standards specified by an Ordinance of the Ministry of Health, Labour and Welfare without a sterilization process or through treating it by pasteurization);
- (viii) Dairy product producing businesses (meaning businesses for producing milk powder, condensed milk, cultured milk, cream, butter, cheese and other food that is mainly made from milk (excluding milk beverages appearing similar to cow's milk));
- (ix) Milk collecting businesses (meaning businesses for collecting and preserving raw cow's milk or raw goat's milk);
- (x) Milk sales businesses (meaning businesses for selling cow's milk, goat's milk, or milk beverages (excluding those packed in conservatory containers and heat-sterilized for 15 minutes or more at 115 degrees C or over) directly served for drinking or cream mainly made from milk);
- (xi) Slaughtering businesses (meaning businesses for slaughtering or dressing poultry other than what are 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 what are provided in Article 3, paragraph (1) of the Slaughterhouse Act (Act No. 114 of 1953) or dividing or chopping meat and organs, etc. of dressed poultry or livestock for the purpose of serving them for human consumption);
- (xii) Processed meat sales businesses;
- (xiii) Processed meat product producing businesses (meaning businesses for

- producing ham, sausage, bacon and the like);
- (xiv) Fish and seafood sales businesses (meaning businesses for setting up shops to sell fresh fish and seafood and excluding businesses for selling live fish and seafood and businesses falling under the following item);
 - (xv) Fish and seafood auction businesses (meaning businesses for selling fresh fish and seafood on fish markets by auction);
 - (xvi) Fish jelly product producing businesses (including businesses for producing fish meat ham, fish meat sausage, whale meat bacon, and the like);
 - (xvii) Food freezer or cold storage businesses;
 - (xviii) Food irradiation businesses;
 - (xix) Carbonated drink producing businesses;
 - (xx) Lactic acid bacteria beverage producing businesses;
 - (xxi) Ice producing businesses;
 - (xxii) Ice sales businesses;
 - (xxiii) Edible fat and oil producing businesses;
 - (xxiv) Margarine or shortening producing businesses;
 - (xxv) Miso producing businesses;
 - (xxvi) Soy sauce producing businesses;
 - (xxvii) Sauce producing businesses (meaning businesses for producing worcester sauce, fruit sauce, fruit puree, ketchup, or mayonnaise);
 - (xxviii) Alcoholic beverage producing businesses;
 - (xxix) Bean curd producing businesses;
 - (xxx) Fermented soybeans producing businesses;
 - (xxxi) Noodles producing businesses;
 - (xxxii) Daily dish producing businesses (meaning businesses for producing boiled dishes (including preservable food boiled down in soy sauce), baked dishes (including fried dishes), deep fried dishes, steamed dishes, vinegared dishes, or marinated dishes generally served as side dishes, and excluding businesses falling under item (xiii), item (xvi), or item (xxix));
 - (xxxiii) Canned or bottled food producing businesses (excluding businesses falling under the preceding items);
 - (xxxiv) Additive producing businesses (meaning businesses for producing additives for which standards have been established pursuant to the provisions of Article 11, paragraph (1) of the Act).

(Investigations of Causes of Poisoning)

Article 36 Investigations to be conducted by the director of a health center pursuant to the provisions of Article 58, paragraph (2) 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 (1) of the following Article) shall be 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 paragraph (2) of the following Article) that have caused poisoning and disease agents;
- (ii) Investigations through microbiological or physicochemical tests or tests using animals with regard to blood, feces, urine, vomit or other material from a poisoned patient, a person suspected of being poisoned, or a corpse thereof, or food, etc. suspected as having caused poisoning.

(Reports concerning Poisoning)

Article 37 (1) With regard to investigations under Article 58, paragraph (2) of the Act (hereinafter referred to as "food poisoning investigations" in this Article), the director of a health center shall sequentially report the implementation of the investigations listed in each item of the preceding Article to a prefectural governor, a city mayor of a city establishing health centers, or a ward mayor of a special ward (hereinafter referred to as a "prefectural governor, etc." in this Article).

- (2) When there has been a report under Article 58, paragraph (3) of the Act (including cases where it is applied mutatis mutandis under Article 62, paragraph (1) of the Act), a prefectural governor, etc. shall sequentially report the number of poisoned patients, food that has caused poisoning, and other matters specified by an Ordinance of the Ministry of Health, Labour and Welfare from among matters for which he/she has received a report under the preceding paragraph, to the Minister of Health, Labour and Welfare.
- (3) After terminating food poisoning investigations, the director of a health center shall promptly prepare a written report and submit it to a prefectural governor, etc., pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.
- (4) A prefectural governor, etc. shall, when receiving a written report set forth in the preceding paragraph, prepare a further written report and submit it to the Minister of Health, Labour and Welfare, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

(Special Provisions for Large Cities, etc.)

Article 38 (1) At designated cities set forth 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 determined by designated cities under Article 67 of the Act shall be as provided in Article 174-34 of the Order for Enforcement of the Local Autonomy Act (Cabinet Order No. 16 of 1947).

- (2) At core cities set forth in Article 252-22, paragraph (1) of the Local Autonomy Act (hereinafter referred to as "core cities" in this Article), affairs to be

determined by core cities under Article 67 of the Act shall be as provided in Article 174-49-13 of the Order for Enforcement of the Local Autonomy Act.

(Businesses Set forth in Article 69, Paragraph (1) of the Act)

Article 39 Businesses specified by a Cabinet Order under Article 69, paragraph (1) of the Act shall be businesses listed in Article 35, item (i), item (ii), item (x), item (xii), item (xiv), and item (xxii).

(Classification of Affairs)

Article 40 Affairs that are to be determined by prefectures, cities establishing health centers, or special wards pursuant to the provisions of Article 37 shall be deemed to be item 1 legally delegated affairs provided in Article 2, paragraph (9), item (i) of the Local Autonomy Act.

(Delegation of Authority)

Article 41 (1) The authority of the Minister of Health, Labour and Welfare specified by this Cabinet Order may be delegated to the directors of the Local Bureaus of Health and Welfare, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

(2) The authority delegated to the directors of the Local Bureaus of Health and Welfare pursuant to the provisions of the preceding paragraph may be delegated to the chiefs of the Local Welfare Bureau Branches, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.