

# **Food Sanitation Law in Japan**

November 2004



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## **Food Sanitation Law**

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## **Food Sanitation Law**

Law No. 233, December 24, 1947  
Last amendment: Law No. 55, May 30, 2003

## Chapter 1. General Provisions

[Purpose]

**Article 1.** The purpose of this Law is to prevent the occurrence of health hazards arising from human consumption of food, by making necessary regulations and taking any measure so as to work for the protection of the health of the people.

[Duty of State, Prefectures, Cities Establishing Health Centers and Special Wards]

**Article 2.** State, any prefecture, any city prescribed by the Cabinet Order under the provisions of the Article 1 Paragraph 1 of the Health Center Law (Law No. 101, 1947) (hereinafter referred as a "city establishing health centers"), and any special ward shall take necessary measures through educational activities and public relations, so as to collect, arrange, analyze and offer information concerning food sanitation, so as to promote investigations concerning food sanitation, so as to improve examination facilities concerning food sanitation, and so as to train a man of ability and to improve the talent.

2. State, prefectures, cities establishing health centers and special wards shall make mutual cooperation so as to carry out measures concerning food sanitation systematically and rapidly.

3. State shall prepare systems concerning collection, arrangement, analysis, offer and research of food sanitation, and arrange systems concerning food sanitation examination of imported foods, food additives, apparatus and containers/packages, shall make necessary measures so as to ensure international cooperation, and shall give technical assistance to prefectures, cities establishing health centers and special wards (shall be referred, hereinafter, as "prefecture, etc.") so as to be able to achieve the qualification prescribed in the two preceding Paragraphs sufficiently.

[Duty of the Business Person of Food, etc.]

**Article 3.** Any business person of food, etc. (a person or a corporation that handles, manufactures, imports, processes, prepares, stores, transports, or sells food or food additives as a business, a person or corporation that manufactures, imports, or sells apparatus and containers/packages as a business, or a person or a corporation that serves foods continuously to the public or a large number of persons; the same, hereinafter) shall voluntarily make an effort to get knowledge and techniques related to the securing of the safety of the food, food additives, apparatus or containers/packages that was handled, manufactured, imported, processed, prepared, stored, transported, sold, offered to the public or a large number of persons, or used for business purpose (hereinafter referred to as "food intended for sale, etc."), related to the securing the safety of the raw materials of food intended for sale, etc., related to the practice of the self-imposed examination, and make an effort to take any other necessary measures.

2. A business person of food etc. shall make a record of the list of the supplier of food intended for sale, etc. and its raw materials, and shall make an effort for its maintenance.

3. A business person of food etc. shall make an effort precisely and quickly so as to work for the effort of the record prescribed in the preceding Paragraph to the state and prefectures, for the disposal of the food intended for sale, etc. which caused the out break of food sanitation hazards, and for any other necessary measure that can be taken.

[Definitions]

**Article 4.** In this Law, the term "food" means all foods and drinks; provided, however, that this term does not include drugs and quasi-drugs prescribed in the Pharmaceutical Affairs Law (Law No. 145, 1960).

**2.** In this Law, the term "food additive" means substances to be used in or on food, in the process of the manufacturing of food or for the purpose of the processing or preserving of food, by adding, mixing, infiltrating, or other means.

**3.** In this Law, the term "natural flavoring agent" means food additives, intended for use for flavoring food, which are substances obtained from animals or plants, or mixtures thereof.

**4.** In this Law, the term "apparatus" means tableware, kitchen utensils, and machines, implements, and other articles which are used for handling, manufacturing, processing, preparing, storing, transporting, displaying, delivering, or consuming food or food additives and which come into direct contact with food or food additives; provided, however, that this term does not include machines, implements, and other articles used for collecting food in agriculture and fisheries.

**5.** In this Law, the term "container/package" means articles in which foods or food additives are contained or packaged and in which foods and food additives are offered when such foods and food additives are delivered.

**6.** In this Law, the term "food sanitation" means hygiene as it relates to human consumption of food. This covers foods, food additives, apparatus, and containers/packages.

**7.** In this Law, the term "business" means, as a business, the handling, manufacturing, importing, processing, preparing, storing, transporting, or selling of food or food additives; or the manufacturing, importing, or selling of apparatus or containers/packages; provided, however, that this term does not include the collecting of food in agriculture and fisheries.

**8.** In this Law, the term "business person" means individuals or corporations who carry on businesses.

**9.** In this Law, the term "registered laboratory" means corporations qualified for registration of the Minister of Health, Labour and Welfare under the provisions of Article 33 Paragraph 1 of the Law.

## **Chapter 2. Food and Food Additives**

[Principles for Handling of Food and Food Additives Intended for Sale]

**Article 5.** Any food or food additive intended for sale (hereinafter in this Law, the term "sale" includes supplying for purposes other than sale to the public or a large number of persons) shall be handled, manufactured, processed, used, prepared, stored, transported, displayed, or delivered in clean and sanitary conditions.

[Food and Food Additives Whose Sale is Prohibited]

**Article 6.** No person shall sell (hereinafter in this Law, the term "sell" includes supplying for purposes other than sale to the public or a large number of persons), or handle, manufacture, import, process, use, prepare, store, or display with intent to sell any food or food additive given below:

(1) Those which are rotten, decomposed, or immature; provided, however, that this Subparagraph does not apply to articles that are generally deemed not to be injurious to human health and are deemed to be fit for human consumption.

(2) Those which contain or bear toxic or injurious substances or which are suspected to contain or bear these substances; provided, however, that this provision does not apply to the cases which are prescribed by the Minister of Health, Labour and Welfare as not injurious to human health<sup>1)</sup>.

(3) Those which are either contaminated with or suspected to be contaminated with pathogenic microorganisms and which may injure human health.

(4) Those which may injure human health due to uncleanness, the admixture or addition of extraneous substances, or any other causes.

(Reference)

1): The proviso of Article 4 (2): Article 1 of the Ministry of Health, Labour and Welfare Ordinance No. 23 (hereinafter in this Law referred to as the "Ministerial Ordinance")

[Prohibition of Sale of Newly Developed Food]

**Article 7.** When any article never before generally served for human consumption, which could possibly injure human health, or any article containing the same is, or is to be, newly sold as food, the Minister of Health, Labour and Welfare may prohibit the sale of such article as a food after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council, when the Minister of Health, Labour and Welfare determines that the action is necessary to prevent the outbreak of food sanitation hazards.

2. When any article generally served for consumption, and in case it is served for consumption in a quite different recipe from the ordinary way of consumption, which could possibly injure human health, the Minister of Health, Labour and Welfare may prohibit the sale of such article as a food, after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council, when the Minister determines that such action is necessary to prevent the outbreak of food sanitation hazards.

3. When a serious hazard broke out related human health, suspected to have been derived from food, and from the mode of the hazard it is suspected that the food is suspected to contain a substance which has never been served for human consumption before, the Minister of Health, Labour and Welfare may prohibit the sale of such food, after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council, when the Minister determines that such action is necessary to prevent the outbreak of food sanitation hazards.

4. In case prohibitions of sale were performed according to the provisions of the preceding Paragraphs, the Minister of Health, Labour and Welfare shall cancel all or a part of the dispositions, when it was confirmed that there will be no more danger of outbreak or injuring from the standpoint of food sanitation, based on the application of the persons concerned with the dispositions or in case of need, after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

5. In case prohibitions of sale were performed according to the provisions of Paragraphs 1 through 3, or in case all or a part of the dispositions were canceled, the Minister of Health, Labour and Welfare shall make a notice on official gazette.

[Prohibition of Sale, Manufacture, Import, etc. of Specified Foods and Food Additives]

**Article 8.** In case specified foods or food additives, which had been collected, manufactured, processed, prepared or stored in specified countries or regions, or which had been collected, manufactured, processed, prepared or stored by specified persons, were found after the inspection specified in Article 26 Paragraphs 1 through 3 or Article 28 Paragraph 1 considerably to fall into the following foods or food additives, or, in case specified foods or food additives are suspected from the standpoint of food sanitation control condition in the production area and from other items prescribed in the Ministerial Ordinance considerably to fall into the following foods or food additives, taking into account the degree of injuring the human health that might happen and other items prescribed in the Ministerial Ordinance, the Minister of Health, Labour and Welfare can prohibit, in order to prevent outbreak of harmful food sanitary hazard, after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council, the sales or collecting, manufacturing, importing, processing, using or preparing with intent to sell any food or food additive given below:

(1) Foods or food additives specified in each Subparagraph of Article 6

(2) Foods specified in Article 10

(3) Foods or food additives not in conformity with the specifications under the provisions of Article 11 Paragraph 1

(4) Foods to which food additives had been used by a method not in conformity with the standards under the provisions of Article 11 Paragraph 1

2. On performing the prohibitions according to the provisions of the preceding Paragraph, the Minister of Health, Labour and Welfare has, in advance, to make a negotiation with the directors of the related administrative organizations.

3. In case prohibitions were performed according to the provisions of Paragraph 1, the Minister of Health, Labour and Welfare shall cancel all or a part of the prohibitions, when it was confirmed that there will be no more danger or outbreak of injuring from the standpoint of food sanitation, based on the application of the persons concerned with the prohibitions or in case of need, after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

4. In case prohibitions were performed according to the provisions of Paragraph 1, or in case all or a part of the prohibitions according to the provisions of Paragraph 1 were canceled, the Minister of Health, Labour and Welfare shall make a notice in official gazette.

[Prohibition of Sale, etc. of Meat, etc. Derived from Diseased Livestock and Poultry]

**Article 9.** No person shall sell as a food, or handle, process, use, prepare, store, or display with intent to sell as a food any meat, bone, milk, viscera, or blood of livestock (livestock designated under the provisions of Article 3 Paragraph 1 of the Abattoir Law (Law No. 114, 1953) and other substances as designated by the Ministerial Ordinance<sup>1)</sup>; the same, hereinafter) which suffers from or is suspected to suffer from diseases specified in Subparagraph 1 or 3, which shows disorder specified in Subparagraph 1 or 3, or which has died of any causes before slaughtering, or any meat, bone, or viscera of poultry (poultry designated under Article 2, Subparagraph 1 of the Law concerning the Regulation of Poultry Plant and Poultry Inspection (Law No. 70, 1990) and other substances designated by the Ministerial Ordinance<sup>2)</sup>; the same, hereinafter) which suffers from or is suspected to suffer from diseases specified in Subparagraph 2 or 3, which shows disorder specified in Subparagraph 2 or 3, or which has died of any causes before slaughtering; provided, however, that this Paragraph does not apply to any meat, bone or viscera of dead livestock or poultry which is determined by the officials concerned as not injurious to human health and fit for human consumption<sup>3)</sup>.



(1) Disease or disorder designated under the Subparagraphs of Paragraph 6 of Article 14 of the Abattoir Law

(2) Disease or disorder designated under the Subparagraphs of Paragraph 4 of Article 15 of the Law concerning the Regulation of Poultry Plant and Poultry Inspection

(3) Disease or disorder other than those indicated in the two preceding Subparagraphs and are specified in the Ministerial Order

2. No person shall import, with intent to sell as a food, any meat or viscera of livestock or poultry or products thereof designated by the Ministerial Ordinance<sup>4)</sup> (hereinafter in this Paragraph, the meat, viscera, and products thereof mentioned above are referred to as "livestock meat etc.") unless it is accompanied with a certificate or a copy thereof issued by a governmental organization of the exporting country, stating that it is not meat or viscera nor any of the products derived from livestock or poultry which suffers from or is suspected to suffer from any of the diseases designated by the Ministerial Ordinance under the preceding Paragraph or which has died of any reason before slaughtering, and describing other items prescribed by the Ministerial Ordinance<sup>5)</sup> (hereinafter in this Paragraph, any statements and necessary items mentioned above are referred to as "sanitation-related information"); provided, however, that this Paragraph does not apply to livestock meat etc. which is imported from a country designated by the Ministerial Ordinance and concerning which sanitation-related information has been transmitted from a governmental organization of such country to the computer used by the Ministry of Health, Labour and Welfare (including input/output unit) on an electric communication line and recorded in a file on the computer.

(References)

- 1): Article 7 Paragraph 2, Subparagraph 1 of the Ministerial Ordinance
- 2): Article 7 Paragraph 2, Subparagraph 2 of the Ministerial Ordinance
- 3): Article 7 Paragraph 4 of the Ministerial Ordinance
- 4): Article 8 of the Ministerial Ordinance
- 5): Article 9 of the Ministerial Ordinance

[Prohibition of Sale, etc. of Food Additives, etc.]

**Article 10.** No person shall sell, or manufacture, import, process, use, store, or display with intent to sell any food additive (excluding any natural flavoring agent and any substance which is generally provided for eating or drinking as a food and which is used as a food additive) or any preparation or food that contains such food additive, unless the Minister of Health, Labour and Welfare designates it as not injurious to human health based upon the opinion of the Pharmaceutical Affairs and Food Sanitation Council<sup>1)</sup>.

(Reference)

- 1): Article 12 of the Ministerial Ordinance (Table 1)

[Establishment of Specifications and Standards for Food or Food Additives]

**Article 11.** The Minister of Health, Labour and Welfare, from the viewpoint of public health, may establish standards for methods of manufacturing, processing, using, preparing, or preserving food or food additives intended for sale or may establish specifications for components of food or food additives intended for sale, based upon the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

2. Where specifications or standards have been established pursuant to the provisions of the preceding Paragraph, any person shall be prohibited from manufacturing, processing, using, preparing, or preserving any food or food additive by a method not complying with the established standards; or from manufacturing, importing, processing, using, preparing, preserving, or selling any food or food additive not complying with the established specifications.

[Request for Cooperation from the Minister of Agriculture, Forestry, and Fisheries]

**Article 12.** The Minister of Health, Labour and Welfare may request from the Minister of Agriculture, Forestry and Fisheries the provision of information concerning ingredients of a pesticide, designated under the provisions of Article 1-2 Paragraph 1 of the Agricultural Chemicals Regulation Law (Law No. 82, 1948), feed additives, designated under the provisions of Article 2 Paragraph 3 of the Law concerning Safety Assurance and Quality Improvement of Feed (Law No. 35, 1953), drugs designated under the provisions of Article 2 Paragraph 1 of the Pharmaceutical Affairs Law, which is to be used exclusively for animals (shall be called, hereinafter as "pesticides, etc.") and other necessary cooperation, if the Minister of Health, Labour and Welfare determines that such action is necessary to establish quantitative limitations on substances (including products formed by a chemical change of the substance), and any other necessary cooperation.

[Comprehensive Sanitation-controlled Manufacturing Process]

**Article 13.** When the Minister of Health, Labour and Welfare has received an application for approval concerning a food for which standards for manufacturing or processing methods have been established pursuant to the provisions of Article 11 Paragraph 1 and which has been designated by the Cabinet Order No. 229<sup>1)</sup> (hereinafter referred to as the "Cabinet Order"), from a person (including a person wishing to manufacture or process such food abroad) who wishes to manufacture or process the food based on comprehensive sanitation-controlled manufacturing process (hereinafter in this Law, such process means a process of manufacturing or processing in which comprehensive measures are taken concerning manufacturing or processing methods and sanitation-control methods, to prevent the occurrence of food sanitation hazards), the Minister of Health, Labour and Welfare may give approval for such manufacturing or processing based on the comprehensive sanitation-controlled manufacturing process, for each type/kind of food and each manufacturing or processing plant.

2. The Minister of Health, Labour and Welfare shall not give the approval prescribed in the preceding Paragraph if the manufacturing or processing method and the sanitation-control method under the comprehensive sanitation-controlled manufacturing process concerning which the application mentioned in the same Paragraph has been made does not comply with the standards prescribed by the Ministerial Ordinance<sup>2)</sup>.

3. Any person who wishes to obtain the approval prescribed in Paragraph 1 shall, as prescribed by the Ministerial Ordinance<sup>3)</sup>, submit an application accompanied by the required documents including test data for the food manufactured or processed according to the comprehensive sanitation-controlled manufacturing process.

4. When a person who has obtained the approval prescribed in Paragraph 1 (hereinafter in Paragraph 5, referred to as an "approval-holder") wishes to change a part of the comprehensive sanitation-controlled manufacturing process under approved such approval, such person may request approval for such partial change. The provisions of the preceding two Paragraphs shall apply in this case.

5. The Minister of Health, Labour and Welfare may cancel all or a part of the approval prescribed

in Paragraph 1 which the approval-holder obtained, if one of the following prevails:

(1) The manufacturing or processing method and sanitation-control method under the comprehensive sanitation-controlled manufacturing process approved under such approval is no longer in compliance with the standards prescribed by the Ministerial Ordinance mentioned in Paragraph 2.

(2) An approval-holder changes a part of the comprehensive sanitation-controlled manufacturing process approved under such approval without obtaining the approval prescribed in the preceding Paragraph.

(3) An approval-holder who manufactures or processes food in accordance with the comprehensive sanitation-controlled manufacturing process approved under such approval in a foreign country (in Subparagraph (4), referred to as an "overseas-manufacturing-approval-holder") fails to submit the report or submits a false report, when the Minister of Health, Labour and Welfare, based on the determination that an action is necessary, has requested such person to submit a required report.

(4) An inspection is refused, obstructed, or evaded, when the Minister of Health, Labour and Welfare, based on the determination that an action is necessary, has required officials to inspect foods, account books, or other articles at manufacturing or processing plants, offices, warehouses, or other places of an overseas-manufacturing-approval-holder.

6. The manufacturing or processing of food based on the comprehensive sanitation-controlled manufacturing process approved under the approval prescribed in Paragraph 1 shall be deemed as the manufacturing or processing of food using a method complying with the standards prescribed in Article 11 Paragraph 1 and shall be subjected to the provisions of this Law or any order based on the this Law.

7. Any person wishing to obtain the approval prescribed in Paragraph 1 or the approval for change prescribed in Paragraph 4 shall pay a fee fixed by the Cabinet Order<sup>4)</sup> in consideration of the expenses required to review the application.

(References)

1) Article 1 Paragraph 1 of the Cabinet Order

2) Article 13 of the Ministerial Ordinance

3) Articles 14 and 15 of the Ministerial Ordinance

4) Article 1 Paragraph 2 of the Cabinet Order

[Term of Validity of Approval of Comprehensive Sanitation-controlled Manufacturing Process]

**Article 14.** Any person who wishes to apply for the renewal of the approval prescribed in Paragraph 1 of the preceding Article shall lose the validity after elapse of not less than 3 years specified by the Cabinet order (shall be called, hereinafter, as "term of validity", in this Article), unless he applies the renewal every time when necessary.

2. The provisions in Paragraphs 2 and 3 of the preceding Article shall apply to the renewal of the preceding item.

3. In case an application was done for the renewal of the preceding Paragraph, when the disposition has not been done by the day of completion of the term of validity, the former approval shall be valid even after the completion of the term of validity until the disposition shall be done.

4. In the preceding Paragraph, when the renewal of approval was done, the term of validity of the approval shall begin from the next day of the completion of the former approval.

5. A person who wishes to get the renewal of the approval prescribed in Paragraph 1 shall pay a fee fixed by Cabinet Order, taking into account the actual cost price necessary for the examination.

### **Chapter 3. Apparatus and Containers/Packages**

[Principle for Handling of Apparatus and Containers/Packages Used in Business]

**Article 15.** Any apparatus and container/package used in business shall be clean and sanitary.

[Prohibition of Sale, etc. of Toxic or Injurious Apparatus or Containers/Packages]

**Article 16.** No person shall sell, manufacture or import with intent to sell, or use in business any apparatus or container/package which contains or bears toxic or injurious substances and may injure human health or any apparatus or container/package which may injure human health by having harmful influence on foods and food additives through contact therewith.

[Prohibition of the Sales, Manufacture, Import, etc. of Specified Apparatus and Container/Package]

**Article 17.** In case specified apparatus or containers/packages, which had been manufactured, in specified countries or regions, or which had been manufactured by specified persons, were found after the inspection specified in Article 26 Paragraphs 1 through 3 or Article 28 Paragraph 1, considerably to fall into the following apparatus and containers/packages, or, in case specified apparatus and containers/packages are specifically needed from the standpoint of food sanitation control in the manufacturing area and from other items prescribed in the Ministerial Ordinance, the Minister of Health, Labour and Welfare can prohibit, after hearing of the Pharmaceutical Affairs and Food Sanitation Council, the sales or manufacturing, importing or using on business with intent to sell any apparatus or container/package given below:

(1) Apparatus or containers/packages specified in the preceding Article

(2) Apparatus or containers/packages not in conformity with the specifications under provisions of the Paragraph 1 of the following Article

2. On performing the prohibitions according to the provisions of the preceding Paragraph, the Minister of Health, Labour and Welfare has in advance, to make a negotiation with the directors of the related administrative organizations.

3. The provisions of Article 8 Paragraphs 3 and 4 shall apply to the cases when prohibitions were performed according to the provisions of Paragraph 1. In these cases, "foods or food additives" used in the same Article Paragraph 3 shall be construed as "apparatus or containers/packages".

[Establishment of Specifications and Standards for Apparatus or Containers/Packages]

**Article 18.** The Minister of Health, Labour and Welfare, from the viewpoint of public health, may establish specifications for apparatus, containers/packages, or raw materials thereof intended for sale or for use in business, or may establish standards for methods of manufacturing apparatus or containers/packages, based upon the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

2. Where specifications or standards have been established pursuant to the provisions of the preceding Paragraph, any person shall be prohibited from selling, manufacturing or importing with intent to sell, or using in business any apparatus or container/package not complying with the established specifications; from using any raw material not complying with the established specifications; or from manufacturing any apparatus or container/package by a method not complying with the established standards.

#### **Chapter 4. Labeling and Advertising**

[Establishment of Standards for Labeling]

**Article 19.** The Minister of Health, Labour and Welfare, from the viewpoint of public health, may establish after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council necessary standards for the labeling of foods or food additives intended for sale, or of apparatus or containers/packages for which specifications or standards have been established pursuant to the provisions of Paragraph 1 of the preceding Article<sup>1)</sup>.

2. No person shall sell, or display with intent to sell, or use in business any food, food additive, apparatus, or container/package for which standards for labeling have been established pursuant to the provisions of the preceding Paragraph, unless it bears labeling complying with the established standards.

(Reference)

1): Tables 3 through 9 of Article 21 of the Ministerial Ordinance

[Prohibition of False Labeling, etc.]

**Article 20.** No person shall falsely or exaggeratedly label or advertise any food, food additive, apparatus, or container/package in any manner which may injure public health.

#### **Chapter 5. The Japanese Standards for Food Additives**

[*The Japanese Standards for Food Additives*]

**Article 21.** The Minister of Health, Labour and Welfare shall compile *The Japanese Standards for Food Additives* to contain therein the standards and specifications for the food additives for which standards and specifications have been established pursuant to the provisions of Article 11 Paragraph 1 and to contain therein the standards for the food additives for which standards have been established pursuant to the provisions of Article 19 Paragraph 1.

#### **Chapter 6. Principle and Plan of Inspection and Guidance**

[Principle of Inspection and Guidance]

**Article 22.** The Minister of Health, Labour and Welfare shall establish principle on the practice (shall be called, hereinafter, as "principle") of the inspection guidance on food sanitation (shall be called, hereinafter, as "inspection and guidance"), performed by the state and prefectures.

2. Principle shall be established on the following items.

(1) Basic destination on the practice of inspection and guidance

- (2) Items on which inspection and guidance shall be performed concentratedly
- (3) Matters on the performance system of inspection and guidance
- (4) Other important subjects on the practice of inspection and guidance

3. When he established or changed the principle, the Minister of Health, Labour and Welfare shall announce it without delay.

[Plan of Inspection and Guidance of Imported Food]

**Article 23.** The Minister of Health, Labour and Welfare shall establish every fiscal year, according to the principle, plan of practice of inspection and guidance of the next year on the import of food, food additives, apparatus and containers/packages, carried out by the state (shall be called, hereinafter, as "plan of inspection and guidance of imported food").

2. Plan of inspection and guidance of imported food shall be established on the following items.

(1) In view of circumstances in the producing district and other circumstances, items to be inspected and guided concentratedly

(2) Items to be guided for persons engaged in import business, concerning practice of self-imposed examination of food sanitation

(3) Other items necessary for the performance of the inspection and guidance

3. The Minister of Health, Labour and Welfare shall establish plan of inspection and guidance of imported food, and shall officially announce it when he established or changed the plan.

4. The Minister of Health, Labour and Welfare shall officially announce on the actual circumstance of the practice of plan of inspection and guidance of imported food.

[Plan of Inspection and Guidance of Food Sanitation of Prefectures, etc.]

**Article 24.** The governor of any prefecture, the mayor of any city establishing health centers, or mayor of any special ward (shall be called, hereinafter, as "governor of prefecture, etc.") shall establish, every fiscal year, according to the principle, plan of practice of inspection and guidance of the next year, carried out by governor of prefecture, etc. (shall be called, hereinafter, as "plan of inspection and guidance of food sanitation of prefecture, etc.").

2. Plan of inspection and guidance of food sanitation of prefecture, etc. shall be established on the following items.

(1) Items on which inspection and guidance shall be performed concentratedly

(2) Items to be guided for business person of food, etc., concerning practice of self-imposed examination of food sanitation

(3) Items related to the secureness of the cooperation of the concerned prefecture, etc. with neighboring prefecture, etc. and with other related administration agencies

(4) Any other items necessary for the practice of inspection and guidance

3. Plan of inspection and guidance of food sanitation of prefecture, etc. shall be established, taking into account the situation of setting up facility of the business person of food, etc. in the area of the prefecture, etc. concerned, actual condition of outbreaks of harmful food sanitary hazard, and other actual state of the area.

4. In case plan of inspection and guidance of food sanitation of prefecture, etc. was established or changed, governor of prefecture, etc. shall officially announce it without delay, and shall report it to the the Minister of Health, Labour and Welfare according to the provisions prescribed in the Ministerial Ordinance.

5. Governor of prefecture, etc. shall officially announce the actual situation of the practice of plan of inspection and guidance of food sanitation of prefecture, etc.

## Chapter 7. Examination

[Product Examination and Prohibition of the Sale of Foods not Labeled with Certificates]

**Article 25.** No person shall sell, display with intent to sell, or use in business any food or food additive or any apparatus or container/package for which specifications have been established pursuant to the provisions of Article 11 Paragraph 1 or Article 18 Paragraph 1, respectively, and which has been designated by the Cabinet Order<sup>1)</sup>, unless it has undergone examinations performed by the Minister of Health, Labour and Welfare, the governor of the prefecture concerned, or a registered laboratory, in accordance with the classification prescribed by the Cabinet Order<sup>1)</sup> and bears a label prescribed by the Ministerial Ordinance<sup>2)</sup> stating that it has passed the examinations.

2. Any person who wishes to apply for examinations by the Minister of Health, Labour and Welfare or a registered laboratory, prescribed in the preceding Paragraph shall pay the fee fixed by the Minister of Health, Labour and Welfare in case of examination performed by the Minister and the fee fixed by the registered laboratory concerned, in case of examination performed by a registered laboratory, respectively, in consideration of actual expenses required for the examinations.

3. The fee of the preceding Paragraph shall become 1) revenue of the National Treasury in the case of examinations performed by the Minister of Health, Labour and Welfare<sup>3)</sup>, and 2) revenue of the registered laboratory concerned in the case of examinations performed by a registered laboratory.

4. In addition to the provisions of the preceding three Paragraphs, necessary items relating to the examinations prescribed in Paragraph 1 and measures to be taken when the product has passed the examinations shall be prescribed by the Cabinet Order<sup>4)</sup>,

5. No person shall file objection under the Administrative Appeals Law (Law No.160, 1962) to any result of the examinations prescribed in Paragraph 1.

(References)

1): Article 4 Paragraph 1 of the Cabinet Order

2): Article 26 of the Ministerial Ordinance

3): Article 31 of the Ministerial Ordinance

4): Article 4 Paragraphs 2 through 4 of the Cabinet Order

[Examination Order]

**Article 26.** If the governor of any prefecture discovers a food, food additive, apparatus, or

container/package which is designated by the Cabinet Order<sup>1)</sup> and which falls under any of the foods, food additives, apparatus, or containers/packages given in each of the Subparagraphs below, the governor may, in accordance with requirements and procedures prescribed by the Cabinet Order<sup>2)</sup>, order the person having manufactured or processed such product to allow examinations performed by the governor of such prefecture or a registered laboratory on such food, food additive, apparatus, or container/package, when the governor determines that in the light of the examination capability of the manufacturer or processor of such product, the food, food additive, apparatus, or container/package manufactured or processed by the same person may continue to fall under any of the foods, food additives, apparatus, or containers/packages given in each of the Subparagraphs below and that the action is necessary to prevent the occurrence of food sanitation hazards.

(1) Foods or food additives prescribed in Article 6 Subparagraph (2) or (3).

(2) Foods or food additives not complying with the specifications established pursuant to the provisions of Article 11 Paragraph 1.

(3) Foods in which food additives are used by methods not complying with the standards established pursuant to the provisions of Article 11 Paragraph 1.

(4) Apparatus or containers/packages prescribed in Article 6.

(5) Apparatus or containers/packages not complying with the specifications established pursuant to the provisions of Article 18 Paragraph 1.

**2.** The Minister of Health, Labour and Welfare may order a person who imports any food, food additive, apparatus, or container/package of the same kind as that manufactured or processed by the person who has previously manufactured or processed a food, food additive, apparatus, or container/package which falls under any of the foods, food additives, apparatus, or containers/packages given in each of the Subparagraphs of the preceding Paragraph, or any of the foods prescribed in Article 10, to allow examinations performed by the Minister of Health, Labour and Welfare or a registered laboratory on such food, food additive, apparatus, or container/package, when the Minister of Health, Labour and Welfare determines that the action is necessary to prevent the occurrence of food sanitation hazards.

**3.** The Minister of Health, Labour and Welfare may order a person who imports any food, food additive, apparatus, or container/package which is suspected to fall under any of the foods, food additives, apparatus, or containers/packages given in each of the Subparagraphs of Paragraph 1, or to fall under any of the foods prescribed in Article 10 in view of circumstances in the producing district and other circumstances, to allow examinations performed by the Minister of Health, Labour and Welfare or a registered laboratory on such food, food additive, apparatus, or container/package, when the Minister of Health, Labour and Welfare determines that such action is necessary to prevent the occurrence of food sanitation hazards.

**4.** No person who has received any examination order prescribed in the preceding three Paragraphs, shall sell, display with intent to sell, or use in business any food, food additive, apparatus, or container/package, unless it undergoes the examinations and such person receives a notice of the examination result\*.

Note \* : "the person receives a notice of the examination result" means "the person receives a notice indicating that the product has no problem concerning food sanitation."

**5.** The notice prescribed in the preceding Paragraph shall, when issued by a registered laboratory, be issued through the governor of such prefecture or the Minister of Health, Labour and Welfare, who ordered the examinations.



6. Any person who wishes to apply for examinations prescribed in Paragraphs 1 through 3 shall, for examinations performed by the Minister of Health, Labour and Welfare, pay a fee determined by the Minister of Health, Labour and Welfare, as appropriate, in consideration of the actual expenses required for the examinations, or shall, for examinations performed by a registered laboratory, pay a fee determined by the examiner under permission of the Minister of Health, Labour and Welfare, in consideration of the actual expenses required for the examinations.

7. The provisions of Paragraphs 3 through 5 of the preceding Article shall apply to the examinations prescribed in Paragraphs 1 through 3.

(References)

1): Article 5 Paragraph 1 of the Cabinet Order

2): Article 5 Paragraphs 2 and 3 of the Cabinet Order

[Import Notification]

**Article 27.** Any person, who wishes to import a food, food additive, apparatus, or container/package intended for sale or for use in business, shall, at each import, notify the Minister of Health, Labour and Welfare as prescribed by the Ministerial Ordinance<sup>1)</sup>.

(Reference)

1): Article 32 of the Ministerial Ordinance

[Request for Reports, On-site Inspection, Collection of Samples]

**Article 28.** The Minister of Health, Labour and Welfare, or governor of prefecture, etc. may request necessary reports from a business person or other related persons, require the officials concerned to visit the place of business, offices, warehouses, or other places in order to inspect foods, food additives, apparatus, or containers/packages intended for sale or for use in business, or the business facilities, books, documents, or other articles, or require such officials to collect samples of foods, food additives, apparatus, or containers/packages intended for sale or for use in business without compensating such samples within the quantity necessary for performing tests<sup>1)</sup>, when the Minister of Health, Labour and Welfare, governor of prefecture, etc. concerned determines that the action is necessary.

2. When the Minister of Health, Labour and Welfare, governor of prefecture, etc., pursuant to the provisions of the preceding Paragraph, requires the officials concerned to make on-site inspections or to collect samples, the Minister of Health, Labour and Welfare, governor, etc. concerned shall have such officials carry certificates stating their status<sup>2)</sup>.

3. The authority endorsed by the provisions of Paragraph 1 shall not be read to mean that it is approved to be used for the execution of criminal investigation.

4. The Minister of Health, Labour and Welfare or prefectural governor, etc. may consign the administrative work related to the testing of foods, food additives, apparatus, or containers/packages collected pursuant to the provisions of Paragraph 1, to a registered laboratory.

(References)

1): Article 35 Paragraph 1 of the Ministerial Ordinance

2): Article 35 Paragraph 2 of the Ministerial Ordinance

[Food Sanitation Examination Facilities]

**Article 29.** The Government and each prefecture shall establish examination facilities to perform the examinations prescribed in Article 25 Paragraph 1 or Article 26 Paragraphs 1 through 3 (hereinafter referred to as "product examination") and to perform administrative work relating to testing of foods, food additives, apparatus, or containers/packages collected pursuant to the provisions of Paragraph 1 of the preceding Article.

2. Each city establishing health centers and each special ward shall establish examination facilities to perform administrative work relating to testing of food, food additives, apparatus, or containers/packages collected pursuant to the provisions of Paragraph 1 of the preceding Article.

3. Requirements relating to food sanitation examination facilities established by each prefecture, etc. shall be prescribed by the Cabinet Order<sup>1)</sup>.

(Reference)

1): Article 8 of the Cabinet Order

[Food Sanitation Inspectors]

**Article 30.** The Minister of Health, Labour and Welfare, the governor of each prefecture, etc. shall appoint food sanitation inspectors to execute the authority of officials prescribed in Article 28 Paragraph 1 and to perform the duties of providing guidance for food sanitation, in each jurisdiction from among the officials of the Government or prefecture, etc.

2. The governor of prefecture, etc. shall require food sanitation inspectors to perform inspections or to provide guidance under the provisions of the plan of inspection and guidance of food sanitation of prefecture, etc.

3. The Minister of Health, Labour and Welfare shall require food sanitation inspectors to perform inspections or to provide guidance concerning import of food, food additives, apparatus and containers/packages under the provisions of the plan of inspection and guidance of imported food.

4. In addition to the provisions of the preceding three Paragraphs, qualifications of food sanitation inspectors and other necessary items relating to food sanitation inspectors shall be prescribed by the Cabinet Order<sup>1)</sup>.

(Reference)

1): Article 9 of the Cabinet Order

## **Chapter 8. Registered Laboratories**

[Application]

**Article 31.** Any person wishing to obtain license of registered laboratory, shall apply registration to the Minister of Health, Labour and Welfare in accordance with the provisions of the Ministerial Ordinance<sup>1)</sup>, paying the fee fixed by the Cabinet Order<sup>2)</sup> in consideration of the actual expenses.

(References)

1): Article 38 of the Ministerial ordinance

2): Article 10 of the Cabinet Order

[Persons Not Qualified for Registration]

**Article 32.** Any person who falls under any of the categories given below shall not be able to obtain the license of registered laboratory.

(1) A person or an executive engaged in the execution of the business has been fined a penalty or sentenced to penal servitude due to a violation of this Law or any disposition under this Law, and two years have not passed from the date of such fine or the completion of serving such sentence or the invalidation of such fine or sentence.

(2) A person whose registration has been revoked pursuant to the provisions of Article 43, and two years have not passed from the date of the revocation.

(3) A person who has been an executive engaged in the execution of the business of a corporation that was revoked pursuant to the provisions of Article 43, within 30 days of the revocation, and two years have not passed from the date of revocation.

[Qualifications Required for Registration of Examination Laboratories]

**Article 33.** The Minister of Health, Labour and Welfare shall register any person who applied registration pursuant to the provisions of Article 31 (shall be called, hereinafter, in this Paragraph as "applicant for registration"), when the applicant for registration complies with each of the following requisites. In such case, the procedures necessary for registration shall be provided by Ministerial Ordinance<sup>1)</sup>.

