

## **Food Sanitation Law**

Law No. 233, December 24, 1947  
Last amendment: Law No. 104, August 7, 2002

## 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 so as to contribute to the improvement and promotion of public health.

[Definitions]

**Article 2.** 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 "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 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 additives and which come into direct contact with food or 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 additives are contained or packaged and in which foods and additives are offered when such foods and additives are delivered.

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

**7.** In this Law, the term "electronic information processing system" means electronic information processing systems connected by an electric communication line between the computer concerned (hereinafter in this Law, including input/output units) used in the Ministry of Health, Labour and Welfare and each input/output unit used by those who wish to make notification pursuant to the provisions of Article 16.

**8.** In this Law, the term "business" means, as a business, the handling, manufacturing, importing, processing, preparing, storing, transporting, or selling of food or 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.

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

## Chapter 2. Food and Additives

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

**Article 3.** Any food or 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

(1) Foods or additives specified in each subparagraph of Article 4

(2) Foods specified in Article 6

(3) Foods or additives not in conformity with the specifications under the provisions of Article 7, Paragraph 1

(4) Foods to which additives had been used by a method not in conformity with the standards under the provisions of Article 7, Paragraph 1

2. On performing the dispositions 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 dispositions were performed according to the provisions of Paragraph 1, the Minister of Health, Labour and Welfare shall cancel by notice all or part of the dispositions, 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 dispositions or in case of need, after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Affairs Council.

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

**Article 5.** 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 (hereinafter in this Law, "livestock" means cattle, horses, pigs, sheep, goats, and other animals as designated by the Ministerial Ordinance<sup>1)</sup> ) which suffers from or is suspected to suffer from any of the diseases designated by the Ministerial Ordinance<sup>2)</sup> or which has died of any causes before slaughtering, or any meat, bone, or viscera of poultry (hereinafter in this Law, "poultry" means chickens, ducks, turkeys, and other fowls as designated by the Ministerial Ordinance) which suffers from or is suspected to suffer from any of the diseases designated by the Ministerial Ordinance<sup>3)</sup> 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>4)</sup>.

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>5)</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>6)</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 concerned prescribed in Article 2 Paragraph 7 on an electric communication line and recorded in a file on the computer.

(Reference)

1): Article 2 Paragraph 2 of the Ministerial Ordinance

2): Article 2 Paragraph 1 of the Ministerial Ordinance

3): Article 2 Paragraph 3 of the Ministerial Ordinance

- 4): Article 2 Paragraph 4 of the Ministerial Ordinance
- 5): Article 2-2 of the Ministerial Ordinance
- 6): Article 2-3 of the Ministerial Ordinance

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

**Article 6.** No person shall sell, or manufacture, import, process, use, store, or display with intent to sell any 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 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 3 of the Ministerial Ordinance (Table 2)

[Establishment of Specifications and Standards for Food or Additives]

**Article 7.** 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 additives intended for sale or may establish specifications for components of food or 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 additive by a method not complying with the established standards; or from manufacturing, importing, processing, using, preparing, preserving, or selling any food or additive not complying with the established specifications.

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

**Article 7-2.** 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 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) comprising pesticides which may remain in foods, as specifications for food components prescribed in Article 7 Paragraph 1.

[Comprehensive Sanitation-controlled Manufacturing Process]

**Article 7-3.** 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 7 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 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 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 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 7 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.

(Reference)

- 1) Article 1 Paragraph 1 of the Cabinet Order
- 2) Article 4 of the Ministerial Ordinance
- 3) Article 42 and 43 of the Ministerial Ordinance
- 4) Article 1 Paragraph 2 of the Cabinet Order

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

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

**Article 8.** 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 9.** 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 additives through contact therewith.

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

**Article 9-2.** 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 15, Paragraphs 1 through 3 or Article 17, 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 Affairs Council, by notice 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 dispositions 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 4-3, Paragraph 3 shall apply to the cases when dispositions were performed according to the provisions of Paragraph 1. In these cases, "foods or additives" used in Article 4, Paragraph 3 shall be construed as "apparatus or containers/packages".

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

**Article 10.** 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 11.** The Minister of Health, Labour and Welfare, from the viewpoint of public health, may establish necessary standards for the labeling of foods or 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, 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 5-5 of Article 5 of the Ministerial Ordinance

[Prohibition of False Labeling, etc.]

**Article 12.** No person shall falsely or exaggeratedly label or advertise any food, additive, apparatus, or container/package in any manner which may injure public health.

#### **Chapter 4-2 The Japanese Standards for Food Additives**

[*The Japanese Standards for Food Additives*]

**Article 13.** The Minister of Health, Labour and Welfare shall compile *The Japanese Standards for Food Additives* to contain therein the standards and specifications for the additives for which standards and specifications have been established pursuant to the provisions of Article 7 Paragraph 1 and to contain therein the standards for the additives for which standards have been established pursuant to the provisions of Article 11 Paragraph 1.

#### **Chapter 5. Examination**

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

**Article 14.** No person shall sell, display with intent to sell, or use in business any food or additive or any apparatus or container/package for which specifications have been established pursuant to the provisions of Article 7 Paragraph 1 or Article 10 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 person designated by the Minister of Health, Labour and Welfare, 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 prescribed in the preceding Paragraph shall pay the fee fixed by the Cabinet Order<sup>1)</sup>, in consideration of the 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>, 2) revenue of the prefecture concerned in the case of examinations performed by the governor of the prefecture concerned, and 3) revenue of the person designated by the Minister of Health, Labour and Welfare in the case of examinations performed by such designated person.

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.

(Reference)

1): Article 12 Paragraph 1 of the Cabinet Order

2): Article 12 of the Ministerial Ordinance

3): Article 14-4 of the Ministerial Ordinance

4): Article 12 Paragraphs 2 through 4 of the Cabinet Order

[Examination Order]

**Article 15.** If the governor of any prefecture discovers a food, additive, apparatus, or container/package which is designated by the Cabinet Order<sup>1)</sup> and which falls under any of the foods, 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 person designated by the Minister of Health, Labour and Welfare on such 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, additive, apparatus, or container/package manufactured or processed by the same person may continue to fall under any of the foods, 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 additives prescribed in Article 4 Subparagraph (2) or (3).

(2) Foods or additives not complying with the specifications established pursuant to the provisions of Article 7 Paragraph 1.

(3) Foods in which additives are used by methods not complying with the standards established pursuant to the provisions of Article 7 Paragraph 1.

(4) Apparatus or containers/packages prescribed in Article 9.

(5) Apparatus or containers/packages not complying with the specifications established pursuant to the provisions of Article 10 Paragraph 1.

2. The Minister of Health, Labour and Welfare may order a person who imports any 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, additive, apparatus, or container/package, which is designated by the Cabinet Order<sup>3)</sup> and which falls under any of the foods, additives, apparatus, or container/packages given in each of the Subparagraphs of the preceding Paragraph, or any of the foods prescribed in Article 6, to allow examinations performed by the Minister of Health, Labour and Welfare or a person designated by the Minister of Health, Labour and Welfare on such 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, additive, apparatus, or container/package which is designated by the Cabinet Order<sup>4)</sup> and which is suspected to fall under any of the foods, 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 6 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 person designated by the Minister of Health, Labour and Welfare on such 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, 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 person designated by the Minister of Health, Labour and Welfare, 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 governor of such prefecture or the Minister of Health, Labour and Welfare, pay a fee determined by the governor of such prefecture or the Minister of Health, Labour and Welfare, as appropriate, in consideration of the actual expenses required for the examinations, within the amount fixed by the Cabinet Order<sup>5)</sup>, or shall, for examinations performed by a person designated by the Minister of Health, Labour and Welfare, 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, within the amount fixed by the Cabinet Order<sup>5)</sup>.

7. The provisions of Paragraphs 3 through 5 of the preceding Article shall apply to the examinations prescribed in Paragraphs 1 through 3<sup>6)</sup>.

(Reference)

1): Article 1-3 Paragraph 1 of the Cabinet Order

2): Article 1-3 Paragraphs 2 through 4 of the Cabinet Order

3): Article 1-4 Paragraph 1 of the Cabinet Order

4): Article 15 Paragraph 1 of the Cabinet Order

5): Article 13 Paragraph 5, Article 14 Paragraph 4, and Article 15 Paragraph 2 of the Cabinet Order

6): Article 1-4 Paragraphs 2 and 3 of the Cabinet Order

[Import Notification]

**Article 16.** Any person, who wishes to import a 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 15 of the Ministerial Ordinance

**Article 16-2.** The Minister of Health, Labour and Welfare may, as prescribed by the Cabinet Order<sup>1)</sup>, require the importer mentioned in the preceding Article to make the notification prescribed by the same Article using the electronic information processing system.

**2.** When notification has been made by using the electronic information processing system pursuant to the provisions of the preceding Paragraph, the Minister of Health, Labour and Welfare may, as prescribed by the Cabinet Order<sup>2)</sup>, issue by using the electric information professing system to such notifier a notice concerning an order for examinations prescribed in Article 15 Paragraph 2 or 3 on any food, additive, apparatus, or container/package for which the notification has been made, and a notice concerning results of the examinations prescribed in Paragraph 4 of the same Article.

**3.** The notification, notice concerning an order, or notice concerning examination results pursuant to the preceding Paragraphs is deemed to have reached the Ministry of Health, Labour and Welfare or to have been issued from the Ministry of Health, Labour and Welfare at the time when the record was made in the file attached to the computer concerned mentioned in Article 2 Paragraph 7. The notice concerning order or notice concerning results is presumed to have reached such notifier at the time when the time normally required for transmission has passed after such record was made.

(Reference)

1): Article 16 of the Cabinet Order

2): Article 17 of the Cabinet Order

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

**Article 17.** The Minister of Health, Labour and Welfare, the governor of any prefecture, or the mayor of any city prescribed by the Cabinet Order under the provisions of Article 1 of the Health Center Law (Law No. 101, 1947) (hereinafter referred to as a "city establishing health centers"), or the mayor of any special ward 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<sup>1)</sup>, when the Minister of Health, Labour and Welfare, governor, city mayor, or ward mayor concerned determines that the action is necessary.

**2.** When the Minister of Health, Labour and Welfare, the governor of any prefecture, the mayor of any city establishing health centers, or the mayor of any special ward, 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, city mayor, or ward mayor concerned shall have such officials carry certificates stating their status<sup>2)</sup>.

(Reference)

1): Article 18 Paragraph 1 of the Ministerial Ordinance

2): Article 18 Paragraph 2 of the Ministerial Ordinance

[Food Sanitation Examination Facilities]

**Article 18.** The Government and each prefecture shall establish examination facilities to perform the examinations prescribed in Article 14 Paragraph 1 or Article 15 Paragraphs 1 through 3 (hereinafter referred to as "product examination") and to perform administrative work relating to testing of foods, 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 foods, 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, each city establishing health centers, and each special ward shall be prescribed by the Cabinet Order<sup>1)</sup>.

(Reference)

1): Article 2 of the Cabinet Order

[Food Sanitation Inspectors]

**Article 19.** The Minister of Health, Labour and Welfare, the governor of each prefecture, the mayor of each city establishing health centers, or the mayor of each special ward shall appoint food sanitation inspectors to execute the authority of officials prescribed in Article 17 Paragraph 1 and to perform the duties of providing guidance for food sanitation, in each jurisdiction from among the officials of the Government, prefecture, city establishing health centers, or special ward.

**2.** The governor of each prefecture, the mayor of each city establishing health centers, and the mayor of each special ward shall, as prescribed by the Cabinet Order<sup>1)</sup>, require food sanitation inspectors to perform inspections or to provide guidance on facilities, etc. of each business.

**3.** 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>2)</sup>.

(Reference)

1): Article 3 of the Cabinet Order

2): Article 4 of the Cabinet Order

## **Chapter 5-2. Designated Laboratories**

[Application]

**Article 19-2.** The designation prescribed in Article 14 Paragraph 1 or Article 15 Paragraphs 1 through 3 shall be made by application from a person wishing to perform product examination.

[Persons Not Qualified for Designation]

**Article 19-3.** Any person who falls under any of the categories given below shall not be designated as prescribed in Article 14 Paragraph 1 or Article 15 Paragraphs 1 through 3.

(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 Article 19-13, and two years have not passed from the date of the revocation.

(3) A person any of whose executives falls under either of the following categories:

a) A person who falls under the category given in Subparagraph (1).

b) A person who has been dismissed due to an order under the provisions of Article 19-10, and two years have not passed from the date of the dismissal.

[Qualifications Required for Designation of Examination Laboratories]

**Article 19-4.** The Minister of Health, Labour and Welfare shall not designate any person as an authorized person, unless the Minister determines that such person who has applied for designation mentioned in Article 14 Paragraph 1 or Article 15 Paragraphs 1 through 3 complies with each of the following:

(1) The applicant shall be a corporation which engages in performing examinations relating to food sanitation and which has been established under the provisions of Article 34 of the Civil Law (Law No. 89, 1896).

(2) The applicant shall have machinery, apparatus, and other facilities designated by the Ministerial Ordinance<sup>1)</sup> and persons to perform product examination who have expertise and experience complying with the conditions prescribed in the Ministerial Ordinance<sup>2)</sup>. The number of such persons shall not be less than that fixed under the Ministerial Ordinance<sup>2)</sup>.

(3) The conditions relating to product examination management conducted by the applicant shall comply with the standards established under the Ministerial Ordinance<sup>3)</sup>.

(4) The applicant shall have accounting capability required to perform product examination accurately and smoothly.

(5) The organization of the applicant's executives or employees or, if the applicant carries on work other than that prescribed in Subparagraph (1), such work shall be determined not to obstruct the fair performance of product examination.

(Reference)

1): Article 18-5 Paragraph 1 of the Ministerial Ordinance

2): Article 18-5 Paragraph 2 of the Ministerial Ordinance

3): Article 186 of the Ministerial Ordinance

[Notification of Establishment, Etc. of Examination Facilities]

**Article 19-5.** When a person who has been designated as prescribed in Article 14 Paragraph 1

or Article 15 Paragraphs 1 through 3 (hereinafter referred to as a "designated laboratory") wishes to newly establish or close an examination facility to perform product examination, or to change its location, such person shall notify the Minister of Health, Labour and Welfare of the planned establishment, closure, or change, at least two weeks before the scheduled date.

[Work Regulations]

**Article 19-6.** Any designated laboratory shall establish regulations concerning product examination work (hereinafter referred to as "work regulations") and obtain approval from the Minister of Health, Labour and Welfare concerning such regulations. When a designated laboratory wishes to change the work regulations, it shall obtain approval as well.

**2.** Items to be stipulated in the work regulations shall be prescribed by the Ministerial Ordinance<sup>1)</sup>.

**3.** The Minister of Health, Labour and Welfare may order a designated 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 18-8 Paragraph 2 of the Ministerial Ordinance

[Suspension or Discontinuance of Examination Work]

**Article 19-7.** Any designated laboratory shall not suspend or discontinue all or part of the product examination work, unless it obtains the permission of the Minister of Health, Labour and Welfare.

[Business Reports and statements of revenues and expenditures]

**Article 19-8.** Any designated laboratory shall prepare a business report and statement of revenues and expenditures for each business year and submit them to the Minister of Health, Labour and Welfare within three months after the end of each business year.

[Appointment of Executives]

**Article 19-9.** The appointment of executives of the designated laboratories who engage in product examination shall not be effective without the approval of the Minister of Health, Labour and Welfare.

[Dismissal Order of Executives, Etc.]

**Article 19-10.** When an executive of a designated laboratory or a person prescribed in Article 19-4 Subparagraph (2) violates this Law, an order or disposition under the this Law, or the established work regulations, the Minister of Health, Labour and Welfare may order such laboratory to dismiss such executive or such person as prescribed in such Subparagraph.

[Position of Executives or Employees]

**Article 19-11.** All executives and employees of any designated laboratory who engage in product examination shall be deemed to be employees engaging in public services under the laws, for purposes of the application of the Criminal Law (Law No. 45, 1907) and other penal provisions to such persons.

[Order to Take Measures for Compliance]

**Article 19-12.** When the Minister of Health, Labour and Welfare determines that a designated laboratory no longer complies with Article 19-4 Subparagraphs (2) through (5), the Minister may order such laboratory to take measures necessary to comply with these provisions.

[Order for Revocation of Designation and Suspension of Work]

**Article 19-13.** The Minister of Health, Labour and Welfare may revoke the designation or may order a designated laboratory to suspend all or part of its product examination work for a certain period of time, if the designated laboratory falls under one of the following categories:

- (1) The laboratory violates a provision under this chapter.
- (2) The laboratory falls under the categories of Article 19-3 Subparagraph (1) or (3).
- (3) The laboratory no longer complies with Article 19-4 Subparagraph (1).
- (4) The laboratory performs product examination, without following the work regulations approved pursuant to Article 19-6 Paragraph 1.
- (5) The laboratory violates an order prescribed in Article 19-6 Paragraph 3, Article 19-10, or the preceding Article.
- (6) The laboratory is designated as mentioned in Article 14 Paragraph 1 or Article 15 Paragraphs 1 through 3 but by unjust means.

[Books]

**Article 19-14.** Any designated 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 the books.

(Reference)

- 1): Article 18-12 Paragraph 2 of the Ministerial Ordinance
- 2): Article 18-12 Paragraph 1 of the Ministerial Ordinance

[Announcement of Designation, Etc.]