(1) The machinery, apparatus, and other facilities listed in Column 2 of Table are provided for each category of Column 1 of the same Table, product estimation shall be carried out by a person who has expertise and experience complying with the conditions prescribed in Column 3 of the same Table, and the number of such persons shall not be less than that indicated in Column 4 of the same Table.

(2) Following procedures shall be taken for assuring quality in the product examination.

a. Executive manager shall be appointed for each of the category of product examination in examination unit.

b. Document has been prepared for the management of product examination and assurance of proficiency.

c. Executive unit shall be put for the control of product examination business and assurance of proficiency according to the document prepared indicated in b).

(3) Applicant for registration shall not be one of the following three categories, being controlled by business person who sells, manufactures with intent to sell, imports, processes or displays, or uses in business, food, food additives, apparatus or containers/packages which have to undergo product examination pursuant to the provisions of Article 25 Paragraph 1, or Article 26 Paragraphs 1 through 3 (shall be called, hereinafter, in this Subparagraph and Article 39 Paragraph 2 as "business person who undergoes examination").

a. In case an applicant for registration is a joint-stock company or a limited company, business person who undergoes examination shall not be a parent company (means parent company specified by Article 211-2 Paragraph 1 of the Commercial Law (Law No. 48, 1899)).

b. The ratio of executives or employees of the business person who undergoes examination (includes those who have been the executives or employees of the business person who undergoes examination in the past two years) in the executives of the applicant for registration (executives or staffs having executive right in case of a general partnership or a limited partnership) shall not surpass one half.

c. The representative executive of the applicant for registration shall not be an executive or an employee of the business person who undergoes examination (includes person who has been an executive or an employee of the business person).

2. Registration shall be performed by recording the following items to the register book.

(1) Date of register and the number of registration

(2) Name of the registered laboratory, name of the representative and address of the main office

(3) Classification of the product examination performed by registered laboratories

(4) Name and address of the facility where product examination of a registered laboratory is performed

[Term of Validity of the Registration of a Registered Laboratory]

**Article 34.** Registration of a registered laboratory shall be renewed within not less than three years designated by the Cabinet Order<sup>1)</sup>, or the register shall lose its validity after the elapse of the period.

2. The provisions from Article 31 to the preceding Article shall be construed to the renewal specified in the preceding Paragraph.

(Reference)

1): Article 12 of the Cabinet Order

[Inspection Business of Registered Laboratories]

**Article 35.** Registered laboratory shall perform product examination, without delay, when the laboratory was requested to perform product examination, excepting the case where there was a serious reason of veto.

2. Registered laboratory shall perform fair product examination by a method in comply with the technical standard provided by the Ministerial Ordinance<sup>1)</sup>.

(Reference)

1): Article 40 of the Ministerial Ordinance

[Notification of Establishment of the Examination Facilities of Registered Laboratory]

**Article 36.** When a registered laboratory wishes to newly establish or close an examination facility to perform product examination, or to change its location, the laboratory shall notify the Minister of Health, Labour and Welfare of the planned establishment, closure, or change, at least one month before the scheduled date.

[Work Regulations]

**Article 37.** Any registered laboratory shall establish regulations concerning product examination work (shall be referred to, hereinafter, as "work regulations") and obtain approval from the Minister of Health, Labour and Welfare concerning such regulations. When a registered laboratory wishes to change the work regulations, it shall obtain approval as well.

2. Work regulations shall comply with the method of performance of product examination, examination fee of product examination, and other items prescribed by the Ministerial Ordinance<sup>1)</sup>.

3. The Minister of Health, Labour and Welfare may order a registered laboratory to change the work regulations, when the Minister determines that such work regulations approved pursuant to Paragraph 1 are no longer appropriate for fair performance of product examination.

(Reference)

1): Article 42 of the Ministerial Ordinance

[Suspension or Discontinuance of Examination Work]

**Article 38.** Any registered laboratory shall not suspend or discontinue all or a part of the product examination work, unless it obtains the permission of the Minister of Health, Labour and Welfare.

[Preparation of Tables, etc. Treating Financial Affairs]

**Article 39.** Any registered laboratory shall prepare, within three months after the elapse of each business year, a list of assets, balance sheet, a statement of profit and loss or a statement of income and outgo, and business report (including the electromagnetic record concerned (in case such record is prepared by electronic, magnetic and by other systems, that cannot be recognized by human sense, being processed by electronic computer; the same in this Article) shall be called as "tables, etc. treating financial affairs" in the following Paragraph and Article 79), which shall be kept for five years in the examination facility.

2. Any business person who undergoes examination and any other person having interest may request the following matters any time within the business hours of the registered laboratory; in case request is done, however, concerning Paragraph 2 or 4, the person has to pay the fee established by the registered laboratory.

(1) In case tables, etc. treating financial affairs are prepared in writing, the perusal of the writing concerned or request of copies of the writing

(2) Request of the transcript or an abstract of the writing

(3) In case the tables, etc. treating financial affairs are prepared by electric magnetic record, request of the perusal or request of copies of items which are indicated by a method prescribed in the Ministerial Ordinance<sup>1)</sup>

(4) Request of offer of the items recorded by the electromagnetic method by the method prescribed in the Ministerial Ordinance<sup>2)</sup>, or request of deliver of the writing of the record of the items concerned

(References)

1): Article 44 of the Ministerial Ordinance

2): Article 45 of the Ministerial Ordinance

[Duty of Keeping Secret of Executives or Employees]

**Article 40.** Executives or employees of a registered laboratory, or those who have been in these post shall not leak the secret they could know concerning the business of the product examination or the office work consigned according to the provisions of Article 28 Paragraph 4 (shall be called "office work consigned" in the following Paragraph).

2. All executives and employees of any registered laboratory who engage in product examination shall be deemed to be employees engaging in public services under the laws, for purpose of the application of the Criminal Law (Law No. 45, 1907) and other provisions to such persons.

[Order to Take Measures for Compliance]

**Article 41.** When the Minister of Health, Labour and Welfare determines that a registered laboratory no longer complies with either of Article 33 Paragraph 1, the Minister may order such laboratory to take measures necessary to comply with these provisions.

[Order to Take Measures for Improving the Business]

**Article 42.** When the Minister of Health, Labour and Welfare recognizes that a registered laboratory violates the provisions of Article 35, or, when a product examination performed by a registered laboratory or the labeling under the provisions of Article 25 Paragraph 1 or record of notice performed according to the provisions of Article 26 Paragraph 1, the Minister may order the registered laboratory concerned, to perform the product examination or to take measures for the improvement of the method of the product examination and other method of performing the laboratory business.

[Order of Revocation of Registration and Suspension of Work]

**Article 43.** The Minister of Health, Labour and Welfare may revoke the registration or may order a registered laboratory to suspend all or a part of its product examination work for a certain period of time, if the registered laboratory falls under one of the following categories:

- (1) The laboratory violates provisions of this chapter.
- (2) The laboratory falls under the categories of Article 32, Subparagraph (1) or (3).
- (3) The laboratory performs product examination, without following the work regulations approved pursuant to Article 37 Paragraph 1.
- (4) The laboratory violates an order prescribed in Article 37 Paragraph 3, or the preceding two Articles.
- (5) The laboratory vetoes requests pursuant to the Subparagraphs of Article 39 Paragraph 2 without justified reason.
- (6) The laboratory is registered as mentioned in Article 33 Paragraph 1 by unjust means.

[Preparation of Books, etc.]

**Article 44.** Any registered laboratory shall, as prescribed by the Ministerial Ordinance<sup>1)</sup>, prepare books, record therein the items prescribed under the Ministerial Ordinance<sup>2)</sup> relating to product examination and retain books.

(References)

1): Article 46 Paragraph 2 of the Ministerial Ordinance

2): Article 46 Paragraph 1 of the Ministerial Ordinance

[Announcement of Registered Book]

**Article 45.** The Minister of Health, Labour and Welfare shall make an announcement in official gazette, when one of the following events occurs:

(1) A laboratory is registered pursuant to the Article 33 Paragraph 1.

(2) Registration of a registered laboratory loses its validity pursuant to the provisions of Article 34 Paragraph 1.

(3) Registration was performed pursuant to the provisions of Article 36 Paragraph 1 or Paragraph 3.

(4) Approval pursuant to Article 38.

(5) Revocation of registration or suspension of product examination is ordered pursuant to the provisions of Article 43.

[Restriction of Labeling etc.]

**Article 46.** Persons other than registered laboratories shall not make labeling, advertisement, or other actions which might be mistaken by other persons that their business is product examination.

2. The Minister of Health, Labour and Welfare may order to other persons than registered laboratories to take measures that business performed by them shall not be mistaken as product examination.

[Request for Reports and On-site Inspection]

**Article 47.** The Minister of Health, Labour and Welfare, within the limit necessary to enforce this Law, may request reports from a registered laboratory of the status of its work or accounting, or may require the officials concerned to visit offices or examination facilities of such laboratory, to inspect the status of such work, or books, documents, or other articles or to question related persons.

2. The provisions of Article 28 Paragraphs 2 and 3 shall apply to the preceding Paragraph.

## **Chapter 9. Business**

[Food Sanitation Supervisors]

**Article 48.** Any business person manufacturing or processing dairy products, food additives designated by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 10, or other foods or food additives which require special sanitation considerations in the course of manufacturing or processing and which are prescribed by the Cabinet Order<sup>1)</sup> shall appoint an exclusive food sanitation supervisor to each facility to allow such supervisor to control such manufacturing or processing in a sanitary manner; provided, however, that this provision does not apply to any facility where the business person is qualified as a food sanitation supervisor and controls his or her facility.

2. Notwithstanding the provisions of the preceding Paragraph, where a business person carries on a manufacturing or processing business, at two or more facilities, which requires food sanitation supervisors pursuant to the provisions of the preceding Paragraph, one food sanitation supervisor may be sufficient for supervising all such facilities, if such facilities are neighboring each other.

3. Any food sanitation supervisor shall supervise the employees engaged in the manufacturing or processing of food or food additives, in order to prevent the violation of this Law or orders or dispositions under this Law with respect to food or food additives under such supervisor's control at such facility.

4. Any food sanitation supervisor shall make necessary notice and necessary comments to business persons, besides those provided in the preceding Paragraphs, on the food or food additives supervised in the facility concerned, concerning items of method of sanitary management and other matters related to food sanitation, in order to prevent violation of the Law or violation of the order or disposition based on the Law, and to prevent the occurrence of health hazards.

5. In case food sanitation supervisor was appointed, any business person shall obey the supervisor's comments.

6. Only persons who fulfill at least one of the following shall be qualified as food sanitation supervisors:

(1) A medical doctor, dentist, pharmacist, or veterinarian.

(2) A graduate who has completed the required course of study in medical science, dentistry, pharmaceutical science, veterinary science, animal husbandry, fishery science, or agricultural chemistry at a university under the School Education Law (Law No. 26, 1947), a university under the University Order (Imperial Ordinance No. 388, 1918), or a college under the College Order (Imperial Ordinance No. 61, 1903).

(3) A person who has completed the specified course at a training institute for food sanitation supervisors designated by the Minister of Health, Labour and Welfare.

(4) A graduate from a high school under the School Education Law or a middle school under the Middle School Order (Imperial Ordinance No. 36, 1943) or a person, by the provisions of the Ministerial Ordinance<sup>2)</sup>, determined to be equal or superior to such graduate in scholarly achievement, who has been engaged in sanitation control relating to the manufacturing or processing of food or food additives for not less than three years at a manufacturing or processing business which requires a food sanitation supervisor prescribed in Paragraph 1 and who has completed the training course registered to the Minister of Health, Labour and Welfare.

7. A person who is qualified as a food sanitation supervisor by fulfilling the provisions of Subparagraph (4) of the preceding Paragraph may become a food sanitation supervisor only at a facility of the same type of manufacturing or processing business in which such person had been engaged in performing sanitation control for not less than three years.



**8.** When any business person prescribed in Paragraph 1 has appointed a food sanitation supervisor or has become a food sanitation supervisor, such person shall, within fifteen days, notify the governor of the prefecture where its facility is located either of the name of the food sanitation supervisor or of the fact that the business person has become a food sanitation supervisor and of other items as prescribed by the Ministerial Ordinance<sup>3)</sup>. This provision shall apply when such business person has changed the food sanitation supervisor.

(References)

- 1): Article 13 of the Cabinet Order
- 2): Article 48 of the Ministerial Ordinance
- 3): Article 49 of the Ministerial Ordinance

[Delegation of a Training Institute or a Training Course of Food Sanitation Supervisors to Cabinet Order and Ministerial Ordinance]

**Article 49.** Necessary items related to the registration of a training institute pursuant to Paragraph 6 Subparagraph (3) of the preceding Article shall be provided by the Cabinet Order<sup>1)</sup>, while necessary items, such as subjects to be taken, related to a training institute prescribed in Subparagraph (3) of the same Paragraph and related to a training course prescribed in Subparagraph (4) of the same Paragraph shall be provided by the Ministerial Ordinance<sup>2)</sup> respectively.

(References)

- 1): Articles 14 - 20 of the Cabinet Order
- 2): Articles 21 - 34 of the Cabinet Order; Articles 52 and 56 of the Ministerial Ordinance

[Establishment of Standards for Preventive Measures against Contamination of Toxic or Injurious Substances]

**Article 50.** The Minister of Health, Labour and Welfare may establish necessary standards relating to measures to prevent the contamination of food or food additives by toxic or injurious substances in the course of the manufacturing or processing of the food or food additives.

**2.** Each prefecture may establish necessary standards relating to public health measures including the maintenance of cleanliness inside and outside of business facilities (excluding poultry slaughtering businesses prescribed in Article 2 Subparagraph (5) of the Poultry Slaughtering Business Control and Poultry Inspection Law) and the destruction or repulsion of rodents, insects, and the like.

**3.** Where standards have been established by the provisions of the preceding two Paragraphs, any business person (excluding poultry slaughterers prescribed in Article 6 Paragraph 1 of the Poultry Slaughtering Business Control and Poultry Inspection Law) shall comply with the established standards.

[Establishment Standards for Business Facilities]

**Article 51.** Each prefecture shall, from the viewpoint of public health, establish necessary standards by type of business for facilities of restaurant businesses and other businesses which have a significant influence on public health (excluding poultry slaughtering businesses prescribed in Article 2 Subparagraph (5) of the Poultry Slaughtering Business Control and Poultry Inspection Law) and which are designated by the Cabinet Order<sup>1)</sup>.

(Reference)

1): Article 35 of the Cabinet Order

[License for Business]

**Article 52.** Any person who wishes to carry on any of the businesses prescribed in the preceding Article shall, in accordance with the provisions of the Ministerial Ordinance<sup>1)</sup>, obtain a licence from the governor of the prefecture concerned.

2. In the case of the preceding Paragraph, the governor of any prefecture shall, when receiving an application for a license, grant a license to such business when the governor determines that each facility of that business complies with the standards under the provisions of the preceding Article; provided, however that, the governor need not grant the license prescribed in Paragraph 1, if such person wishing to carry on the businesses provided in the same Article falls under any of the following:

(1) A person who has been fined a penalty or sentenced to penal servitude due to a violation of this Law or any disposition under the this Law, and two years have not passed from the date of the payment of such fine or the completion of serving such sentence or the invalidation of such fine or sentence.

(2) A person whose license has been revoked pursuant to the provisions of Articles 54 through 56, and two years have not passed from the date of the revocation.

(3) A corporation any of whose executives falls under either of the two preceding Subparagraphs.

3. The governor of any prefecture may attach to the license prescribed in Paragraph 1 necessary conditions, such as a term of validity of not less than four years.

(Reference)

1): Article 67 of the Ministerial Ordinance

[Inheritance of the Status of Licenced Business Persons]

**Article 53.** When there is inheritance or, merger or partition (limited to cases where the business concerned is inherited) involving the person (in this Article, referred to as a "licenced business person") having obtained a license under Paragraph 1 of the preceding Article, the inheritor(s) (if there are two or more legal inheritors, and one of them is appointed to inherit such business with the consent of all of the inheritors, such appointed person is the inheritor), the corporation which has remained after the merger or the corporation which has been established newly by the merger or the corporation which has inherited the business concerned after partition shall inherit the status of a licensed business person.

2. Any person who has inherited the status of a licensed business person under the preceding Paragraph shall, without any delay, notify the governor of the prefecture concerned, producing documents to that effect<sup>1)</sup>.

(Reference)

1): Articles 68 to 70 of the Ministerial Ordinance

[Disposal of Food, etc., Order of Removal of Hazards]

**Article 54.** When a business person violates the provisions of Articles 6, Article 9, Article 10, Article 11 Paragraph 2, Article 16, Article 18 Paragraph 2 or Article 20, or when a business person violates the prohibitions by the provisions of Article 8 Paragraph 1 or Article 17 Paragraph 1, the Minister of Health, Labour and Welfare or the governor of the prefecture concerned may make such business person or officials concerned dispose such foods, food additives, apparatus or containers/packages, or order such business person to take necessary measures to remove food sanitation hazards.

[Revocation of License, Prohibition or Suspension of Business]

**Article 55.** When a business person violates the provisions of Articles 6, Article 9, Article 10, Article 11 Paragraph 2, Article 16, Article 18 Paragraph 2, Article 19 Paragraph 2, Article 20, Article 25 Paragraph 1, Article 26 Paragraph 4, Article 48 Paragraph 1 or Article 50 Paragraph 3, when a business person violates the prohibitions by the provisions of Article 7 Paragraphs 1 to 3, Article 8 Paragraph 1 or Article 17 Paragraph 1, or when a business person falls under Article 52 Paragraph 2 Subparagraph (1) or (3), or violates the conditions under the provisions of Paragraph 3 of the same Article, the governor of the prefecture concerned may revoke the license prescribed in Paragraph 1 of the same Article, prohibit all or a part of the business, or suspend all or a part of the business for a certain period of time.

2. When a business person (limited to person or corporation who imports food, food additives, apparatus or containers/packages) violates the provisions of Article 6, Article 9 Paragraph 2, Article 10, Article 11 Paragraph 2, Article 16, Article 18 Paragraph 2, Article 26 Paragraph 4 or Article 50 Paragraph 3, or when a business person violates the prohibitions by the provisions of Article 7 Paragraphs 1 through 3, Article 8 Paragraph 1 or Article 17 Paragraph 1, the Minister of Health, Labour and Welfare may prohibit all or a part of the business, or suspend all or a part of the business for a certain period of time.

[Dispositions of Business Facilities in Violation of Standards]

**Article 56.** When a business person violates the standards under the provisions of Article 51 for any facility of such business, the governor of the prefecture concerned may order such business person to correct noncompliant conditions of the facility; or revoke the license prescribed in Article 52 Paragraph 1, prohibit all or a part of the business, or suspend all or a part of the business for a certain period of time.

## **Chapter 10. Miscellaneous Provisions**

[Payment from National Treasury]

**Article 57.** The National Treasury shall, as prescribed by the Cabinet Order, bear half of the following expenses of each prefecture or each city establishing health centers:

(1) The expenses required for collection of samples pursuant to the provisions of Article 28 Paragraph 1 (including cases where such provisions are applied based on Article 62 Paragraphs 1 and 3).

(2) The expenses required for appointment of food sanitation inspectors pursuant to the provisions of Article 30 Paragraph 1 (including cases where such provisions are applied based on Article 62 Paragraphs 1 and 3).

(3) The expenses required for license for businesses pursuant to the provisions of Article 52 Paragraph 1 (including cases where such provisions are applied based on Article 62 Paragraph 1).

(4) The expenses required for disposal pursuant to the provisions of Article 54 (including cases where such provisions are applied based on Article 62 Paragraphs 1 and 3).

(5) The expenses required for autopsies of corpses pursuant to the provisions of Article 59 Paragraph 1 or 2 (including cases where such provisions are applied based on Article 62 Paragraph 1).

(6) The expenses required for judicial suits relating to the enforcement of this Law and the expenses required for any compensation paid as a result thereof.

[Notification of Poisoned Persons or their Corpses]

**Article 58.** Any medical doctor who has examined a person poisoned by or suspected to be poisoned by a food, food additive, apparatus or container/package (shall be called, hereinafter, as "food poisoning patient, etc."), or who has examined the corpse of such person shall immediately notify the director of the nearest health center of such fact.

2. On receiving the notification prescribed in the preceding Paragraph, or on noticing any other occurrence of food poisoning patient, etc., the director of the health center shall report the fact immediately to prefecture, etc. and shall make an investigation pursuant to the provisions of Cabinet Order<sup>1)</sup>

3. When receiving the report from the director pursuant to the provisions of the preceding Paragraph, and in case number of outbreak of food poisoning patient surpasses or may surpass the number specified by the Ministerial Ordinance<sup>2)</sup>, the governor of the prefecture shall immediately report it to the Minister of Health, Labour and Welfare.

4. In case an investigation was performed, pursuant to the provisions of Paragraph 2, the director of the health center shall report the result to the governor of prefecture, etc.

(Reference)

1): Article 36 of the Cabinet Order

2): Article 73 of the Ministerial Ordinance

[Autopsy of Corpses]

**Article 59.** The governor of prefecture, etc. may, with the consent of the family of the decedent, have an autopsy performed on the corpse of such person who has died from a disease caused by or suspected to be caused by a food, food additive, apparatus, or container/package, when the governor concerned determines that the action is necessary to identify the cause of death.

2. In the case of the preceding Paragraph, the governor of prefecture, etc. may have an autopsy performed on the corpse even without the consent of the family of the decedent after notifying the family of that fact, when the governor concerned determines that the cause of death cannot be identified without performing an autopsy and, as a result, such case may present serious hazard to public health.

3. The provisions of the preceding two Paragraphs shall not preclude any compulsory action under the provisions relating to criminal suits.

4. When an autopsy of any corpse is performed pursuant to the provisions of Paragraph 1 or 2, care shall be taken not to be indecorous to the deceased.

[Request of Investigation etc. by the Minister of Health, Labour and Welfare]

**Article 60.** In case number of outbreak of food poisoning patient surpass or may surpass the number specified by the Ministerial Ordinance, or in case outbreak of food poisoning patient etc. spreads or may spread to a wide area, and, when it becomes urgent for the prevention of food sanitation hazards, the Minister of Health, Labour and Welfare may order the governor of prefecture, etc. to investigate the incident and report the result within due time.

[Advice of Local Governments to Restaurant-Business Operating Persons and Food Sanitation Promoting Leaders]

**Article 61.** Each prefecture, etc. shall endeavor to give advice, guidance, or other necessary support to business persons of food, etc. in order to prevent the possible occurrence of any food-poisoning as well as to improve food sanitation in their area of the responsibility.

2. Each prefecture, etc. may appoint food-sanitation promoting leaders from among those who have the public's confidence, and enthusiasm and expertise for improvement in food sanitation, in order to promote activities conducted by restaurant-business operating persons concerning improvement in food sanitation.

3. Each food-sanitation promoting leader shall cooperate in programs conducted by the prefecture, etc. concerned, receive consultation from restaurant-business operating persons, advise such persons, and conduct other related activities, concerning sanitation controlling methods for restaurant-business facilities and other food sanitation-related matters.

[Provisions for Application to Toys, Etc.]

**Article 62.** The provisions of Articles 6, 8, 10, 11, 16 through 20, 25 through 56, and 58 through 60 shall apply to the toys designated by the Minister of Health, Labour and Welfare as potentially injurious to infant health through contact therewith<sup>1)</sup>. In this case, "food additives (excluding natural flavoring agents, and substances which are both generally provided for eating and drinking as food and used as food additives)" prescribed in Article 10 shall be construed as "synthetic chemicals (i.e., substances obtained by causing chemical reaction other than degradation to elements or compounds using chemical means) intended for use in or on toys as additives."

2. The provisions of Articles 6 and 11 shall apply to detergents intended for use in washing vegetables, fruits, or tableware.

3. The provisions of Articles 15 through 18, Article 25 Paragraph 1, Articles 28 through 30, Article 51, and Articles 54 through 56 shall apply to cases where, for purposes other than businesses, a food is supplied to the public or a large number of persons on a continuous basis at dormitories, schools, hospitals, and other facilities.

(Reference)

1): Article 78 of the Ministerial Ordinance

[Official Announcement of the Names, etc.]

**Article 63.** In order to prevent outbreaks of food hygienically harmful incidents, the Minister of Health, Labour and Welfare and the governor of each prefecture shall officially announce the names of the violators against this Law or dispositions by the Law, and shall make an effort for making clear the actual condition of the e food hygienically harmful incidents.

[Audition of Comments of the People]

**Article 64.** In case of establishing the cases provided under the proviso of Article 6 Subparagraph (2) (including cases where the proviso of Article 6 Subparagraph (3) applies in Article 62 Paragraphs 1 and 2 of the Law) as not injurious to human health, in case of establishing the case of prohibition of sale provided under the provisions of Article 7 Paragraphs 1 through 3 or in case of canceling all or a part of prohibitions provided under the provisions of Paragraph 4 of the same Article, in case of establishment, revision or repeal of the Article 9 of the Ministerial Ordinance, in case of establishing the cases of being not injurious to human health provided under the provisions of Article 10, in case of establishing specifications or standards under the provisions of Article 11 Paragraph 1 (including cases where Article 11 Paragraph 1 is applied in Article 62 Paragraphs 1 and 2), in case standards or specifications are established under the provisions of Article 18 Paragraph 1 (including cases where Article 18 Paragraph 1 is applied in Article 62 Paragraphs 1 and 3), in case standards are established under the provisions of Article 19 Paragraph 1 (including cases where Article 19 Paragraph 1 is applied in Article 62 Paragraph 1), in case principle specified in Article 22 Paragraph 1 is either established or changed, or in case standards are established under the provisions of Article 50 Paragraph 1, the Minister of Health, Labour and Welfare shall officially announce the scope, contents and other necessary items to hear widely opinion of the people; provided, however, that this Paragraph shall not be applied when there is no time of hearing opinion of the people beforehand.

2. When any governor of prefecture establishes or changes the plan of inspection and guidance of food sanitation of the prefecture, provided under Article 24 Paragraph 1, the governor shall officially announce the scope, contents or other necessary items to hear widely of opinion of the people.

3. In case of proviso of Paragraph 1, the Minister of Health, Labour and Welfare shall ask widely opinion of the people, ex post facto, without delay.

**Article 65.** The Minister of Health, Labour and Welfare and a governor of prefecture, etc. shall officially announce the actual state of practice of food sanitary measures, and shall hear widely of opinions of the people and inhabitants, in order to reflect opinions of the people or the inhabitants on the measures concerned, and in order to undertake the promotion of exchange of information and opinions.

[Provision for Reading of "Governor" ]

**Article 66.** "Governor" used in the provisions of Article 48, in each of the Article of Articles 52 through 56 and Article 63 shall be construed as "mayor" for any city establishing health centers or any special ward, whichever is appropriate; provided, however, that this Article does not apply to dispositions under the Cabinet Order, relating to businesses prescribed by the Cabinet Order.

[Special Treatments for Large Cities]

**Article 67.** In addition to the provisions of the main clause of the preceding Article, administrative work considered in this Law to be handled by each prefecture or administrative work considered to be under the authority of the governor of each prefecture, which is prescribed by the Cabinet Order<sup>1)</sup> shall, in any designated city (hereinafter referred to as a "designated city") under Article 252-19 Paragraph 1 of the Local Autonomy Law (Law No. 67, 1947) and in any core city (hereinafter referred to as a "core city") under Article 252-22 Paragraph 1 of the same Law, be handled by each designated city or core city (hereinafter referred to as "designated city, etc.") or performed by the mayor of each designated city, etc., as prescribed by the Cabinet Order<sup>1)</sup>. In this case, in this Law, the provisions relating to each prefecture or the governor of each prefecture shall apply to each designated city, etc. or the mayor of each designated city, etc. as the provisions relating to each designated city, etc. or the mayor of each designated city, etc.

(Reference)

1): Article 38 of the Cabinet Order

[Appeal for Re-examination]

**Article 68.** Any person who objects to the decision made in response to a request for examination regarding dispositions to be taken by the directors of local public organizations (excluding prefectures) [confined to Subparagraph (1) officially delegated administrative work pursuant to Article 2 Paragraph 9, Subparagraph (1) of the Local Autonomy Law (Referred to as "Subparagraph (1) officially delegated administrative work" in the following Article)], may appeal for reexamination to the Ministry of Health Labour and Welfare.

[Classification of Administrative Work]

**Article 69.** The administrative work considered to be handled by each prefecture under the provisions of Article 25 Paragraph 1 (including cases where such provisions are applied based on Article 62 Paragraphs 1 and 3), Article 26 Paragraph 1 (including cases where such provisions are applied based on Article 62 Paragraph 1), Article 28 Paragraph 1 (including cases where such provisions are applied based on Article 62 Paragraphs 1 and 3, the same hereinafter in this Law), Article 30 Paragraph 2 [excluding those related to inspections or guidances of license for businesses prescribed in Article 51 (confined to restaurant businesses and other selling businesses designated by the Cabinet Order), and including cases where such provisions are applied based on Article 62 Paragraphs 1 and 3, the same hereinafter in this Law], Article 54 (including cases where such provisions are applied based on Article 62 Paragraph 1 and 3) and Article 59 Paragraph 1 (including cases where such provisions are applied based on Article 62 Paragraph 1, the same hereinafter in this Law) shall be the Subparagraph (1) officially delegated administrative work.

2. The administrative work, considered to be handled by each city establishing health centers or by each special ward under the provisions of Article 28 Paragraph 1, Article 30 Paragraph 2, Article 54, Article 58 (including cases where such provisions are applied based on Article 62 Paragraph 1), shall be the Subparagraph (1) officially delegated administrative work.

[Delegation of Authority]

**Article 70.** The authority of the Minister of Health, Labour and Welfare pursuant to this Law may be transferred, as prescribed by the Ministerial Ordinance, to the directors of the Local Bureaus of Health and Welfare.

2. The authority transferred to the directors of the Local Bureaus of Health and Welfare pursuant

to the preceding Paragraph may be transferred, as prescribed by the Ministerial Ordinance, to the directors of the Local Branch Bureaus of Health and Welfare.

## Chapter 11. Penal Provisions

[Penal Provisions]

**Article 71.** Any person who falls under any of the following Subparagraphs shall be punished by penal servitude of not more than three years or by a fine of not more than 3,000,000 yen.

(1) A person who violates the provisions of Article 6 (including cases where the application of this Paragraph is based on Article 62 Paragraphs 1 and 2), Article 9 Paragraph 1 or Article 10 (including cases where the application of this Paragraph is based on Article 62 Paragraph 1).

(2) A person who violates the prohibitions under the provisions of Article 7 Paragraphs 1 through 3.

(3) A business person who does not obey the order of the Minister of Health, Labour and Welfare or the governor of the prefecture concerned (the city mayor or ward mayor concerned when the governor is construed as the city mayor or ward mayor pursuant to the provisions of Article 66), pursuant to the provisions of Article 54, or a person who has carried on a business in violation of the dispositions under the provisions of Article 55 (including cases where the application of this Paragraph is based on Article 62 Paragraphs 1 and 3).

2. Any person who commits any offense of the preceding Paragraph may, under circumstances, be subject to both penal servitude and a fine.

**Article 72.** Any person who violates the provisions of Article 11 Paragraph 2 (including cases where the application of this Paragraph is based on Article 62 Paragraphs 1 and 2), Article 16 (including cases where the application of this Article is based on Article 62 Paragraphs 1 and 3), Article 19 Paragraph 2 (including cases where the application of this Article is based on Article 62 Paragraph 1), Article 20 (including cases where the application of this Article is based on Article 62 Paragraph 1), or Article 52 Paragraph 1 (including cases where the application of this Article is based on Article 62 Paragraph 1) shall be punished by penal servitude of not more than two years or by a fine of not more than 2,000,000 yen.

2. Any person who commits any offense of the preceding Paragraph may, under certain circumstances, be subject to both servitude and a fine.

**Article 73.** Any person who falls under any of the following Subparagraphs shall be punished by penal servitude of not more than one year or by a fine of not more than 1,000,000 yen.

(1) A person who violates the provisions of Article 9 Paragraph 2, Article 18 Paragraph 2 (including cases where the application of this Paragraph is based on Article 62 Paragraphs 1 and 3), Article 25 Paragraph 1 (including cases where the application of this Paragraph is based on Article 62 Paragraphs 1 and 3), Article 26 Paragraph 4 (including cases where the application of this Paragraph is based on Article 62 Paragraph 1) or Article 58 Paragraph 1 (including cases where the application of this Paragraph is based on Article 62 Paragraph 1).

(2) A person who violates the prohibitions under the provisions of Article 8 Paragraph 1 (including cases where the application of this Paragraph is based on Article 62 Paragraph 1) or the provisions of Article 17 Paragraph 1 (including cases where the application of this Paragraph



is based on Article 62 Paragraph 1).

(3) A person who violates the provisions prescribed in Article 40 by leaking the secret he could know concerning the office work.

(4) A person who violates the standards prescribed under the provisions of Article 51 (including cases where the application of this Paragraph is based on Article 62 Paragraphs 1 and 3) or who violates the conditions prescribed under the provisions of Article 52 Paragraph 3 (including cases where the application of this Paragraph is based on Article 62 Paragraph 1).

(5) A business person who disobeys the order of the Minister of Health, Labour and Welfare or the governor of the prefecture concerned (the city mayor or ward mayor pursuant to the provisions of Article 66) prescribed in Article 56 (hereinafter in this Subparagraph, Article 56 includes cases where the application of this Article is based on Article 62 Paragraphs 1 and 3) (including cases of supplier of food, provided in the same Paragraph), or a business person who has carried on a business in violation of the dispositions under the provisions of Article 56.

**Article 74.** When a violation of an order of the suspension of work occurs, executives or employees of a registered laboratory which do such act shall be punished by penal servitude of not more than one year or by a fine of 1,000,000 yen.

**Article 75.** Any person who falls under any of the following Subparagraphs shall be punished by a fine of not more than 500,000 yen:

(1) A person who refuses, obstructs, or evades on-site inspections or collection of samples by officials pursuant to the provisions of Article 28 Paragraph 1.

(2) A person who fails to make reports pursuant to the provisions of Article 28 Paragraph 1, or a person who makes false reports.

(3) A person who fails to make notification pursuant to the provisions of Article 27 or Article 48 Paragraph 8 (respectively, including cases where the application of this Paragraph is based on Article 62 Paragraph 1), or a person who makes false reports.

(4) A person who violates order pursuant to the provisions of Article 46 Paragraph 3.

**Article 76.** When any of the violations given below occurs, executives or employees of a registered laboratory which do such act shall be punished by a fine of not more than 500,000 yen.

(1) A registered laboratory discontinues all of its product examination work without obtaining the permission prescribed in Article 38.

(2) A registered laboratory, in violation of Article 44, fails to record in books the items prescribed in the same Article or to retain the books, or makes false records.

(3) A registered laboratory fails to make reports as prescribed in Article 47 Paragraph 1 or makes false reports.

(4) A registered laboratory refuses, obstructs, or evades on-site inspection prescribed in Article 47 Paragraph 1, or fails to respond to questions prescribed in the same Paragraph or makes false responses.

**Article 77.** If any food sanitation supervisor has neglected its duties prescribed in Article 48 Paragraph 3, when there is an act which falls under any of the violations prescribed in Articles 71 through 73 on food or food additives under such supervisor's control at such facility, such supervisor shall be punished by a fine of the corresponding Article according to the circumstances of such illegal act; provided, however, that this Article does not apply to cases where such food sanitation supervisor commits the act.

[Double Punishment Provision]

**Article 78.** When the representative of any corporation, or a proxy, employee, or any other worker of any corporation or individual commits an illegal act as prescribed in the following each Subparagraph, relating to the work under the duty of such corporation or individual, not only the performer of the act but also such corporation or individual shall be punished by a fine of the corresponding Article; provided, however, that this Article does not apply to any individual where the individual is, by the provisions of the preceding Article, punished by a fine as food sanitation supervisor.

(1) Article 71 or Article 72 (limited to provisions related to Article 11 Paragraph 2 (including cases where the application of this Article is based on Article 62 Paragraph 1), Article 19 Paragraph 2 (including cases where the application of this Article is based on Article 62 Paragraphs 1 and 2), and Article 20 (including cases where the application of this Article is based on Article 62 Paragraph 1)) Punished by a fine of not more than 100,000,000 yen

(2) Article 72 (excluding parts related to Article 11 Paragraph 2 (including cases where the application of this Article is based on Article 62 Paragraphs 1 and 2), Article 19 Paragraph 2 (including cases where the application of this Article is based on Article 62 Paragraph 1), and Article 20 (including cases where the application of this Article is based on Article 62 Paragraph 1)), Article 73, or Article 75 Punished by a fine provided under each Article

**Article 79.** A person who violates the provisions of Article 39 Paragraph 1 by not keeping the tables etc. treating financial affairs, not recording items to be recorded in tables etc. treating financial affairs or, recording false records, or a person who vetoed request pursuant to each Subparagraph of the same Article Paragraph 2, without justified reason, shall be fined not more than 200,000 yen.

### **Supplementary Provisions**

[Enforcement Date]

**Article 1.** This Law shall come into force from January 1, 1948.

[Abolition of Laws and Ordinances]

**Article 2.** The following laws and ordinances shall be abolished.

(1) Law for the Control of Food, Beverages, and Other Articles (Law No. 15, 1900).

(2) Matters concerning Enforcement of the Law for the Control of Food, Beverages, and Other Articles and the Ordinances for the Control of Poisonous Food, Beverages, etc. (The Ordinance of the Ministry of Health and Welfare, No. 10, 1947).

- (3) Regulation for Control of Trade of Food and Beverages (The Ordinance of the Ministry of Health and Welfare, No. 15, 1947).
- (4) Regulation for Control of Trade of Cow's Milk (The Ordinance of the Ministry of Home Affairs, No. 37, 1933).
- (5) Regulation for Control of Trade of Nonalcoholic Beverages (The Ordinance of the Ministry of Home Affairs, No. 30, 1900).
- (6) Regulation for Control of Trade of Snow and Ice (The Ordinance of the Ministry of Home Affairs, No. 37, 1900).
- (7) Regulation for Control of Trade of Artificial Sweetening Agents (The Ordinance of the Ministry of Home Affairs, No. 31, 1901).
- (8) Regulation for Control of Methyl Alcohol (The Ordinance of the Ministry of Home Affairs, No. 8, 1912).
- (9) Regulation for Control of Harmful Coloring Agents (The Ordinance of the Ministry of Home Affairs, No. 17, 1900).
- (10) Regulation for Control of Preservatives and Bleaching Agents of Food and Beverages (The Ordinance of the Ministry of Home Affairs, No. 22, 1928).
- (11) Regulation for Control of Utensils for Food and Beverages (The Ordinance of the Ministry of Home Affairs, No. 50, 1900).

[Interim Provisions relating to License for Business under the Old Law]

**Article 3.** Any person who, on the date of the enforcement of this Law, performs a business under the license obtained as prescribed by the order pursuant to the preceding Article shall be deemed to have obtained the license as prescribed in Article 52 Paragraph 1 of this Law, where such business requires the license by the provisions of the same Paragraph.

**2.** The provisions of Article 52 Paragraph 3 shall apply to the license under the provisions of the preceding Paragraph.

## Appendix

### **The Law Concerning Amendments to the Food Sanitation Law and the Nutrition Improvement Law**

(Law No. 101, May 24, 1995) (Excerpt)

**Article 1.** This Law hereby amends the Food Sanitation Law (Law No. 233, 1947).

#### **Supplementary Provisions**

[Enforcement Date]

**Article 1.** This Law shall come into force from the date when the one-year period beginning on the date of promulgation (May 24, 1995) has passed.

[Interim Measures Concerning the Existing Food Additives]

**Article 2.** The Minister of Health, Labour and Welfare shall compile a list containing the names of the food additives given below (excluding chemically synthesized food additives prescribed in Article 2 Paragraph 3 of the Food Sanitation Law (hereinafter referred to as "the Old Food Sanitation Law") being effective before the amendment, as prescribed in Article 1 of this Law, natural flavorings defined in Article 2 Paragraph 3 of the Food Sanitation Law (hereinafter referred to as "the Amended Food Sanitation Law") being effective after the amendment, as prescribed in Article 1 of the same law, and substances which are both generally provided for eating or drinking as foods and used as food additives) and publish it within the three-month period beginning on the date of the promulgation of this Law.

(1) Food additives which had already been sold, or had been manufactured, imported, processed, used, stored, or displayed with intent to sell, on the date of the promulgation of this Law.

(2) Food additives which are included in a preparation or food which had already been sold, or had been manufactured, imported, processed, used, stored, or displayed with intent to sell, on the date of the promulgation of this Law.

2. When any person deems it necessary to correct the list of the existing food additives published pursuant to the preceding Paragraph, he or she may, as prescribed by the Ministry of Health and Welfare Ordinance (No. 50, 1995), propose that effect to the Minister of Health, Labour and Welfare within the six-month period beginning on the date of the announcement thereof.

3. When the Minister of Health, Labour and Welfare has received a proposal and has determined that there is a sufficient reason for the amendment, the Minister shall add to, or withdraw from, the list of the existing food additives the name of the food additive for which the amendment is being proposed, and shall notify the proposer of that effect.

4. The Minister of Health, Labour and Welfare shall publish the list of the existing food additives, for which addition or withdrawal has been made pursuant to the provisions of the preceding Paragraph, at least 30 days before the date of the enforcement of this Law.

**Article 2-2.** When the Minister of Health, Labour and Welfare recognizes that a food additive whose name is enlisted in the list of the existing food additives is injurious to human health, the Minister may delete the name of the food additive concerned from the list of existing food additives, after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

2. When the name of food additive, whose name is enlisted in the list of the existing food additives, is to be deleted from the list, the Minister of Health, Labour and Welfare shall officially announce the scope, contents, and other necessary items to hear widely opinion of the people; provided, however, that this Paragraph shall not be applied when there is no time of hearing opinion of the people beforehand.

3. In case of proviso of preceding Paragraph, the Minister of Health, Labour and Welfare shall ask widely opinion of the people, ex post facto, without delay.

4. The Minister of Health, Labour and Welfare shall officially announce the list of the existing food additives, to which deletion has been performed pursuant to the provisions of Paragraph 1, without delay.

**Article 2-3.** When the the Minister of Health, Labour and Welfare recognizes that, concerning a food additive whose name is enlisted in the list of the existing food additives, from the actual state of its sales, manufacture, import, processing, use, storage and display, food additive preparations or food containing the food additive concerned is not actually served for sale. the Minister may prepare a table in which the food additive concerned is recorded (shall be called, hereinafter, "list of food additives to be deleted").

2. The Minister of Health, Labour and Welfare shall officially announce the list of food additives to be deleted, in case the Minister has prepared the list pursuant to the provisions of the preceding Paragraph.

3. Any person may request, concerning the list of food additives to be deleted, when he or she considers it necessary to revise the list, within six months after the official announcement, to the the Minister of Health, Labour and Welfare, pursuant to the provisions of the Ministerial Ordinance<sup>1)</sup>.

4. In case request has been done according to the preceding Paragraph, when the request is justified, the name of the food additive related with the request shall be added to the list of food additives to be deleted, or shall be deleted from the list of food additives to be deleted and a statement to the effect shall be done to the person who has made the request.

5. The Minister of Health, Labour and Welfare shall, within one year from the day of the official announcement pursuant to Paragraph 2, delete from the list of the existing food additives the name of the food additive enlisted in the list of food additives to be deleted (in case of addition or deletion was carried out, the list of the food additives to be deleted, to which either the addition or the deletion has been carried out), and shall be officially informed to the effect without delay.

(Reference)

1): Ministry of Health, Labour and Welfare Ordinance No. 50, August 1995

**Article 3.** Any food additive appearing in the list published by the Minister of Health, Labour and Welfare pursuant to the provisions of Paragraph 4 of the preceding Article, and any food or preparation containing the food additive, shall not be subject to the provision of Article 10 of the Amended Food Sanitation Law.

**Table (related to Article 33)**

<p>Physico-chemical examinations</p>	<ol style="list-style-type: none"> <li>1. Centrifuge</li> <li>2. Purified water preparation apparatus</li> <li>3. Super-low temperature thermostat</li> <li>4. Homogenizer</li> <li>5. Gas chromatograph</li> <li>6. Gas chromatograph-mass spectrometer (Limited to persons performing inspections of residues of pesticides provided under the Agricultural Chemicals Regulation Law)</li> <li>7. Atomic absorption spectrophotometer</li> <li>8. High performance liquid chromatograph</li> </ol>	<p>The persons specified in the right column shall fall into one of the following sections:</p> <ol style="list-style-type: none"> <li>1. Graduates who have completed the required course of study in medical science, dentistry, pharmaceutical science, veterinary science, animal husbandry, fishery science, agricultural chemistry or applied chemistry, or a course equivalent to one of the former courses at a university (excluding colleges) under the School Education Law, a university under the University Order, or a college under the College Order, and who have experience of not less than one year in work concerning physicochemical examinations.</li> <li>2. Graduates who have completed the required course of industrial chemistry at a college or higher professional school under the School Education Law or a course equivalent to the former course, and who have experience of not less than three years in work concerning physicochemical examinations.</li> <li>3. Persons who have been determined as having knowledge and experience equal or superior to one of the persons mentioned in the preceding two sections.</li> </ol>	<p>4 persons</p>
<p>Bacteriological examinations</p>	<ol style="list-style-type: none"> <li>1. Centrifuge</li> <li>2. Purified water preparation apparatus</li> <li>3. Super-low temperature thermostat</li> <li>4. Homogenizer</li> <li>5. Hot air sterilizer</li> <li>6. Optical microscope</li> <li>7. Autoclave</li> <li>8. Incubator</li> </ol>	<p>The persons specified in the right column shall fall into one of the following sections:</p> <ol style="list-style-type: none"> <li>1. Graduates who have completed the required course of study in medical science, dentistry, pharmaceutical science, veterinary science, animal husbandry, fishery science, agricultural chemistry or biology, or a course equivalent to one of the former courses at a university (excluding colleges) under the School Education Law, a university under the University Order, or a college under the College Order, and who have experience of not less than one year in work concerning bacteriological examinations.</li> <li>2. Graduates who have completed the required course of biology at a college or higher professional school under the School Education Law or a course</li> </ol>	<p>4 persons</p>

(continued)

		<p>equivalent to the former course, and who have experience of not less than three years in work concerning bacteriological examinations.</p> <p>3. Persons who have been determined as having knowledge and experience equal or superior to one of the persons mentioned in the preceding two sections.</p>	
Examinations by use of animals	<ol style="list-style-type: none"><li>1. Centrifuge</li><li>2. Purified water preparation apparatus</li><li>3. Super-low temperature thermostat</li><li>4. Homogenizer</li></ol>	<p>The persons specified in the right column shall fall into one of the following sections:</p> <ol style="list-style-type: none"><li>1. Graduates who have completed the required course of study in medical science, dentistry, pharmaceutical science, veterinary science, animal husbandry, fishery science, agricultural chemistry or biology, or a course equivalent to one of the former courses at a university (excluding colleges) under the School Education Law, a university under the University Order, or a college under the College Order, and who have experience of not less than one year in work concerning examinations by use of animals.</li><li>2. Graduates who have completed the required course of biology at a college or higher professional school under the School Education Law or a course equivalent to the former course, and who have experience of not less than three years in work concerning examinations by use of animals.</li><li>3. Persons who have been determined as having knowledge and experience equal or superior to one of the persons mentioned in the preceding two sections.</li></ol>	3 persons

## **Food Sanitation Law Enforcement Ordinances**

Cabinet Order No. 229, August 31, 1953  
Last amendment: Cabinet Order No. 511, December 12, 2003



(Approval of Comprehensive Sanitation-controlled Manufacturing Process)

**Article 1.** The foods designated by Cabinet Order No. 229 (hereinafter referred to as the "Cabinet Order") under Article 13 Paragraph 1 of the Food Sanitation Law, No. 233 (hereinafter referred to as "Law") are as follows:

(1) Cow's milk, goat's milk, skim milk, and processed milk.

(2) Cream, ice cream, evaporated milk, evaporated skim milk, fermented milk, lactic acid bacterial beverages, and milk drinks.

(3) Nonalcoholic beverages

(4) Meat products (in this section and Article 13, meat products mean ham, sausage, bacon, and other similar products).

(5) Fish-paste products (fish-paste products mean fish ham, fish sausage, whale bacon, and other similar products).

(6) Foods packed into containers/packages and pasteurized under pressure.  
(hereinafter these products mean foods [excluded foods listed in each Subparagraph of this Article, whale meat products (excluded whale meat bacon)] packed into hermetic containers/packages, tightly sealed, and pasteurized under pressure).

**2.** The fees prescribed by the Cabinet Order under Article 13 Paragraph 7 of the Law shall be as listed in the following Subparagraphs given below for each category of persons indicated.

(1) Persons who wish to obtain the approval prescribed in Article 13 Paragraph 1: 239,700 yen

(2) Persons who wish to obtain approval for the changes prescribed in Article 13 Paragraph 4: 96,900 yen

(Term of Validity of Comprehensive Sanitation-controlled Manufacturing Process)

**Article 2.** The term provided under the provisions of Article 14 Paragraph 1 by Cabinet Order shall be one year.

(Fee for the Approval of Comprehensive Sanitation-controlled Manufacturing Process)

**Article 3.** The fee provided under the provisions of Article 14 Paragraph 1 by Cabinet Order shall be 170,200 yen.

(Examinations Prescribed by Article 25 Paragraph 1 of the Law)

**Article 4.** The food additives and classification designated by the Cabinet Order under Article 25 Paragraph 1 of the Law shall be tar colors, and shall be examined by registered laboratories.

**2.** Any person who wishes to have a product examined pursuant to the provisions of Article 25 Paragraph 1 of the Law shall, as prescribed by Ministry of Health, Labour and Welfare Ordinance No. 23 (hereinafter referred to as the "Ministerial Ordinance")<sup>1)</sup>, submit applications to the Minister of Health, Labour and Welfare, the governor of the prefecture concerned, or a registered laboratory.

3. After receiving the applications prescribed in the preceding Paragraph, the Minister of Health, Labour and Welfare, the governor of any prefecture, or a registered laboratory shall collect test samples, as prescribed by the Ministerial Ordinance<sup>2)</sup>.

4. The Minister of Health, Labour and Welfare, the governor of such prefecture, or such registered laboratory shall, as prescribed by the Minister of Health, Labour and Welfare (Ministry of Health and Welfare Notification No. 286, 1972), perform examinations on the samples collected pursuant to the provisions of the preceding Paragraph and shall attach to the product the label prescribed by the Ministerial Ordinance under Article 25 Paragraph 1 of the Law, based on the determination that the product has passed the examinations, when the samples comply with the standards established by the Minister of Health, Labour and Welfare.

(Reference)

1): Article 24 of the Ministerial Ordinance

2): Article 25 of the Ministerial Ordinance

(Examinations Prescribed by Article 26 Paragraph 1 of the Law)

**Article 5.** The order pursuant to the provisions of Article 26 Paragraph 1, shall be performed to the persons designated by prefectural governors, after the notice by prefectural governors to take necessary measures for prevention of outbreak of food sanitation hazards within a period of not exceeding two months established by prefectural governors according to the written examination orders in which the items of examinations, collection of test samples, methods of examinations and other items established by the Ministerial Order<sup>1)</sup> are prescribed.

2. Any person who wishes to apply for examination prescribed under the provisions of Article 26 Paragraph 1 of the Law, shall submit an application to prefectural governors or registered laboratories pursuant to the provisions provided by the Ministerial Order<sup>2)</sup>.

3. On receiving the application submitted pursuant to the preceding Paragraph the prefectural governor or the registered laboratory shall collect test samples and perform examinations according to the prescriptions of the written examination order.

(Reference)

1): Article 27 of the Ministerial Ordinance

2): Article 28 of the Ministerial Ordinance

(Examinations Prescribed by Article 26 Paragraph 2 of the Law)

**Article 6.** Any person who wishes to apply for examinations pursuant to the provisions of Article 26 Paragraph 2 of the Law, shall submit an application form, provided under the provisions of the Ministerial Ordinance<sup>1)</sup>, to the Minister of Health, Labour and Welfare or registered laboratories.

2. On receiving the application form, the Minister of Health, Labour and Welfare or the registered laboratory shall collect samples and perform examinations according to the prescriptions of the written examination order.

(Reference)

1): Article 29 of the Ministerial Ordinance

(Examinations Prescribed by Article 27 Paragraph 3 of the Law)

**Article 7.** The provisions of the preceding Article shall be applied to the examinations pursuant to Article 26 Paragraph 3 of the Law.

(Food Sanitation Examination Facilities)

**Article 8.** Any food sanitation examination facility established by each prefecture, each city establishing health centers, or each special ward, pursuant to the provisions of Article 29 Paragraph 1 or 2 of the Law, shall be staffed adequately for examinations or tests, provided with physicochemical examination rooms, microbiological examination rooms, animal rooms, and administrative offices, and equipped with instruments and apparatus which are required for examinations or tests and which have been prescribed by the Ministerial Ordinance<sup>1)</sup>.

2. The food sanitation examination facilities prescribed in the preceding Paragraph shall manage administrative work concerning examinations or tests, as prescribed by the Ministerial Ordinance<sup>2)</sup>.

(Reference)

1): Article 36 of the Ministerial Ordinance

2): Article 37 of the Ministerial Ordinance

(Qualification of Food Sanitation Inspectors)

**Article 9.** Each food sanitation inspector shall fulfill one of conditions given in the following categories:

(1) A person who has completed the specified course at a training institute for food sanitation inspectors registered to the Minister of Health, Labour and Welfare.

(2) A medical doctor, dentist, pharmacist, or veterinarian.

(3) A graduate who has completed the required course of study in medical science, dentistry, pharmaceutical science, veterinary science, animal husbandry, fishery science, or agricultural chemistry at a university or college of technology under the School Education Law (Law No. 26, 1947), a university under the University Order (Imperial Ordinance No. 388, 1918), or a college under the College Order (Imperial ordinance No. 61, 1903).

(4) A licensed nutritionist with experience of not less than two years in work relating to food sanitation administration.

2. Provisions in Article 14 through Article 20 shall be construed in the training institute of the preceding Paragraph Subparagraph (1).

(Registration Fee of Registered Laboratories)

**Article 10.** The registration fee established by Cabinet Order pursuant to Article 31 of the Law shall be 222,600 yen.

(Term of Validity of Registration of Registered Laboratories)

**Article 11.** The term of validity established by Cabinet Order pursuant to the Article 34

Paragraph 1 shall be five years.

(Registration Renewal Fee of the Registered Laboratories)

**Article 12.** The fee established by Cabinet Order pursuant to the Article 31 of the Law shall be 131,000 yen.

(Designation of Foods, etc.)

**Article 13.** The foods and food additives prescribed by the Cabinet Order under Article 48 Paragraph 1 of the Law are:

Whole milk powder (confined to products contained in cans with a capacity of not more than 1,400g), sweetened milk powder, formulated milk powder; meat products; fish ham, fish sausage; irradiated foods; edible fats and oils (confined to products manufactured through a process of decoloring or deodorizing); margarine, shortening; and food additives (confined to products for which specifications have been established pursuant to the provisions of Article 11 Paragraph 1 of the Law).

(Registration of Training Institutes)

**Article 14.** In case the Minister of Health, Labour and Welfare performs registration of a training institute pursuant to the Article 48 Paragraph 6 Subparagraph (3) of the Law, the Minister shall perform the business pursuant to the standards established by the Ministerial Ordinance<sup>1)</sup> on qualification of the entrance to the institute, the years required for graduation, subjects to be taken, and other items.

(Reference)

1): Article 50 of the Ministerial Ordinance

(Application of Registration)

**Article 15.** An establisher of an institute who wishes to obtain registration of the training institute pursuant to the Article 48 Paragraph 6 Subparagraph (3) of the Law shall submit an application form to the Minister of Health, Labour and Welfare pursuant to the provisions of the Ministerial Ordinance<sup>1)</sup>.

(Reference)

1): Article 51 of the Ministerial Ordinance

(Notification on Change)

**Article 16.** In case there was a change in the items provided under the provisions of the Ministerial Ordinance, the establisher of a training institute which was registered pursuant to the Article 48 Paragraph 6 Subparagraph (3) of the Law (shall be referred, hereinafter, as "registered training institute") shall notify the change within one month from the corresponding day to the Minister of Health, Labour and Welfare.

(Request of Report)

**Article 17.** The Minister of Health, Labour and Welfare may request the establisher of a registered training institute a report concerning the institute, if the Minister determines that such action is necessary.

(Cancellation of Registration)

**Article 18.** The Minister of Health, Labour and Welfare may cancel the registration, when it was confirmed that a registered training institute no more complies with the standards established by the Ministerial Ordinance provided pursuant to the provisions of Article 14 of the Cabinet Order.

(Application of the Cancellation of Registration)

**Article 19.** An establisher of a registered training institute shall submit an application form, prepared pursuant to the provisions of Ministerial Ordinance<sup>1)</sup>, to the Minister of Health, Labour and Welfare, in case the person wishes to cancel the registration performed by the Minister of Health, Labour and Welfare.

(Reference)

1): Article 54 of the Ministerial Ordinance

(Official Announcement)

**Article 20.** The Minister of Health, Labour and Welfare shall officially announce it on official gazette in the following cases.

(1) An institute was registered pursuant to the Article 48 Paragraph 6 Subparagraph (3).

(2) A notification was performed pursuant to the Article 16 (confined to those provided by the Ministerial Ordinance<sup>1)</sup>).

(3) The registration pursuant to the Article 48 Paragraph 6 Subparagraph (3) was cancelled under the provisions of Article 18.

(Reference)

1): Article 55 of the Ministerial Ordinance

(Registration of a Training Course)

**Article 21.** An establisher of a training course who wishes to obtain registration of the training course pursuant to the Article 48 Paragraph 6 Subparagraph (4) shall submit an application form for registration to the Minister of Health, Labour and Welfare.

(Persons Not Qualified for Registration)

**Article 22.** Any person who falls under any of the categories given below shall not be able to obtain the registration of a training course pursuant to the Article 48 Paragraph 6 Subparagraph (4) of the Law.

(1) A person who has been sentenced a fine or a severer punishment, and two years have not

passed from the date of such fine or completion of serving such sentence or the invalidation of such fine or sentence.

(2) A person whose registration has been revoked pursuant to the provisions of the Article 30, and two years have not passed from the date of the revocation.

(3) A corporation whose executives, engaged in the execution of the business, might fall in under any of the two preceding Subparagraphs.

(Standards of Registration)

**Article 23.** The Minister of Health, Labour and Welfare shall register a training course, in case the applied person of the promoter of the training course is going to hold the course pursuant to the provisions established by the Ministerial Ordinance under the Article 49 of the Law.

(Duty of Holding a Training Institute)

**Article 24.** The promoter of the training course registered pursuant to the Article 48 Paragraph 6 Subparagraph (3) (shall be called, hereinafter, as "registered training course") shall prepare a plan of practice of the registered training course (excepting the cases of justified reasons), and the training course shall be practised according its plan.

2. The promoter of the registered training course shall practise the course fairly and in a manner in accordance with the standards established by the Ministerial Ordinance<sup>1)</sup>.

3. The promoter of the registered training course shall notify, before practice, the plan prepared pursuant to the provisions of Paragraph 1 to the Minister of Health, Labour and Welfare. When the promoter wishes to change the plan, it shall be notified as well.

(Reference)

1): Article 59 of the Ministerial Ordinance

(Notification on Change)

**Article 25.** In case the promoter of the registered training course wishes to make changes in the items established by the Ministerial Ordinance<sup>1)</sup>, the promoter shall notify to the Minister of Health, Labour and Welfare not later than two weeks before the day to be changed.

(Reference)

1): Article 60 of the Ministerial Ordinance

(Suspension or Discontinuance of Work)

**Article 26.** In case the promoter of the registered training course wishes to suspend or discontinue all or a part of the work related to registered training course, the promoter of the course shall notify to the Minister of Health, Labour and Welfare pursuant to the provisions established by the Ministerial Ordinance<sup>1)</sup>.

(Reference)

1): Article 61 of the Ministerial Ordinance

(Preparation of Tables etc. treating Financial affairs, Perusal, etc.)

**Article 27.** The promoter of the registered training course shall prepare, pursuant to the provisions established by the Ministerial Ordinance<sup>1)</sup> a list of assets, balance sheet, a statement of profit and loss or a statement of income and outgo, and business report (includes the electromagnetic record concerned (in case such record is prepared by electronic, magnetic and by other systems, that cannot be recognized by human sense, being processed by electronic computer; the same in this Article) shall be called as "tables, etc. treating financial affairs" in the following Article), which shall be kept in the office.

2. Any person who wishes to take a training course and any other person having interest may request the following matters any time within the business hours of the promoter of the training course; in case request is done, however, concerning Paragraph 2 or 4, the person has to pay the fee established by the promoter.

(1) In case tables, etc. treating financial affairs are prepared in writing, the perusal of the writing concerned or request of copies of the writing.

(2) Request of the transcript of an abstract of the writing.

(3) In case the tables, etc. treating financial affairs are prepared by electromagnetic record, request of the perusal or request of copies of items which are indicated by a method prescribed in the Ministerial Ordinance<sup>2)</sup>.

(4) Request of offer of the items recorded by the electromagnetic method by the method prescribed in the Ministerial Ordinance<sup>3)</sup>, or request of deliver of the writing of the items concerned.

(Reference)

1): Article 62 of the Ministerial Ordinance

2): Article 63 of the Ministerial Ordinance

3): Article 64 of the Ministerial Ordinance

(Order to Take Measures for Compliance)

**Article 28.** When the Minister of Health, Labour and Welfare recognizes that a promoter of a registered training course no longer promotes the course pursuant to the provisions established by the Ministerial Ordinance as prescribed under Article 49 of the Law the Minister may order the promoter of the training course to take measures in order to carry out the registered training course pursuant to the provisions established by the Ministerial Ordinance under the same Article of the Law.

(Order to Take Measures for Improvement)

**Article 29.** When the Minister of Health, Labour and Welfare recognizes that a promoter of a training course violates the provisions of Article 24, the Minister may order the promoter of the registered training course to carry out the course, or to take measures for the improvement of the method of performance of the registered training course and other method of performing the business.

(Revocation of Registration, etc.)

**Article 30.** The Minister of Health, Labour and Welfare may revoke the registration or may order to suspend all or a part of the business concerning the training course for a certain period, if the promoter of a registered training course falls under one of the following categories:

- (1) The promoter falls under the categories of Article 22 Paragraph 1 or Paragraph 2.
- (2) The promoter violates provisions of Article 24 through Article 26, Article 27 Paragraph 1 or the following Article.
- (3) The promoter vetoes requests pursuant to the provisions of each Subparagraph of Article 27 Paragraph 2.
- (4) The promoter violates an order pursuant to the provisions of the preceding two Articles.
- (5) The promoter gets registration under the Article 48 Paragraph 6 Subparagraph (4) by unjust means.

(Record in Books)

**Article 31.** Any promoter of a training course shall, as prescribed by the Ministerial Ordinance<sup>1)</sup>, prepare books, record therein the items prescribed under the Ministerial Ordinance relating to registered training course and retain books.

(Reference)

1): Article 65 of the Ministerial Ordinance

(Request for Reports)

**Article 32.** The Minister of Health, Labour and Welfare, within the limit necessary to enforce the Law and the Cabinet Order, may request the promoter of the training course the reports of the status of the work or accounting concerning the training course.

(On-site Inspections)

**Article 33.** The Minister of Health, Labour and Welfare, within the limit necessary to enforce the Law and the Cabinet Order, may require the officials concerned to visit offices or facilities of the promoter of the registered training course, to inspect the status of such work, or books, documents or other articles.

**2.** The officials to make on-site inspections shall carry certificates stating their status and show them to the related persons.

**3.** The right of on-site inspection under the Paragraph 1 shall not be taken to have been authorized for criminal investigation.

(Announcement)

**Article 34.** The Minister of Health, Labour and Welfare shall make an announcement in official gazette, when one of the following event occurs:



- (1) A training course is registered pursuant to the Article 48 Paragraph 6 Subparagraph (4).
- (2) Registration is performed pursuant to the provisions of Article 25 or Article 26.
- (3) Revocation of the registration of the registered training course or suspension of business related to the registered training course is ordered pursuant to the provisions of Article 30.

(Designation of Businesses)

**Article 35.** Businesses, for facilities of which the governor of each prefecture shall establish standards pursuant to Article 51 of the Law, are as follows:

- (1) Restaurant businesses (i.e., general eating-establishments, Japanese-style restaurants, SUSHI restaurants, Japanese noodle shops, Japanese-style inns, catering shops, boxed-lunch shops, Western-style restaurants, cafes, bars, cabarets, and other businesses which serve foods to customers by preparing foods or by establishing facilities, excluding businesses falling under the following Subparagraph).
- (2) Tea- and coffee-shop businesses (i.e., tea- and coffee-shops, salons, and other businesses which serve to customers drinks other than alcohol or confections by establishing facilities).
- (3) Confection- and savory-manufacturing businesses (including bread manufacturers).
- (4) AN (sweetened bean paste)-manufacturing businesses.
- (5) Ice cream-product-manufacturing businesses (i.e., businesses which manufacture ice cream, ice sherbet, ice candy, or other foods made by freezing liquid foods or liquid foods mixed with other foods).
- (6) Milk-processing businesses (i.e., businesses which process or manufacture cow's milk (including skim milk and other milk drinks similar in appearance to cow's milk) or goat's milk ).
- (7) Certified-milk-processing businesses (i.e., businesses which milk cows and, either by non-pasteurization or by holder pasteurization, process the milk into products in accordance with the specifications established by the Ministerial Ordinance concerning Compositional Standards Etc. for Milk and Milk Products).
- (8) Dairy-product-manufacturing businesses (i.e., businesses which manufacture powdered milk, evaporated milk and sweetened condensed milk, fermented milk, cream, butter, cheese, or other foods consisting mainly of milk (excluding milk drinks similar in appearance to cow's milk)).
- (9) Milk-collecting businesses (i.e., businesses which collect and store raw cow's milk or raw goat's milk).
- (10) Milk-selling businesses (i.e., businesses which sell cow's milk, goat's milk, or milk drinks (excluding those placed in preservative containers and sterilized at not lower than 115°C for not shorter than 15 minutes) intended for direct consumption or cream consisting mainly of milk).
- (11) Meat-processing businesses (i.e., businesses which, for human consumption, slaughter or eviscerate poultry other than those prescribed by Article 2 Subparagraph (1) of the Poultry Slaughtering Business Control and Poultry Inspection Law (Law No. 70, 1990) or livestock other than those prescribed by Article 2 Paragraph 1 of the Livestock Farm Law (Law No. 114, 1953), or divide into blocks or chop meat of eviscerated poultry or livestock or removed viscera, etc.).

- (12) Meat-selling businesses.
- (13) Meat-product-manufacturing businesses (i.e., businesses which manufacture ham, sausages, bacon, or other similar products).
- (14) Fish/shellfish-selling businesses (i.e., businesses which establish shops and sell fresh fish/shellfish, excluding businesses selling live fish/shellfish and businesses falling under the businesses listed in Subparagraph (12) below).
- (15) Fish/shellfish-auctioning businesses (i.e., businesses which, by auctioning, sell fresh fish/shellfish at fish/shellfish markets).
- (16) Fish-paste-product-manufacturing businesses (including businesses which manufacture fish ham, fish sausage, whale bacon, or other similar products).
- (17) Food-freezing and -refrigerating businesses.
- (18) Food-irradiation businesses.
- (19) Nonalcoholic-beverage-manufacturing businesses.
- (20) Lactic-acid-bacterial-beverage-manufacturing businesses.
- (21) Ice-manufacturing businesses.
- (22) Ice-selling businesses.
- (23) Edible-fat/oil-manufacturing businesses.
- (24) Margarine- or shortening-manufacturing businesses.
- (25) MISO (fermented soybean paste)-manufacturing businesses
- (26) Soy sauce-manufacturing businesses.
- (27) Sauce-manufacturing businesses (i.e., businesses which manufacture Worcester sauce, fruit sauce, fruit puree, ketchup, or mayonnaise).
- (28) Alcoholic beverage-manufacturing businesses.
- (29) TOFU (soybean curd)-manufacturing businesses.
- (30) NATTO (fermented soybeans)-manufacturing businesses.
- (31) Noodle-manufacturing businesses.
- (32) Ready-to-eat-food-preparing businesses (i.e., businesses which prepare foods into NIMONO (boiled foods with Japanese seasonings, including TSUKUDANI), YAKIMONO (grilled or roasted foods, including sauteed foods), AGEMONO (deep-fried foods), MUSHIMONO (steamed foods), SUNOMONO (foods seasoned with vinegar), or AEMONO (mixed foods with seasonings), excluding businesses falling under section (13), (16), or (29)).
- (33) Canned- or bottled-food-manufacturing businesses (excluding those falling under any of the businesses listed above).

(34) Food additive-manufacturing businesses (i.e., businesses manufacturing food additives for which specifications have been established pursuant to Article 11 Paragraph 1 of the Law ).

(Investigation of Causes of Food Poisoning)

**Article 36.** Pursuant to the provisions of Article 58 Paragraph 2 of the Law (including cases where such provisions are applied based on Article 62 Paragraph 1 of the Law), the investigations to be performed by the Director of the health center concerned shall be as follows:

(1) Epidemiological investigations required to trace foods, food additives, apparatus, containers/packages, or toys (hereinafter in this Article and in the following Article, referred to as "food etc.") having caused the poisoning, and poisoning-causing substances existing in such products.

(2) Investigations by microbiological or physicochemical examinations, or animal experiments on blood, feces, urine, vomit, or other related substances from the person poisoned or suspected to be poisoned or the corpse of such person; or on food, food additives, apparatus, containers/packages, or toys considered to have caused the poisoning.

(Reports concerning Poisoning)

**Article 37.** After receiving the investigation results pursuant to the provisions of Article 58 Paragraph 2 (hereinafter in this Article, referred to as "food poisoning"), the director on any health center shall successively report the actual condition of practice of the investigation pursuant to each Paragraph of the preceding Article to the governor of the prefecture, the mayor of the city establishing health centers, or mayor of the special ward (hereinafter in this Article, referred to as "governor of prefecture, etc.").

2. In case report was done pursuant to the provisions of Article 58 Paragraph 3 of the Law (including cases when such provisions are applied based on Article 62 Paragraph 1), the governor of prefecture, etc. shall, among the items reported pursuant to the provisions of the preceding Paragraph, report number of poisoned persons, food having caused the poisoning and other items established by the Ministerial Ordinance<sup>1)</sup> successively to the Minister of Health, Labour and Welfare.

3. The director of any health center shall, after the completion of the investigation of food poisoning case, prepare a report pursuant to the provisions established by the Ministerial Ordinance<sup>2)</sup> and submit it to the governor of prefecture, etc.

4. After receiving the report preceding Paragraph, the governor of any prefecture shall, as prescribed by the Ministerial Ordinance<sup>3)</sup>, make a report and submit it to the Minister of Health, Labour Welfare.

(Reference)

1): Article 74 of the Ministerial Ordinance

2): Article 75 of the Ministerial Ordinance

3): Article 76 of the Ministerial Ordinance

(Special Treatment for Large Cities)

**Article 38.** In the designated cities prescribed in Article 252-19 Paragraph 1 of the Local

Autonomy Law (Law No.67, 1947)(in this Article, referred as the "designated cities"), the administrative work to be handled by each designated city or the administrative work to be performed by each designated city, pursuant to the provisions of Article 67 of the Law, shall be as prescribed in the provisions of Article 174-34 of the Local Autonomy Law Enforcement Ordinances (Cabinet Order No.16, 1947).

2. In the core cities prescribed in Article 252-22 Paragraph 1 of the Local Autonomy Law (in this Article, referred as the "core cities" ), the administrative work to be handled by each core city, pursuant to the provisions of Article 67 of the Law, shall be as prescribed in the provisions of Article 174-49-13 of the Local Autonomy Law Enforcement Ordinances.

(Business Prescribed in Article 69 Paragraph 1 of the Law)

**Article 39.** The business prescribed by the Cabinet Order under Article 69 Paragraph 1 of the Law are businesses stated in Subparagraphs (1), (2), (10), (12), (14) and (22) of Article 69.

(Classification of Administrative Work)

**Article 40.** The administrative work considered to be handled by each prefecture, each city establishing health center or each special ward under the provisions of Article 37 of the Cabinet Order shall be the Subparagraph (1) officially delegated administrative work pursuant to the Article 2 Paragraph 9, Subparagraph (1) of the Local Autonomy Law.