**Article 19-15.** The Minister of Health, Labour and Welfare shall make an announcement in KANPO (official gazette), when one of the following events occurs:

- (1) The Minister designates a person as a designated laboratory pursuant to Article 14 Paragraph 1 or Article 15 Paragraphs 1 through 3.
- (2) The Minister receives notification pursuant to the provisions of Article 19-5.

(3) The Minister gives permission pursuant to Article 19-7.

(4) The Minister revokes the designation of a laboratory or orders the suspension of product examination work, pursuant to the provisions of Article 19-13.

[Request for Reports and On-site Inspections]

**Article 19-16.** The Minister of Health, Labour and Welfare, within the limit necessary to enforce this Law, may request reports from a designated 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 17 Paragraph 2 shall apply to the preceding Paragraph.

## Chapter 6 Business

[Food Sanitation Supervisors]

**Article 19-17.** Any business person manufacturing or processing dairy products, additives designated by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 6, or other foods or 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 under the permission prescribed in Article 7-3 Paragraph 1 or 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 additives, in order to prevent the violation of this Law or orders or dispositions under this Law with respect to food or additives under such supervisor's control at such facility.

4. 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 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 designated by the Minister of Health, Labour and Welfare.

5. 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.

6. 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.

(Reference)

1): Article 4-2 of the Cabinet Order

2): Article 19 of the Ministerial Ordinance

3): Article 19-2 of the Ministerial Ordinance

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

**Article 19-18.** The Minister of Health, Labour and Welfare may establish necessary standards relating to measures to prevent the contamination of food or additives by toxic or injurious substances in the course of the manufacturing or processing of the food or additives.

2. The governor of 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 (Law No. 70, 1990)) 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 20.** The governor of 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 5 of the Cabinet Order

[License for Business]

**Article 21.** 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 one of the businesses designated in Article 20 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 22 through 24, and two years have not passed from the date of the revocation.

(3) A corporation any of whose executives falls under either of the 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): Articles 20 and 21 of the Ministerial Ordinance

[Inheritance of the Status of Licenced Business Persons]

**Article 21-2.** When there is inheritance or merger 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), or the corporation which has remained after the merger or the corporation which has been established newly by the merger 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 20-2 and 20-3 of the Ministerial Ordinance

[Disposal of Food, etc., Revocation of License, Prohibition or Suspension of Business]

**Article 22.** When a business person violates the provisions of Articles 4 through 6, Article 7 Paragraph 2, Article 9, Article 10 Paragraph 2 or Article 12, or when a business person violates

the prohibitions by the provisions of Article 4-3 Paragraph 1 or Article 9-2 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, additives, apparatus, or containers/packages or order such business person to take necessary measures to remove food sanitation hazards.

[Revocation of License, or Prohibition or Suspension of Business]

**Article 23.** When a business person violates the provisions of Articles 4 through 6, Article 7 Paragraph 2, Article 9, Article 10 Paragraph 2, Article 11 Paragraph 2, Article 12, Article 14 Paragraph 1, Article 15 Paragraph 4, Article 19-17 Paragraph 1 or Article 19-18 Paragraph 3, when a business person violates the prohibitions by the provisions of Article 4-3 Paragraph 1 or Article 9-2 Paragraph 1, when a business person falls under Article 21 Paragraph 2 Subparagraph (1) or (3), or when a business person violates the conditions under the provisions of Article 21 Paragraph 3, the governor of the prefecture concerned may revoke the license prescribed in Article 21 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.

[Dispositions of Business Facilities in Violation of Standards]

**Article 24.** When a business person violates the standards under the provisions of Article 20 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 21 Paragraph 1, prohibit all or a part of the business, or suspend all or part of the business for a certain period of time.

**Chapter 7** Repealed

**Article 25.** Repealed

**Chapter 8** Miscellaneous Provisions

[Payment from National Treasury]

**Article 26.** 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 17 Paragraph 1 (including cases where such provisions are applied based on Article 29 Paragraphs 1 and 3).

(2) The expenses required for appointment of food sanitation inspectors pursuant to the provisions of Article 19 Paragraph 1 (including cases where such provisions are applied based on Article 29 Paragraphs 1 and 3).

(3) The expenses required for license for businesses pursuant to the provisions of Article 22 Paragraph 1 (including cases where such provisions are applied based on Article 29 Paragraph 1).

(4) The expenses required for disposal pursuant to the provisions of Article 22 (including cases where such provisions are applied based on Article 29 Paragraphs 1 and 3).

(5) The expenses required for autopsies of corpses pursuant to the provisions of Article 28 Paragraph 1 or 2 (including cases where such provisions are applied based on Article 29 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 27.** Any medical doctor who has examined a person poisoned by or suspected to be poisoned by a food, additive, apparatus, or container/package 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, the director of any health center shall, in accordance with the provisions of the Cabinet Order<sup>1)</sup>, investigate the case and submit a report to the governor of the prefecture concerned.

3. On receiving the report prescribed in the preceding Paragraph, the governor of any prefecture shall, in accordance with the provisions of the Cabinet Order<sup>2)</sup>, submit a report to the Minister of Health, Labour and Welfare.

(Reference)

1): Article 6, Article 7 Paragraphs 1 and 2 of the Cabinet Order

2): Article 7 Paragraph 3 of the Cabinet Order

[Autopsy of Corpses]

**Article 28.** The governor of any prefecture, the mayor of any city establishing health centers, or the mayor of any special ward 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, additive, apparatus, or container/package, when the governor, city mayor, or ward mayor concerned determines that the action is necessary to identify the cause of death.

2. In the case of the preceding Paragraph, the governor of any prefecture, the mayor of any city establishing health centers, or the mayor of any special ward 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, city mayor, or ward mayor 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.

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

**Article 28-2.** Each prefecture, city establishing health centers, or special ward shall endeavor

to give advice, guidance, or other necessary support to restaurant-business operating persons and other persons who continuously supply food to the public or a large number of persons (hereinafter in this Article, referred to as "restaurant-business operating persons"), 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, city establishing health centers, or special ward 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, city establishing health centers, or special ward 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 29.** The provisions of Articles 4, 4-3, 6, 7, 9 through 12, 14 through 25, 27, and 28 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, "additives (excluding natural flavoring agents, and substances which are both generally provided for eating and drinking as food and used as additives)" prescribed in Article 6 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 4 and 7 shall apply to detergents intended for use in washing vegetables, fruits, or tableware.

3. The provisions of Articles 8 through 10, Article 14 Paragraph 1, Articles 17 through 19, Article 20, and Articles 22 through 24 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 26-4 of the Ministerial Ordinance

[Official Announcement of the Names, etc.]

**Article 29-2.** 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.

[Provision for Reading of "Governor" ]

**Article 29-2-2.** "Governor" used in the provisions of Article 19-17, in each of the articles of Articles 21 through 24 and the preceding Article 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<sup>1)</sup>, relating to businesses prescribed by the Cabinet Order<sup>1)</sup>.

(Reference)

1): Article 8 of the Cabinet Order

[Special Treatments for Large Cities]

**Article 29-3.** 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 9 of the Cabinet Order

[Appeal for Re-examination]

**Article 29-4.** 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 re-examination to the Ministry of Health Labour and Welfare.

[Classification of Administrative Work]

**Article 29-5.** The administrative work considered to be handled by each prefecture under the provisions of Article 14 Paragraph 1 (including cases where such provisions are applied based on Article 29 Paragraphs 1 and 3), Article 15 Paragraph 1 (including cases where such provisions are applied based on Article 29 Paragraphs 1), Article 17 Paragraph 1 (including cases where such provisions are applied based on Article 29 Paragraphs 1 and 3, the same hereinafter in this Law), Article 19 Paragraph 2 [excluding those related to inspections or guidances of license for businesses prescribed in Article 20 (confined to restaurant businesses and other selling businesses designated by the Cabinet Order), and including cases where such provisions are applied based on Article 29 Paragraphs 1 and 3, the same hereinafter in this Law], Article 22 (including cases where such provisions are applied based on Article 29 Paragraph 1 and 3) and Article 28 Paragraph 1 (including cases where such provisions are applied based on Article 29 Paragraph 1, the same hereinafter in this Law) shall be the Subparagraph 1 officially delegated administrative work.

[Delegation of Authority]

**Article 29-6.** 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 9 Penal Provisions

[Penal Provisions]

**Article 30.** Any person who violates the provisions of Article 4 (including cases where the application of this Article is based on Article 29 Paragraphs 1 and 2), Article 5 Paragraph 1, or Article 6 (including cases where the application of this Article is based on Article 29 Paragraph 1) or any person who violates the prohibitions under the provisions of Article 4-2 shall be punished by penal servitude of not more than three years or by a fine of not more than 3,000,000 yen.