(Delegation of Authority)

**Article 41.** The authority of the Minister of Health, Labour and Welfare pursuant to the Cabinet Order may be transferred, as prescribed by the Ministerial Ordinance, to the directors of the Local Bureaus of Health and Welfare.

The authority transferred to the directors of the Local Bureau of Health and Welfare may be transferred to the to the directors of the Local Branch Bureaus of Health and Welfare.



## **Food Sanitation Law Enforcement Regulations**

Ministry of Health and Welfare Ordinance No. 23, July 13, 1948  
Last amendment: March 31, 2004  
Ministry of Health, Labour and Welfare Ordinance No. 78

## Chapter 1. Food, Food Additives, Apparatus, and Containers/packages

[Cases Not Injurious to Human Health]

**Article 1.** The cases which are not injurious to human health under the proviso to Article 6 Subparagraph (2) of the Food Sanitation Law (Law No. 233, 1947, hereinafter referred to as the "Law") are as follows:

(1) Cases where substances, which, though toxic or injurious, are naturally occur in or on foods or food additives and, are deemed not injurious to human health, judging from the degree of the toxicity or injuriousness thereof or the treatments to be applied thereto.

(2) Cases where it is not possible to avoid mixing or adding toxic or injurious substances in the course of the manufacturing of foods or food additives and the finished foods or food additives are deemed not injurious to human health.

[Application for the Cancellation of the Disposition of Prohibition of Sale]

**Article 2.** An application for the cancellation designated in the provisions of Article 7 Paragraph 4 of the Law shall be performed by submitting an application form stating the items given in each of the following Subparagraphs to the Minister of Health, Labour and Welfare, with papers attached certifying that there will be no more danger of outbreak of injuring from the standpoint of food sanitation.

(1) The address and name of the applicant (in the case of a corporation, its name, the address of its main office, and the name of its representative).

(2) Scope of foods or substances to which application for the cancellation has been performed.

(3) The reason that there will be no more danger of outbreak of injuring derived from the foods or substances related with the prohibition concerned, and other items approved by the Minister of Health, Labour and Welfare to be necessary.

[Reasons to Be Taken into Account When Determining That Foods etc. Considerably Falls into Violation of the Law]

**Article 3.** The reasons designated by the Ministerial Ordinance established pursuant to the provisions of Article 8 Paragraph 1 of the Law are as follows:

(1) In case specified foods or food additives (hereinafter shall be referred to as "specified foods, etc."), which had been collected, manufactured, processed, prepared or stored in specified countries or regions, or which had been collected, manufactured, processed or stored by specified persons, underwent examinations pursuant to the provisions of Article 26 Paragraphs 1 through 3 or Article 28 Paragraph 1 of the Law, or examinations performed by the business persons pursuant to the administrative guidance (means administrative guidance prescribed in Article 2 Subparagraph (6) of the Administrative Procedures Law (Law No. 88, 1993), the same in Article 17 Paragraph 1 Subparagraph (1)) given by the nation, the prefecture or the city, prescribed by the Cabinet Order under the provisions of Article 5 Paragraph 1 of the Health Center Law (Law No. 101, 1947) (hereinafter referred as a "city establishing health center") or special ward, number of the foods or food additives which falls under any of each Subparagraph of Article 8 Paragraph 1 shall be, generally, not less than 5 percent by ratio, of the total foods or food additives examined.

(2) Substance of the regulations and measures, related to food sanitation, on the specified foods, etc. in the country or region where the specified foods etc. were collected, manufactured, processed, prepared or stored, examination system and other food sanitation control system of the specified foods, etc. by the government or local organizations in the country or region of the related country or region, actual condition of the examination result of the specified foods, etc. by the government of the related country or region or the local organizations, and other conditions of the food sanitation control in the related country or region on the specified foods, etc.

(3) On the specified foods, etc., outbreak of human injury derived from food poisoning provoked by the concerned specified foods, etc. or suspected to have been provoked by the concerned specified foods, etc.

(4) On the specified foods, etc., outbreak of dangerous situation that contaminates the specified foods, etc. or that could possibly contaminate the specified foods, etc.

2. The provisions in the preceding Paragraph shall be construed on the items prescribed in the Ministerial Ordinance designated by Article 8 Paragraph 1 construed in Article 62 Paragraph 1 of the Law. In this case, "foods and food additives" prescribed in Paragraph 1 of the preceding Article shall be read as "toys", "specified foods" in the same Subparagraph and Subparagraphs (2) and (4) of the same Paragraph as "specified toys", "on the specified foods, etc." in the same Paragraph as "on the specified toys" and "food poisoning provoked by the concerned specified foods, etc. or suspected to have been provoked by the concerned specified foods, etc." as "the concerned specified toys or suspected to have been provoked by the concerned specified toys".

[Items to Be Taken into Account When Determining That It Is Specially Needed to Prohibit Specified Foods, etc.]

**Article 4.** The items designated by the Ministerial Ordinance established pursuant to the provisions of Article 8 Paragraph 1 of the Law are as follows:

(1) Degree of danger of injuring human health by specified foods, etc.

(2) Items given in each Subparagraph of Paragraph 1 of the preceding Article

(3) Possibility of continuously sold, or collected, manufactured, imported, processed, used or prepared with intent to sell the specified foods, etc. that might fall into foods or food additives given in each Subparagraph of Article 8 Paragraph 1 of the Law.

(4) Impact of measures other than prohibitions according to the provisions of Article 8 Paragraph 1 for the prevention of outbreak of food sanitation hazards by specified foods, etc.

2. The provisions in the preceding Paragraph shall be construed in the items designated in Article 8 Paragraph 1, established by the Ministry of Health, Labour and Welfare, which are construed in Article 62 Paragraph 1 of the Law. In this case, "specified food, etc." in Subparagraphs (1), (3) and (4) of the preceding Paragraph shall be construed as "specified toys" and "foods or food additives" in Subparagraph (3) of the preceding Paragraph shall be read as "toys".

[Items to Be Taken into Account on Cancelling the Dispositions of Prohibition]

**Article 5.** On cancellation of the prohibitions which were performed on specified foods, etc. pursuant to the provisions of Article 8 Paragraph 1, basing on the application of the persons concerned with the prohibitions or in case of need, for the confirmation of no more danger of outbreak of injuring from the standpoint of food sanitation, the Minister of Health, Labour and



Welfare shall take into account the items giving in each Subparagraph of the Paragraph 1 of the preceding Article on the specified foods with respect to the prohibitions to be cancelled.

2. The provisions in the preceding Article shall be construed when cancelling the prohibition performed pursuant to the provisions of Paragraph 1 of the preceding Article, basing on the provisions of Article 8 Paragraph 3 construed in Article 62 Paragraph 1 of the Law. In this case, "specified foods, etc." in the preceding Subparagraph shall be read as "specified toys".

[Items to Be Described in Application for the Cancellation of the Dispositions of Prohibition]

**Article 6.** Application for the cancellation pursuant to the provisions of Article 8 Paragraph 3 of the Law shall be performed by submitting an application form to the Minister of Health, Labour and Welfare, in which the items given in each following Subparagraph are stated, being attached with papers certifying there is no more danger of outbreak of injuring from the standpoint of food sanitation, related with the foods or food additives on which application of the cancellation of the concerned prohibitions has been performed.

(1) The name and address of the applicant (in the case of a corporation, its corporate name, address of the main office and the name of its representative).

(2) Scope of foods or food additives to which application of the prohibition has been performed.

(3) Other items approved by the Minister of Health, Labour and Welfare to be necessary.

2. The provisions in the preceding Article shall be construed in the application of the prohibitions basing on the provisions of Article 8 Paragraph 3 construed in Article 62 Paragraph 1 of the Law. In this case, "foods or food additives" in the preceding Paragraph shall be read as "toys".

[Meat, etc. of Livestock Suffering from Disease]

**Article 7.** The livestock designated by the Ministerial Ordinance prescribed in Article 9 Paragraph 1 of the Law is water buffalo.

2. The cases designated by the Ministerial Ordinance prescribed in Article 9 Paragraph 1 of the Law are as follows:

(1) Cases where any animal suffering from one or more of the diseases given in the left Column of Table 5 of the Abattoir Law Enforcement Regulations (Ministry of Health, Labour and Welfare Ordinance No. 44, 1953), or any animal which is deemed to have some abnormal features given in the same Column, has been treated with necessary measures, such as abolition or other measures for the prevention of being served for human consumption.

(2) Cases where, following the inspection after the removal of internal organs pursuant to the Article 33 Paragraph 1 Subparagraph (3) of the Law concerning Regulation of Poultry Business and Poultry Inspection Enforcement Regulations (Ministry of Health, Labour and Welfare Ordinance No. 40, 1990), abolition or other measures have been taken on the left Column of Table 10, to the parts indicated in the right Column.

3. Under the proviso to Article 9 Paragraph 1 of the Law, the case where the officials concerned determine products to be not injurious to human health and fit for human consumption is the case which healthy livestock have met with instant death from unforeseen accidents.

[Products Derived from Meat, etc. of Livestock]

**Article 8.** The products prescribed by the Ministerial Ordinance under Article 9 Paragraph 2 of the Law shall be meat products.

[Items to be Described in Certificates]

**Article 9.** The items prescribed by the Ministerial Ordinance under Article 9 Paragraph 2 of the Law are as follows.

(1) For meat or viscera of any livestock or poultry, the species of the livestock or poultry; for any of the products prescribed in the preceding Article, the name of the product and the kinds of meat or viscera used as its ingredients.

(2) The number and weight.

(3) The name and address of the consignor (in the case of a corporation, its name and address)

(4) The name and address of the consignee (in the case of a corporation, its name and address).

(5) For meat or viscera of any livestock or poultry (excluding those divided, chopped, or otherwise processed), the items, given below, relating to the name, etc. of the laboratory which has performed the inspection:

a. For any livestock, the name of the laboratory which has performed such meat inspection (hereinafter "meat inspection" means ante-mortem inspection performed before slaughter, post-mortem inspection performed before dressing, and post-mortem inspection performed after dressing) or the title and name of the official who has performed such meat inspection.

b. For any poultry, the name of the laboratory which has performed such poultry inspection (hereinafter "poultry inspection" means ante-mortem inspection, inspection performed after removing feathers, and inspection performed after evisceration) or the title and name of the official who has performed such poultry inspection.

(6) The name and address of the facility at which any of the slaughtering, etc., given below, has been performed:

a. For meat or viscera of any livestock (excluding those divided into blocks, chopped, or otherwise processed), the slaughterhouse where the slaughtering or dressing has been performed.

b. For meat or viscera of any poultry (excluding those divided into blocks, chopped, or otherwise processed), the poultry processing plant where the slaughtering, feather-removing, and eviscerating have been performed.

c. For meat or viscera of any livestock or poultry divided, cut up, or otherwise processed, the facility where such treatments have been performed.

d. For products prescribed in the preceding Article, the plant where the products have been manufactured.

(7) A statement to the effect that the processing, including slaughtering, dressing, feather-removing, eviscerating, dividing, and chopping, or the manufacturing, which is prescribed in 'a' through 'd' of the preceding Subparagraph (6), has been done in a sanitary manner pursuant to the domestic laws of the exporting country.

(8) The date when the slaughtering or other activity, given below, have been performed:

- a. For meat or viscera of any livestock (excluding those divided, chopped, or otherwise processed), the date of slaughtering and meat inspection.
- b. For meat or viscera of any poultry (excluding those divided, chopped, or otherwise processed), the date of slaughtering and poultry inspection.
- c. For meat or viscera of any livestock or poultry which has been divided, chopped, or otherwise processed, the date of such processing.
- d. For products prescribed in the preceding Article, the date of manufacturing.

[Attachment of Copies of Certificates]

**Article 10.** When the certificate prescribed in Article 9 Paragraph 2 of the Law is related to meat or viscera of any livestock which has undergone the meat inspection in a country other than the exporting country of such product, or is related to meat or viscera of any poultry which has undergone the poultry inspection in a country other than the exporting country of such product, such certificate shall be accompanied with a copy of a certificate stating the items prescribed in the preceding Article, which has been issued by the governmental agency concerned of the country having performed such meat inspection or poultry inspection.

[Countries Designated by the Ministry of Health, Labour and Welfare Ordinance]

**Article 11.** The countries designated by the Ministerial Ordinance under the proviso of Article 9 Paragraph 2 are the United State of America, the Commonwealth of Australia, and New Zealand.

[Food Additives not Injurious to Human Health]

**Article 12.** The food additives which, by the provisions of Article 10 of the Law, have been deemed as not injurious to human health are those listed in Table 1.

[Standards for Comprehensive Sanitation-controlled Manufacturing Process]

**Article 13.** The standards prescribed in the Ministerial Ordinance under Article 13 Paragraph 2 of the Law (including cases where Article 13 Paragraph 2 of the Law applies in Paragraph 4 of the same Article and in Article 14 Paragraph 2 of the Law) are as follows.

(1) The documents given below shall be prepared, concerning the comprehensive sanitation-controlled manufacturing process for the product:

- a. A product description, indicating the name, kind, raw materials, and other necessary items of the product.
- b. Documents concerning manufacturing or processing processes, indicating the performance of machinery and apparatus used in manufacturing or processing, and other necessary items.
- c. A drawing of the facility, indicating the structure of the facility/equipment, the traveling route of products (the entire route from the entry of raw materials to the shipment of the product, etc.),

and other necessary items.

(2) Documents shall have been prepared, indicating the items prescribed in the Subparagraphs listed below, concerning the comprehensive sanitation-controlled manufacturing process for the product:

a. For all food sanitation hazards which may occur as to the product, measures to prevent the occurrence of each hazard shall be prescribed, for each substance causing such hazard and each process in which such hazard may occur; and if the substances for which such measures are prescribed do not include one or more of the substances causing the hazards listed in the right Column of Table 2 for the foods listed in the left Column of the same Table, the reason for the absence shall be clarified.

b. Among the measures prescribed in 'a' above, measures which require continuous or frequent confirmation of their enforcement status to prevent the occurrence of food sanitation hazards concerning the product, shall be prescribed.

c. The method of confirmation as prescribed in 'b' above shall be specified.

(3) Documents shall have been prepared, indicating corrective measures to be taken when the confirmation prescribed in 'b' above has found that the measures prescribed in the same Letter were not taken appropriately.

(4) Documents shall have been prepared, indicating sanitation-control methods under the comprehensive sanitation-controlled manufacturing process for the product, concerning sanitation control of the facility and equipment, sanitary training for employees, and other necessary items.

(5) Documents shall be prepared, indicating methods to verify that the occurrence of food sanitation hazards has been appropriately prevented, such as testing methods for the product, concerning the comprehensive sanitation-controlled manufacturing process for the product.

(6) Documents shall have been prepared, indicating methods of recording the items given below, and methods and the period of retention of the record.

a. Items concerning the confirmation prescribed in Subparagraph (2) 'b'.

b. Items concerning the corrective measures prescribed in Subparagraph (3).

c. Items concerning the sanitation-control methods prescribed in Subparagraph (4).

d. Items concerning the verification prescribed in the preceding Subparagraph.

(7) As to the comprehensive sanitation-controlled manufacturing process for the product, a person to assume responsibility concerning the work given below shall have been placed. The person shall perform such work (excluding the work prescribed in the following Subparagraph) personally or shall have persons, who have previously been appointed in accordance with the contents of the work, perform part or all of such work.

a. Examine whether the measures prescribed in Subparagraph (2) 'b' are adequately taken, check whether the confirmation prescribed in the same Subparagraph is adequately performed, and keep records concerning such examination.

b. Maintain machinery and apparatus used for the confirmation prescribed in Subparagraph (2) 'b' (including calibration of gauges) and keep records concerning such maintenance.

c. Other necessary work

(8) As to the verification prescribed in Subparagraph (5), a person to assume responsibility concerning the work given below shall have been placed. The person shall perform such work personally or shall have persons, who have previously been appointed in accordance with the contents of the work, perform such work.

a. Perform tests on products.

b. Maintain machinery and apparatus used for the tests prescribed in 'a' above (including calibration of gauges) and keep records concerning such maintenance.

c. Other necessary work.

[Application for Approval]

**Article 14.** Application for the approval prescribed in Article 13 Paragraph 1 of the Law shall be made by submitting an application stating the items given below to the Minister of Health, Labour and Welfare.

(1) The address, name, and birthday of the applicant (in the case of a corporation, its name, the address of its main office, and the name of its representative).

(2) The kind of product.

(3) The name and address of the manufacturing or processing plant.

(4) An outline of the comprehensive sanitation-controlled manufacturing process of the product.

**2.** The application prescribed in the preceding Paragraph shall be accompanied by the materials given below.

(1) Documents prescribed in Subparagraphs (1) through (6) of the preceding Article.

(2) Materials as to what effects the measures prescribed in accordance with Subparagraph (2) 'b' of the preceding Article have.

(3) Materials describing on items indicated in Subparagraph (2) and on kept records, based on the documents prescribed in Subparagraph (6) of the preceding Article.

**3.** On the application prescribed in Paragraph 1 shall be put a revenue stamp equivalent to the amount.

[Application for Approval of Change]

**Article 15.** Application for the approval for change prescribed in Article 13 Paragraph 4 of the Law shall be made by submitting an application stating the items given below to the Minister of Health, Labour and Welfare.

(1) The items given in Subparagraphs (1) through (4) of the preceding Article.

(2) The number and date of approval which has already been obtained.

2. The application prescribed in the preceding Paragraph shall be accompanied by the materials given below.

(1) Materials on items planned to be changed, out of the descriptions of the documents given in Paragraph 2 Subparagraph (1) of the preceding Article and the materials given in Subparagraph (2) of the same Paragraph (for the documents given in Subparagraph (1) of the same Paragraph, a list comparing new and old descriptions shall be given).

(2) Materials given in Paragraph 2 Subparagraph (3) of the preceding Article.

3. On the application prescribed in Paragraph 1 shall be put a revenue stamp equivalent to the amount.

[Application for Renewal of Approval]

**Article 16.** Application for the renewal of approval prescribed in the Article 14 Paragraph 1 of the Law shall be made by submitting an application stating the items given in each Subparagraph of Paragraph 1 of the preceding Article to the Minister of Health, Labour and Welfare.

2. The application prescribed in the preceding Paragraph shall be accompanied by the materials given below.

(1) Documents prescribed in Article 13, Subparagraph (1) and Subparagraphs (4) through (6) (Documents without change not necessary to be accompanied, concerning items with a list comparing new and old descriptions shall be given.).

(2) Documents prescribed in Article 13 Subparagraphs (2) and (3).

(3) Materials describing on items given in the Article 13 Subparagraph (6) 'a', 'b' and 'd', and on kept records, based on the documents prescribed in the same Subparagraph.

3. On the application prescribed in Paragraph 1 shall be put a revenue stamp equivalent to the fee.

[Reasons to Be Taken into Account When Determining That Apparatus, etc. Considerably Falls into Violation of the Law]

**Article 17.** The items designated by the Ministerial Ordinance established pursuant to the provisions of Article 17 Paragraph 1 of the Law are as follows:

(1) In case specified apparatus or containers/packages (hereinafter shall be called "specified apparatus, etc."), which had been manufactured in specified countries or regions, or which had been manufactured by specified persons, underwent examinations pursuant to the provisions of Article 26 Paragraphs 1 through Paragraph 3 or Article 28 Paragraph 1, or examinations performed by business persons pursuant to the administrative guidance given by the nation, the prefecture, city establishing health centers or special ward, number of the apparatus or containers/packages which falls in under Article 17 Paragraph 1 of the Law shall be, generally, not less than 5 percent by ratio, of total apparatus or containers/packages.

(2) Contents of the food sanitary regulations and dispositions on specified apparatus, etc. in the countries or regions where the specified apparatus, etc. are manufactured.

(3) On the specified apparatus, etc., outbreak of human injury derived from the specified apparatus, etc. concerned, or suspected to have derived from the specified apparatus, etc.

(4) On the specified apparatus, etc., outbreak of dangerous situation that contaminates the specified apparatus, etc. or that could possibly contaminate the specified apparatus, etc.

2. The provisions in the preceding Paragraph shall be construed on the items prescribed in the Ministerial Ordinance designated by Article 17 Paragraph 1 construed in the Article 62 Paragraph 1 of the Law.

[Items to Be Taken into Account When Determining That It Is Specially Needed to Perform Prohibition Disposition of Specified Apparatus, etc.]

**Article 18.** The items designated by the Ministerial Ordinance established pursuant to the provisions of Article 17 Paragraph 1 of the Law shall be as follows:

(1) Degree of danger of injuring health by specified apparatus, etc.

(2) Items given in each Subparagraph of Paragraph 1 of the preceding Article.

(3) Possibility of continuously sold, or manufactured or imported, or used on business the specified apparatus, etc. that might fall into apparatus or containers/packages given in each Paragraph of Article 17 Paragraph 1 of the Law.

(4) Impact of measures other than dispositions pursuant to the provisions of Article 17 Paragraph 1 of the Law for the prevention of outbreak of food sanitation hazards by specified apparatus, etc.

2. The provisions in the preceding Paragraph shall be construed in the items, designated in Article 17 Paragraph 1 established by the Ministerial Ordinance of Health, Labour and Welfare, which are construed in Article 62 Paragraph 1 of the Law.

[Items to Be Taken into Account on Cancelling the Dispositions of Prohibition]

**Article 19.** On cancellation of the prohibitions which were performed on specified apparatus, etc., pursuant to the provisions of Article 17 Paragraph 1 of the Law, according to the provisions of Article 8 Paragraph 3 which are construed after reading in Article 17 Paragraph 3 basing on the application of the persons concerned with the prohibitions, for the confirmation of no more danger of outbreak of food sanitation hazards, the Minister of Health, Labour and Welfare shall take into account the items given in each Subparagraph of the Paragraph 1 of the preceding Article on the specified apparatus, etc. with respect to the prohibitions to be cancelled.

2. The provisions in the preceding Article shall be construed in case of cancelling the prohibitions pursuant to the provisions of Article 17 Paragraph 1 of the Law which are construed in Article 62 Paragraph 1 of the Law, based on the provisions of Article 8 Paragraph 3 which are construed in Article 62 Paragraph 1 of the Law after being read and construed in Article 17 Paragraph 3 of the Law.

[Items to Be Described in Application of the Cancellation of Dispositions of Prohibition]

**Article 20.** Application for the cancellation pursuant to the provisions of Article 8 Paragraph 3, after being read and construed in Article 17 Paragraph 3, shall be performed by submitting application form to the Minister of Health, Labour and Welfare, in which the items given in each following Subparagraph are stated, being attached with papers certifying there is no more danger

of outbreak of injuring from the standpoint of food sanitation, related with the apparatus or containers/packages on which the application of the cancellation of the prohibitions of the concerned prohibitions has been performed.

(1) The name and address of the applicant (in case of a corporation, its corporate name, address of the main office and the name of its representative).

(2) Scope of apparatus or containers/packages to which application of the prohibitions has been performed.

(3) Other items approved by the the Minister of Health, Labour and Welfare to be necessary.

2. The provisions in the preceding Article shall be construed in the application of the prohibitions by the provisions of Article 8 Paragraph 3, being read and construed in Article 17 Paragraph 1 of the Law which is construed in Article 62 Paragraph 1 of the Law.

## Chapter 2. Labeling

[Standards for Labeling]

**Article 21.** The standards for labeling of the foods and food additives which are prescribed in Table 3 and which are intended for sale are as follows:

(1) The items given below shall be declared in a conspicuous place on the container/package (or on the package for the items given in this Subparagraph and those given in Paragraphs 5 through 8, Paragraphs 16 and 19 of this Article, when the product is wrapped for retail sale) in a manner that is easily readable without opening the container/package.

a. Name [in the case of a food additive listed in Table 1 (excluding food additives listed in Table 4), only the same name as mentioned in Table 1 may be used].

b. For a food or food additive whose quality may rapidly deteriorate when stored under the specified storing conditions, the date (including the year) preceded by certain letters indicating "use-by date" (hereinafter "use-by date" means the date which signifies the end of the period through which a food or food additive is determined not to provide any health hazards resulting from the deterioration of the product, including rot and decomposition, when stored under the specified storing conditions). For a food or food additive other than the foods or food additives mentioned above, the date (including the year) preceded by certain letters indicating "best-before-date" (hereinafter "best-before-date" means the date which signifies the end of the period through which all expected qualities of the product are possible to be completely retained, when stored under the specified storing conditions).

c. The address of the manufacturing or processing plant (or hereinafter, in the case of an imported product, the address of the business office of its importer) and the name of the manufacturer or processor (hereinafter, in the case of an imported product, the name of its importer)(in the case of a corporation, its name); provided, however, that it is possible.

d. For a food additive preparation, the name and percentage by weight of each ingredient (excluding ingredients used for flavoring) (when an ingredient is a vitamin A derivative, the percentage by weight as vitamin A).

e. For a food which contains food additives used for one or more of the purposes listed in the middle Column of Table 5 [excluding substances used for fortifying nutrition, processing aids (hereinafter in this Letter e, "processing aids" means substances added to a food in processing the



food, which are: ① removed from the food before the completion of the food, ② derived from raw materials of the food and converted into components normally included in the food but do not significantly increase the amounts of the components, or ③ present in the finished food at insignificant levels but do not have any technical or functional effect of these components on the food), and carry-overs ("carry-over" means substances which are used in manufacturing or processing raw materials of a food and not used in manufacturing or processing the food and which are present in the finished food at levels less than those normally required to achieve any technical or functional effect in the food)], the names of these food additives and one of the appropriate items listed in the right Column of the same Table. For a food containing food additives which are not mentioned above, the names of these food additives.

f. For a processed food which uses any of the foods given in Table 6 (excluding milk) as a raw material and excluding any food which has no antigenic property and any of the foods given in Table 3, Entry No. 2), a statement to the effect that the product contains milk as designated by the Minister of Health, Labour and Welfare.

g. For a food containing a food additive (excluding that which has no antigenic property and flavoring agent; the same in 'j') derived from foods given in Table 6 (hereinafter referred to as "specified raw material"), a statement to the effect that the food contains the food additive and that the food additive contained in the food is derived from the specified material.

h. The method of storing (for a food or food additive for which standards for methods of storing have been established pursuant to the provisions of Article 11 Paragraph 1 of the Law, the method of storing complying with such standards), and for a food or food additive for which standards for methods of use have been established pursuant to the provisions of the same Paragraph, the method of use complying with such standards.

i. For a food additive (excluding the food additives prescribed in 'j'), the words "食品添加物" in Japanese.

j. For a food additive derived from specific raw material, the words "食品添加物" in Japanese and that the food additive is derived from specific raw material.

k. For a tar color preparation, the name of the color actually produced in food, preceded by the words "製剤" in Japanese.

l. For a food additive for which the declaration of content is stipulated in the specifications established pursuant to the provisions of Article 11 Paragraph 1 of the Law, the percentage by weight.

m. For a vitamin A derivative as a food additive, the percentage by weight as vitamin A.

n. For aspartame or a preparation or food containing aspartame, a statement to the effect that the product is an L-phenylalanine compound or that the product contains L-phenylalanine.

o. For mineral water and other similar products ("mineral water and similar products" means all nonalcoholic beverages consisting of only water), in whose container/package the pressure of carbon dioxide is lower than 98 kPa at 20°C and which have not been pasteurized or treated for microbe-removal (hereinafter "microbe-removal" means the elimination by filtration or other means of microbes, derived from the water source, which may occur and grow in such food), a statement to the effect that the water is not pasteurized or treated for microbe-removal.

p. For a frozen fruit juice ("frozen fruit juice" means products obtained by freezing a squeezed fruit juice or the concentrate thereof, excluding fruit juices used as ingredients), the words "冷凍

果実飲料" in Japanese.

q. For a canned food, the names of the main ingredients.

r. For meat, the species of livestock or poultry.

s. For meat, to which treatment by use of an edge to cut short tendons and fibers keeping its original form, treatment by soaking in flavorings, connecting treatment with other fragment of meat and/or any other treatment by which contamination of pathogenic bacteria might prevail into the inside have been performed, a statement to the effect that such treatment has been performed and that it is necessary to heat the whole meat enough when served for human consumption.

t. For any of the foods given in Table 3, Entry No. 4, the names of the meat used as ingredients (labeling shall be done in descending order of predominance by weight of the ingredients contained by the provisions of Subparagraph (1) 'o'; when an ingredient is fish meat, the food shall be labeled with the words "魚肉" in Japanese).

u. For a dried meat product (hereinafter "dried meat products" means products obtained by drying meat, which are offered for sale as dried meat products), a statement to the effect that the product is a dried meat product.

v. For an unheated meat product (hereinafter "unheated meat products" means products obtained by salting and smoking or drying meat, which have not been pasteurized either by holding their center at 63 °C for 30 minutes or by any other method providing a comparable or superior effect and which are offered for sale as unheated meat products, excluding dried meat products), a statement to the effect that the product is an unheated meat product, and the pH and water activity.

w. For a specifically heated meat product (hereinafter "specifically heated meat products" means products obtained by pasteurizing meat using a method other than any method enabling their center to be held at 63 °C for 30 minutes or any method providing a comparable or superior effect, excluding dried meat products and unheated meat products), a statement to the effect that the product is a specifically heated meat product, and the water activity.

x. For a heated meat product (hereinafter "heated meat products" means meat products other than dried meat products, unheated meat products, and specifically heated meat products), a statement to the effect that the product is a heated meat product and a statement to the effect that the pasteurization was performed after the product was packed or that it was performed before it was packed.

y. For a meat product, whale meat product, fish sausage, fish ham, or specially wrapped KAMABOKO (fish-paste cake), which was tightly packed into a hermetic container/package and pasteurized either by holding its center at 120 °C for 4 minutes or by any other method providing a comparable or superior effect (excluding canned or bottled products), the method of pasteurization.

z. For fish sausage, fish ham, or a specially wrapped KAMABOKO (fish-paste cake), whose pH is not more than 4.6 or whose water activity is not more than 0.94 (excluding canned or bottled products), the pH or water activity.

aa. For a product obtained by freezing a manufactured or processed food, (hereinafter in this Article this excludes nonalcoholic beverages, meat products, whale meat products, fish-paste products, boiled octopus and boiled crab), a statement of whether or not the food requires heating before consumption.

- bb. For a frozen food requiring heating before consumption (hereinafter "frozen food requiring heating before consumption" means a product obtained by freezing a manufactured or processed food, which requires heating before consumption), a statement of whether or not the food was heated just before it was frozen.
- cc. For raw oysters or a frozen product of filleted fresh fish or shucked fresh shellfish (excluding raw oysters), a statement of whether or not the product is intended to be consumed raw.
- dd. For filleted fresh fish or shucked fresh shellfish (excluding raw oysters) intended to be served for raw consumption (excluding frozen product), a statement to the effect that the product is intended to be consumed raw.
- ee. For any of the foods listed in Table 3, Entry No. 8, a statement to the effect that the food was treated with ionizing radiation.
- ff. For any of the foods listed in Table 3, Entry No. 9 (excluding canned and bottled foods), a statement to the effect that the food was packed in a hermetic container/package, tightly sealed, and pasteurized under pressure.
- gg. For poultry eggs with shells (only cases for raw consumption), a statement to the effect that the product is for raw consumption, had better be stored at not higher than 10 °C and shall be pasteurized by heating when the product is served for human consumption in cases the product has passed the "best-before-date".
- hh. For poultry eggs with shells (excluding those for raw consumption), a statement to the effect that the product is for heating and manufacturing use, and shall be pasteurized by heating when the product is served for human consumption.
- ii. For liquid poultry eggs [shelled eggs from poultry eggs, (the same, hereinafter, in this Article)], the conditions of pasteurization in cases the product was pasteurized.
- jj. For liquid poultry eggs, excepting those which has not been pasteurized, a statement to the effect that the product has not been pasteurized, and shall be pasteurized by heating when the product is served for human consumption.
- kk. For raw oysters (only cases for raw consumption), the sea, lakes or marshes where they were collected.
- ll. For boiled crab, whether it shall be pasteurized by heating or not when it is served for human consumption.
- mm. For an instant noodle product treated with fats or oils, a statement to the effect that the product was treated with fats or oils.
- nn. For any of the foods and processed foods listed in Table 3 Entry No. 12, the items given in the following i) to iii) according to the following classifications i) to iii).
- i) For a food of farm product obtained by application of recombinant DNA techniques (means among the farm products listed in the left Column of Table 7 product contained by application of recombinant techniques [means techniques in which recombinant DNA molecule is prepared by combining DNA through the measures of breakage and reunion by use of enzymes, etc., to be introduced into living cells and multiplied, the same herein after]), to which management of distinguished production and distribution (means management performed under notice of a good controller at each stage of production, distribution and processing to distinguish the product, which is proved clearly by certification paper) from farm products obtained by no application of

recombinant DNA techniques (means among the farm products listed in the left Column of Table 7 product obtained by no application of recombinant DNA techniques, the same hereinafter), or for a processed food produced from farm product obtained by application of recombinant DNA techniques as a raw material (includes that which is obtained from the concerned processed food as a raw material): according the following classification (i) or (ii), items given in the following (i) or (ii).

(i) Food of farm product: shall be stated that the food of farm product was obtained by recombinant DNA techniques.

(ii) Processed food: shall be stated the name of the raw materials of the farm product, listed in the left Column of Table 7, and shall be stated that the related farm product was obtained by recombinant DNA techniques.

ii) For a food product, to which farm product obtained by application of recombinant DNA techniques has not been distinguished from farm product obtained by no application of recombinant DNA techniques in the stage of production, distribution or processing, or for a processed food manufactured by use of farm product, to which farm product obtained by application of recombinant DNA techniques has not been distinguished from farm product obtained by no application of recombinant DNA techniques, as a raw material (including that which uses the processed food concerned as a raw material; the same in (ii)): according to the following classification (i) or (ii), items given in the following (i) or (ii).

(i) Food of farm product: shall be stated that food of farm product obtained by application of recombinant DNA techniques has not been distinguished from food of farm product obtained by no application of DNA techniques.

(ii) Processed food: shall be stated the name of the raw material of the farm product, listed in the left Column of Table 7, and shall be stated that farm product obtained by application of recombinant DNA techniques has not been distinguished from farm product obtained by no application of recombinant DNA techniques.

iii) For a processed food, containing farm product obtained by no application of recombinant DNA techniques, to which management of distinguished production and distribution was confirmed to have been performed (including that which uses the processed food concerned as a raw material): name of the farm product, listed in the left Column of Table 7, which is the raw material of the processed food concerned.

oo. For foods for specified health uses [hereinafter foods for specified health uses mean foods which label that they can be expected to contribute to maintain and promote health for those people who intake the foods for specific maintenance and promotion of health in the food life; which are permitted pursuant to Article 26 Paragraph 1 of the Health Promotion Law (Law No. 103, 2002) or approved pursuant to Article 29 Paragraph 1 of the Law (shall be called "permission or approval" hereinafter in the provision 'oo') statements to the effect that they are foods for specified health uses, contents of the labeling they got permission or approval, quantities of nutritional components, energy, names of the raw materials, net weight, standard quantity of daily intake, methods of intake and notice for intake.

pp. For a food with nutritional function [food which labels special function of a specified nutritional component contained in the food according to the standards designated by the Minister of Health, Labour and Welfare (excluding fresh foods but poultry eggs, the same, hereinafter), a statement to the effect that the food is qualified as a food with nutritional function, function of the nutritional component which is to be labeled to cope with the standards established by the Minister of Health, Labour and Welfare, quantity of the nutrient, energy, appropriate amount of daily intake, method of daily intake, method of intake and notice for intake.

qq. For a food for specified health uses, to which recommended dietary allowances have been established on the nutrient components contributing for health purposes, or for food with nutritional functions, to which recommended daily allowance have been established on the components labeling on the function, the ratios of the nutrient components contained in the appropriate amounts of daily intake to the recommended daily allowances concerned.

rr. For a food with nutritional function, which does not belong to foods for specified health uses (mean foods for specified health uses designated under the provisions of Article 26 Paragraph 5 of the Health Promotion Law), a statement to the effect that it has not undergone separate examination by the Minister of Health, Labour and Welfare.

ss. For foods for specified health uses or a food with nutritional function, to which special notice shall be necessary on the methods of preparation and preservation, the notice items concerned.

(2) The items given in the preceding Subparagraph shall be declared accurately in Japanese using wording easily readable and understandable to general persons who buy or use these foods or food additives.