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

**Article 30-2.** Any person who violates the provisions of Article 7 Paragraph 2 (including cases where the application of this Paragraph is based on Article 29 Paragraphs 1 and 2), Article 9 (including cases where the application of this Article is based on Article 29 Paragraphs 1 and 3), or Article 21 Paragraph 1 (including cases where the application of this Paragraph is based on Article 29 Paragraph 1) shall be punished by penal servitude of not more than one year or by a fine of not more than 1,000,000 yen.

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

**Article 30-3.** Any executive or employee who violates a suspension order of work under the provisions of Article 19-13 shall be punished by penal servitude of not more than one year or by a fine of not more than 1,000,000 yen.

**Article 31.** Any person who falls under any of the following Subparagraphs shall be punished by penal servitude of not more than six months or by a fine of not more than 300,000 yen:

(1) A person who violates the provisions of Article 5 Paragraph 2, Article 10 Paragraph 2 (including cases where the application of this Paragraph is based on Article 29 Paragraphs 1 and 3), Article 11 Paragraph 2 (including cases where the application of this Paragraph is based on Article 29 Paragraph 1), Article 12 (including cases where the application of this Article is based on Article 29 Paragraph 1), Article 14 Paragraph 1 (including cases where the application of this Paragraph is based on Article 29 Paragraphs 1 and 3), Article 15 Paragraph 4 (including cases where the application of this Paragraph is based on Article 29 Paragraph 1), or Article 27 Paragraph 1 (including cases where the application of this Paragraph is based on Article 29 Paragraph 1).

(2) A person who violates the prohibitions under the provisions of Article 4-3 Paragraph 1 (including cases where the application of this Paragraph is based on Article 29 Paragraph 1) or the provisions of Article 9-2 Paragraph 1 (including cases where the application of this Paragraph is based on Article 29 Paragraphs 1 and 3).

(3) A person who violates the standards prescribed under the provisions of Article 20 (including cases where the application of this Article is based on Article 29 Paragraphs 1 and 3), or a person who violates the conditions prescribed under the provision of Article 21 Paragraph 3 (including

cases where the application of this Paragraph is based on Article 29 Paragraph 1).

(4) A business person who disobeys the orders 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 29-2) prescribed in Article 22 (hereinafter in this Subparagraph, Article 22 includes cases where the application of this Article is based on Article 29 Paragraphs 1 and 3) or Article 24 (hereinafter in this Subparagraph, Article 24 includes cases where the application of this Article is based on Article 29 Paragraphs 1 and 3), or a person who has carried on a business in violation of the dispositions under the provisions of Article 22, Article 23 (including cases where the application of this Article is based on Article 29-2 Paragraphs 1 and 3), or Article 24.

**Article 32.** Any person who falls under any of the following Subparagraphs shall be punished by a fine of not more than 300,000 yen:

(1) A person who refuses, obstructs, or evades on-site inspections or collection of samples by officials pursuant to the provisions of Article 17 Paragraph 1 (in this Subparagraph and the following Subparagraph, Article 17 Paragraph 1 includes cases where the application of this Paragraph is based on Article 29 Paragraphs 1 and 3).

(2) A person who fails to make reports pursuant to the provisions of Article 17 Paragraph 1, or a person who makes false reports.

(3) A person who fails to make notification pursuant to the provisions of Article 16 or Article 19-17 Paragraph 6 (respectively, including cases where the application of this Paragraph is based on Article 29 Paragraph 1), or a person who makes false reports.

**Article 32-2.** When any of the violations given below occurs, executives or employees of a designated laboratory which do such act shall be punished by a fine of not more than 300,000 yen.

(1) A designated laboratory discontinues all of its product examination work without obtaining the permission prescribed in Article 19-7.

(2) A designated laboratory, in violation of Article 19-14, fails to record in books the items prescribed in the same Article or to retain the books, or makes false records.

(3) A designated laboratory fails to make reports as prescribed in Article 19-16 Paragraph 1 or makes false reports.

(4) A designated laboratory refuses, obstructs, or evades on-site inspection prescribed in Article 19-16 Paragraph 1, or fails to respond to questions prescribed in the same Paragraph or makes false responses.

**Article 32-3.** If any food sanitation supervisor has neglected its duties prescribed in Article 19-17 Paragraph 3, when there is an act which falls under any of the violations prescribed in Article 30, 30-2, or 31 on food or 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 33.** When the representative of any corporation, or a proxy, employee, or any other worker of any corporation or individual commits an illegal act prescribed in Article 30, 30-2,

31, or 32 relating to 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.

### **Supplementary Provisions**

[Enforcement Date]

**Article 34.** This Law (Law No. 233, December 24, 1947) shall come into force from January 1, 1948.

[Abolition of Laws and Ordinances]

**Article 35.** The following laws and ordinances shall be abolished.

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

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).

Regulation for Control of Trade of Food and Beverages (The Ordinance of the Ministry of Health and Welfare, No. 15, 1947).

Regulation for Control of Trade of Cow's Milk (The Ordinance of the Ministry of Home Affairs, No. 37, 1933).

Regulation for Control of Trade of Nonalcoholic Beverages (The Ordinance of the Ministry of Home Affairs, No. 30, 1900).

Regulation for Control of Trade of Snow and Ice (The Ordinance of the Ministry of Home Affairs, No. 37, 1900).

Regulation for Control of Trade of Artificial Sweetening Agents (The Ordinance of the Ministry of Home Affairs, No. 31, 1901).

Regulation for Control of Methyl Alcohol (The Ordinance of the Ministry of Home Affairs, No. 8, 1912).

Regulation for Control of Harmful Coloring Agents (The Ordinance of the Ministry of Home Affairs, No. 17, 1900).

Regulation for Control of Preservatives and Bleaching Agents of Food and Beverages (The Ordinance of the Ministry of Home Affairs, No. 22, 1928).

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 36.** Any person who, on the date of the enforcement of this Law, performs a business under the license obtained as prescribed by the order issued under the old law shall be deemed to have obtained the license as prescribed in Article 21 Paragraph 1 of this Law, where such business requires the license by the provisions of the same Paragraph.

2. The provisions of Article 21 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 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 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 additives) and publish it within the three-month period beginning on the date of the promulgation of this Law.

(1) 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) 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 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 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 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 3.** Any 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 additive, shall not be subject to the provision of Article 6 of the Amended Food Sanitation Law.



## **Food Sanitation Law Enforcement Ordinances**

Cabinet Order No. 229, August 31, 1953  
Last amendment: Cabinet Order No. 260, July 26, 2002

(Approval prescribed in Article 7-3 of the Law)

**Article 1.** The foods designated by Cabinet Order No. 229 (hereinafter referred to as the "Cabinet Order") under Article 7-3 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 4-2, meat products mean ham, sausage, bacon, and other similar products).
- (5) Fish-paste products (in this Subparagraph and Article 1-5 Paragraph 1 Subparagraph (1) f, fish-pasteproducts 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 Subparagraphs (1), (2), and(3) of this Article, nonalcoholic beverages, whale meat products (excluded whale meat bacon), and fish-past products (hereinafter fish-past products mean fish ham, fish sausage, whale bacon, and other similar products;)] packed into hermetic containers/packages, tightly sealed, and pasteurized under pressure.

2. The fees prescribed by the Cabinet Order under Article 7-3 Paragraph 7 of the Law shall be as listed in the following Subparagraphsgiven below for each category of persons indicated.

- (1) Persons who wish to obtain the approval prescribed in Article 7-3 Paragraph 1: 137,800 yen
- (2) Persons who wish to obtain approval for the changes prescribed in Article 7-3 Paragraph 4: 30,700 yen

(Examinations Prescribed by Article 14 Paragraph 1 of the Law)

**Article 1-2.** The additives and classification designated by the Cabinet Order under Article 14 Paragraph 1 of the Law and the fee fixed by the Cabinet Order under Paragraph 2 of the same Article relating to examinations of the same Paragraph shall be as shown in the following table:

Item	Person to perform examinations	Fee
Tar colors	The Minister of Health, Labour and Welfare	125,900 yen / examination

2. Any person who wishes to have a product examined pursuant to the provisions of Article 14 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 person designated by the Minister of Health, Labour and Welfare.

3. After receiving the applications prescribed in the preceding Paragraph, the Minister of Health, Labour and Welfare, the governor of any prefecture, or any person designated by the Minister of Health, Labour and Welfare 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 person designated by the Minister of Health, Labour and Welfare 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 14 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 10 of the Ministerial Ordinance

2) : Article 11 of the Ministerial Ordinance

(Examinations Prescribed by Article 15 Paragraph 1 of the Law)

**Article 1-3.** The food, additives, and apparatus designated by the Cabinet Order under Article 15 Paragraph 1 of the Law shall be as follows:

(1) Food

- a. Nonalcoholic beverages\* (excluding canned or bottled beverages).
- b. Powdered nonalcoholic beverages.
- c. Ham, sausage, and bacon.
- d. KAMABOKO (fish-paste cake) packed in casings, fish ham, fish sausage, and whale meat bacon.

\* : Nonalcoholic beverages exclude milk and milk products designated under the Ministerial Ordinance concerning Compositional Standards Etc. for Milk and Milk Products.

(2) Additives

Additives for which specifications have been established pursuant to the provisions of Article 7 Paragraph 1 of the Law (excluding those given in the left-hand column of the table mentioned in Paragraph 1 of the preceding Article).

(3) Apparatus

- a. Tableware made of pottery/porcelain with surfaces coming into direct contact with food, which are colored with pigments containing lead.
- b. Tableware made of phenol resin, melamine resin, or urea resin.

2. Any order prescribed in Article 15 Paragraph 1 of the Law shall be made by a written examination order indicating examination items, sampling methods, examination methods, and other items prescribed by the Ministerial Ordinance<sup>1)</sup> for foods, additives, or apparatus manufactured or processed by the person prescribed in the same Paragraph, within a certain period of time determined by the governor of the prefecture concerned which will not exceed two months after notification by the governor to such person to the effect that necessary measures to prevent the occurrence of food sanitation hazards are to be taken.

3. Any person who wishes to have a product examined pursuant to the provisions of Article 15 Paragraph 1 of the Law shall, as prescribed by the Ministerial Ordinance<sup>2)</sup>, submit application forms to the governor of the prefecture concerned or a person designated by the Minister of Health,

Labour and Welfare.

4. After receiving the applications of the preceding Paragraph, the governor of any prefecture or any person designated by the Minister of Health, Labour and Welfare shall collect samples and perform the examinations in accordance with the descriptions in the written examination order.

5. The fee fixed by the Cabinet Order under Article 15 Paragraph 6 of the Law relating to the examinations prescribed in Paragraph 1 of the same Article is 149,400 yen per examination item.

(Reference)

1): Article 13 of the Ministerial Ordinance

2) : Article 14 of the Ministerial Ordinance

(Examinations Prescribed by Article 15 Paragraph 2 of the Law)

**Article 1-4.** The foods designated by the Cabinet Order under Article 15 Paragraph 2 of the Law are as follows:

- (1) Candy, chocolate, and chewing gum.
- (2) Pies, biscuits, sponge cakes, cookies, and other similar bakery products.
- (3) Worcester sauce, fruit sauce, fruit puree, ketchup, and mayonnaise.

2. Any person who wishes to have a product examined pursuant to the provisions of Article 15 Paragraph 2 of the Law shall, as prescribed by the Ministerial Ordinance<sup>1)</sup> submit applications to the Minister of Health, Labour and Welfare or a person designated by the Minister of Health, Labour and Welfare.

3. After receiving the applications prescribed in the preceding Paragraph, the Minister of Health, Labour and Welfare or any person designated by the Minister of Health, Labour and Welfare shall collect samples and perform the examinations in accordance with the descriptions of the original written examination order. (When the Minister of Health, Labour and Welfare has issued a notice concerning the order for examinations using the electronic information processing system pursuant to Article 16-2 Paragraph 2, the electronic copy of the original examination order may be used instead.)

4. The provisions of Paragraph 5 of the preceding Article shall apply to the examinations prescribed in Article 15 Paragraph 2 of the Law.

(Reference)

1): Article 14-2 of the Ministerial Ordinance

(Examinations Prescribed in Article 15 Paragraph 3 of the Law)

**Article 1-5.** The foods, additives, or apparatus designated by the Cabinet Order under Article 15 Paragraph 3 of the Law are as follows:

(1) Foods

- a. Nonalcoholic beverages.
- b. Powdered nonalcoholic beverages.
- c. Meat and viscera of cattle or swine.
- d. Meat and viscera of chickens.

- e. Meat and viscera of reindeer, and processed products thereof.
- f. Fish-paste products.
- g. SUJIKO (salted salmon roe).
- h. Agar and processed products of chlorella or spirulina.
- i. Corn and Job's tears (*Coix lachryma-jobi* var. *ma-yuen*).
- j. Pulses and legumes.
- k. Fruits and processed products thereof (confined to dried fruits, preserved fruits in syrup, and fruit paste).
- l. Vegetables and processed products thereof.
- m. Nuts and cotton seeds, and processed products thereof.
- n. Noodles.
- o. Frozen foods (confined to foods for which specifications have been established pursuant to Article 7 Paragraph 1 of the Law and which are consumed uncooked).
- p. Edible fats and oils (confined to vegetable products).
- q. Candies and chocolates.
- r. Pies, biscuits, sponge cakes, cookies, and other similar bakery products.
- s. Natural cheese.
- t. Eel, prawn (confined to cultured eel and prawn), shellfish, tilapia, puffer, and processed products of eel, prawn, shellfish, and crab.
- u. Seasonings and soups.
- v. Spices and unprocessed source materials thereof.
- w. Herbs and processed products thereof (confined to dried herbs).
- x. Processed products of snakes (confined to dried snakes).
- y. Foods put in gelatin capsules.
- z. Foods in tablet form.
- aa. Honey and processed products thereof.

## (2) Additives

Additives for which specifications have been established pursuant to Article 7 Paragraph 1 of the Law (excluding those listed in the left column of the table mentioned in Article 1-2 Paragraph 1)

## (3) Apparatus

- a. Products made of synthetic resin or rubber.
- b. Tableware made of tin or pottery/porcelain.
- c. Tableware made of enamelware.

2. The provisions of Article 1-3 Paragraph 5 and Paragraphs 2 and 3 of the preceding Article shall apply to examinations prescribed in Article 15 Paragraph 3.

(Methods for Notification Using the Electronic Information Processing System)

**Article 1-6.** Any person who wishes to make notification as prescribed in Article 16 of the Law using the electronic information processing system (including cases where such provisions are applied based on Article 29 Paragraph 1) shall input the items required for the notification prescribed under Article 16 of the Law into the input/output units prescribed in Article 2 Paragraph 7 of the Law (hereinafter in this Article, confined to the units used by such person wishing to make such notification).

2. The input prescribed in the preceding Paragraph shall be done using the input/output units of which such person has already notified the Minister of Health, Labour and Welfare, as prescribed by the Ministerial Ordinance<sup>1)</sup>.

(Reference)

1): Article 15-2 of the Ministerial Ordinance

(Methods for Notice Using Electronic Information Processing System)

**Article 1-7.** When the Minister of Health, Labour and Welfare gives a notice of an order for examinations prescribed in Article 15 Paragraph 2 or 3 or a notice of results of the examinations prescribed in Paragraph 4 of the same Article (hereinafter referred to as a "special notice") using the electronic information processing system, the Minister shall input the contents of such special notice into the input/output units prescribed in Article 2 Paragraph 7 of the Law (confined to the units used by the Ministry of Health, Labour and Welfare) and shall record them in the file concerned.

2. The Minister of Health, Labour and Welfare shall obtain prior consent from the receiver concerning the giving of such special notice using the electronic information processing system.

(Food Sanitation Examination Facilities)

**Article 2.** Any food sanitation examination facility established by each prefecture, each city establishing health centers, or each special ward, pursuant to the provisions of Article 18 Paragraph 1 or 2 of the Law, shall be staffed adequately for examinations or tests, provided with chemical examination rooms, bacteriological 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.

(Reference)

1): Article 18-2 of the Ministerial Ordinance

(Inspection or Guidance)

**Article 3.** Inspection or guidance prescribed in Article 19 Paragraph 2 of the Law (including cases where such provisions are applied based on Article 29 Paragraphs 1 and 3 of the Law) shall be performed for business facilities listed in the left-hand column of the table below, at the frequency prescribed in the right-hand column of the same table, and points to be considered in the performance of the inspection or guidance and other necessary items relating to the inspection or guidance shall be as prescribed by the Ministerial Ordinance<sup>1)</sup>.

Type of business	Frequency of inspection or guidance
The businesses listed in Article 5 Subparagraphs (1), (3), (5) through (8), (11) through (14), and (29), and the facilities prescribed in Article 29 Paragraph 3 of the Law.	12 times a year
The businesses listed in Article 5 Subparagraphs (2), (3)-2, (4), (8)-2 through (10), (16), (19) through (28), and (30).	6 times a year

(continued)

The businesses listed in Article 5 Subparagraphs (14)-2 and (15), and the milking businesses.	4 times a year
The businesses listed in Article 5 Subparagraphs (17) and (18), and the manufacturing businesses and selling businesses of foods or additives, other than businesses listed in the same Article.	Twice a year
The manufacturing businesses and selling businesses of apparatus, containers/packages, or toys.	Once a year

(Reference)

1): Article 18-3 of the Ministerial Ordinance

(Qualification of Food Sanitation Inspectors)

**Article 4.** 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 designated by 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.

(Designation of Foods, etc.)

**Article 4-2.** The foods and additives prescribed by the Cabinet Order under Article 19-17 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 additives (confined to products for which specifications have been established pursuant to the provisions of Article 7 Paragraph 1 of the Law).