(3) In the cases of foods other than foods for specified health uses and food with nutritional function (shall be called hereinafter as food for special dietary use), names misleading to food for dietary use, labeling that function of nutritional components and purpose of specified health use can be expected, shall be prohibited; while in the case of food with nutritional function that is not belonging to foods for specified health uses labeling of expectation for specified health use shall be prohibited.

(4) For a food other than foods of farm product obtained by no application of recombinant DNA techniques, on which management of distinguished production and distribution was confirmed to have been performed, or other than processed foods containing farm product obtained by no application of recombinant DNA techniques as a raw material (including that which contains the processed food concerned as a raw material), on which management of distinguished production and distribution was confirmed have been performed, a statement to the effect that the food of the farm product concerned is food of a farm product obtained by no application of recombinant DNA techniques or a statement to the effect that the raw material of the processed food given in the left Column of Table 7 is a farm product obtained by no application of recombinant DNA techniques shall be prohibited.

2. Notwithstanding the provisions of Subparagraph (1) of the preceding Paragraph, poultry eggs with shells among those in Table 3, Entry No. 10, foods given in Table 3, Entry No. 11-c, and among foods of farm product given in the same Table Entry No. 12 those to which notice is given in near place of the food of farm product or the name is stated in a conspicuous place do not have to be labeled with the name.

3. Notwithstanding the provisions of Paragraph 1 Subparagraph (1), if the period from the date of manufacturing or processing the product to the best-before-date of the product exceeds three months, the date (including year) preceded by certain letters indicating "best-before-date" may be replaced by labeling of the year and month preceded by certain letters indicating "best-before-date".

4. Notwithstanding the provisions of Paragraph 1 Subparagraph (1), any of the foods listed in Entry No. 2 of Table 3, any of the foods contained in glass bottles (excluding bottles with paper caps) or polyethylene containers/packages out of those listed in Entry No. 3 of the same Table, any of the foods listed in Entry No. 11-b of the same Table (excluding canned food, bottled food, barreled food, and potted food), any of the foods listed in Entry No. 11-c, any of the foods as farm product listed in Entry No. 12 at the same Table and any of the food additives listed in Entry No.14

of the same Table may be exempted from the declaration of the use-by date or the best-before-date preceded by certain letters indicating the "use-by date" or "best-before-date" (hereinafter referred to as the "specified date") and method of storing (any food or food additive for which standards for a method of storing have been established pursuant to the provisions of Article 11 Paragraph 1 of the Law may be exempted from the requirements regarding the labeling of the specified date).

**5.** Notwithstanding the provisions of Paragraph 1 Subparagraph (1), for any of the foods listed in Table 3, Entry No. 6, the date of import of the food preceded by certain letters indicating the "date of import" shall be declared, instead of the specified date and method of storing thereof, in a conspicuous place on the container/package or package in a manner that is easily readable without opening the container/package.

**6.** Notwithstanding the provisions of Paragraph 1 Subparagraph (1), for any of the foods listed in Table 3, Entry No. 8, the date of irradiation preceded by certain letters indicating the "date of irradiation" shall be declared, instead of the specified date and method of storing (the specified date, in the case of any food for which standards for a method of storing have been established pursuant to the provisions of Article 11 Paragraph 1 of the Law), in a conspicuous place on the container/package or package in a manner that is easily readable without opening the container/package.

**7.** Notwithstanding the provisions of Paragraph 1 Subparagraph (1), for poultry eggs with shells (except cases for raw consumption) listed in Table 3, Entry No. 10, the labeling on the limit date or the method of storing may be replaced by declaring the date (including the year) of laying poultry eggs, the date of collecting them, the date of selecting them according to weight or quality, or the date of packaging them, preceded by certain letters indicating the kind of the date on the containers/packages or package in a manner that is easily readable without opening the container-package or package.

**8.** Notwithstanding the provisions of Paragraph 1 Subparagraph (1), for poultry eggs with shells listed in Table 3, Entry No. 10, the address of the manufacturing or processing place as well as the name of manufacturer or processor shall be replaced by declaring the address of the facility of collecting eggs or facility of selecting them according to weight or quality and packaging them (in the case of an imported product, the address of the importer), as well as the name of collector of eggs or the person who selected eggs with shells according to weight and quality and packaged them (in the case of an ported product, the name of the importer) on the container-packages or package in a manner that is easily readable without opening the container-package or package.

**9.** Notwithstanding the provisions of Paragraph 1 Subparagraph (1), the labeling of a statement to the effect that the product can be stored at room temperature may be exempted.

**10.** Notwithstanding the provisions of Paragraph 1 Subparagraph (1), in the case of any food or food additive other than the foods listed in the same Table, Entry No. 11-c, any of the foods as farm product listed in Entry No. 12 at the same Table, the labeling of the address of the manufacturing plant and the name of the manufacturer may be replaced with the address and name of such manufacturer (hereinafter in this Paragraph, if the manufacturer is a corporation, its corporate name.) and the specific code for such manufacturing plant (hereinafter in this Paragraph, characters used for codes shall be limited to Arabic numerals, Roman letters, HIRAGANA, KATAKANA, or combinations thereof) which has been submitted by such manufacturer to the Minister of Health, Labour and Welfare or with the address and name of such seller preceded by the word "seller", and the specific code for the manufacturing plant which has been submitted by both seller and manufacturer in their joint names to the Minister of Health, Labour and Welfare. Also, any of the foods listed in Table 3, Entry No. 11-c may be exempted from the requirements regarding of the labeling of the address of such manufacturing or processing plant and the name of such manufacturer or processor.

**11.** Notwithstanding the provisions of Paragraph 1 Subparagraph (1), the names of the food additives contained may be replaced with names commonly used in the public or with an appropriate term listed in the right Column of Table 8 for a food which contains food additives used for any of the purposes listed in the left Column of the same Table. Any of the foods listed in Table 3, Entry No. 11-c (these foods shall be confined to those containing any food additive used for any of the purposes not listed in the middle Column of Table 5, Entry No. 8) and foods of farm product listed in the same Table, Entry No. 12 may be exempted from the labeling of the names of the food additives contained in such food.

**12.** Notwithstanding the provisions of Paragraph 1 Subparagraph (1):

(1) The food may be exempted from the declaration of "着色料" for food color or "合成着色料" for synthetic food color, when a word indicating a color is included in the labeling of the food additives that the food contains.

(2) The food may be exempted from the labeling of "増粘剤" for thickening agent or "糊料" for thickener, when the words "増粘" are included in the labeling of the food additives that the food contains.

(3) The food may be exempted from the labeling of an appropriate item listed in the right column of Table 5 in the case of any of the foods listed in Table 3 Entry No. 11-c, when the food contains a food additive other than those used for the uses which are listed in the middle Column of Table 5, Entry No. 8.

**13.** Notwithstanding the provisions of Paragraph 1 Subparagraph (1), processed food containing specified raw material as a raw material, which can be easily distinguished from the name that it contains the specified raw material as a raw material (shall be called, hereinafter, as "specified processed food") does not have to be labeled that it contains the specified raw material as a raw material; as for processed food using specified processed food (except for those using milk (means milk designated in Article 2 Paragraph 1 of the Ministerial Ordinance concerning Compositional Standards, Etc. for Milk and Milk Products [Ministry of Health and Welfare Ordinance No. 52, 1951], the same hereinafter) as a raw material) as a raw material, the labeling of containing specified raw material as a raw material may be replaced by stating that the processed food contains the specified processed food as a raw material; as for food containing food additive derived from specified raw material, in case it is stated that it contains the specified raw material concerned or specified processed food made from the specified raw material concerned, and in case it can be easily distinguished from the name that it contains the specified raw material as a raw material, it does not have to be labeled that the food additive contained in the food concerned comes from the specified raw material concerned; as for a food additive that comes from specified raw material, in case it can be easily distinguished from the name that it comes from specified raw material, it does not have to be labeled that the food additive comes from the specified raw material concerned.

**14.** Notwithstanding the provisions of Paragraph 1 Subparagraph (1), in the case of food given in each of the Subparagraphs below, it does not have to be stated of the items related to Paragraph 1 Subparagraph (1) from 'nn' (1) to (3).

(1) Processed food not containing farm products listed in the left Column of Table 7 or not containing processed food prepared by use of those as the principal materials (those which are ranked not lower than third position by mass of the raw materials and, at the same time, ratio in the mass shall be not lower than 5 percent).

(2) Processed food other than those, listed in the right Column of Table 7, in which recombinant DNA or protein formed through the recombination remains after processing.

(3) Among foods of farm product listed in Table 3, Entry No. 12, those to which notice on items related to Paragraph 1 Subparagraph (1) from 'nn' (1) to (3) is given in a near place to the food of the related farm product.

(4) Among processed foods listed in Table 3 Entry No. 12, those which fall into the category of Paragraph 1 Subparagraph (1) 'nn' (3), using only one of the farm products listed in the left Column of Table 7 as a raw material.

(5) Food which is not intended for direct sale to consumers.

**15.** Notwithstanding the performance of distinguished production and distribution management, in case unintentional to a certain extent migration of farm product obtained by application of recombinant DNA techniques or of farm product obtained by no application of recombinant DNA techniques, if it becomes clear that the confirmation according to Paragraph 1 Subparagraph (1) from 'nn' (1) to (3) has been performed adequately, it is deemed that distinguished production and distribution management has been confirmed to have been conducted. and the provisions of Paragraph 1 Subparagraph (1) shall be applied.

**16.** Notwithstanding the provisions of Paragraph 1 Subparagraph (1), any of the foods listed in Table 3 Entry No. 11-b and processed foods listed in Entry No. 12 of the same Table may be exempted from the labeling of corresponding items, if the food is determined by the Minister of Health, Labour and Welfare as a food whose container/package is too small in area for legible labeling of the required items prescribed in Paragraph 1.

**17.** Notwithstanding the provisions of Paragraph 1 Subparagraph (1), the labeling on the container/package may be replaced with an invoice concerning the items specified in the same Subparagraph (excluding the items specified in 'a' and 'c' of same Subparagraph), when any of the foods listed in the left Column of Table 9 satisfies the corresponding condition listed in the right Column of the same Table. In this case, a code by which such food may be identified shall be declared in a conspicuous place on the container/package in a manner that is easily readable without opening the container/package; and the items specified in 'a' and 'c' of the same Subparagraph, such code, and the name and address of the purchaser (in the case of a corporation, its corporate name and the address of its main office) shall be declared in such invoice.

**18.** The provisions of Paragraphs 3 and 9 through 12 shall be applied when the items specified in Paragraph 1 Subparagraph (1) are declared in the invoice in accordance with the provisions of the preceding Paragraph.

**19.** Notwithstanding the provisions of Paragraph 1 Subparagraph (1), the labeling of a statement to the effect that the foods for specified health uses can be expected to contribute to maintain and promote health, and the labeling of function of nutritional component can be replaced by declaring in an attached document, instead of declaration on container/package.

### **Chapter 3. Plan of Inspection and Guidance**

[Submission of Plan of Inspection and Guidance]

**Article 22.** The governor of any prefecture, the mayor of any city establishing health centers, or mayor of any special ward (shall be called, hereinafter, as "governor of prefecture, etc.") shall submit, every year, plan of inspection and guidance of food sanitation of prefectures, etc. before the beginning of the fiscal year, to the Minister of Health, Labour and Welfare.

**2.** In case plan of inspection and guidance of food sanitation of prefecture, etc. is to be changed, it



has to be submitted to the Minister of Health, Labour and Welfare before the enforcement of the change.

[Official Announcement of the Result of Plan of Inspection and Guidance]

**Article 23.** Governor of prefecture, etc. shall officially announce every fiscal year, the outline of the result of practice of the plan of inspection and guidance of food sanitation of prefecture, etc. not later than June 30th of the next fiscal year, and shall officially announce after collection of the result of the practice concerned as soon as possible.

2. Besides those established in the preceding Article, governor of prefecture, etc. shall prepare an outline of the result of practice of a plan of inspection and guidance of food sanitation of prefecture, etc. for summer time, year-end or for other necessary period, and shall officially announce it as soon as possible after the preparation.

3. At the time of official announcement pursuant to the provisions of the preceding two Paragraphs, governor of prefecture, etc. shall make an effort to be commonly known to the inhabitants through the official bulletin, public information papers, by use of internet system and by any other appropriate method.

#### **Chapter 4. Product Examinations**

[Application for the Examinations Prescribed in Article 25 Paragraph 1 of the Law]

**Article 24.** Application for the examination prescribed in Article 25 Paragraph 1 of the Law shall be made by submitting an application stating the items given below for each lot of products.

- (1) The name and address of the applicant (in the case of a corporation, its corporate name and address and the name of its representative).
- (2) The product name.
- (3) The name and address of the manufacturing plant.
- (4) The name of the food sanitation supervisor.
- (5) The date of manufacture.
- (6) The quantity of the lot requiring an application.
- (7) The number of subdivided containers of the product comprising the lot, according to each content.
- (8) The results, if such examinations have been performed by the manufacturer.

[Collection of Test Samples]

**Article 25.** Test samples for examinations shall, as prescribed in Article 4 Paragraph 3 of the Food Sanitation Law Enforcement Ordinance (Cabinet Order No. 229, 1953, hereinafter referred to as the "Cabinet Order"), be collected for each product forming lots. The quantity collected shall be the minimum amount necessary for such examinations.

[Labeling]

**Article 26.** The label prescribed by the Ministerial Ordinance under Article 25 Paragraph 1 of the Law shall be an examination certificate of Form No. 1, with which the container/package of the product has been sealed.

[Items to be Described in Written Examination Orders]

**Article 27.** The items prescribed by the Ministerial Ordinance under Article 5 Paragraph 1 of the Cabinet Order are as follows:

- (1) The name and address of the person to allow such examinations (in the case of a corporation, its corporate name, the address of its main office, and the name of its representative).
- (2) The name of the product to undergo such examinations.
- (3) The name and address of the manufacturing or processing plant.
- (4) The period of time during which the product to undergo such examinations will be manufactured or processed.
- (5) The specific reason for ordering that the product undergo such examinations.

[Application for Examinations by Persons Receiving Product Examination Orders]

**Article 28.** Application for examinations prescribed in Article 26 Paragraph 1 of the Law shall be made by submitting an application stating the following items for each product forming lots:

- (1) The name and address of the applicant (in the case of a corporation, its corporate name, the address of its main office, and the name of its representative).
- (2) The product name.
- (3) The name and address of the manufacturing or processing plant.
- (4) The date of manufacture or processing.
- (5) The quantity of the lot requiring an application.

**2.** The application prescribed in the preceding Paragraph shall be accompanied by a copy of the written examination order prescribed in Article 5 Paragraph 1 of the Cabinet Order; provided, however, that this provision does not apply to the case where an application under the same order has already been made and a copy of the written examination order has been submitted.

**Article 29.** Application for examinations prescribed in Article 26 Paragraph 1 of the Law shall be made by submitting an application stating the following items:

- (1) The name and address of the applicant (in the case of a corporation, its corporate name and the address of its main office).
- (2) The product name.

- (3) The name and address of the manufacturer or processor (in the case of a corporation, its corporate name and the address of its main office).
- (4) The name and address of the manufacturing or processing plant.
- (5) The date of arrival of the product at the port.
- (6) The location of storage of the product.
- (7) The quantity of the lot requiring the application.

2. The application prescribed in the preceding Paragraph shall be accompanied by a copy of the written examination order (a paper indicating the output descriptions of such order, when the Minister of Health, Labour and Welfare has issued a notice concerning an examination order using the electronic information processing system pursuant to Article 34 Paragraph 1 ).

**Article 30.** The provisions of the preceding Article shall apply to the application for the examinations prescribed in Article 26 Paragraph 3 of the Law. In such cases, "items" indicated in Paragraph 1 of the same Article and "address" indicated in Paragraph 1 Subparagraph (4) of the same Article shall be construed as "items (excluding the items listed in Subparagraph (3), for application for examinations of foods other than processed foods)" and as "address (the location where the product was grown, for application for examinations of foods other than processed foods)", respectively.

[Methods of Payment of Examination Fees]

**Article 31.** Fees for examinations performed by the Minister of Health, Labour and Welfare shall be paid by attaching to the application, prescribed in Article 4 Paragraph 2 or Article 6 Paragraph 1 of the Cabinet Order (including cases where such provisions are applied based on Article 7), a revenue stamp equivalent to the amount determined by the Minister of Health, Labour and Welfare fixed by Article 25 Paragraph 2 of the Law or the amount determined by the Minister of Health and Welfare in accordance with Article 26 Paragraph 6 of the Law.

## Chapter 5. Import Notification

[Items to be Described by Importers of Foods, etc. in Import Notifications]

**Article 32.** Any person (referred to as an "importer" in the provisions of following Paragraph, Paragraphs 4 and 5) prescribed in Article 27 of the Law (the same in Paragraph 7, Paragraph 8, and the following Article, including cases where such provisions are applied based on Article 62 Paragraph 1 of the Law) shall, except when such person wishes to import any of the foods listed in Table 10, submit an import notification stating the items given below (excluding the item listed in Subparagraph (12) below, when such import notification has been submitted before the cargo is brought into the bonded warehouse (in this Paragraph, referred to as "entry of cargo"), on or after the seventh day before the estimated date of arrival of the cargo (or after the entry of the cargo, when accidents might have happened to the cargo) to the director of the quarantine station listed in the right Column of Table 11 for any of the places listed in the corresponding left Column of the same Table; provided, however, that if there has been any accident to the cargo, for which such import notification had been submitted before the entry of the cargo, a report outlining such accident shall be submitted to the director of such quarantine station immediately after the entry of the cargo:

- (1) The name and address of the importer (in the case of a corporation, its name and the address

of its main office).

(2) The classification of the cargo as a food, food additive, apparatus, container/package, or toy; the product name; the amount and weight of the cargo; the type and purpose of the packing; and when the cargo is marked with a code or number, the code or number.

(3) When the cargo is a food containing food additives used for purposes other than flavoring (substances, which are generally provided for eating or drinking as foods and which are used as food additives, are confined to those for which standards or specifications have been established pursuant to Article 11 Paragraph 1 of the Law), the names of the food additives.

(4) When the cargo is a processed food, its ingredients and the manufacturing or processing method.

(5) When the cargo is a food of farm product or processed food listed in Table 3 Entry No. 12 (excluding those listed in Article 21 Paragraph 14 Subparagraph (1) from 'nn' (1) to (3) according to the classifications indicated in the same Subparagraph from 'nn' (1) to (3).

(6) When the cargo is a preparation containing food additives (excluding substances used for flavoring purposes and substances which are generally provided for eating or drinking as foods and which are used as food additives), the components of the food additives.

(7) When the cargo is an apparatus, container/package, or toy, its materials.

(8) The name and address of the manufacturer or processor of the cargo (processed foods only) (in the case of a corporation, its corporate name and the address of its main office).

(9) The name and address of the manufacturing or processing plant of the cargo (in the case of a food other than a processed food, the place of production), the port of shipping, the date of shipping, the port of unloading, and the date of arrival.

(10) The name of the vessel or the flight number of the aircraft carrying the cargo.

(11) The name and address of the warehouse storing the cargo and the date of entry of the cargo.

(12) Accidents to the cargo, if any, and brief description of such accidents.

**2.** When there have been any changes in descriptions of the items listed in Subparagraphs (9) through (11) of the preceding Paragraph (in the case of items listed in Subparagraph (9), only the port of unloading and the date of arrival), the importer shall promptly submit a notification stating that effect to the Director of the quarantine station concerned, as prescribed in the preceding Paragraph.

**3.** Notwithstanding the performance of distinguished production and distribution management, in case unintentional to a certain extent of migration of farm product obtained by application of recumbent DNA techniques or of farm product obtained by no application of recombinant DNA techniques, if it becomes clear that the confirmation according to Article 21 Paragraph 1 Subparagraph (1) 'nn' (1) or (3) has been performed adequately, it is deemed that distinguished production and distribution management has been confirmed to have been conducted, and the provisions of Paragraph 1 shall be applied.

**4.** Notwithstanding the provisions of Paragraph 1, when the importer has imported any of the foods, food additives, apparatus or containers/packages listed in the middle Column of Table 12 (hereinafter, in this Article referred to as "foods, etc.") and if such importer had submitted a notification stating an import plan, which is valid for the period of time listed in the

corresponding right Column of the same Table and is related to products the same as or similar to such foods, etc. (hereinafter referred to as "the same foods, etc.") (hereinafter "import plan" means a plan indicating the weight, port of unloading, and estimated date of arrival, of the cargo whose import is planned for such period of time), such importer may, in the case of import of the same foods, etc. intended within the same period, substitute such notification for the legally required import notification prescribed in Paragraph 1; provided, however, that such provisions do not apply to the case where such foods, etc. intended for import fall under or are suspected to fall under any of the following categories:

- (1) Foods or food additives listed in any of the Subparagraphs of Article 6 of the Law.
- (2) Foods or food additives prescribed by Article 10 of the Law.
- (3) Foods or food additives manufactured by methods not complying with the standards established pursuant to the provisions of Article 11 Paragraph 1 of the Law.
- (4) Foods or food additives not complying with the specifications established pursuant to the provisions of Article 11 Paragraph 1 of the Law.
- (5) Apparatus or containers/packages prescribed in Article 16 of the Law.
- (6) Apparatus or containers/packages not complying with the specifications established pursuant to the provisions of Article 18 Paragraph 1 of the Law.

**5.** In any case to which the preceding Paragraph applies, the importer of the foods, etc. listed in the middle Column of Table 12 No. 3 shall submit an import notification stating the import plan, as prescribed in the preceding Paragraph, by indicating import records of the same foods, etc. ("import record" means a record indicating the name of the importer (in the case of a corporation, its corporate name) and the weight, port of unloading, and date of arrival of the cargo, with respect to each importation made within such period of time), within the three years prior to the date of the submission of such import notification.

**6.** When the provisions of Paragraph 4 apply, if there has been any accident involving the cargo, the expressions "for which the import notification has been submitted before the entry of the cargo" and "the director of such quarantine station" in the proviso of Paragraph 1 shall be construed as "for such import" and "the director of the quarantine station listed in the corresponding right Column of Table 11 for the places listed in the left Column of the same Table", respectively\*.

\*: Under Paragraph 5, the proviso of Paragraph 1 reads as follows:

If there has been any accident involving the cargo for such import, a report outlining such accident shall be submitted to the director of the quarantine station listed in the corresponding right Column of Table 11 for the places listed in the left Column of the same Table immediately after the entry of the cargo.

**7.** The Minister of Health, Labour and Welfare may, require the importer, to make a notification prescribed in Article 27 of the Law by use of the electronic information processing system (hereinafter "electric information processing system" means electric information processing system connected by an electronic communication line between the computer concerned (including input/output units; the same, hereinafter) used in the Ministry of Health, Labour and Welfare and each input/output unit used by those who wish to make notification, the same, hereinafter, in this Chapter).

**8.** In the case of application of Paragraphs 1 and 2 concerning persons who wish to make notification, as prescribed in Article 27 of the Law, using the electronic information processing

system, the provisions and proviso of Paragraph 1 shall be construed as follows:

Paragraph 1:

Any person (referred to as an "importer" in the provisions of Paragraphs 2 through 4) prescribed in Article 27 of the Law (in this Paragraph, Paragraph 6, and Article 33, including cases where such provisions are applied based on Article 62 Paragraph 1 of the Law) shall, except when such person wishes to import any of the foods listed in Table 10, input into the input/output units prescribed in Paragraph 7 (in this Paragraph and Paragraph 7, the units are confined to those used by persons wishing to make such notification) and record in the file concerned, the items given below (excluding the item listed in Subparagraph (12) below, when such person inputs such items into the input/output units concerned and records such items in a file before the cargo is brought into the bonded warehouse (in this Paragraph, referred to as "entry of cargo")), on or after the seventh day before the estimated date of arrival of the cargo (or after the entry of the cargo, when accidents might have happened to the cargo); provided, however, that if there has been any accident involving the cargo, for which such items had been input into the input/output units concerned and recorded in the file concerned before the entry of the cargo, such person shall input into such input/output units and record in such file, a report outlining such accident immediately after the entry of the cargo.

Paragraph 2:

When there have been any changes in descriptions of the items listed in Subparagraphs (9) through (11) of the preceding Paragraph (the items are confined to the port of unloading and the date of arrival, in the case of items listed in Subparagraph (9)), the importer shall promptly input into the input/output units concerned and record in the file concerned, such information.

9. The provisions of Paragraphs 4 through 6 shall not apply to any person prescribed in the preceding Paragraph.

[Notification of input/output units]

**Article 33.** The input pursuant to the provisions of Paragraphs 1 and 2 of the preceding Article, applied after the construe of the provisions of Paragraph 1 of the preceding Article, shall be done by use of the input/output units of which such person has already notified Minister of Health, Labour and Welfare.

2. The notification pursuant to the provisions of the preceding Paragraph shall be made in the same manner in which a person who wishes to make notification as prescribed in Article 27 of the Law using the electronic information processing system submits a notification, stating the following items to the Minister of Health, Labour and Welfare, for the input/output units which such person will use:

(1) The name and address of the notifier (in the case of a corporation, its corporate name and the address of its main office).

(2) Identification symbol (Arabic numerals, Roman letters, or any combination of 12 characters).

(3) The locations where the input/output units are placed, and the name and model number of such units.

(4) When a person other than the notifier manages the input/output units, the name and address of such person (in the case of a corporation, its corporate name and the address of its main office).

3. The person who has made notification as prescribed in the preceding Paragraph shall promptly

make notification to the Minister of Health, Labour and Welfare when there has been any change in the items listed in each Subparagraph of the same Paragraph or when such person has discontinued the use of the input/output units for which the notification had been made.

[Methods for Notice Using the Electronic Information Processing System]

**Article 34.** When the Minister of Health, Labour and Welfare gives a notice of an order for examination prescribed in Article 26 Paragraph 2 or Paragraph 3, on the food, food additive, apparatus or container/package notified by a person by use of electronic information processing system pursuant to the provisions of Article 32 Paragraph 7, or a notice of results of the examination prescribed in Paragraph 4 of the same Article (hereinafter referred as a "special notice" in this Article), the Minister may do it by use of electronic information processing system.

2. In case special notice is made by use of electronic information processing system, the content of the special notice shall be input from the input/output units (limited to those used by the Ministry of Health, Labour and Welfare) and shall be recorded in filing system.

3. In case special notice is made by use of electronic information processing system, the agreement of the opposite side shall previously be obtained.

## **Chapter 6. Food Sanitation Examination Laboratories and Food Sanitation Inspectors**

[Issuance of Collection Certificates and Forms of Certificates and Badges]

**Article 35.** When a food sanitation inspector collects foods, food additives, apparatus, containers/packages or toys prescribed in each item of Article 78 (shall be called, hereinafter, as "food, etc.") pursuant to the provisions of Article 28 of the Law (including cases where such provisions are applied based on Article 62 Paragraph 1 of the Law.), such inspector shall issue a collection certificate using Form No. 2 to the business person.

2. The certificate to be carried by food sanitation inspectors while on duty shall comply with Form No. 3 and the badge indicating that the person bearing such badge is a food sanitation inspector shall comply with Form No. 4.

3. In case administration work on examinations is consigned to a registered laboratory pursuant to the provisions of Paragraph 4 of the Article 28 of the Law, the Minister of Health, Labour and Welfare and governor of prefecture, etc. shall order an examiner of the registered laboratory concerned, and shall request to perform the examination concerned at the same or higher level provided in each item of the Article 40.

[Machinery and Apparatus Required for Examinations, etc.]

**Article 36.** The machinery and apparatus prescribed by the Ministerial Ordinance under Article 8 Paragraph 1 f the Cabinet Order are water purifying devices, thermostatic dryers, deep freezers, electric furnace muffles, gas chromatographs, spectrophotometers, autoclaves, hot air sterilizers, thermostatic incubators, anaerobic-culture apparatus, thermostatic baths, and other necessary instruments and apparatus.

[Management of Administrative Work Concerning Examinations]

**Article 37.** The management of administrative work concerning the examinations and tests provided in Article 8 Paragraph 2 of the Cabinet Order (in this Article and Table 13, referred to as "examinations, etc.") shall be conducted as prescribed below:

- (1) Confirm that examinations, etc. are adequately performed in accordance with the standard operation procedure made as prescribed in Subparagraph (11).
- (2) Perform regular internal checks for the management of work concerning examinations, etc. in accordance with the documents prepared as prescribed in Subparagraph (12).
- (3) Perform internal proficiency tests (hereinafter such tests aim at ensuring the proficiency of examiners required to maintain the accuracy of tests) in accordance with the documents prepared as prescribed in Subparagraph (13).
- (4) Receive regular external inspections of proficiency tests (hereinafter such inspection means inspection performed concerning such proficiency tests by competent persons such as governmental agencies) in accordance with the documents prepared as prescribed in Subparagraph (14).
- (5) Keep records of results concerning internal checks prescribed in Subparagraph (2), internal proficiency tests prescribed in Subparagraph (3), and external inspections of proficiency tests prescribed in the preceding Subparagraph (including contents of corrective measures if such measures are required to be taken).
- (6) Take corrective measures concerning work of examinations, etc. in accordance with the records kept as prescribed in the preceding Subparagraph as soon as possible.
- (7) In performing the product examination, in case deviation from the standard operation procedure prescribed in Subparagraph (11) or from the documents prescribed in Subparagraphs (12) and (13) took place, evaluation of the actual state shall be made and necessary measures shall be taken.
- (8) Employees to do work prescribed in Subparagraph (1) and two preceding Subparagraphs shall not perform examinations, etc.
- (9) Employees who do work prescribed in Subparagraphs (2) through (5) (in this Article, such work is referred to as "reliability assurance work") shall perform neither examinations, etc. nor work prescribed in Subparagraph (1) or (6).
- (10) Make reliability assurance work become independent of examinations, etc.
- (11) Prepare a standard operation procedure as prescribed in Table 13.
- (12) Prepare documents describing methods of the internal check concerning the management of work concerning examinations, etc.
- (13) Prepare documents describing methods of the internal proficiency test.
- (14) Prepare documents describing a plan for receiving the regular external inspections of the proficiency test.
- (15) Prepare documents describing a training plan for employees to perform reliability assurance work.
- (16) Keep records of items given below and retain them for three years from the date of



recording.

- a. The name and address of a person who has applied for examinations prescribed in Article 25 Paragraph 1 of the Law or Article 26 Paragraphs 1 through 3 of the same Law (hereinafter such examinations are referred to as "product examinations"), or a person from whom samples have been collected pursuant to Article 28 Paragraph 1 of the same Law (if the person is a corporation, its corporate name and the address of the main office thereof).
- b. The date of receiving an application for product examinations or the date of collection of samples pursuant to Article 28 Paragraph 1 of the Law.
- c. The name of product examined or tested.
- d. The date of examinations, etc.
- e. Items of examinations etc.
- f. The quantity of samples examined or tested (number/weight)
- g. The name of a employee who has performed examinations, etc.
- h. Results of examinations, etc.
- i. Records prescribed in Subparagraph (5).
- j. Records based on the standard operation procedure prepared as prescribed in Subparagraph (11).
- k. Records concerning the training mentioned in preceding Subparagraph.

## **Chapter 7. Registered Laboratories**

[Application for Registered Laboratories]

**Article 38.** Any person who wishes to apply for registration of Article 31 of the Law shall submit to the Minister of Health, Labour and Welfare application Form No. 5, accompanied by the documents given below.

- (1) The articles of incorporation or article of association and the certified copy of register book.
- (2) Private histories of persons who have been determined as having knowledge and experience (shall be referred, hereinafter, as "examiner").
- (3) Papers clarifying the structure of the unit established under the provisions of Paragraph 1 Subparagraph (2) 'a' of the Article 33 of the Law (shall be referred to, hereinafter, as "product examination unit") and the structure of the executive unit established under the provisions of 'c' of the same Subparagraph (shall be referred to, hereinafter, as "reliability assurance unit").
- (4) As the documents prescribed in Article 33 Paragraph 1 Subparagraph (2), the standard operation procedure prescribed in Article 40 Subparagraph (8) and the documents prescribed in Subparagraphs (9) through (12).
- (5) Documents indicating the following items:

- a. Whether or not the person falls under any of the categories given as Subparagraphs of Article 32.
  - b. Of the product examinations listed in Column 1 of the Table of the Law, kind of examinations to be performed.
  - c. The number and performance of the machinery, apparatus, and other facilities used for product examinations, and a declaration as whether they are owned or leased, of those listed in Column 2 of the Table.
  - d. Names of examiners and the kind of product examination to be performed.
  - e. Names of the product examination unit, name of the director of the product examination unit prescribed in Article 40 Subparagraph 1, name of the supervisor of the examination category, and the kind of product examination administered.
  - f. Name of the reliability assurance unit and name of the director of the reliability assurance unit prescribed in Article 40 Subparagraph (3).
  - g. An outline of the work on testing relating to food sanitation which the person is carrying out.
  - h. Whether or not the person falls under any of the categories given as Subparagraphs 'a' through 'c' of Article 33 Paragraph 1 Subparagraph (3).
  - i. In case of a joint-stock company or a limited company, the name of corporation, addresses, number of stocks owned of stockholders having not less than five hundredths of the issued stocks, or prices of investment of investors.
  - j. The names, addresses, whether or not the representative partner, and resumes of executives (executives having executive right in case of a general partnership or a limited partnership) (those who are the executives or employees of the business person who undergoes examination under the provisions of Paragraph 1 Subparagraph (3) of the Article 33 of the Law (includes those who have been the executives or employees of the business person who has undergone examination in the past two years)).
  - k. If the person is engaged in work other than examination concerning food sanitation, the type and outline of such work.
2. The application in the preceding Paragraph shall be attached by a revenue stamp equivalent to the amount of the registration fee.

[Papers to be Attached to the Application of Registration Renewal of the Registered Laboratories]

**Article 39.** Any person wishing to renew the registration pursuant to the Paragraph 1 of the Article 34 of the Law, shall submit an application pursuant to Form No. 6 being attached with the following papers, to the Minister of Health, Labour and Welfare.

- (1) Papers indicated in the preceding Article Subparagraphs (1) through (3).
- (2) Papers describing the items indicated in the preceding Article Paragraph 1 Subparagraph (5), 'a' and 'c' through 'k'.
- (3) References concerning actual results of the product examination.

2. The application in the preceding Paragraph shall be attached by a revenue stamp equivalent to the amount of the renewal fee.

[Standards for Administrative Work of the Product Examination]

**Article 40.** The standards established by the Ministerial Ordinance under Article 35 Paragraph 2 of the Law are as follows:

(1) In the product examination unit a person to perform the work given below (hereinafter, such person is referred to as "director of the product examination unit") shall have been placed .

- a. Direct work covered by the product examination unit.
- b. Take corrective measures for the corresponding work, based on written reports received in accordance with the provisions of Subparagraph (3) 'd' of this Paragraph.
- c. Other necessary work.

(2) For each category of the physicochemical, bacteriological and animal examinations in the product examination unit, a person to confirm whether the product examination is performed appropriately in accordance with the standard operation procedure prescribed in Subparagraph (8) and to perform the following work (hereinafter, such person is referred to as the "supervisor of the examination category") shall have been placed.

- a. In the product examination, in case a deviation from the standard operation procedure prescribed in Subparagraph (8) or from the written report occurred, the content shall be evaluated and necessary measures shall be taken.
- b. Of the product examination, confirmation that the examination is performed appropriately in accordance with the standard operation procedure, and other necessary administrative work.

(3) Of the reliability assurance unit, a person who personally perform the work or who have been appointed in advance in accordance with the contents of the work (hereinafter, such person is referred as the "supervisor of reliability assurance unit") shall have been placed.

- a. Perform regular internal checks on product examination management in accordance with the documents made as prescribed in Subparagraph (9) of this Paragraph.
- b. Perform internal proficiency tests in accordance with the documents prepared as prescribed in Subparagraph (10) of this Paragraph, and when a deviation from the documents was observed, evaluate the content and take necessary measures.
- c. Perform clerical work, in accordance with the documents prepared as prescribed in Subparagraph (11) of this Paragraph, required to receive regular external inspections of proficiency tests.

d. Report in writing to the director of the product examination unit results (including corrective measures if any correction is necessary) of the internal checks prescribed in Subparagraph (3) 'a', the proficiency tests prescribed in Subparagraph (3) 'b', and the external inspections prescribed in Subparagraph (3) 'c', and keep records on such results in the books prescribed in Article 44 of the Law (hereinafter, such books are referred to as "books").

- e. Other necessary work

- (4) The quality assurance unit shall be independent of the product examination unit.
- (5) The directors of the product examination unit and the quality assurance unit shall be executives of the registered laboratory.
- (6) Neither the director of the product examination unit nor the supervisor of each examination category shall double as an examiner.
- (7) Neither the director of the quality assurance unit nor persons appointed in accordance with the provisions of Subparagraph (3) shall double as any of the director of the product examination unit, supervisor of the examination category, and examiners.
- (8) A standard operation procedure shall have been prepared as prescribed in Table 13. In this case, "performance of examinations" and "examinations, etc." in this Table shall be construed as "performance of product examinations" and "product examinations", respectively.
- (9) Documents shall have been prepared, describing methods of the internal check concerning the management of product examination work.
- (10) Documents shall have been prepared, describing methods of the internal proficiency test.
- (11) Documents shall have been prepared, describing a plan to receive regular external inspections of the proficiency test.
- (12) Documents shall have been prepared, describing a training plan for the director of the quality assurance unit and the persons appointed in accordance with the provisions of Subparagraph (3).

[Notification of Establishment of Examination Facilities]

**Article 41.** Any person who wishes to notify the Minister of Health, Labour and Welfare of the establishment or closure of an examination facility, or a change in the location of a facility pursuant to the provisions of Article 36 Paragraph 1 of the Law, shall submit a notification of Form 7 to the Minister of Health, Labour and Welfare.

2. Any person who wishes to notify the Minister of Health, Labour and Welfare of the change in an examination facility pursuant to the provisions of Article 36 Paragraph 2 of the Law shall submit a notification of Form 8 to the Minister of Health, Labour and Welfare.

[Work Regulations]

**Article 42.** When any person wishes to obtain approval for regulations concerning product examination work pursuant to the former part of Article 37 Paragraph 1 (hereinafter referred to as "work regulations"), such person shall submit to the Minister of Health, Labour and Welfare application Form No. 9 accompanied by such work regulations.

2. The work regulations prescribed by Article 37 Paragraph 2 of the Law shall stipulate:

- (1) Specifics on the kind of product examinations, on practice and administration of work.
- (2) Specifics on work hours for product examinations and laboratory holidays.
- (3) Specifics on the upper limit of product examinations of receiving the application of product

examinations.

(4) Specifics on the place where product examinations are performed.

(5) Specifics on the amounts of examination fees and the methods of receipt of the examination fees of product examinations.

(6) Specifics on the appointment and dismissal of the director of the product examination unit, the supervisors of the examination categories, and examiners.

(7) Specifics on the placement of the director of the product examination unit, the supervisor of the examination category, and examiners.

(8) Specifics on retention of application forms and other papers for product examinations.

(9) Specifics on the preparation of tables, etc. treating financial affairs (means tables, etc. treating financial affairs prescribed in Article 39 Paragraph 1; the same, hereinafter, in this Article) and on the reception of request of perusal etc. of tables, etc. treating financial affairs.

(10) Other related specifics regarding product examination work.

**3.** Any registered laboratory which wishes to apply for the approval of the change in the work regulations as prescribed by the latter part of Article 37 Paragraph 1 of the Law shall submit application Form No. 10 to the Minister of Health, Labour and Welfare. In this case, when the concerned change is accompanied with the change in examination fee of the product examination, data required for the determination of such fee shall be attached.

[Suspension or Discontinuance of Work]

**Article 43.** Any registered laboratory which wishes to obtain permission for suspension or discontinuance of all or part of product examination work pursuant to the provision of Article 38 of the Law shall submit application Form 11 to the Minister of Health, Labour and Welfare.

[Method of Indication of Electromagnetically Recorded Items]

**Article 44.** The method prescribed by the Ministerial Ordinance under Article 39 Paragraph 2 Subparagraph (3) of the Law shall be a method to indicate the items recorded in the electromagnetic record on paper or on picture of output unit.

[Method of Offer of Electromagnetically Recorded Items by Electromagnetic Method]

**Article 45.** The electromagnetic method prescribed by the Ministerial Ordinance under Article 39 Paragraph 2 Subparagraph (4) of the Law shall be the method chosen by a registered laboratory from the following Subparagraphs.

(1) A method which uses the electronic information processing system in which the computer of a sender is connected with the computer of a receiver by an electric communication line; information is sent through the electric communication line concerned, and is recorded in filing system of the receiver.

(2) Information is recorded in filling system prepared by a substance that can record a definite amount of information soundly, by use of magnetic disc or by some other analogous method; from

which information shall be offered.

[Items Which Shall be Recorded in Books]

**Article 46.** The items prescribed by the Ministerial Ordinance under Article 44 of the Law shall include:

- (1) The name and address of the applicant for the product examination (in the case of a corporation, its corporate name and the address of its main office).
  - (2) The date of receipt of an application for the product examination.
  - (3) The name of the product which has undergone the product examination.
  - (4) The date of performance of the product examination.
  - (5) Items on which the product examination is performed.
  - (6) The number of test samples on which a product examination has been performed.
  - (7) The name of the examiner who performed the product examination.
  - (8) The result of the product examination.
  - (9) Items required to be recorded in books by the provisions of Article 40 Subparagraph (3) 'd'.
  - (10) Items required to be recorded in books as specified in the standard operation procedure made pursuant to the provisions of Article 40 Subparagraph (8).
  - (11) Documents concerning training prescribed in Article 40 Subparagraph (12).
2. The books shall be retained for three years from the date of final writing.

[Certificates]

**Article 47.** The certificates which officials are required to carry pursuant to the provisions of Article 28 Paragraph 2 of the Law, that are applied in Article 47 Paragraph 2 of the Law, shall comply with Form No. 12.

## **Chapter 8. Business**

[Scholarly Achievement Required as Qualification for Food Sanitation Supervisors]

**Article 48.** As prescribed in Article 48 Paragraph 6 Subparagraph (4) of the Law, a person who has been determined to be equal or superior in scholarly achievement to a graduate from a high school under the School Education Law (Law No.26, 1947) or to a graduate from a middle school under the Middle School Order (Imperial Ordinance No. 36, 1943) are as follows:

- (1) A person who has completed the first year of the higher course or special course at a girls' high school under the Middle School Order which requires, as an entrance qualification, graduation from a girls' high school with a four-year course under the same Order which requires, as an entrance qualification, the completion of the primary course at a national elementary school under

the National Elementary School Order (Imperial Ordinance No. 148, 1941)(hereinafter referred to as a "national elementary school").

(2) A person who has completed the first year of the special course at a vocational middle school under the Middle School Order which requires, as an entrance qualification, graduation from a vocational middle school with a four-year course under the same Order which requires, as an entrance qualification, the completion of the primary course at a national elementary school.

(3) A person who has completed the preparatory course of a normal school under the Normal School Education Order (Imperial Ordinance No. 109, 1943).

(4) A person who has graduated from an attached middle school or an attached girls' middle school under the Normal School Education Order.

(5) A person who has completed the third year of the regular course of a normal school under the Normal School Education Order before the revision of the same Ordinance (Imperial Ordinance, No. 346, 1897).

(6) A person who has graduated from a middle school or a person who is treated at the same level as the person given in (1) of this Article under the provisions of Article 2 or 5 of the Educational Ministry Ordinance No. 63 1943 (regulations concerning entrance into and transfer to other schools of students, pupils or graduates, etc. of schools in regions other than Japan proper).

(7) A person who has graduated from the ordinary course at a boys' school (excluding any schools with a two-year course) under the Boys' School Order (Imperial Ordinance No. 254, 1939).

(8) A person who has passed the examinations under the College Entrance Qualification Authorization Regulations (Educational Ministry Ordinance No. 22, 1938) based upon the College Order (Imperial Ordinance No. 61, 1903), or a person designated by the Minister of Education pursuant to the provisions of Article 11 Paragraph 2 of the same Regulations as equal or superior to a graduate from a middle school or girls' middle school in scholarly achievement required for the entrance to a college.

(9) A person who has passed the examinations under the Vocational Middle School Graduation Qualification Authorization Regulations (Educational Ministry Ordinance No. 30, 1939).

(10) A person who has passed examinations under the provisions of Article 7 of the High School Education Examination Order (Imperial Ordinance No. 15, 1929).

(11) A person who has a school teacher's license given in the left column of Entry No. 2, 3, 6, or 9 of the table given in Article 1 Paragraph 1 of the Law concerning the Enforcement of School Teacher's Licenses (Law No. 148, 1949), or a person who has a qualification listed in the left column of Entries No. 9, Nos. 18 through 20-4, No. 21, or No. 23 of the table of Article 2 Paragraph 1 of the same Law.

(12) Besides the persons given in the preceding Subparagraphs, a person who has been determined by the Minister of Health, Labour and Welfare as equal or superior to a graduate from a high school or middle school in scholarly achievement required for the qualification of food sanitation supervisors.

[Items Required to Be Indicated in Notifications of Food Sanitation Supervisors]

**Article 49.** Notification under the provisions of Article 48 Paragraph 8 of the Law shall be performed by submitting a written form stating the items given below.

- (1) The name and address of the notifier (in the case of a corporation, its corporate name, address, and the name of its representative).
- (2) The categories of foods or food additives, prescribed in Article 13 of the Cabinet Order.
- (3) The names and addresses of the facilities concerned.
- (4) The names, addresses, and dates of birth of the food sanitation supervisors.
- (5) The occupational titles of the food sanitation supervisors, and the types and details of the work of such supervisors.
- (6) The date of appointment or change of the food sanitation supervisors.

2. The notification form of the preceding Paragraph shall be accompanied by the résumé of each food sanitation supervisor, a document stating that the person falls under one of the Subparagraphs of Article 48 Paragraph 6 of the Law, and a document showing the relationship between each supervisor and the business person.

[Standards of Registration of a Training Institute]

**Article 50.** the standards established by the Ministerial Ordinance under Article 14 of the Cabinet Order (including cases where the provisions are construed in Article 9 Paragraph 2 of the Cabinet Order).

(1) A university under the School Education Law or an educational institute establishing courses performing education equivalent to university or university-graduate student course under the provisions of Article 68-2 Paragraph 3 Subparagraph (2) of the same Law.

(2) From each of the curriculum listed in the left Column of Table 14, one or more subjects indicated in the corresponding right Column shall be studied, and the total sum of the subjects passed through shall be not less than 22 units.

(3) The subjects listed in the Subparagraph and indicated in Table 15 shall be studied, and the total sum of the subjects passed through shall be not less than 40 units.

(4) Schooling shall be performed as a rule by use of the machinery, apparatus and other facilities listed in Column 2 of the Table of the Law.

[Items Which Shall Be Described in Application Form of a Training Institute]

**Article 51.** An application provided in Article 15 of the Cabinet Order (including cases where the provisions are construed in Article 9 Paragraph 2 of the Cabinet Order 9) shall be attached with the papers in which the following items are recorded.

- (1) Name and address of the training institute.
- (2) Name and address of the founder and the date of establishment of the training institute.
- (3) Name and address of the director of the training institute.
- (4) Name and address of the teachers, their careers, subjects they are in charge of, and whether



they are executive or serving concurrently.

(5) Schooling plan of each school year on the subjects, number of units, whether subjects are required or elective subjects.

(6) The number (capacity) of trainee of a training institute.

(7) Qualification and season for entrance.

(8) The years required for graduation.

(9) List of machinery, apparatus and other facilities, and books used for teaching and for practice.

(10) Plan and arrangement of school area and school buildings.

(11) School regulations.

(12) Any other items for reference.

[Items to be Described in Register Ledger of a Training Institute]

**Article 52.** Registration of a training institute shall be performed by recording the following items on the register ledger.

(1) Registration date and registration number.

(2) Name, address and the name of the director of a registered training institute (means a training institute provided in Article 16 of the Cabinet Order; the same, hereinafter).

2. The provisions in the preceding Paragraph shall be construed in the registration of a training institute under Article 9 Paragraph 1 Subparagraph (4) of the Cabinet Order.

[Change in Items of Registered Training Institute]

**Article 53.** Items provided under the provisions of Article 16 of the Cabinet Order (including cases construed in Article 9 Paragraph 2), shall be those indicated in Article 51 Paragraphs 1 through 3, Paragraphs 5 through 8, Paragraph 9 (limited to those related to machinery, apparatus and other facilities listed in Column 2 of the Table of the Law), Paragraph 10, and Paragraph 11.

[Items to Be Described in Application Form of the Cancellation of Registration]

**Article 54.** Application form under Article 19 (including cases construed in Article 9 Paragraph 2) shall be attached with papers describing the following items.

(1) The reason why the person wishes to cancel the registration.

(2) Scheduled date when the cancellation of the registration comes into force.

(3) In case there are students studying in the institute, measures to be taken.

[Officially Announced Items of the Change in Items of a Training Institute]

**Article 55.** Those provided by the Ministerial Ordinance under the Article 20 Paragraph 2 of the Cabinet Order (including cases construed in Article 9 Paragraph 2 of the Cabinet Order) shall be items indicated in Article 51 Paragraph 1.

[Qualification Required for the Curriculum of a Training Course of Food Sanitation Supervisors]

**Article 56.** The curriculum of a training course under Article 48 Paragraph 6 Subparagraph (4) shall comply with each of the following requirements.

(1) Subjects indicated in Column 1 of Table 16 and indicated in any of Columns 2 through 7 shall be taught, and the total hours of teaching shall be not less than the hours indicated in the Table.

(2) Lecturers shall be those who belong to the course at universities under the School Education Law where such subjects are taught, those who are engaged in state, prefectures, cities establishing health centers or special wards either in food sanitation administration or in food sanitation examination business, or those who have been determined as having equal knowledge and experience.

(3) Qualification of the trainee: Any trainee shall be a graduate from a high school under the School Education Law or a middle school under the Middle School Order or shall be a person having scholastic achievement to any of each Paragraph of Article 48, who has been engaged in sanitation control of food or food additives for not less than two years at a manufacturing or processing business which requires a food sanitation supervisor prescribed in Article 48 Paragraph 1.

(4) Examination shall be imposed to trainees at the conclusion of the training course.

**2.** Notwithstanding the provisions of the preceding Paragraph Subparagraph (1), any person indicated in each of the following Subparagraphs may be exempted from attending the subjects provided in each Subparagraph.

(1) Any person who has studied at a university under the School Education Law, at a university under the University Order (Imperial Ordinance No. 388, 1918), or at a college under the College Order equal or higher level of subjects listed in Column 1 of Table 16:       The subject concerned.

(2) Any person who has completed a registered training course:       A person who has completed the subjects listed in Column 1 of Table 16, or the subjects listed in Column 2 or 3, bacteriological practice listed in Column 3 of the Table or bacteriological practice listed in Column 2 of the Table, respectively.

[Items Which Shall Be Described in Application Form of a Training Course]

**Article 57.** A person who wishes to apply registration pursuant to the provisions of Article 21 of the Cabinet Order, shall submit the application form to the Minister of Health, Labour and Welfare, being attached with the copy of the resident card (in case of a corporation, the articles of the corporation, and a transcript of the register), and papers describing the following items.

(1) Name and address of the promoter of the training course (in case of a corporation, its name, address of the main office and the name of the representative).

(2) Whether or not the person falls under any of the categories given as Subparagraphs of Article 22 of the Cabinet Order.

- (3) In case of a corporation, the names, addresses, and resumes of executives.
- (4) Name and address of the place where the training course is held.
- (5) Name and address of the place where the practice is carried out.
- (6) Period of the training course and the schedule.
- (7) Expected number of trainees.
- (8) Subjects and hours of the course.
- (9) Names and occupations of the lecturers, the subjects they teach and hours of each subject.

[Items to Be Described in Registration Ledger of a Training Course]

**Article 58.** Registration of a training course under Article 21 of the Cabinet Order shall be performed by recording the following items to the registration ledger.

- (1) Registration date and registration number.
- (2) Name and address of the promoter of the registered training course (in case of a corporation, its name, address of the main office, and the name of the representative).
- (3) Period of the registered training course.

[Qualification Standards of Registration Training Course]

**Article 59.** The standards, provided by the Ministerial Ordinance under Article 24 Paragraph 2 of the Cabinet Order shall be as follows:

- (1) Confirmation that a trainee is a qualified person to attend the course by the personal history, papers certifying the relation between the trainee and the business place where he was employed and worked.
- (2) To those who have completed the curriculum of training course certificates of completion shall be issued.
- (3) Registered training course shall be held pursuant to the provisions of Article 56.

[Notification Items of Change in Registration Items of Registered Training Course]

**Article 60.** Items which shall be provided by the Ministerial Ordinance under the Article 25 of the Cabinet Order are as follows:

- (1) Name and address of the promoter of the registered training course (in case of a corporation, its name, address of the main office and name of the representative).
- (2) Period of the registered training course.

[Notification Items of Suspension of the Business of a Training Course]

**Article 61.** In case a promoter of a training course wishes to suspend or cancel the business of a training course, the following items shall be notified to the Minister of Health, Labour and Welfare.

- (1) The reason of suspension or cancellation, and its scheduled date.
- (2) In case of suspension, scheduled period of suspension.

[Preparation of Tables, etc. Treating Financial Affairs and Its Keeping]

**Article 62.** A promoter of a training course shall prepare tables, etc. treating financial affairs of the previous business year (means tables, etc. treating financial affairs provided under the Article 27 Paragraph 1; the same, hereinafter, in this Article) (In case three months have not passed after completion of the previous business year, tables, etc. treating financial affairs of the two business years previous may be used, instead.), and shall keep it in the business place until the closure of the training course.

[Method of Indication of Electromagnetic Records]

**Article 63.** Provisions of Article 44 shall be construed in the method provided by the Ministerial Ordinance under Article 27 Paragraph 2 Subparagraph (3) of the Cabinet Order.

[Method of Offer of the Electromagnetically Recorded Items by electromagnetic Method]

**Article 64.** Provisions of Article 45 shall be construed in the electromagnetic method provided by the Ministerial Ordinance under Article 27 Paragraph 2 Subparagraph (4).

[Items Which Shall Be Recorded in Books]

**Article 65.** Items which shall be provided by the Ministerial Ordinance under Article 31 of the Cabinet Order shall be as follows:

- (1) Names and personal history of the trainees.
  - (2) Number of trainees.
  - (3) Names, dates of birth, addresses, and the names of business places and their addresses where they are working , of the persons who have received the certificates of completion of the training course.
2. The books provided by the Article 31 of the Cabinet Order shall be kept for three years after the last day of the recording.

[Certificates of Officials for On-site Inspections]

**Article 66.** The certificates which officials are required to carry pursuant to the provisions of Article 33 Paragraph 2 of the Cabinet Order shall comply with Form No. 13.

[Application for Business License]

**Article 67.** Any person who wishes to obtain a business license under the provisions of Article 52 Paragraph 1 of the Law shall submit an application stating the items given below, which is accompanied by drawings showing the structures of the business facilities, to the governor of the prefecture concerned having jurisdiction over the location of the business office (or through both the director of the health center concerned and the mayor of the city or ward concerned, in the case of a city establishing health centers or a special ward) in the case of a business requiring a license from the governor of a prefecture; or to the mayor of the city or ward concerned having jurisdiction over the location of the business office in the case of a business requiring a license from the mayor of a city or special ward:

- (1) The name, address, and date of birth of the applicant (in the case of a corporation, the name and address of the main office thereof, and the name of its representative).
- (2) The address of the business office.
- (3) The name, store name, or trade name of the business office.
- (4) The type of the business.
- (5) Brief descriptions of the business facilities.
- (6) A statement of whether or not such person falls under any of the categories given in each Subparagraph of Article 52 Paragraph 2 of the Law, and its description.

**2.** Notwithstanding the items prescribed in each of the Subparagraphs of the preceding Paragraph, when a person licensed by the provisions of Article 52 Paragraph 1 of the Law (in the following Paragraph through Article 21, referred to as a "licensed business person") wishes to obtain continuous license for the same business at the expiration of the validity of the license, such person shall state the following items in the application for renewal:

- (1) The items given in (1), (2), (4), and (6) of the preceding Paragraph.
- (2) The number of the business license and the date of issuance of such license.

[Notification of Inheritance of the Position of Licensed Business Persons]

**Article 68.** Any person who wishes to make notification that such person has inherited the status of a licensed business person based on the inheritance pursuant to the provisions of Article 53 Paragraph 2 of the Law, shall submit a notification indicating the items given below to the governor of the prefecture concerned through the director of the health center having jurisdiction over the location of the business office (or through both the director of the health center concerned and the mayor of the city or ward concerned, in the case of a city establishing health centers or a special ward) in the case of a person licensed by the governor of a prefecture; or to the mayor of the city or ward concerned through the director of the health center having jurisdiction over the location of the business office in the case of a person licensed by the mayor of a city or special ward.

- (1) The name, address, and date of birth of the notifier, and the relationship with the inheritee.
- (2) The name and address of the inheritee.

- (3) The date of the beginning of inheritance.
- (4) The address of the business office of the inheritee.
- (5) The type of the business of the inheritee.
- (6) The number of the business license of the inheritee and the date of acquisition of such license.

2. The notification prescribed in the preceding Paragraph shall be accompanied by the following documents.

- (1) A copy of such inheritor's family register.
- (2) If there are two or more legal inheritors, in the case of a person who has been appointed as the inheritor of the status of a licensed business person with the consent of all of such inheritors, the written consent of all the persons concerned.

[Notification of Inheritance of the Position of Licensed Business Persons by Merger]

**Article 69.** Any person who wishes to make notification that such person has inherited the status of a licensed business person based on the merger pursuant to the provisions of Article 53 Paragraph 2 of the Law, shall submit a notification indicating the items given below, in the case of a person licensed by the governor of a prefecture, to the governor of the prefecture concerned; or in the case of a person licensed by the mayor of a city establishing health centers or special ward, to the mayor of the city or ward concerned having jurisdiction over the location of the business office.

- (1) The name, address of the main office, and name of the representative, of the notifier.
- (2) The corporate name, address of the main office, and name of the representative, of a corporation having ceased to exist after the merger.
- (3) The date of merger.
- (4) The address of the business office of such corporation.
- (5) The type of the business of such corporation.
- (6) The number of the current business license and the date of issuance of such license.

2. The notification prescribed in the preceding Paragraph shall be accompanied by a certified copy of the register of the corporation existing after the merger or the corporation newly established by the merger.

[Notification of Inheritance of the Position of Licensed Business Person by Partition]

**Article 70.** Any person who wishes to make notification that such person has inherited status of a licensed business person based on the partition pursuant to the provisions of Article 53 Paragraph 2 of the Law, shall submit a notification indicating the items given below, in the case of a person licensed by the governor of a prefecture, to the governor of the prefecture concerned; or in the case of a person licensed by the mayor of the city establishing health centers or a special ward, to the mayor of the city or ward concerned having jurisdiction over the location of the business office.

- (1) The name, address of the main office, and name of the representative, of the notifier.
  - (2) The corporate name, address of the main office, and name of the representative, of a corporate before partition.
  - (3) The date of partition.
  - (4) The address of the business office of such corporation.
  - (5) The type of the business of such corporation.
  - (6) The number of the current business license and the date of issuance of such license.
2. The notification prescribed in the preceding Paragraph shall be accompanied by a certified copy of the register of the corporation which inherited the business after partition.

[Notification by Licensed Business Persons of Changes in Declared Items]

**Article 71.** When there has been any change in the items stated in Article 67 Paragraph 1 Subparagraph (1), (3), or (5), Article 68 Paragraph 1 Subparagraph (1), Article 69 Paragraph 1 Subparagraph (1), or Paragraph 1 Subparagraph (1) of the preceding Article, the business person concerned shall, without delay, notify of the effect, in the case of a person having obtained the license from the governor of a prefecture, the governor of the prefecture concerned ; or, in the case of a person having obtained the license from the mayor of a city establishing health centers or a special ward, the mayor of the city or special ward concerned.

## **Chapter 9. Miscellaneous Provisions**

[Notification of Poisoned Persons or Their Corpses]

**Article 72.** Notification by a medical doctor under the provisions of Article 58 Paragraph 1 of the Law (including cases when such provisions are applied based on Article 62 Paragraph 1 of the Law, the same , hereinafter) shall be made with respect to the following items by documents, telephone, or direct verbal reports within twenty-four hours:

- (1) The address and name of the medical doctor.
- (2) The address, name, and age of the person poisoned or suspected to be poisoned or the dead person.
- (3) The cause of the food poisoning (hereinafter, food poisoning means any poisoning attributable to any of the food, etc. the same, hereinafter).
- (4) The date and time of the onset of the poisoning.
- (5) The date and time of the diagnosis of the poisoning or examination of the corpse.

[Scope of Food Poisoning Incident to be Reported]

**Article 73.** The number of outbreaks of food poisoning provided by the Ministerial Ordinance under the Article 58 Paragraph 3 (including cases construed in Article 62 Paragraph 1; the same,

hereinafter) shall be 50 persons.

2. The cases, provided by Article 58 Paragraph 3, shall be as follows:

- (1) In case death of patients has occurred by the poisoning concerned.
- (2) In case the poisoning concerned has arisen or is suspected to have arisen from the consumption of imported food, etc.
- (3) In case the poisoning concerned has arisen or is suspected to have arisen from the pathogenic substances listed in Table 17.
- (4) In case the location of patients, etc. are distributed in plural prefectures.
- (5) In case it seems to be difficult, from the situation of outbreaks of the food-poisoning concerned, etc. to investigate the category of the poisoning.
- (6) In case it seems to be difficult, from the situation of outbreaks of the food-poisoning concerned, etc. to perform the dispositions pursuant to the provisions of Article 54 through 56 of the Law (Shall be called, hereinafter, as "disposition"), or judge the suitability of the content.

[Items to Be Reported from Prefectural Governor, etc. to the Minister of Health, Labour and Welfare]

**Article 74.** Items to be provided by the Ministerial Ordinance under Article 37 Paragraph 2 of the Cabinet Order are as follows:

- (1) Address of patients, etc. and date of notification pursuant to the provisions of Article 58 Paragraph 1.
- (2) Number of patients, etc. and their symptoms.
- (3) Food, etc. which caused poisoning or which are suspected to have caused poisoning (Shall be called, hereinafter, as "poisoned food") and the reason of its specification.
- (4) Pathogenic substances which caused poisoning or which are suspected to have caused poisoning and the reason of their specification.
- (5) Facilities which caused poisoning or which are suspected to have caused poisoning (Shall be called, hereinafter, as "causative facilities"), and the reason of their specification.
- (6) Any other items, besides that which is indicated in each of the preceding Subparagraphs, which is regarded as important item in the investigation of category of the poisoning.

[Report to Be Prepared by a Director of Health Center]

**Article 75.** The reports provided under the provisions of Article 37 Paragraph 3 shall be made according to the category of food poisoning incident pursuant to each Subparagraph.

- (1) Food poisoning incident which was immediately reported pursuant to the provisions of Article 58 Paragraph 3 from prefectural governor, etc. to the Minister of Health, Labour and Welfare:  
Food-poisoning incident card prepared on the basis of Form No. 14, for each incident, and the detailed report of the food-poisoning incident.



(2) Food poisoning incident besides food-poisoning incident indicated in the preceding Subparagraph: Food-poisoning incident card prepared on the basis of Form No. 14.

2. The detailed report prescribed in the preceding Article Paragraph 1, the following items shall be described.

(1) An outline of the outbreak of food-poisoning including the following items.

- a. Date of outbreak.
- b. Place of outbreak.
- c. Number of persons who took in the poisoned food.
- d. Number of deceased persons.
- e. Number of patients
- f. Poisoned food, etc.
- g. Pathogenic substance.

(2) Items on the grasp of the information of outbreak of the food poisoning.

(3) Items on the situation of patients and dead persons indicated in the following 'a' through 'e'.

- a. Numbers of patients and dead persons classified by age, male and female.
- b. Numbers of patients and dead persons classified by date and time of outbreak.
- c. Ratios of numbers of patients and deceased persons those who have taken poisoned food.
- d. Hours elapsed for patients and deceased persons from the time of taking the poisoned food until the onset of illness.
- e. Symptoms of the patients and deceased persons and numbers classified by symptoms.

(4) Following items related with the poisoned food, etc. and the contamination route.

- a. Process until specifying the poisoned food and the reason of specification.
- b. Contamination route of poisoned food.

(5) Items on facilities.

- a. Water supply and draining and other sanitary conditions of the facilities.
- b. Health condition of employees of the facilities.

(6) Process until specifying the pathogenic substance and the reason of specification.

(7) Contents of dispositions and other measures taken by prefectural governor, etc.

[Report to Be Prepared by Prefectural Governor, etc.]

**Article 76.** The report designated by Article 37 Paragraph 4 shall be the report established in each following Subparagraph in accordance with the classification of food-poisoning incident.

(1) Food-poisoning incidents which were immediately notified by prefecture governor etc. to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 58 Paragraph 3:

Report on the result of investigation of food-poisoning incident; and the detailed report on the result of investigation of the food-poisoning incident.

(2) Food-poisoning incident other than those which are indicated in the preceding Subparagraph:  
Report on the result of investigation of food-poisoning incident.

2. Report on the result of investigation of food-poisoning indicated in each Subparagraph of the preceding Paragraph shall be prepared on the basis of Form No. 15.

3. The report on the result of investigation of food-poisoning incident shall be submitted each month, being attached with the food-poisoning incident cards, prescribed in each Subparagraph of Paragraph 1 of the preceding Article, by 10th of the next month.

4. The detailed report on the result of investigation of food-poisoning incident prescribed in Article 1 Paragraph 1 shall be prepared by describing the items indicated in each Subparagraph of Paragraph 2 of the preceding Article.

5. The detailed report on the result of investigation of food-poisoning incident prescribed in Paragraph 1 Subparagraph (1) of this Article shall be prepared immediately after the detailed report of food-poisoning prescribed in Paragraph 1 Subparagraph (1) of the preceding Article, under the provisions of Article 37 Paragraph 3 of the Cabinet Order.

**Article 77.** The number of food-poisoning patients provided by the Ministerial Ordinance under Article 60 of the Law shall be 500 persons.

[Toys Which May Be Injurious to Human Health by Infants' Contact]

**Article 78.** The toys prescribed in Article 62 Paragraph 1 of the Law are as follows:

(1) Toys which are made of paper, wood, bamboo, rubber, leather, celluloid, plastic, metal, or china and which naturally come into contact with infants' mouths during their use.

(2) Mouth crackers.

(3) Copy pictures, "ORIGAMI" papers (folding papers), and building blocks.

(4) Toys listed below, which are made of rubber, plastic, or metal:  
Tumblers, masks, rattles, toy telephones, toy animals, dolls, clay, toy vehicles (excluding spring-driven or electric-powered vehicles), balloons, blocks, balls, and household toys.

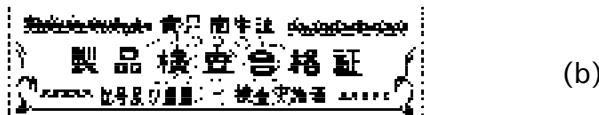
[Delegation of Authority]

**Article 79.** The authority of the Minister of Health, Labour and Welfare prescribed in Article 41, Article 42, Article 46 Paragraph 2 and Article 47 Paragraph 1 of the Law, and Article 17, Article 28, Article 29, Article 32 and Article 33 Paragraph 1 of the Cabinet Order pursuant to the provision of the Article 70 Paragraph 1 of the Law, and Article 41 of the Cabinet Order shall be

transferred to the directors of the Local Bureau of Health and Welfare.

Forms and Tables

Form No. 1. (related to Article 26)



Food Sanitation Law	
<b>Product Examination Certificate</b>	
Code and Weight	Examiner

Remarks:

1. The size of the paper shall be 22 mm vertically and 104 mm horizontally for (a), 14 mm vertically and 55 mm horizontally for (b), and 14 mm vertically and 30 mm horizontally for (c).

2. The code shall be based on the classification of the following table:

A	
B	
C	タール色素 <sup>1)</sup>
D	
E	
F	
G	

1) Tar colors

3. The weight in grams shall be expressed as a three-digit Arabic number, for example, "015", for (a) and (b), and shall be expressed as a one-digit Arabic number for example, "1", for (c). Numbers including decimal fractions shall be rounded off to the nearest whole number by eliminating any decimal value less than 0.5 and increasing by one for decimal values of 0.5 or greater, and when the units are kilograms the letter "k" shall be attached to the end of the number.

4. The examiner shall be the Minister of Health, Labour and Welfare, the governor of the prefecture concerned, the mayor of the city concerned, or a designated laboratory.

Form No.2 (related to Article 35)

○		○						
<div style="border: 1px solid black; padding: 2px; display: inline-block;">甲<sup>4)</sup></div>	収 去 証 <sup>1)</sup>	<table border="1" style="border-collapse: collapse;"> <tr> <td style="padding: 2px;">記 号</td> <td style="width: 50px;"></td> <td style="font-size: 8px; vertical-align: top;">2)</td> </tr> <tr> <td style="padding: 2px;">番 号</td> <td></td> <td style="font-size: 8px; vertical-align: top;">3)</td> </tr> </table>	記 号		2)	番 号		3)
記 号		2)						
番 号		3)						
<p>1 被収去者の住所又は営業所所在地<sup>5)</sup></p> <p>2 被収去者の氏名又は法人名<sup>6)</sup></p> <p>3 収去品名<sup>7)</sup></p> <p>4 収去数量<sup>8)</sup></p> <p>5 収去目的<sup>9)</sup></p> <p>6 収去日時 平成 年 月 日 午後 時<sup>10)</sup></p> <p>7 収去場所<sup>11)</sup></p> <p>食品衛生法第 2 8 条の規定に基づき、上記のように収去する。<sup>12)</sup></p> <p>平成 年 月 日<sup>13)</sup></p> <p>収去者<sup>14)</sup> <table border="1" style="border-collapse: collapse; display: inline-table; vertical-align: middle;"> <tr> <td style="padding: 2px;">所 属 庁</td> </tr> <tr> <td style="padding: 2px;">職</td> </tr> <tr> <td style="padding: 2px;">所 属 庁 印</td> </tr> </table> 氏 名<sup>16)</sup> ㊟</p> <p>備 考<sup>17)</sup></p>			所 属 庁	職	所 属 庁 印			
所 属 庁								
職								
所 属 庁 印								

Note:

1. Use JIS (Japanese Industrial Standards) A5- (148 x 210 mm) or JIS A6-size (105 x 74 mm) paper.
2. Use red ink for authorities' seal.
3. Use a two- sheet form with carbon paper, composed of sheet A and sheet B.
4. For Sheet B, do not provide a perforated line for binding, omit the authorities' seal and collector's seal, and print the words "Copy of Collection Certificate" and "B" instead of the words "Collection Certificate" and "A", respectively.