(Designation of Businesses)

**Article 5.** Businesses, for facilities of which the governor of each prefecture shall establish standards pursuant to Article 20 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).

(3)-2 AN (sweetened bean paste)-manufacturing businesses.

(4) 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).

(5) 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 ).

(6) 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).

(7) 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)).

(8) Milk-collecting businesses (i.e., businesses which collect and store raw cow's milk or raw goat's milk).

(8)-2 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).

(8)-3 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.).

(9) Meat-selling businesses.

(10) Meat-product-manufacturing businesses (i.e., businesses which manufacture ham, sausages, bacon, or other similar products).

(11) 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).

(12) Fish/shellfish-auctioning businesses (i.e., businesses which, by auctioning, sell fresh fish/shellfish at fish/shellfish markets).

(13) Fish-paste-product-manufacturing businesses (including businesses which manufacture

fish ham, fish sausage, whale bacon, or other similar products).

(14) Food-freezing and -refrigerating businesses.

(14)-2 Food-irradiation businesses.

(15) Nonalcoholic-beverage-manufacturing businesses.

(16) Lactic-acid-bacterial-beverage-manufacturing businesses.

(17) Ice-manufacturing businesses.

(18) Ice-selling businesses.

(19) Edible-fat/oil-manufacturing businesses.

(20) Margarine- or shortening-manufacturing businesses.

(21) MISO (fermented soybean paste)-manufacturing businesses

(22) Soy sauce-manufacturing businesses.

(23) Sauce-manufacturing businesses (i.e., businesses which manufacture Worcester sauce, fruit sauce, fruit puree, ketchup, or mayonnaise).

(24) Alcoholic beverage-manufacturing businesses.

(25) TOFU (soybean curd)-manufacturing businesses.

(26) NATTO (fermented soybeans)-manufacturing businesses.

(27) Noodle-manufacturing businesses.

(28) 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 (10), (13), or (25)).

(29) Canned- or bottled-food-manufacturing businesses (excluding those falling under any of the businesses listed above).

(30) Additive-manufacturing businesses (i.e., businesses manufacturing additives for which specifications have been established pursuant to Article 7 Paragraph 1 of the Law ).

(Investigation of Causes of Food Poisoning)

**Article 6.** Pursuant to the provisions of Article 27 Paragraph 2 of the Law (including cases where such provisions are applied based on Article 29 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, additives, apparatus, containers/packages, or toys having caused the poisoning, and poisoning-causing substances existing in such products.

(2) Investigations by bacteriological or physicochemical examinations 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, additives, apparatus, containers/packages, or toys considered to have caused the poisoning.

(Reports concerning Poisoning)

**Article 7.** After receiving the notification prescribed in Article 27 Paragraph 1 of the Law, the Director of any health center shall, as prescribed by the Ministerial Ordinance<sup>1)</sup>, prepare a report and submit it to the governor of the prefecture concerned.

2. Submission of the report prescribed in the preceding Paragraph shall be made through the mayor of the city or ward concerned for cities establishing health centers or special wards.

3. After receiving the report prescribed by Paragraph 1 above, the governor of any prefecture shall, as prescribed by the Ministerial Ordinance<sup>2)</sup>, make a report and submit it to the Minister of Health, Labour Welfare.

(Reference)

1) : Article 26-2 of the Ministerial Ordinance

2) : Article 26-3 of the Ministerial Ordinance

(Special Treatment for Large Cities)

**Article 8.** 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 29-3 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 29-3 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 29-5, Paragraph 1 of the Law)

**Article 9.** The business prescribed by the Cabinet Order under Article 29-5 Paragraph 1 of the Law are businesses stated in Subparagraphs (1), (2), (8)-2, (9) and (18) of Article 5.

(Classification of Administrative Work)

**Article 10.** The administrative work considered to be handled by each prefecture, each city establishing health center or each special ward under the provisions of Article 7 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 11.** 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: April 6, 2002  
Ministry of Health, Labour and Welfare Ordinance No. 118

## Chapter 1. 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 4 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 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 additives and the finished foods or additives are deemed not injurious to human health.

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

**Article 1-2.** The reasons designated by the Ministerial Ordinance established pursuant to the provisions of Article 4-3 Paragraph 1 of the Law are as follows:

- (1) In case specified foods or 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 15 Paragraphs 1 through 3 or Article 17 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 4-4 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"), number of the foods or additives which falls under any of each subparagraph of Article 4-3 Paragraph 1 shall be, generally, not less than 5 percent by ratio, of the total foods or 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 4-3 Paragraph 1 construed in Article 29 Paragraph 1 of the Law. In this case, "foods and 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 1-3.** The items designated by the Ministerial Ordinance established pursuant to the provisions of Article 4-3 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 additives given in each subparagraph of Article 4-3 Paragraph 1 of the Law.
- (4) Impact of measures other than dispositions according to the provisions of Article 4-3 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 4-3 Paragraph 1, established by the Ministry of Health, Labour and Welfare, which are construed in Article 29 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 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 1-4.** On cancellation of the dispositions which were performed on specified foods, etc. pursuant to the provisions of Article 4-3 Paragraph 1, basing on the application of the persons concerned with the dispositions or in case of need, for the confirmation of no more danger of outbreak of injuring from the stand point 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 dispositions to be cancelled.

**2.** The provisions in the preceding article shall be construed when cancelling the disposition performed pursuant to the provisions of Paragraph 1 of the preceding articles, basing on the provisions of Article 4-3 Paragraph 3 construed in Article 29 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 1-5.** Application for the cancellation pursuant to the provisions of Article 4-3 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 additives on which application of the cancellation of the concerned dispositions 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 additives to which application of the disposition 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 dispositions basing on the provisions of Article 4-3 Paragraph 3 construed in Article 29 Paragraph 1 of the Law. In this case, "foods or additives" in the preceding paragraph shall be read as "toys".

[Meat, etc. of Livestock Suffering from Disease]

**Article 2.** The diseases of livestock prescribed in Article 5 Paragraph 1 of the Law are those listed in Table 1 and shall be treated as prescribed in the same Table.

2. The livestock prescribed by Ministry of Health and Welfare Ordinance No. 23 (hereinafter referred to as the "Ministerial Ordinance") under Article 5 Paragraph 1 of the Law are water buffalo.

3. The diseases of poultry prescribed in Article 5 Paragraph 1 of the Law are those listed in Attached Table 1-2 and the measures shall be taken as prescribed in the same Table.

4. Under the proviso to Article 5 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 2-2.** The products prescribed by the Ministerial Ordinance under Article 5 Paragraph 2 of the Law shall be meat products.

[Items to be Described in Certificates]

**Article 2-3.** The items prescribed by the Ministerial Ordinance under Article 5 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 2-4.** When the certificate prescribed in Article 5 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 2-5.** The countries designated by the Ministerial Ordinance under the proviso of Article 5, Paragraph 2 are the United State of America, the Commonwealth of Australia, and New Zealand.

[Additives not Injurious to Human Health]

**Article 3.** The food additives which, by the provisions of Article 6 of the Law, have been deemed as not injurious to human health are those listed in Attached Table 2.

[Standards for Comprehensive Sanitation-controlled Manufacturing Process]

**Article 4.** The standards prescribed in the Ministerial Ordinance under Article 7-3 Paragraph 2 of the Law (including cases where Article 7-3 Paragraph 2 of the Law applies in Paragraph 4 of the same Article) 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 2-2 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).
- e. 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 4-2.** Application for the approval prescribed in Article 7-3 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) Documents as to what effects the measures prescribed in accordance with Subparagraph (2)-b of the preceding Article have.

(3) Documents describing results of the test for product, etc. based on the documents prescribed in Subparagraph (5) of the preceding Article.

[Application for Approval of Change]

**Article 4-3.** Application for the approval for change prescribed in Article 7-3 Paragraph 4 of the Law shall be made by submitting an application stating the items given below to the Minister of Health 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.

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

**Article 4-4.** The items designated by the Ministerial Ordinance established pursuant to the provisions of Article 9-2 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 15 Paragraphs 1 through Paragraph 3 or Article 17 Paragraph 1, or examinations performed by business persons pursuant to the administrative guidance given by the nation, the prefecture or city establishing health centers, number of the apparatus or containers/packages which falls in under Article 9-2 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 9-2 Paragraph 1 construed in the Article 29 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 4-5.** The items designated by the Ministerial Ordinance established pursuant to the provisions of Article 9-2 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 9-2 Paragraph 1 of the Law.

(4) Impact of measures other than dispositions pursuant to the provisions of Article 9-2 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 9-2 Paragraph 1 established by the Ministerial Ordinance of Health, Labour and Welfare, which are construed in Article 29-2 Paragraph 1 of the Law.

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

**Article 4-6.** On cancellation of the dispositions which were performed on specified apparatus, etc., pursuant to the provisions of Article 9-2 Paragraph 1 of the Law, according to the provisions of Article 4-3 Paragraph 3 which are construed after reading in Article 9-2 Paragraph 3 basing on the application of the persons concerned with the dispositions, 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 dispositions to be cancelled.

2. The provisions in the preceding article shall be construed in case of cancelling the dispositions pursuant to the provisions of Article 9-2 Paragraph 1 of the Law which are construed in Article 29 Paragraph 1 of the Law, based on the provisions of Article 4-3 Paragraph 3 which are construed in Article 29 Paragraph 1 of the Law after being read and construed in Article 9-2 Paragraph 3 of the Law.

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

**Article 4-7.** Application for the cancellation pursuant to the provisions of Article 4-3 Paragraph 3, after being read and construed in Article 9-2 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 dispositions of the concerned dispositions 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 dispositions 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 dispositions by the provisions of Article 4-3 Paragraph 3, being read and construed in Article 9-2 Paragraph 3 of the Law which is construed in Article 29 Paragraph 1 of the Law.

## Chapter 2. Labeling

[Standards for Labeling]

**Article 5.** The standards for labeling of the foods and 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, Paragraph 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 an additive listed in Table 2 (excluding additives listed in Table 4), only the same name as mentioned in Table 2 may be used].

b. For a food or 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 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 additive other than the foods or additives mentioned above, the date (including the year) preceded by certain letters indicating "date of minimum durability" (hereinafter "date of minimum durability" means the date which signifies the end of the period through which a food or additive is determined to completely retain all qualities of the product, when stored under the specified storing conditions) (hereinafter the date of minimum durability includes certain letters determined by the Minister of Health, Labour and Welfare to be appropriate for indicating the date of minimum durability).

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).

d. For an 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 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 additives and one of the appropriate items listed in the right column of the same Table. For a food containing additives which are not mentioned above, the names of these additives.
- f. For a processed food which uses any of the foods given in Table 5-2 (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 an additive (excluding that which has no antigenic property and flavoring agent; the same in 'j') derived from foods given in Table 5-2 (hereinafter referred to as "specified raw material"), a statement to the effect that the food contains the additive and that the additive contained in the food is derived from the specified material.
- h. The method of storing (for a food or additive for which standards for methods of storing have been established pursuant to the provisions of Article 7 Paragraph 1 of the Law, the method of storing complying with such standards), and for a food or 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 an additive (excluding the additives prescribed in 7j'), the words "食品添加物" in Japanese.
- j. For an additive derived from specific raw material, the words "食品添加物" in Japanese and that the 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 an additive for which the declaration of content is stipulated in the specifications established pursuant to the provisions of Article 7 Paragraph 1 of the Law, the percentage by weight.
- m. For a vitamin A derivative as an 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, and boiled octopus), 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 "date of minimum durability".
- 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 5-3 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 5-3 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 5-3, 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 5-3, 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 5-3, 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 12 Paragraph 1 of the Nutrition Improvement Law (Law No. 248, 1952) or approved pursuant to Article 15 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 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 12 Paragraph 5 of the Nutrition Improvement 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 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 5-3 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 date of minimum durability of the product exceeds three months, the date (including year) of minimum durability preceded by certain letters indicating "the date of minimum durability" may be replaced by labeling of the year and month preceded by certain letters indicating "the date of minimum durability."

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 additives listed in Entry No.14 of the same Table may be exempted from the declaration of the use-by date or the date of minimum durability preceded by certain letters indicating "the use-by date" or "the date of minimum durability" (hereinafter referred to as the "specified date") and method of storing (any food or additive for which standards for a method of storing have been established pursuant to the provisions of Article 7 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 7 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 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 additives contained may be replaced with names commonly used in the public or with an appropriate term listed in the right column of Table 5-2 for a food which contains 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 additive used for any of the purposes not listed in the middle column of Table 5, Entry No. 8) may be expected from the labeling of the names of the 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 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 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 an 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 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 additive contained in the food concerned comes from the specified raw material concerned; as for an 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 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 5-3 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 5-3, 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 5-3 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 Attached 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 5-5 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.

**Article 6. through Article 9.** Repealed.

### **Chapter 3. Product Examinations**

[Application for Product Examinations]

**Article 10.** Application for the examination prescribed in Article 14 Paragraph 1 of the Law shall be made by submitting an application stating the items given below for each lot of products. The maximum quantity of a lot is that given in the right column of Table 6 for the products given in

the left column of the same Table.

- (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 11.** Test samples for examinations shall, as prescribed in Article 1-2 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 12.** The label prescribed by the Ministerial Ordinance under Article 14 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 13.** The items prescribed by the Ministerial Ordinance under Article 1-3 Paragraph 2 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 14.** Application for examinations prescribed in Article 15 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 1-3 Paragraph 2 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 14-2.** Application for examinations prescribed in Article 15 Paragraph 2 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 16-2 Paragraph 2 ).

**Article 14-3.** The provisions of the preceding Article shall apply to the application for the examinations prescribed in Article 15 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 14-4.** Fees for examinations performed by the Minister of Health, Labour and Welfare shall be paid by attaching to the application, prescribed in Article 1-2 Paragraph 2 or Article 1-4 Paragraph 2 of the Cabinet Order (including cases where such provisions are applied based on Article 1-5 Paragraph 2), a revenue stamp equivalent to the amount fixed by Article 1-2 Paragraph 1 of the Cabinet Order or the amount determined by the Minister of Health and Welfare in accordance with Article 15 Paragraph 6 of the Law.

## Chapter 3-2. Import Notification

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

**Article 15.** Any person (referred to as an "importer" in the provisions of following Paragraph, Paragraphs 4 and 5) prescribed in Article 16 of the Law (in this Paragraph, Paragraph 6, and Article 15-2, including cases where such provisions are applied based on Article 29 Paragraph 1 of the Law) shall, except when such person wishes to import any of the foods listed in Table 6-2, submit an import notification stating the items given below (excluding the item listed in Subparagraph (11) 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 6-3 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, 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 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 7 Paragraph 1 of the Law), the names of the 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 5 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 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 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 5 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, additives, apparatus or containers/packages listed in the middle column of Table 6-4 (hereinafter 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 additives listed in any of the Subparagraphs of Article 4 of the Law.
- (2) Foods or additives prescribed by Article 6 of the Law.
- (3) Foods or additives manufactured by methods not complying with the standards established pursuant to the provisions of Article 7 Paragraph 1 of the Law.
- (4) Foods or additives not complying with the specifications established pursuant to the provisions of Article 7 Paragraph 1 of the Law.
- (5) Apparatus or containers/packages prescribed in Article 9 of the Law.
- (6) Apparatus or containers/packages not complying with the specifications established pursuant to the provisions of Article 10 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 6-4 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 3 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 6-3 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 6-3 for the places listed in the left column of the same Table immediately after the entry of the cargo.

**7.** In the case of application of Paragraphs 1 and 2 concerning persons who wish to make notification, as prescribed in Article 16 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 16 of the Law (in this Paragraph, Paragraph 6, and Article 15-2, including cases where such provisions are applied based on Article 29 Paragraph 1 of the Law) shall, except

when such person wishes to import any of the foods listed in Table 6-2, input into the input/output units prescribed in Article 2 Paragraph 7 of the Law (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.

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

[Notification of input/output units]

**Article 15-2.** The notification prescribed in Article 1-6 Paragraph 2 of the Cabinet Order shall be made in the same manner in which a person who wishes to make notification as prescribed in Article 16 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).

2. 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.

#### **Chapter 4. Food Sanitation Examination Laboratories and Food Sanitation Inspectors**

**Article 16 through Article 17** Repealed.

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

**Article 18.** When a food sanitation inspector collects foods, etc. pursuant to the provisions of Article 17 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.

[Machinery and Apparatus required for Examinations, etc.]

**Article 18-2.** The machinery and apparatus prescribed by the Ministerial Ordinance under Article 2 Paragraph 1 of 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 18-2-2.** The management of administrative work concerning the examinations and tests provided in Article 2 Paragraph of the Cabinet Order (in this Article and Table 7, 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 (10).
- (2) Perform regular internal checks for the management of work concerning examinations, etc. in accordance with the documents prepared as prescribed in Subparagraph (11).
- (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 (12).
- (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 (13).
- (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.
- (7) Employees to do work prescribed in Subparagraphs (1) and (6) shall not perform examinations, etc.
- (8) 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).

- (9) Make reliability assurance work become independent of examinations, etc.
- (10) Prepare a standard operation procedure as prescribed in Attached Table 7.
- (11) Prepare documents describing methods of the internal check concerning the management of work concerning examinations, etc.
- (12) Prepare documents describing methods of the internal proficiency test.
- (13) Prepare documents describing a plan for receiving the regular external inspections of the proficiency test.
- (14) Prepare documents describing a training plan for employees to perform reliability assurance work.
- (15) 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 14 Paragraph 1 of the Law or Article 15 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 17 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 17 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 (10).
  - k. Records concerning the training mentioned in preceding Subparagraph.