Translation:

- 1) Collection Certificate
- 2) Code
- 3) Serial No.
- 4) Sheet "A"
- 5) Address of collectee or business establishment
- 6) Name or corporate name of collectee
- 7) Name of collected item
- 8) Quantity (number/amount)
- 9) Purpose of collection
- 10) Date and time of collection Year (HEISEI) Month Day AM/PM Time
- 11) Place of collection
- 12) I hereby collect the item given above pursuant to Article 28 of the Food Sanitation Law.
- 13) Year (HEISEI) Month Day
- 14) Collector
- 15) Authorities concerned  
Position (Food Sanitation Inspector)  
Authorities' seal
- 16) Collector's name and seal
- 17) Notes

Form No. 3 (related to Article 35)

(Face)

8 cm

12 cm

<sup>1)</sup> 写 真 ち ょ う 付 面

<sup>2)</sup> 番 号

<sup>3)</sup> 所 属 庁

<sup>4)</sup> 所 属 庁 印

<sup>5)</sup> 氏

<sup>6)</sup> 生 年 月 日 名

<sup>7)</sup> 食 品 衛 生 監 視 員 の 証

<sup>8)</sup> 平 成 年 月 日 発 行

<sup>9)</sup> ( 一 年 間 有 効 )

<sup>10)</sup>この証票を携帯する者は、食品衛生法又は健康増進法により臨検検査又は収去をする職権を行なう者で、その関係条文は、以下のとおりである。

<sup>11)</sup>食品衛生法抜粋

第二十八条 厚生労働大臣又は都道府県知事等は、必要があると認めるときは、営業その他の関係者から必要な報告を求め、当該官吏に営業の場所、事務所、倉庫その他の場所に臨検し、販売の用に供し、若しくは営業上使用する食品、添加物、器具若しくは容器包装、営業の施設、帳簿書類その他の物件を検査させ、又は試験の用に供するのに必要な限度において、販売の用に供し、若しくは営業上使用する食品、添加物、器具若しくは容器包装を無償で収去させることができる。

前項の規定により当該官吏に臨検検査又は収去をさせる場合においては、これにその身分を示す証票を携帯させ、かつ、関係者の請求があるときは、これを提示させなければならない。

第一項の規定による権限は、犯罪捜査のために認められたものと解釈してはならない。

第三十条 第二十八条第一項に規定する当該官吏の職権及び食品衛生に関する指導の職務を行わせるために、厚生労働大臣又は都道府県知事等は、官吏又は当該都道府県等の官吏のうちから食品衛生監視員を命ずるものとする。

都道府県知事等は、都道府県等食品衛生監視指導計画の定めるところにより、食品衛生監視員に監視指導を行わせなければならない。

厚生労働大臣は、輸入食品監視指導計画の定めるところにより、食品衛生監視員に食品、添加物、器具及び容器包装の輸入に係る監視指導を行わせるものとする。

<sup>12)</sup>健康増進法抜粋

(特別用途食品の検査及び収去)

第二十七条 厚生労働大臣又は都道府県知事は、必要があると認めるときは、当該職員に特別用途食品の製造施設、貯蔵施設又は販売施設に立ち入らせ、販売の用に供する当該特別用途食品を検査させ、又は試験の用に供するのに必要な限度において当該特別用途食品を収去させることができる。

2 前項の規定により立入検査又は収去をする職員は、その身分を示す証明書を携帯し、関係者に提示しなければならない。

3 第一項に規定する当該職員の権限は、食品衛生法第三十条第一項に規定する食品衛生監視員が行うものとする。

4 第一項の規定による権限は、犯罪捜査のために認められたものと解釈してはならない。

(特別用途表示の承認)

第二十九条 本邦において販売に供する食品につき、外国において特別用途表示をしようとする者は、厚生労働大臣の承認を受けることができる。

2 第二十六条第二項から第五項までの規定は前項の承認について、第二十七条の規定は同項の承認に係る食品について、前条の規定は同項の承認を受けて特別用途表示をする者について準用する。この場合において、第二十六条第二項中「その営業所の所在地の都道府県知事を経由して厚生労働大臣」とあるのは「厚生労働大臣」と、第二十七条第一項中「製造施設、貯蔵施設」とあるのは「貯蔵施設」と、前条中「同条第五項」とあるのは「次条第二項において準用する第二十六条第五項」と読み替えるものとする。

(勧告等)

第三十二条(第一項及び第二項 略)

3 第二十七条の規定は、販売に供する食品であつて栄養表示がされたもの(特別用途食品及び第二十九条第一項の承認を受けた食品を除く。)について準用する。

(勧告等)

第三十二条の三(第一項及び第二項 略)

3 第二十七条の規定は、食品として販売に供する物であつて健康増進効果等についての表示がされたもの(特別用途食品、第二十九条第一項の承認を受けた食品及び販売に供する食品であつて栄養表示がされたものを除く。)について準用する。



Translation:

- 1) Photo
- 2) No.
- 3) Authorities concerned
- 4) Seal
- 5) Name
- 6) Date of birth
- 7) Certificate of Food Sanitation Inspector
- 8) Issued on date ( Year (Heisei) Month Day)
- 9) Valid for one year
- 10) This is to certify that the person who carries this certificate is authorized to perform on-site inspections or collection of samples under the Food Sanitation Law or Health Promotion Law. Applicable provisions are as follows:

11) Food Sanitation Law (Excerpt)

Article 28. The Minister of Health, Labour and Welfare or the governor of prefecture, etc. may request necessary reports from a business person or other related persons, require the officials concerned to visit the place of business, offices, warehouses, or other places in order to inspect foods, additives, apparatus, or containers/packages intended for sale or for use in business, or the business facilities, books, documents, or other articles, or require such officials to collect samples of foods, additives, apparatus, or containers/packages intended for sale or for use in business without compensating such samples within the quantity necessary for performing tests, when the Minister of Health, Labour and Welfare, governor, city mayor, or ward mayor concerned determines that the action is necessary. When the Minister of Health, Labour and Welfare or the governor of prefecture, etc. pursuant to the provisions of the preceding Paragraph, requires the officials concerned to make on-site inspections or to collect samples, the Minister of Health, Labour and Welfare or governor concerned shall have such officials carry certificates stating their status, and shall show them upon request from related people.

Article 30. The Government, each prefecture, etc. shall appoint food sanitation inspectors to execute the authority of officials prescribed in Article 28 Paragraph 1 and to perform the duties of providing guidance for food sanitation.

Food sanitation inspectors shall be appointed in each jurisdiction from among the officials of the Government or prefecture, etc. by the Minister of Health, Labour and Welfare or the governor of the prefecture, etc. as appropriate.

The governor of prefecture, etc. shall, as prescribed by the plan of inspection and guidance of food sanitation of prefecture, etc., require food sanitation inspectors to perform inspections or to provide guidance.

The Minister of Health, Labour and Welfare shall require food sanitation inspectors to perform or to provide guidance concerning import of food, food additives, apparatus and containers/packages under the provisions of the plan of inspection and guidance of imported food.

12) Health Promotion Law (Excerpt)

(Examination and collection of samples of "foods for special uses")

Article 27. The Minister of Health, Labour and Welfare or the governor of any prefecture may require the officials concerned to visit the facility for manufacturing, storing, or selling of foods for special uses in order to inspect foods for special uses intended for sale, or may require such officials to collect samples of foods for special uses within the quantity necessary for performing tests, when the Minister of Health, Labour and Welfare or the governor determines that the action is necessary.

2. When the officials, pursuant to the provisions of the preceding Paragraph, perform on-site inspections or collect samples, such officials shall carry certificates stating their status and show them.

3. The responsibilities provided in Paragraph 1 shall be executed by food sanitation inspectors as prescribed in Article 30 Paragraph 1 of the Food Sanitation Law.

(Approval of labeling for special uses)

Article 29. Any person outside Japan wishing to label a product intended for sale in Japan as a food for special uses may receive approval from the Minister of Health, Labour and Welfare.

2. The provisions of Article 26 Paragraphs 2 through 5, the provisions of Article 27, and the provisions of the preceding Article shall apply to the approval mentioned in the preceding Paragraph, to foods under the approval mentioned in the same Paragraph, and to the person who labels a product as a food for special uses, respectively.

In these cases, "the Minister of Health, Labour and Welfare through the governor of the prefecture where the business place is located" as mentioned in Article 26 Paragraph 2, "facilities for manufacturing or storing" as mentioned in Article 27 Paragraph 1, and "the same Article Paragraph 5" mentioned in the preceding Article shall be construed as "the Minister of Health, Labour and Welfare", "facilities for storing", and "Article 26 Paragraph 5 applied to Paragraph 2 of the following Article", respectively.

(Recommendations, etc.)

Article 32. (The first Paragraph and the second Paragraph are omitted.)

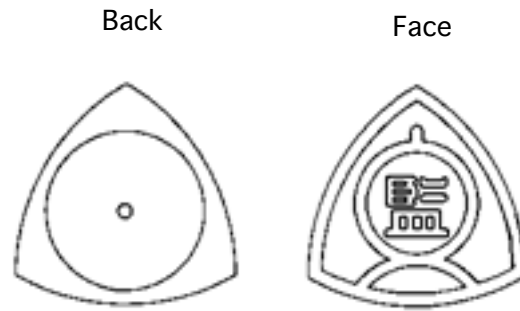
3. The provisions in Article 27 shall be construed on foods intended for sale, to which nutrition labeling is attached (excluding foods for special uses and foods under the approval mentioned in Article 29 Paragraph 1).

(Recommendations, etc.)

Article 32-3. (The first Paragraph and the second Paragraph are omitted.)

3. The provisions in Article 27 shall be construed on products intended for sale as food, to which labeling is attached mentioning health retaining and promotion effect, etc. (excluding foods for special uses, foods under the approval mentioned in Article 29 Paragraph 1, and foods to which nutrition labeling is attached).

**Form No. 4 (related to Article 35)**



Form of badge

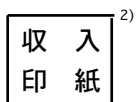
1. Diagram

- (1) The character "監" shall be placed in the center of a circle of 17 millimeters diameter, inscribed in a pattern designed from the character "食" in the shape of a roundish triangle.
- (2) The character "食" shall be made into a design and that design and the character "監" shall be embossed.
- (3) A buttonhole screw-in type metal fitting shall be attached to the back.

2. Material

- (1) The badge shall be made from a brass base covered with baked black lacquer.
- (2) The character "監" shall be silver-plated and the pattern of the character "食" shall be gold-plated.

Form No. 5 (related to Article 38)



登 録 申 請 書<sup>1)</sup>

年 月 日<sup>3)</sup>

厚生労働大臣殿<sup>4)</sup>

所 在 地<sup>5)</sup>

名 称<sup>6)</sup>

代表者の氏名



第 2 5 条 第 1 項  
食品衛生法 第 2 6 条 第 1 項 の登録検査機関の登録を受けたいので、同法第 3 1 条の規定  
第 2 6 条 第 2 項  
第 2 6 条 第 3 項

により次のとおり申請します。<sup>8)</sup>

- 1 製品検査の種類
- 2 製品検査を行う事業所の名称及び所在地

Note:

1. Use JIS A4-size (210 x 297 mm) paper.
2. In the column of "category to be registered", the category to be registered indicated in the first Column of Table of the Food Sanitation Law shall be filled in.
3. Papers indicated in each Subparagraph of Article 38 shall be attached.
4. Revenue stamps shall not be cancellation stamped.

Translation:

- 1) Application for Registration
- 2) Revenue stamp
- 3) Date
- 4) Addressed to Minister of Health, Labour and Welfare
- 5) Address
- 6) Name of applicant
- 7) Name of representative and seal
- 8) I hereby apply for the registration of the registered laboratory under the following category prescribed in Article 25 Paragraph 1/Article 26 Paragraph 1/Article 26 Paragraph 2/Article 26 Paragraph 3 of the Food Sanitation Law, pursuant to the provisions of Article 31 of the same Law:
  1. Category to be registered
  2. Name and address of examination facility performing product examinations

Form No. 6 (related to Article 39)

収入<sup>2)</sup>  
印紙

登録更新申請書<sup>1)</sup>

年 月 日<sup>3)</sup>

厚生労働大臣殿<sup>4)</sup>

所在地<sup>5)</sup>

名称<sup>6)</sup>

代表者の氏名

印<sup>7)</sup>

第25条第1項  
食品衛生法 第26条第1項 の登録検査機関の登録の更新を受けたいので、同法  
第26条第2項  
第26条第3項

第34条第1項の規定により、次のとおり申請します。<sup>8)</sup>

- 1 登録番号
- 2 登録の有効期限 年 月 日
- 3 製品検査の種類
- 4 製品検査を行う事業所の名称及び所在地

Note:

1. Use JIS A4-size (210 x 297 mm) paper.
2. Papers indicated in each Subparagraph of Article 39 shall be attached.
3. Revenue stamps shall not be cancellation stamped.

Translation:

- 1) Application for Renewal of Registration
- 2) Revenue stamp
- 3) Date
- 4) Addressed to Minister of Health, Labour and Welfare
- 5) Address
- 6) Name of applicant
- 7) Name of representative and seal
- 8) I hereby apply for the renewal of registration of the following category prescribed in Article 25 Paragraph 1/Article 26 Paragraph 1/Article 26 Paragraph 2/Article 26/Paragraph 3 of the Food Sanitation Law, pursuant to the provisions of Article 34 Paragraph 1 of the Law.
  1. Registration number
  2. Term of validity
  3. Category of registration
  4. Name and address of examination facility performing product examinations

Form No. 7 (related to Article 41)

設 置  
事 業 所 廃 止 届<sup>1)</sup>  
変 更

年 月 日<sup>2)</sup>

厚生労働大臣殿<sup>3)</sup>

所 在 地<sup>4)</sup>

名 称<sup>5)</sup>

代表者の氏名

印<sup>6)</sup>

設置

製品検査を行う事業所を廃止したいので、食品衛生法第36条第1項の規定により次  
変更

のとおり届け出ます。<sup>7)</sup>

設置

- 1 廃止しようとする事業所の名称及び所在地  
変更

設置

設置

- 2 廃止の理由及び廃止の予定年月日  
変更 変更

設置

- 3 廃止しようとする事業所における製品検査のための機械器具その他の設備  
変更

Note:

1. Use JIS A4-size (210 x 297 mm) paper.
2. For the Notification of Change, Nos 1 and 3 above should be given for both conditions before and after the change.

Translation:

- 1) Notification of Establishment/Closure/Change of Examination Facility
- 2) Date
- 3) Addressed to Minister of Health, Labour and Welfare
- 4) Address
- 5) Name of notifier
- 6) Name of representative and seal
- 7) I hereby notify the Minister of Health, Labour and Welfare of the establishment/closure/change of the following examination facility pursuant to the provisions of Article 36 Paragraph 1 of the Food Sanitation Law:
  1. Name and address of the examination facility to be established/closed/changed.
  2. Reason for establishment/closure/change and planned date of establishment/closure/change.
  3. Machinery/apparatus used for product examinations at the examination facility to be established/closed/changed.

Form No. 8 (related to Article 41)

登録事項変更届<sup>1)</sup>

年 月 日<sup>2)</sup>

厚生労働大臣殿<sup>3)</sup>

所在地<sup>4)</sup>

名称<sup>5)</sup>

代表者の氏名

印<sup>6)</sup>

次の事項の変更につき、食品衛生法第36条第2項の規定により届け出ます。<sup>7)</sup>

- 1 変更の内容
- 2 変更の理由
- 3 変更の年月日

Note:

1. Use JIS A4-size (210 x 297 mm) paper.
2. For the Notification of Change, Nos 1 and 3 above should be given for both conditions before and after the change.

Translation:

- 1) Notification of Change in Registered Items
- 2) Date
- 3) Addressed to the Minister of Health, Labour and Welfare
- 4) Address
- 5) Name of notifier
- 6) Name of representative
- 7) I hereby notify the Minister of Health, Labour and Welfare change in the following items pursuant to the provisions of Article 36 Paragraph 2 of the food Sanitation Law.
  1. Description
  2. Reason for change
  3. Date of change

Form No. 9 (related to Article 42)

業 務 規 程 認 可 申 請 書<sup>1)</sup>

年 月 日<sup>2)</sup>

厚生労働大臣殿<sup>3)</sup>

所 在 地<sup>4)</sup>

名 称<sup>5)</sup>

代表者の氏名

印<sup>6)</sup>

業務規程の認可を受けたいので、食品衛生法第37条第1項の規定により別添のとおり申請します。<sup>7)</sup>

Note:

Use JIS A4-size paper.

Translation:

- 1) Application for Approval of Work Regulations
- 2) Date
- 3) Addressed to Minister of Health, Labour and Welfare
- 4) Address
- 5) Name of applicant
- 6) Name of representative and seal
- 7) I hereby apply for approval of the work regulations, as stipulated in the attachment, pursuant to the provisions of Article 37 Paragraph 1 of the Food Sanitation Law.



Form No. 10 (related to Article 42)

業 務 規 程 変 更 認 可 申 請 書<sup>1)</sup>

年 月 日<sup>2)</sup>

厚生労働大臣殿<sup>3)</sup>

所 在 地<sup>4)</sup>

名 称<sup>5)</sup>

代表者の氏名

印<sup>6)</sup>

業務規程の変更の認可を受けたいので、食品衛生法第37第1項の規定により次のとおり申請します。<sup>7)</sup>

- 1 変更の内容
- 2 変更の理由

Note:

1. Use JIS A4-size paper.
2. Give both descriptions, before and after the change, in No. 1 above.

Translation:

- 1) Application for Approval to Change Work Regulations
- 2) Date
- 3) Addressed to Minister of Health, Labour and Welfare
- 4) Address
- 5) Name of applicant
- 6) Name of representative and Seal
- 7) I hereby apply for approval for the following change in the Work Regulations pursuant to Article 37 Paragraph 1 of the Food Sanitation Law:
  1. Description
  2. Reason for change

Form No. 11 (related to Article 43)

業務 休止 許可 申請 書<sup>1)</sup>

年 月 日<sup>2)</sup>

厚生労働大臣殿<sup>3)</sup>

所在地<sup>4)</sup>

名称<sup>5)</sup>

代表者の氏名

印<sup>6)</sup>

製品検査の業務の全部の休止の許可を受けたいので、食品衛生法第38条の規定により次  
一部 廃止

のとおり申請します。<sup>7)</sup>

- 1 休止しようとする製品検査の業務の範囲  
廃止
- 2 休止の年月日  
廃止
- 3 休止の期間
- 4 休止の理由  
廃止

Note:  
Use JIS A4-size paper.

Translation:

- 1) Application for Permission for Suspension/Discontinuation of Work
- 2) Date
- 3) Addressed to Minister of Health, Labour and Welfare
- 4) Address
- 5) Name of applicant
- 6) Name of representative and seal
- 7) I hereby apply for permission for suspension/discontinuation of product examination work of the following scope, pursuant to the provisions of Article 38 of the Food Sanitation Law:
  1. Scope of product examination work to be suspended/discontinued
  2. Date of suspension/discontinuation
  3. Duration of discontinuation
  4. Reason for suspension/discontinuation

(face)  
12 cm

<p style="text-align: center;">第<sup>2)</sup>号</p> <p style="text-align: center;">官職名<sup>3)</sup> 氏名<sup>4)</sup> 生年月日<sup>5)</sup></p> <p style="text-align: center;">食品衛生法第四十七条第一項の規定による立入 検査を行う職員<sup>6)</sup>の証</p> <p style="text-align: center;">発行年月日<sup>7)</sup></p> <p style="text-align: center;">厚生労働大臣又は地方厚生局長<sup>8)</sup></p> <div style="text-align: center; margin-top: 20px;"> <span style="border: 1px solid black; padding: 2px 5px;">印</span> </div>	<p style="text-align: center;">写<sup>1)</sup></p> <p style="text-align: center;">真</p>
--	--

8 cm

(back)

<sup>9)</sup> この証を携帯する者は、食品衛生法により立入検査又は質問をする職権を行う者で、その関係条文は、次のとおりである。

食品衛生法抜粋

第四十七条 厚生労働大臣は、この法律の施行に必要な限度において、登録検査機関に対し、その業務若しくは経理の状況に関し報告をさせ、又は当該職員に、登録検査機関の事務所若しくは事業所に立ち入り、業務の状況若しくは帳簿、書類その他の物件を検査させ、若しくは関係者に質問させることができる。

第二十八条第二項及び第三項の規定は、前項の場合に準用する。

第二十八条 (第一項 略)

前項の規定により当該官吏に臨検検査又は収去をさせる場合においては、これにその身分を示す証票を携帯させ、かつ、関係者の請求があるときは、これを提示させなければならない。

第一項の規定による権限は、犯罪捜査のために認められたものと解釈してはならない。

Translation:

- 1) Photo
- 2) No.
- 3) Title
- 4) Name
- 5) Date of birth
- 6) Certificate for Officials to Perform On-site Examinations Pursuant to Article 47 Paragraph 1 of the Food Sanitation Law
- 7) Issued on date (Year Month Day)
- 8) Minister of Health, Labour and Welfare or Director of Local Bureau of Health and Welfare and seal
- 9) This is to certify that the person who carries this certificate is authorized to perform on-site examinations or ask questions under the Food Sanitation Law. Applicable provisions are as follows:

Food Sanitation Law (Excerpt)

Article 47. The Minister of Health, Labour and Welfare, within the limit necessary to enforce this Law, may request reports from a registered laboratory of the status of its work or accounting, or may require the officials concerned to visit offices or examination facilities of such laboratory, to inspect the status of such work, or books, documents, or other articles or to question related persons.

The provisions of Article 28 Paragraph 2 and Paragraph 3 shall apply to the preceding Paragraph.

Article 28. (The first Paragraph is omitted)

When the Minister of Health, Labour and Welfare or the governor of prefecture, etc. pursuant to the provisions of the preceding Paragraph, requires the officials concerned to make on-site inspections or to collect samples, the Minister of Health, Labour and Welfare or governor, etc. concerned shall have such officials carry certificates stating their status, and shall show them upon request from related people.

The right endorsed by the provisions of Paragraph 1 shall not be taken to have been authorized to be used for criminal investigation.

(face)  
12 cm

<p style="text-align: center;">第<sup>2)</sup>号</p> <p style="text-align: center;">官職名<sup>3)</sup> 氏名<sup>4)</sup> 生年月日<sup>5)</sup></p> <p style="text-align: center;">食品衛生法施行令第三十三条第一項の規定による立入検査を行う職員の証<sup>6)</sup></p> <p style="text-align: center;">発行年月日<sup>7)</sup></p> <p style="text-align: center;">厚生労働大臣又は地方厚生局長<sup>8)</sup></p> <p style="text-align: center;">印</p>	<p>写<sup>1)</sup></p> <p>真</p>
--	--------------------------------

8 cm

(back)

この証明書を携帯する者は、食品衛生法施行令により立入検査又は質問をする職権を行う者で、その関係条文は、次のとおりである。

食品衛生法施行令抜粋  
(立入検査)

第三十三条 厚生労働大臣は、法及びこの政令の施行に必要な限度において、その職員に、登録講習会の実施者の業務を行う場所に立ち入り、業務の状況又は帳簿、書類その他の物件を検査させることができる。

2 前項の規定により立入検査をする職員は、その身分を示す証明書を携帯し、関係者に提示しなければならない。

3 第一項の立入検査の権限は、犯罪捜査のために認められたものと解釈してはならない。

Translation:

- 1) Photo
- 2) No.
- 3) Title
- 4) Name
- 5) Date of birth
- 6) Certificate for Officials to Perform On-site Examinations Pursuant to Article 33 Paragraph 1 of the Food Sanitation Law Enforcement Ordinances
- 7) Issued on date (Year Month Day)
- 8) Minister of Health, Labour and Welfare or Director of Local Bureau of Health and Welfare and seal
- 9) This is to certify that the person who carries this certificate is authorized to perform on-site examinations or ask questions under the Food Sanitation Law Enforcement Ordinances.  
Applicable provisions are as follows:  
Food Sanitation Law Enforcement Ordinances (Excerpt)  
(On-site examinations)  
Article 33. The Minister of Health, Labour and Welfare, within the limit necessary to enforce the Law and the Cabinet Order, may require the officials concerned to visit offices or facilities of the promoter of the registered training course, to inspect the status of such work, or books, documents or other articles.  
2. The officials to make on-site inspections shall carry certificates stating their status and show them to the related persons.  
3. The right of on-site inspection under the Paragraph 1 shall not be taken to have been authorized for criminal investigation.

F	. . . . . <sup>2)</sup>	食 中 毒 事 件 票 <sup>1)</sup>	都道府県事等件番号 <sup>4)</sup>	
	保健所符号 <sup>3)</sup>		保健所事番号 <sup>5)</sup>	
(1)	原因となつた家庭・業者・施設等の所在地 <sup>6)</sup>	町 区 村	都 道 府 県	市 郡
(2)	初 発 患 者 <sup>7)</sup>	年 月 日	年 月 日	年 月 日
(3)	原因となつた業者・施設等の名称 <sup>8)</sup>			
(4)	原因となつた家庭・業者・施設等の種別 <sup>9)</sup>			
(5)	原 因 食 品 名 <sup>10)</sup>			
(6)	原 因 食 品 の 種 別 <sup>11)</sup>			
(7)	原 因 食 品 の 判 定 <sup>12)</sup>			
(8)	撰 取 場 所 <sup>13)</sup>			
(9)	撰 取 場 所 の 種 別 <sup>14)</sup>			
(10)	撰取場所における調理の有無別 <sup>15)</sup>			

1	家庭	B 寄宿舍	口 小学校	C その他	6 飲食店	1 2 不			
2	A 事業場	C その他	ハ 中学校	4 病院	7 販売店	1 4 複合調理食品			
A	給食施設	3 学 校	ニ その他	A 給食施設	8 製造所	1 5 その他			
a	事業所等	A 給食施設	b 共同調理場	B 寄宿舍	9 仕 出 所	1 6 不			
b	保育所	a 単独調理場	c その他	C その他	1 0 採取場所	1 1 他			
c	老人ホーム	イ 幼稚園	B 寄宿舍	5 旅 館	1 1 他	1 2 不			

[魚介類]	[魚介類加工品]	7 卵類及びその加工品	1 0 豆	1 4 複合調理食品
1 貝類	4 魚肉練り製品	8 乳類及びその加工品	1 1 きこの類	1 5 その他
2 ふぐ	5 そ の 他	9 穀類及びその加工品	1 2 そ の 他	1 6 不
3 その他	6 肉類及びその加工品	[野菜類及びその加工品]	1 3 菓子類	1 1 他

原因食品の種別番号				
確 定	1	1	1	1
推 定	2	2	2	2

1	家庭	b 保育所	3 学 校	c 中学校	4 病院	5 旅 館			
2	A 事業場	c 老人ホーム	A 食堂又は教室	d その他	A 病室	6 飲食店	6 飲食店	6 飲食店	6 飲食店
A	食堂又は居室	B 寄宿舍	a 幼稚園	B 寄宿舍	B 寄宿舍	7 その他	7 その他	7 その他	7 その他
a	事業所等	C その他	b 小学校	C その他	C その他	8 不	8 不	8 不	8 不

1	有	2	無	3	不明
---	---	---	---	---	----





Translation:

- 1) Food-Poisoning Incident Card
- 2) Date
- 3) Code of Health Center
- 4) Prefecture, etc. Incident No.
- 5) Health Center Incident No.
- 6) Location of home/business persons/facilities, etc. involved in the poisoning
  1. Domestic (Prefecture City/District Ward/Town/Village)
  2. Overseas
  3. Unknown
- 7) First poisoning case  
Date of onset                      Date of the receipt of report by health center
- 8) Name of business person/facility/etc. involved in the poisoning
- 9) Category of home/business person/facility/etc. involved in the poisoning
  1. Home
  2. Business place
    - A. Catering establishment
      - a. Company, etc.
      - b. Nursery school
      - c. Nursing home for aged people
    - B. Dormitory
    - C. Others
  3. School
    - A. School-lunch catering establishment
      - a. School-owned lunch preparation facility
        - 1) Kindergarten
        - 2) Primary school
        - 3) Junior high school
        - 4) Others
      - b. Plural schools-shared preparation facility
      - c. Others
    - B. Dormitory
    - C. Others
  4. Hospital
    - A. Food catering establishment
    - B. Dormitory
    - C. Others
  5. Hotel or inn
  6. Eating establishment
  7. Selling establishment
  8. Manufacturing establishment
  9. Caterer
  10. Collecting place (i.e., a place where foods in question were collected, in the case of fish/shellfish or mushrooms, etc.)
  11. Others
  12. Unknown
- 10) Poisoned food
- 11) Category of poisoned food  
[Fish/shellfish]: 1. Shellfish 2. Blowfish 3. Other  
[Processed fish/shellfish]: 4. Fish-paste products 5. Other.  
6. Meat and its processed products  
7. Eggs and their processed products  
8. Milk and its processed products  
9. Cereal grains and their products

- [Vegetables and their products]: 10. Pulses 11. Mushrooms 12. Other
13. Confections
  14. Assorted prepared foods
  15. Other
  16. Unknown
- 12) Judgment of poisoned food
    - Category number of poisoned food
    - Determined 1
    - Presumed 2
  - 13) Place of consumption
  - 14) Category of place of consumption
    1. Home
    2. Business place
      - A. Dining room, or office or room other than dining room
        - a. Company, etc.
        - b. Nursery school
        - c. Nursing home for aged people
      - B. Dormitory
      - C. Others
    3. School
      - A. Dining room or class room
        - a. Kindergarten
        - b. Primary school
        - c. Junior high school
        - d. Others
    4. Hospital
      - A. Patient room
      - B. Dormitory
      - C. Others
    5. Hotel or inn
    6. Eating establishment
    7. Others
    8. Unknown
  - 15) Whether or not cooking was done at the place of consumption
    1. Yes 2. No 3. Unknown
  - 16) Pathogenic substance
  - 17) Category of pathogenic substance
    1. Salmonella 2. Staphylococcus 3. Botulinus 4. Enteritis vibrio 5. Enterohemorrhagic escherichia coli 6. Pathogenic coliform bacteria 7. Welch bacteria 8. Cereus bacteria 9. Yersinia enterocolitica 10. Campylobacter jejuni/coli 11. Nagvibrio 12. Vibrio cholerae 13. Shigella dysenteriae 14. Salmonella typhi 15. Salmonella paratyphi A 16. Other bacteria 17. Noro virus 18. Other viruses 19. Chemical substances 20. Phytotoxins 21. Animal inherent toxins 22. Others 23. Unknown
  - 18) Examination
  - 19) Examination
  - 20) Sample
  - 21) Performance of examination
    1. Yes 2. No
  - 22) Presence or absence of pathogenic substances (mark only when the above section is marked as "yes".)
    3. Presence 4. Absence
  - 23) Substances taken from poisoned persons
  - 24) Substances taken from other persons
  - 25) Foods
  - 26) Apparatus and containers/packages

- 27) Others
- 28) Numbers of persons poisoned and deceased, and number of persons who consumed the poisoned food.
- 29) Numbers of persons poisoned and deceased
- 30) Age
- 31) Male
- 32) Female
- 33) Poisoned
- 34) Deceased
- 35) Total number
- 36) Zero-year old
- 37) Unknown
- 38) Number of persons poisoned (Total)
- 39) Number of persons deceased(Total)
- 40) Number of persons who consumed poisoned food
- 41) Sent to: Prefecture From Health Center Pages
- 42) Notes

Form No. 15 (Related to Article 76)

F

食中毒事件調査結果報告書<sup>1)</sup>

平成 年 月 日<sup>2)</sup>

都道府県知事等 印<sup>3)</sup>

厚生労働大臣 殿<sup>4)</sup>

平成 年 月分食中毒事件調査の結果を下記の通り報告する。<sup>5)</sup>

食中毒事件票 枚<sup>6)</sup>

(内訳)<sup>7)</sup>

都道府県等事件番号 <sup>8)</sup>	病因物質名 <sup>9)</sup>	患者数 <sup>10)</sup>	死者数 <sup>11)</sup>	原因食品名 <sup>12)</sup>

JIS A4-size paper

Translation:

- 1) Report on Investigation Result Concerning Food-Poisoning Incidents
- 2) Date
- 3) Governor of Prefecture (or Mayor of Designated City) and seal (reporter)
- 4) Addressed to Minister of Health, Labour and Welfare
- 5) I hereby report the investigation results concerning food-poisoning incidents for (month of year (HEISEI)).
- 6) No. of Food-Poisoning Incident Cards      Pages
- 7) Items
- 8) Incident No. of Prefecture, etc.
- 9) Pathogenic substance
- 10) Number of persons poisoned (Total)
- 11) Number of persons deceased (Total)
- 12) Poisoned food

**Table 1 (related to Articles 12 and 21)**

Acesulfame potassium (Acesulfame K) (12)	L-Ascorbyl Stearate (Vitamin C Stearate) (7)
Acetic Acid, Glacial (249)	Aspartame ( $\alpha$ -L-Aspartyl-L-Phenylalanine-Methyl Ester) (11)
Acetone (15)	Benzaldehyde (283)
Acetophenone (14)	Benzoic Acid (23)
Adipic Acid (3)	Benzoyl Peroxide (61)
DL-Alanine (18)	Benzyl Acetate (118)
Aliphatic Higher Alcohols (141)	Benzyl Alcohol (282)
Aliphatic Higher Aldehydes (except harmful substances) (142)	Benzyl Propionate (274)
Aliphatic Higher Hydrocarbons (except harmful substances) (143)	Biotin (239)
Allyl Cyclohexylpropionate (129)	Bisbentiamine (Benzoyl Thiamine Disulfide) (241)
Allyl Hexanoate (Allyl Caproate) (277)	<i>d</i> -Borneol (293)
Allyl Isothiocyanate (Volatile Oil of Mustard) (33)	Butyl Acetate (117)
Aluminium Ammonium Sulfate (crystal: Ammonium Alum, exsiccated: Ammonium Alum, Exsiccated) (324)	Butyl Butyrate (312)
Aluminium Potassium Sulfate (crystal: Alum, Potassium Alum, exsiccated: Alum, Exsiccated) (325)	Butyl <i>p</i> -Hydroxybenzoate (233)
Ammonia (26)	Butylated Hydroxyanisole (265)
Ammonium Bicarbonate (Ammonium Hydrogen Carbonate) (183)	Butylated Hydroxytoluene (137)
Ammonium Carbonate (180)	Butyric Acid (308)
Ammonium Chloride (49)	Calcium 5'-Ribonucleotide (318)
Ammonium Dihydrogen Phosphate (Monoammonium Phosphate, Acid Ammonium Phosphate) (338)	Calcium Carbonate (182)
Ammonium Persulfate (63)	Calcium Carboxymethylcellulose (Calcium Cellulose Glycolate) (64)
Ammonium Sulfate (326)	Calcium Chloride (51)
$\alpha$ -Amylcinnamaldehyde ( $\alpha$ -Amylcinnamic Aldehyde) (17)	Calcium Citrate (75)
Anisaldehyde ( <i>p</i> -Methoxybenzaldehyde) (16)	Calcium Dihydrogen Phosphate (Monobasic Calcium Phosphate, Acidic Calcium Phosphate) (342)
L-Arginine L-Glutamate (20)	Calcium Dihydrogen Pyrophosphate (Acidic Calcium Pyrophosphate) (254)
Aromatic Alcohols (284)	Calcium Disodium Ethylenediaminetetraacetate (Calcium Disodium EDTA) (43)
Aromatic Aldehydes (except harmful substances) (285)	Calcium Ferrocyanide (Calcium Hexacyanoferrate (II)) (264)
L-Ascorbic Acid (Vitamin C) (5)	Calcium Gluconate (88)
L-Ascorbic Acid 2-Glucoside (6)	Calcium Glycerophosphate (83)
L-Ascorbyl Palmitate (Vitamin C Palmitate) (9)	Calcium Hydroxide (Slaked Lime) (171)
	Calcium Lactate (223)
	Calcium Monohydrogen Phosphate (Dibasic Calcium Phosphate, Calcium Hydrogen Phosphate) (341)

Calcium Pantothenate (237)  
 Calcium Propionate (272)  
 Calcium Stearoyl Lactylate (175)  
 Calcium Sulfate (327)  
 Carbon Dioxide (Carbonic Acid, Anhydrous) (220)  
 $\beta$ -Carotene (66)  
 Chlorine Dioxide (218)  
 Cholecalciferol (Vitamin D<sub>3</sub>) (105)  
 1, 8-Cineole (Eucalyptol) (135)  
 Cinnamaldehyde (Cinnamic Aldehyde) (169)  
 Cinnamic Acid (96)  
 Cinnamyl Acetate (112)  
 Cinnamyl Alcohol (168)  
 Citral (132)  
 Citric Acid (72)  
 Citronellal (133)  
 Citronellol (134)  
 Citronellyl Acetate (111)  
 Citronellyl Formate (69)  
 Copper Chlorophyll (208)  
 Copper Salts (limited to Copper Gluconate and Cupric Sulfate) (206)  
 Cyclohexyl Acetate (110)  
 Cyclohexyl Butyrate (311)  
 L-Cysteine Monohydrochloride (130)  
 Decanal (Decyl Aldehyde) (197)  
 Decanol (Decyl Alcohol) (198)  
 Diammonium Hydrogen Phosphate (Diammonium Phosphate, Dibasic Ammonium Phosphate) (337)  
 Dibenzoyl Thiamine (138)  
 Dibenzoyl Thiamine Hydrochloride (139)  
 Diphenyl (Biphenyl) (136)  
 Dipotassium Hydrogen Phosphate (Dipotassium Phosphate, Dibasic Potassium Phosphate) (339)  
 Disodium 5'-Cytidilate (Sodium 5'-Cytidilate) (131)  
 Disodium Dihydrogen Pyrophosphate (Acidic Disodium Pyrophosphate) (255)  
 Disodium Ethylenediaminetetraacetate (Disodium EDTA) (44)  
 Disodium Glycyrrhizinate (84)  
 Disodium 5'-Guanylate (Sodium 5'-Guanylate) (71)  
 Disodium Hydrogen Phosphate (Disodium Phosphate, Dibasic Sodium Phosphate) (343)  
 Disodium 5'-Inosinate (Sodium 5'-Inosinate) (35)  
 Disodium 5'-Ribonucleotide (Sodium 5'-Ribonucleotide) (319)  
 Disodium Succinate (104)  
 Disodium DL-Tartrate (Disodium *dl*-Tartrate) (150)  
 Disodium L-Tartrate (Disodium *d*-Tartrate) (151)  
 Disodium 5'-Uridilate (Sodium 5'-Uridilate) (38)  
 Ergocalciferol (Calciferol, Vitamin D<sub>2</sub>) (48)  
 Erythorbic Acid (Isoascorbic Acid) (46)  
 Ester Gum (40)  
 Esters (41)  
 Ethers (45)  
 Ethyl Acetate (108)  
 Ethyl Acetoacetate (13)  
 Ethyl Butyrate (310)  
 Ethyl Cinnamate (97)  
 Ethyl Decanoate (Ethyl Caprate) (199)  
 Ethyl Heptanoate (Ethyl Oenanthatate) (280)  
 Ethyl Hexanoate (Ethyl Caproate) (279)  
 Ethyl *p*-Hydroxybenzoate (232)  
 Ethyl Isovalerate (31)  
 Ethyl Octanoate (Ethyl Caprylate) (57)  
 Ethyl Phenylacetate (261)  
 Ethyl Propionate (271)  
 Ethylvanillin (42)  
 Eugenol (55)  
 Fatty Acids (140)  
 Ferric Ammonium Citrate (78)  
 Ferric Chloride (52)  
 Ferric Citrate (77)  
 Ferric Pyrophosphate (256)

Ferrous Gluconate (89)  
 Ferrous Sulfate (328)  
 Folic Acid (307)  
 Food Blue No. 1 (Brilliant Blue FCF) and its Aluminium Lake (164)  
 Food Blue No. 2 (Indigo Carmine) and its Aluminium Lake (165)  
 Food Green No. 3 (Fast Green FCF) and its Aluminium Lake (163)  
 Food Red No. 102 (New Coccine) (157)  
 Food Red No. 104 (Phloxine) (158)  
 Food Red No. 105 (Rose Bengale) (159)  
 Food Red No. 106 (Acid Red) (160)  
 Food Red No. 2 (Amaranth) and its Aluminium Lake (154)  
 Food Red No. 3 (Erythrosine) and its Aluminium Lake (155)  
 Food Red No. 40 (Allura Red AC) and its Aluminium Lake (156)  
 Food Yellow No. 4 (Tartrazine) and its Aluminium Lake (161)  
 Food Yellow No. 5 (Sunset Yellow FCF) and its Aluminium Lake (162)  
 Fumaric Acid (266)  
 Furfurals and its derivatives (except harmful substances) (268)  
 Geraniol (100)  
 Geranyl Acetate (109)  
 Geranyl Formate (68)  
 Gluconic Acid (86)  
 Glucono  $\delta$ -Lactone (85)  
 L-Glutamic Acid (91)  
 Glycerol (81)  
 Glycerol Esters of Fatty Acids (82)  
 Glycine (80)  
 Hexanoic Acid (Caproic Acid) (277)  
 High-Test Hypochlorite (101)  
 L-Histidine Monohydrochloride (240)  
 Hydrochloric Acid (54)  
 Hydrogen Peroxide (60)  
 Hydroxycitronellal (244)  
 Hydroxycitronellal Dimethylacetal (245)  
 Hydroxypropyl Methylcellulose (246)  
 Hypochlorous Acid Water (126)  
 Imazalil (36)  
 Indole and its derivatives (37)  
 Ion Exchange Resin (28)  
 Ionone (27)  
 Iron Lactate (224)  
 Iron Sesquioxide (Iron Oxide Red) (125)  
 Isoamyl Acetate (107)  
 Isoamyl Butyrate (307)  
 Isoamyl Formate (67)  
 Isoamyl Isovalerate (30)  
 Isoamyl Phenylacetate (259)  
 Isoamyl Propionate (270)  
 Isobutyl p-Hydroxybenzoate (230)  
 Isobutyl Phenylacetate (260)  
 Isoeugenol (29)  
 L-Isoleucine (34)  
 Isopropyl Citrate (73)  
 Isopropyl p-Hydroxybenzoate (231)  
 Isothiocyanates (except harmful substances) (32)  
 Ketones (99)  
 Lactic Acid (222)  
 Lactones (except harmful substances) (313)  
 Linalool (317)  
 Linalyl Acetate (120)  
 L-Lysine L-Aspartate (314)  
 L-Lysine L-Glutamate (316)  
 L-Lysine Monohydrochloride (315)  
 Magnesium Carbonate (186)  
 Magnesium Chloride (53)  
 Magnesium Oxide (124)  
 Magnesium Stearate (174)  
 Magnesium Sulfate (330)  
 DL-Malic Acid (*d,l*-Malic Acid) (331)  
 Maltol (294)  
 D-Mannitol (D-Mannite) (295)  
*d l*-Menthol (304)  
*l*-Menthol (305)

*l*-Menthyl Acetate (119)  
 DL-Methionine (298)  
 L-Methionine (299)  
 Methyl Anthranilate (25)  
 Methylcellulose (301)  
 Methyl Cinnamate (98)  
 Methyl Hesperidin (Soluble Vitamin P) (303)  
 Methyl N-Methylantranilate (300)  
 Methyl Salicylate (123)  
 Methyl  $\beta$ -Naphthyl Ketone (302)  
*p*-Methylacetophenone (235)  
 Monocalcium Di-L-Glutamate (93)  
 Monomagnesium Di-L-Glutamate (95)  
 Monopotassium Citrate and Tripotassium Citrate (74)  
 Monopotassium L-Glutamate (92)  
 Monosodium Fumarate ( Sodium Fumarate) (267)  
 Monosodium L-Aspartate (10)  
 Monosodium L-Glutamate (94)  
 Monosodium Succinate (103)  
 Morpholine Salts of Fatty Acids (306)  
 Nicotinamide (Niacinamide) (216)  
 Nicotinic Acid (Niacin) (215)  
 $\gamma$ -Nonalactone (Nonalactone) (226)  
 Octanal (Octyl Aldehyde, Caprylic Aldehyde) (56)  
 Oxalic Acid (144)  
*l*-Perillaldehyde (281)  
 Phenethyl Acetate (Phenylethyl Acetate) (116)  
 Phenol Ethers (except harmful substances) (262)  
 Phenols (except harmful substances) (263)  
 L-Phenylalanine (258)  
*o*-Phenylphenol and Sodium *o*-Phenylphenate (58)  
 Phosphoric Acid (333)  
 Piperonal (Heliotropine) (247)  
 Piperonyl Butoxide (248)  
 Polybutene (Polybutylene) (290)  
 Polyisobutylene (Butyl Rubber) (288)  
 Polyvinyl Acetate (115)  
 Polyvinylpolypyrrolidone (289)  
 Potassium DL-Bitartrate (Potassium Hydrogen DL-Tartrate, Potassium Hydrogen *d*-Tartrate) (148)  
 Potassium L-Bitartrate (Potassium Hydrogen L-Tartrate, Potassium Hydrogen *d*-Tartrate) (149)  
 Potassium Bromate (145)  
 Potassium Carbonate, Anhydrous (181)  
 Potassium Chloride (50)  
 Potassium Dihydrogen Phosphate (Monopotassium Phosphate, Monobasic Potassium Phosphate) (340)  
 Potassium Ferrocyanide (Potassium Hexacyanoferrate (II)) (264)  
 Potassium Gluconate (87)  
 Potassium Hydroxide (Caustic Potash) (170)  
 Potassium Metaphosphate (296)  
 Potassium Nitrate (152)  
 Potassium Norbixin (227)  
 Potassium Polyphosphate (291)  
 Potassium Pyrophosphate (Tetrapotassium Pyrophosphate) (253)  
 Potassium Pyrosulfite (Potassium Hydrogen Sulfite, Potassium Metabisulfite) (251)  
 Potassium Sorbate (179)  
 Propionic Acid (269)  
 Propyl Gallate (286)  
 Propyl *p*-Hydroxybenzoate (234)  
 Propylene Glycol (275)  
 Propylene Glycol Alginate (22)  
 Propylene Glycol Esters of Fatty Acids (276)  
 Pyridoxine Hydrochloride (Vitamin B<sub>6</sub>) (250)  
 Riboflavin (Vitamin B<sub>2</sub>) (320)  
 Riboflavin 5'-Phosphate Sodium (Sodium Riboflavin Phosphate, Sodium Vitamin B<sub>2</sub> Phosphate) (322)  
 Riboflavin Tetrabutryate (Vitamin B<sub>2</sub> Tetrabutryate) (321)  
 Saccharin (121)  
 Silicon Dioxide (Silica Gel) (219)



Silicone Resin (Polydimethyl Siloxane) (167)

Sodium Acetate (114)

Sodium Alginate (21)

Sodium L-Ascorbate (Vitamin C Sodium) (8)

Sodium Benzoate (24)

Sodium Bicarbonate (Sodium Hydrogen Carbonate, Bicarbonate of Soda) (184)

Sodium Carbonate (crystal: Carbonate of Soda, anhydrous: Soda Ash) (185)

Sodium Carboxymethylcellulose (Sodium Cellulose Glycolate) (65)

Sodium Carboxymethylstarch (204)

Sodium Caseinate (62)

Sodium Chlorite (2)

Sodium Chondroitin Sulfate (106)

Sodium Copper Chlorophyllin (207)

Sodium Dehydroacetate (201)

Sodium Dihydrogen Phosphate (Monosodium Phosphate, Monobasic Sodium Phosphate) (344)

Sodium Erythorbate (Sodium Isoascorbate) (47)

Sodium Ferrocyanide (Sodium Hexacyanoferrate (II))(264)

Sodium Ferrous Citrate (76)

Sodium Gluconate (90)

Sodium Hydrosulfite (128)

Sodium Hydroxide (Caustic Soda) (172)

Sodium Hypochlorite (Hypochlorite of Soda) (127)

Sodium Iron Chlorophyllin (200)

Sodium Lactate (225)

Sodium DL-Malate (Sodium *d*-Malate) (332)

Sodium Metaphosphate (297)

Sodium Methoxide (Sodium Methylate) (214)

Sodium Nitrate (153)

Sodium Nitrite (4)

Sodium Norbixin (228)

Sodium Oleate (59)

Sodium Pantothenate (238)

Sodium Polyacrylate (287)

Sodium Polyphosphate (292)

Sodium Propionate (273)

Sodium Pyrophosphate (Tetrasodium Pyrophosphate) (257)

Sodium Pyrosulfite (Sodium Hydrogen Sulfite, Sodium Metabisulfite, Acidic Sulfite of Soda) (252)

Sodium Saccharin (Soluble Saccharin) (122)

Sodium Starch Phosphate (205)

Sodium Sulfate (329)

Sodium Sulfite (Sulfite of Soda) (19)

Sorbic Acid (178)

Sorbitan Esters of Fatty Acids (176)

D-Sorbitol (D-Sorbit) (177)

Succinic Acid (102)

Sucralose (Trichloro Galactosucrose) (173)

Sucrose Esters of Fatty Acids (166)

Sulfur Dioxide (Sulfurous Acid, Anhydride) (217)

Sulfuric Acid (323)

DL-Tartaric Acid (*d*-Tartaric Acid) (146)

L-Tartaric Acid (*l*-Tartaric Acid) (147)

Terpene Hydrocarbons (203)

Terpineol (202)

Terpinyl Acetate (113)

L-Theanine (196)

Thiabendazole (187)

Thiamine Dicetylsulfate (Vitamin B<sub>1</sub> Dicetylsulfate) (190)

Thiamine Dilaurylsulfate (Vitamin B<sub>1</sub> Dilaurylsulfate) (193)

Thiamine Hydrochloride (Vitamin B<sub>1</sub> Hydrochloride) (188)

Thiamine Mononitrate (Vitamin B<sub>1</sub> Mononitrate) (189)

Thiamine Naphthalene-1,5-Disulfonate (Vitamin B<sub>1</sub> Naphthalene-1,5-Disulfonate) (192)

Thiamine Thiocyanate (Vitamin B<sub>1</sub> Rhodanate) (191)

Thioethers (except harmful substances) (194)

Thiols (Thioalcohols) (except harmful

substances) (195)	Phosphate) (345)
DL-Threonine (212)	DL-Tryptophan (210)
L-Threonine (213)	L-Tryptophan (211)
Titanium Dioxide (221)	$\gamma$ -Undecalactone (Undecalactone) (39)
<i>dl</i> - $\alpha$ -Tocopherol (209)	L-Valine (236)
Tricalcium Phosphate (Tribasic Calcium Phosphate) (335)	Vanillin (229)
Trimagnesium Phosphate (Tribasic Magnesium Phosphate) (336)	Vitamin A (Retinol) (242)
Tripotassium Phosphate (Tribasic Potassium Phosphate) (334)	Vitamin A Esters of Fatty Acids (Retinol Esters of Fatty Acids) (243 )
Trisodium Citrate (Sodium Citrate) (79)	Xylitol (70)
Trisodium Phosphate (Tribasic Sodium	Zinc Salts (limited to Zinc Gluconate and Zinc Sulfate) (1)

**Table 2 (related to Article 13 )**

Category of foods	Substances which become causes for health hazards.
Nonalcoholic beverages	<ol style="list-style-type: none"> <li>1. Foreign contaminants</li> <li>2. <i>Yerushinia enterocolitica</i></li> <li>3. <i>Staphylococcus aureus</i></li> <li>4. <i>Campylobacter jejuni</i></li> <li>5. <i>Campylobacter coli</i></li> <li>6. <i>Clostridium</i> genus</li> <li>7. Antimicrobial substances [limited to "synthetic chemicals" contained in milk, etc. as raw materials ("milk, etc." means those defined as "milk, etc." in the Ministerial Ordinance concerning Compositional Standards, ETC. for Milk and Milk Products, or in their processed products; the same, hereinafter, in this Table), excluding antibiotics.]</li> <li>8. Antibiotics</li> <li>9. Bactericides</li> <li>10. <i>Salmonellae</i> genus</li> <li>11. Heavy metals and their compounds (target heavy metals and their compounds are confined to those which limits of quantity have been established as constituents of foods pursuant to Article 11 Paragraph 1 of the Law, being contained in raw materials, excluding antibiotics.)</li> <li>12. <i>Bacillus cereus</i></li> <li>13. Detergents</li> <li>14. Food additives (target food additives are confined to those for which standards for methods of use have been established pursuant to Article 11 Paragraph 1 of the Law, excluding bactericides; the same, hereinafter, in this Table.)</li> </ol>

(Continued)

Meat products	<ol style="list-style-type: none"><li>15. Substances which are ingredients of anthelmintics [target substances are confined to those for which the limits of quantity have been established as specifications for constituents of foods pursuant to Article 11 Paragraph 1 of the Law (including substances chemically formed from the substances); the same, hereinafter, in this Table.]</li><li>16. Substances which are ingredients of pesticides [target substances are confined to those for which the limits of quantity have been established as specifications for constituents of foods pursuant to Article 11 Paragraph 1 of the Law (including substances chemically formed from the substances); the same, hereinafter, in this Table.]</li><li>17. Enteropathogenic Escherichia coli</li><li>18. Putrefactive microbe (bacteria)</li><li>19. Listeria monocytogenes</li><li>1. Aflatoxin (in the case of aflatoxin, hereinafter target meat products are confined to those in which spices are used as raw materials)</li><li>2. Foreign contaminants</li><li>3. Staphylococcus aureus</li><li>4. Campylobacter jejuni</li><li>5. Campylobacter coli</li><li>6. Clostridium genus</li><li>7. Antimicrobial substances (limited to "synthetic chemicals" contained in milk, etc., meat, poultry eggs or fish/shellfish, or in their processed products, excluding antibiotics; the same, hereinafter, in this Table.)</li><li>8. Antibiotics</li><li>9. Bactericides</li><li>10. Salmonellae genus</li><li>11. Bacillus cereus</li><li>12. Detergents</li><li>13. Trichina worm</li><li>14. Vibrio parahaemolyticus (target meat products are confined to those in which fish/shellfish, whale meat or its processed products are used as raw materials.)</li><li>15. Food additives</li><li>16. Substances which are ingredients of anthelmintics</li><li>17. Enteropathogenic Escherichia coli</li><li>18. Putrefactive microbe (bacteria)</li><li>19. Substances which are ingredients of hormones [target hormones are confined to those (including those which are formed by chemical change of such substances) for which the limits of quantity have been established as specifications for constituents of meat pursuant to Article 11 Paragraph 1 of the Law.]</li></ol>
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(Continued)

Fish-paste products	<ol style="list-style-type: none"><li>1. Anisaks</li><li>2. Aflatoxin</li><li>3. Foreign contaminants</li><li>4. Staphylococcus aureus</li><li>5. Clostridium genus</li><li>6. Bactericides</li><li>7. Salmonellae genus</li><li>8. Pseudoterranova</li><li>9. Bacillus cereus</li><li>10. Detergents</li><li>11. Diplogonoporous grandis</li><li>12. Vibrio parahaemolyticus</li><li>13. Food Additives</li><li>14. Histamine (target foods are confined to those in which fish/shellfish or its processed products are used as raw materials.)</li><li>15. Enteropathogenic Escherichia coli</li><li>16. Putrefactive microbe</li></ol>
Foods packed into containers/packages and sterilized under pressure	<ol style="list-style-type: none"><li>1. Aflatoxin</li><li>2. Foreign contaminants</li><li>3. Staphylococcus aureus</li><li>4. Clostridium genus</li><li>5. Diarrheal and paralytic shellfish poison (target foods are confined to those in which shellfish or its processed products are used as raw materials.)</li><li>6. Antimicrobial substances</li><li>7. Antibiotics</li><li>8. Bactericides</li><li>9. Heavy metals and their compounds</li><li>10. Bacillus cereus</li><li>10. Detergents</li><li>12. Food additives</li><li>13. Substances which are ingredients of anthelminthics</li><li>14. Substances which are ingredients of pesticides</li><li>15. Histamine</li><li>16. Putrefactive microbes</li><li>17. Substances which are ingredients of hormones</li></ol>

**Table 3 (related to Article 21)**

1. Margarine
2. Alcoholic beverages (i.e., beverages which contain not less than 1 percent of alcohol by volume (including products in powder form for drinking which contain not less than 1 percent of alcohol by volume when dissolved))
3. Nonalcoholic beverage
4. Meat products
5. Fish ham, fish sausage, whale bacon, and such other products
6. Pulses which contain cyanide compounds
7. Frozen foods (i.e., manufactured or processed foods (except for meat products, whale meat products, fish-paste products, boiled octopus and boiled crabs) and cut or shelled fresh fish and shellfish (except for raw oysters) which are frozen and packed in containers or packages.)
8. Irradiated foods
9. Packaged products sterilized under pressure (i.e., foods which are packed into hermetic containers/packages, tightly sealed, and pasteurized under pressure.)
10. Poultry eggs
11. Foods (except for those listed above) packed in containers/packages which are listed below:
  - (a) Meat, raw oysters, raw noodles (including boiled noodles), instant noodles, ready-made lunches, prepared bread (i.e., bread between which a ready-to-eat food, such as ham, croquette, or salad, is sandwiched), fish-paste products, moist confectioneries, cut or shelled fish and shellfish (except for raw oysters), and boiled crabs.
  - (b) Processed foods other than those listed in (a)
  - (c) Citrus fruits, banana
12. Food of farm product listed in the left column of Table 7, and processed food that which uses the food as a raw material (including any food which uses the processed food as a raw material)
13. Food for special dietary use
14. Food additives

**Table 4 (related to Article 21)**

Aliphatic Higher Alcohols  
Aliphatic Higher Aldehydes  
Aliphatic Higher Hydrocarbons  
Aromatic Alcohol  
Aromatic Aldehydes  
Esters  
Ethers  
Fatty Acids  
Furfural and its Derivatives  
Indole and its Derivatives  
Isothiocyanates  
Ketones  
Lactones  
Phenol Ethers  
Phenols  
Terpene Hydrocarbons  
Thioethers  
Thiols

**Table 5 (related to Article 21)**

1. Sweetener	“甘味料”, “人工甘味料” or “合成甘味料”
2. Food color	“着色料” or “人工着色料”
3. Preservative	“保存料” or “合成保存料”
4. Thickening agent, stabilizer, gelling agent or KORYO (thickener)	“増粘剤” or “糊料”, where the substance is used mainly for thickening. “安定剤” or “糊料”, where the substance is used mainly for stabilizing. “ゲル化剤” or “糊料”, where the substance is used mainly for gelling.
5. Antioxidant	“酸化防止剤”
6. Color fixative	“発色剤”
7. Bleaching agent	“漂白剤”
8. Antimold agent	“防かび剤” or “防ばい剤”

**Table 6 (related to Article 21)**

Wheat  
Buckwheat  
Egg  
Milk  
Peanut

**Table 7 (related to Article 21)**

Farm product	Processed Food
Soybeans (including immature soybeans and bean sprout)	<ol style="list-style-type: none"> <li>1 TOFU (soybean curd) and ABURAAGE (fried soybean curd)</li> <li>2 KOORIDOFU (frozen soybean curd), OKARA (dried refuse of TOFU) and YUBA (dried membrane of soybean milk)</li> <li>3 NATTO (fermented soybeans)</li> <li>4 Soybean milk</li> <li>5 MISO (fermented soybean paste)</li> <li>6 Soybean NIMAME (sweetened cooked soybeans)</li> <li>7 Canned soybeans and bottled soybeans</li> <li>8 KINAKO (roasted soybean flour)</li> <li>9 Roasted soybeans</li> <li>10 Food which uses those given in Nos. 1 through the precedent No. as the principal raw materials</li> <li>11 Food which uses soybean for preparation as the principal raw material</li> <li>12 Food which uses soybean flour as the principal raw material</li> </ol>

(Continued)

Farm product	Processed Food
	13 Food which uses soybean protein as the principal raw material 14 Food which uses immature soybean as the principal raw material 15 Food which uses soybean sprouts as the principal raw material
Corn	1 Corn snack confectionery 2 Corn starch 3 Popcorn 4 Frozen corn 5 Canned corn and bottled corn 6 Food which uses corn flour as the principal raw material 7 Food which uses corn grits as the principal raw material (excluding corn flakes) 8 Food which uses corn for preparation as the principal raw material 9 Food which uses those given in Nos. 1 through 5 as the principal raw materials
Potato	1 Potato snack confectionery 2 Dried potato 3 Frozen potato 4 Potato starch 5 Food which uses potato for preparation as the principal raw material 6 Food which uses those given in Nos. 1 through 4 as the principal raw materials
Rapeseed	
Cottonseed	

**Table 8 (related to Article 21)**

Yeast food	“ イーストフード ”
Gum base	“ ガムベース ”
KANSUI <sup>1)</sup>	“ かんすい ”
Enzyme	“ 酵素 ”
Glazing agent	“ 光沢剤 ”
Flavoring agent	“ 香料 ” or “ 合成香料 ”
Acidifier	“ 酸味料 ”

(Continued)

Softener for chewing gum	“軟化剤”
CHOMIRYO (excluding sweeteners where the substance is composed exclusively or acidifiers) <sup>2)</sup>	“調味料(アミノ酸)”, where the substance is composed exclusively of amino acids. “調味料(アミノ酸等)”, where the substance is composed mainly of amino acids (except where the substance is composed exclusively of amino acids). “調味料(核酸)”, where the substance is composed exclusively of nucleic acids. “調味料(核酸等)”, where the substance is composed mainly of nucleic acids (except where the substance is composed exclusively of nucleic acids). “調味料(有機酸)”, where the substance is composed exclusively of organic acids. “調味料(有機酸等)”, where the substance is composed mainly of organic acids (except where the substance is composed exclusively of organic acids). “調味料(無機塩)”, where the substance is composed exclusively of inorganic salts. “調味料(無機塩等)”, where the substance is composed mainly of inorganic salts(except where the substance is composed exclusively of inorganic salts).
Coagulant for TOFU <sup>3)</sup>	“豆腐用凝固剤” or “凝固剤”
Bittering agent	“苦味料”
Emulsifier	“乳化剤”
Acidity regulator	“pH調整剤”
Raising agent	“膨脹剤”, “膨張剤”, “ベーキングパウダー”, or “ふくらし粉”

Note

1): Alkaline preparations for Chinese noodles

2): Food Additives and their preparations used for imparting a taste or improving the original taste, such as seasoning or taste quality controlling

3): Soybean curd



**Table 9 (related to Article 21)**

Fruit juice as an ingredient (confined to products contained in cans with a capacity of not less than 200 liters)	When a delivery unit consisting of 10 cans or more is sold to a person licensed for a nonalcoholic-beverage-manufacturing business as prescribed in Article 35 Subparagraph (19) of the Cabinet Order.
Concentrated coffee for ingredient (confined to products contained in cans with a capacity of not less than 20 liters)	When a delivery unit consisting of 20 cans or more is sold to a person licensed for a nonalcoholic-beverage-manufacturing business as prescribed in Article 35 Subparagraph (19) of the Cabinet Order.
SURIMI as an ingredient (confined to products contained in containers/packages with a capacity of not less than 20 kilograms)	When a delivering unit consisting of 10 or more of containers/packages concerned is sold to a person licensed for a fish-paste-product-manufacturing business as prescribed in Article 35 Subparagraph (16) or for a ready-to-eat-food-preparing business as prescribed in Article 35 Subparagraph (32) of the Cabinet Order.

**Table 10 (related to Article 32)**

<p>Raw salt</p> <p>Copra</p> <p>Fats or oils of animal origin or plant origin which are used in the manufacture of edible fats and oils.</p> <p>Raw sugar</p> <p>Crude alcohol</p> <p>Molasses</p> <p>Malt</p> <p>Hop</p>
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**Table 11 (related to Article 32)**

Places of customs clearance	Names of quarantine stations
Hokkaido	Otaru
Aomori Pref., Iwate Pref., Miyagi Pref., Akita Pref., Yamagata Pref., Fukushima Pref.	Sendai
Chiba Pref. (confined to Narita C.; Oei-machi, Katori D.; Tako-machi, Katori D.; Shibayama-machi, Yamatake D. )	Narita Airport

(Continued)

Ibaragi Pref., Tochigi Pref., Gunma Pref., Saitama Pref., Chiba Pref. (excluding areas under the jurisdiction of the Narita Airport Quarantine Station), Tokyo Metropolis, Kanagawa Pref. (confined to Kawasaki C.), Yamanashi Pref., Nagano Pref.	Tokyo
Kanagawa Pref. (excluding areas under the jurisdiction of the Tokyo quarantine office)	Yokohama
Niigata Pref.	Niigata
Shizuoka Pref., Gifu Pref., Aichi Pref., Mie Pref., Wakayama Pref. (confined to Shingu C. and Higashi-muro D.)	Nagoya
Toyama Pref., Ishikawa Pref., Fukui Pref., Shiga Pref., Kyoto Pref., Osaka Pref. (excluding areas under the jurisdiction of the Kansai Airport Quarantine Station), Nara Pref., Wakayama Pref. (excluding areas under the jurisdiction of the Nagoya Quarantine Station)	Osaka
Osaka Pref. (confined to the Kansai Airport Quarantine Station)	Kansai Airport
Hyogo Pref., Okayama Pref., Tokushima Pref., Kagawa Pref.	Kobe
Tottori Pref., Shimane Pref., Hiroshima Pref., Ehime Pref., Kochi Pref.	Hiroshima
Yamaguchi Pref., Fukuoka Pref., Saga Pref., Nagasaki Pref., Kumamoto Pref., Ooita Pref., Miyazaki Pref., Kagoshima Pref.	Fukuoka
Okinawa Pref.	Naha

Note: The areas listed above are based on administrative areas as of September 1, 1993 and other areas.

**Table 12 (Related to Article 32)**

1	Machines used for the manufacture of foods Apparatus or containers/packages made of aluminium Apparatus or containers/packages made of stainless steel Apparatus or containers/packages made of colorless glass	Three years from the date of the submission of an import notification
2	Alphanized rice Ethyl alcohol Barley Canned foods or bottled foods (excluding meat products or wine) Original alcohol not bottled for retail (excluding original wine) Kaoliang Sesame Wheat	One year from the date of the submission of an import notification

(Continued)

	<p>Rice</p> <p>Safflower seeds</p> <p>Distilled alcohol</p> <p>Foods (excluding meat products) which are placed in airtight containers/packages, sealed, then autoclaved (pressure-and heat-sterilized) (excluding canned foods and bottled foods)</p> <p>Vegetable protein</p> <p>Soybean</p> <p>Starch (excluding tapioca starch)</p> <p>Animal fats and oils (excluding fats and oils of fish and sea mammals)</p> <p>Rapeseed</p> <p>Sunflower seeds</p> <p>Indian millet</p> <p>Rye</p> <p>Apparatus or containers/packages made of materials other than Aluminium, stainless steel, colorless glass, or synthetic resins</p>	
3	<p>The following foods which had been continuously imported before the submission of an import notification stating the items specified in Article 32, Paragraph 4 and had never fallen into any of the items specified in the same Paragraph for three years before the submission of the notification.</p> <p>AN (sweetened bean paste)</p> <p>Fruits and fruit peels temporarily stored</p> <p>Roasted coffee beans or ground roasted coffee beans</p> <p>Locusts boiled in water</p> <p>Fish roes (limited to those which were dried)</p> <p>Fish TSUKUDANI</p> <p>Fats and oils of fish or sea mammals</p> <p>Oat meal</p> <p>Seaweeds</p> <p>Cacao beans (excluding roasted ones)</p> <p>Original wine</p> <p>Frozen foods requiring heating before consumption</p> <p>Gymnema tea</p> <p>Fruit juices for ingredients</p> <p>Flours of cereals, beans, or potatoes</p> <p>Cocoa products (excluding powdered nonalcoholic beverages)</p> <p>Coffee extract</p> <p>Coffee beans (excluding roasted ones)</p> <p>Corn flakes</p> <p>KONNYAKU (jelly made of taro)</p>	<p>One year from the date of the submission of an import notification</p>

(Continued)

Salt	
Vegetable creaming powders	
Shortening	
SAKE (rice wine)	
Tea	
Chocolates	
Sugar	
Tochu tea	
NIMAME (cooked beans)	
Larvae of wasps boiled in water	
Honey with beehives	
Breads	
Bread mixes	
Beer	
Margarine	
Mate tea	
MIRIN (a sweet kind of SAKE)	
Noodles	
Vegetables boiled in water	
Vegetables purée or paste	
Frozen fruits (excluding frozen manufactured or processed fruits)	
Frozen vegetables (excluding frozen manufactured or processed vegetables)	
Food additives other than those listed in Attached Table 1 (excluding additives for which standards or specifications have been established pursuant to Article 11, Paragraph 1.)	
Apparatus or containers/packages made of synthetic resin	

**Table 13 (related to Articles 37 and 40)**

Type of standard operation procedure	Items which must be indicated
Maintenance of machinery/apparatus	<ol style="list-style-type: none"> <li>1. The name of the machinery/apparatus</li> <li>2. The method used for routine maintenance (including calibration of gauges)</li> <li>3. A plan for regular maintenance</li> <li>4. Measures to be taken if a breakdown occurs (including how to handle test samples if a breakdown occurs during testing.)</li> <li>5. The method for keeping record books concerning maintenance</li> <li>6. The dates of preparing and revising the standard operation procedure</li> </ol>
Reagents, etc. management	<ol style="list-style-type: none"> <li>1. The method of labeling the containers used for reagents, test solutions, culture medium, reference standards, standard solutions, and standard microorganism strains (referred to as reagents, etc.)</li> <li>2. Cautions concerning management of reagents, etc.</li> <li>3. The method for keeping record books concerning managing reagents, etc.</li> <li>4. The dates of preparing and revising the standard operation procedure</li> </ol>
Animal husbandry management	<ol style="list-style-type: none"> <li>1. The method for managing animal breeding rooms</li> <li>2. Cautions regarding receiving animals</li> <li>3. The method for animal husbandry</li> <li>4. The method for observation of health conditions</li> <li>5. The method for handling animals suffering from or suspected of suffering from diseases</li> <li>6. The method for keeping record books concerning animal husbandry</li> <li>7. The date of preparing and revising the standard operation procedure</li> </ol>
Handling of test sample	<ol style="list-style-type: none"> <li>1. Cautions on collecting, moving, and receiving test samples</li> <li>2. The method for managing test samples</li> <li>3. The method for keeping record books concerning management of test samples</li> <li>4. The date of preparing and revising the standard operation procedure</li> </ol>

(Continued)

Performance of examinations	<ol style="list-style-type: none"><li>1. Items (Types) of examinations, etc.</li><li>2. The name of the product</li><li>3. The method for performing examination, etc.</li><li>4. Methods for selecting and preparing reagents</li><li>5. The method of handling standard microbe strains for microbiological tests</li><li>6. The method of preparing samples</li><li>7. The method of operating machinery/apparatus used for examinations, etc.</li><li>8. Cautions on performing examinations, etc.</li><li>9. The method of processing data obtained by examinations, etc.</li><li>10. The method for keeping record books concerning examinations, etc.</li><li>11. The dates of preparing and revising the standard operation procedure</li></ol>
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**Table 14. (Related to Article 50)**

Curriculum	Subjects
Chemistry	Analytical chemistry, Organic chemistry, Inorganic chemistry
Biological chemistry	Biological chemistry, Food chemistry, Physiology, Food analysis, Toxicology
Microbiology	Microbiology, Food microbiology, Food preservation, Food manufacture
Public health	Public health, Food hygiene, Environmental hygiene, Health administration, Epidemiology

**Table 15. (Related to Article 50)**

Fishery chemistry, Livestock chemistry, Radiation chemistry, Dairy chemistry, Meat chemistry, High polymer chemistry, Biological organic chemistry, Analysis of environmental pollution substances, Enzyme chemistry, Physical and chemical study of food, Fishery physiology, Livestock physiology, Plant physiology, Environmental biology, Applied microbiology, Dairy microbiology, Pathology, Outline of medical science, Anatomy, Medical chemistry, Industrial medical science, Blood science, Genetics, Parasite science, Veterinary medicine, Nutritional chemistry, Health statistics, Nutritional science, Environmental health, Health supervision, Fishery manufacture, Livestock products manufacture, Agricultural products manufacture, Manufacture of brewery products and seasoning products, Dairy products manufacture, Distilled wine manufacture, Canned products engineering, Food engineering, Food preservation, Freezing and cold storage, Quality control, and other subject related to food sanitation

**Table 16. (Related to Article 56)**

	Classification	Subjects	
1	General common subjects	1. Outline of public health 2. Food Sanitation Law and related laws, ordinances and regulations 3. Specifications and standards of foods, food additives, etc. 4. Outline of chemistry 5. Introduction to bacteriology 6. Toxicology 7. Food poisoning 8. Food science (including Nutritional science) 9. Sanitation control in facilities	9 18 18 18 18 9 15 18 9
2	Subjects related to dairy products	1. Specifications and standards of dairy products 2. Practice on bacteriology 3. Examination methods of dairy products 4. Practice on dairy products examination 5. Visits to facilities and on-site trainings	12 18 6 18 15
3	Subjects related to meat products	1. Specifications and standards of meat products 2. Practice on bacteriology 3. Examination methods of meat products 4. Practice on meat products examination 5. Visits to facilities and on-site trainings	12 18 6 18 15
4	Subjects related to fish ham and fish sausage	1. Related laws, ordinances and regulations concerning fish ham and fish sausage, and specifications and standards 2. Practice on bacteriology 3. Examination methods of fish ham and fish sausage 4. Practice on fish ham and fish sausage examination 5. Visits to facilities and on-site trainings	15 18 9 15 15
5	Subjects related to edible fats and oils	1. Outline of fat and oil chemistry 2. Foods and food additives with standards 3. Business work of food sanitation supervisor 4. Responsibility of food sanitation supervisor 5. Theory and practice on examination methods of fat and oil 6. Visits to facilities and on-site trainings	10 14 4 3 28 10

(continued)

6	Subjects related to margarine and shortenings	1. Nutritional science and analytical methods	6
		2. Sanitation control in manufacturing process	6
		3. Sanitation standards in manufacturing process	3
		4. Judgment method of food additives	6
		5. Practice on analytical methods	16
		6. Practice on judgment method of food additives	15
		7. Visits to facilities and on-site trainings	21
7	Subjects related to food additives	1. Outline of analytical methods of food additives	9
		2. Judgment method of food additives	9
		3. Practice on judgment method of food additives	24
		4. Visits to facilities and on-site trainings	15

**Table 17. (Related to Article 73)**

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



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