[Methods of Inspection or Guidance]

**Article 18-3.** Specific considerations in performing inspections or giving guidance pursuant to the provisions of Article 3 of the Cabinet Order are as listed in the left column of Attached Table 8.

**2.** When the governor of each prefecture, the mayor of each city establishing health centers, or the mayor of each ward, by the provisions of Article 19 Paragraph 3 of the Law, has food sanitation inspectors perform inspections of or give guidance concerning facilities, etc. to each

business, such governor, city mayor, or ward mayor shall have them score such facilities, etc. as prescribed in the right column of Attached Table 8, concerning the considerations listed in the left column of the same Table, have them prepare food sanitation inspection card Form No. 5 based on such scores, and have them put up the copies of such reports inside such facilities.

3. The food sanitation inspection reports prescribed in the preceding Paragraph shall be retained for at least one year in the health center responsible for the area where such facilities are located.

#### **Chapter 4-2. Designated Laboratories**

[Application for Designated Laboratories]

**Article 18-4.** Any person who wishes to apply for designation under the provisions of Article 19-2 of the Law shall submit to the Minister of Health, Labour and Welfare application Form No. 6, accompanied by the documents given below.

(1) The articles of incorporation or article of association and the certified copy of register book.

(2) A list of assets and balance sheet for the business year immediately preceding the business year including the date of application.

(3) A business program and budget document of revenue and expenditure for the business year including the date of application, and for the following business year.

(4) The standard operation procedure prescribed in Article 18-6 Subparagraph (8) and the documents prescribed in Article 18-6 Subparagraphs (9) through (12).

(5) Documents indicating the following items:

a) The names and resumes of executives, and in the case of an incorporated association, its name and the names or corporate names of the members involved.

b) An outline of the work on testing relating to food sanitation which the person is carrying out.

c) The number and performance of the machinery, apparatus, and other facilities used for product examinations, and a declaration as to whether they are owned or leased.

d) The names and brief resumes of persons prescribed in Article 19-4 Subparagraph (2) of the Law (hereinafter referred to as "examiners").

e) The names of the persons prescribed in Article 18-6 Subparagraphs (1) through (3).

f) If the person is engaged in work other than that prescribed in Article 19-4 Subparagraph (1) of the Law, the type and outline of such work.

[Machinery/Apparatus and Other Facilities]

**Article 18-5.** The machinery, apparatus, and other facilities prescribed by the Ministerial Ordinance under Article 19-4 Subparagraph (2) of the Law are as listed in each of the following Subparagraphs for the category of the person designated in the corresponding Subparagraph:

(1) The person designated under Article 15 Paragraph 1 of the Law: the machinery, apparatus, and other facilities listed in Column 2 of Table 9 for each category of Column 1 of the same Table.

(2) The person designated under Article 15 Paragraph 2 of the Law: the machinery, apparatus, and other facilities listed in Column 2 of Table 10 for each category of Column 1 of the same Table.

(3) The person designated under Article 15 Paragraph 3 of the Law: the machinery, apparatus, and other facilities listed in the corresponding category of Column 2 of Table 11 for each category of Column 1 of the same Table.

2. The conditions and number prescribed by the Ministerial Ordinance under Article 19-4 Subparagraph (2) of the Law are as listed in each of the following Subparagraphs for the category of the person designated in the corresponding Subparagraph:

(1) The person designated under Article 15 Paragraph 1 of the Law: the conditions listed in Column 3 of Table 9 and the number listed in Column 4 of the same Table for each category of Column 1 of the same Table.

(2) The person designated under Article 15 Paragraph 2 of the Law: the conditions listed in Column 3 of Table 10 and the number listed in Column 4 of the same Table for each category of Column 1 of the same Table.

(3) The person designated under Article 15 Paragraph 3 of the Law: the conditions listed in the corresponding category of Column 3 of Table 11 and the number listed in the corresponding category of Column 4 of the same Table for each category of Column 1 of the same Table.

[Standards for Administration of Work]

**Article 18-6.** The standards established by the Ministerial Ordinance under Article 19-4 Subparagraph (3) of the Law are as follows.

(1) In a unit to perform the product examination (in this Article, such unit is referred to as the "Product Examination Unit"), a person to perform the work given below (in this Article and Article 18-8, such person is referred to as the "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 other necessary work (in this Article and Article 18-8, such person is referred to as the "Supervisor of the Examination Category") shall have been placed.

(3) In a unit to assure reliability of the product examination (in this Article, such unit is referred to as the "Quality Assurance Unit"), a person to assume responsibility concerning quality assurance (in this Article and Article 18-8, such person is referred to as the "Director for the Quality Assurance Unit") shall have been placed. The Director shall personally perform the work given below, or shall have persons, who have been appointed in advance in accordance with the contents of the work, perform part or all categories of such work.

- 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.
- 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 in writing (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 19-14 of the Law (in Article 18-12 and Table 7 hereinafter such books are referred to as the "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 person wishing to apply for designation.

(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 7. 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 18-7.** 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 19-5 of the Law, shall submit a notification of Form 7 to the Minister of Health, Labour and Welfare.

[Work Regulations]

**Article 18-8.** When any person who has been designated as prescribed in Article 14 Paragraph 1 or Article 15 Paragraphs 1 through 3 (hereinafter referred to as a "designated laboratory") wishes to obtain approval for regulations concerning product examination work pursuant to the former part of Article 19-6 Paragraph 1 (hereinafter referred to as "work regulations"), such person shall submit to the Minister of Health, Labour and Welfare application Form No. 8 accompanied by such work regulations.

2. The work regulations prescribed by Article 19-6 Paragraph 2 of the Law shall stipulate:

- (1) Specifics on work hours for product examinations and laboratory holidays.
- (2) Specifics on the place where product examinations are performed.
- (3) Specifics on the receipt of fees.
- (4) Specifics on the appointment and dismissal of the Director of the Product Examination Unit, the Supervisors of the Examination Categories, examiners, and the Director of the Quality Assurance Unit.
- (5) Specifics on the placement of examiners.
- (6) Specifics on retention of application forms for product examinations.
- (7) Other related specifics regarding product examination work.

3. Any designated laboratory which wishes to apply for the approval of a change in the work regulations as prescribed by the latter part of Article 19-6 Paragraph 1 of the Law shall submit application Form No. 9 to the Minister of Health, Labour and Welfare.

[Fees]

**Article 18-9.** Any designated laboratory who wishes to receive the approval of an examination fee pursuant to the provisions of Article 15 Paragraph 6 shall submit to the Minister of Health, Labour and Welfare application Form No. 10 accompanied by documents indicating such examination fee and data required for the determination of such fee.

[Suspension or Discontinuance of Work]

**Article 18-10.** Any designated laboratory who wishes to obtain permission for suspension or discontinuance of all or part of product examination work pursuant to the provision of Article 19-7 of the Law shall submit application Form 11 to the Minister of Health, Labour and Welfare.

[Appointment of Executives]

**Article 18-11.** Any designated laboratory which wishes to obtain approval for the appointment of executives as prescribed by Article 19-9 of the Law shall submit to the Minister of Health, Labour and Welfare application Form No. 12.

[Items Which Shall be Recorded in Books]

**Article 18-12.** The items prescribed by the Ministerial Ordinance under Article 19-14 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 18-6 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 18-6 Subparagraph (8).

(11) Documents concerning training prescribed in Article 18-6 Subparagraph (12).

2. The books shall be retained for three years from the date of final writing.

[Certificates]

**Article 18-13.** The certificates which officials are required to carry pursuant to the provisions of Article 17 Paragraph 2 of the Law, that are applied in Article 19-16 Paragraph 2 of the Law, shall comply with Form No. 13.

## Chapter 5. Business

[Scholarly Achievement Required as Qualification for Food Sanitation Supervisors]

**Article 19.** As prescribed in Article 19-17 Paragraph 4 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 19-2.** Notification under the provisions of Article 19-17 Paragraph 6 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 additives, prescribed in Article 4-2 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 19-17 Paragraph 4 of the Law, and a document showing the relationship between each supervisor and the business person.

[Application for Business License]

**Article 20.** Any person who wishes to obtain a business license under the provisions of Article 21 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 one of the categories given in Subparagraphs (1) through (3) of Article 21 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 21 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 20-2.** 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 21-2 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 Licenced Business Persons by Merger]

**Article 20-3.** 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 21-2 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 through the director of the health center having jurisdiction over the location of the business office (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); or in the case of a person licensed by the mayor of a city or special ward, 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.

- (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 by Licensed Business Persons of Changes of Declared Items]

**Article 21.** When there has been any change in the items stated in Article 20 Paragraph 1 Subparagraph (1), (3), or (5), Article 20-2 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 through the director of the health center having jurisdiction over the location of the business office (in the case of a city establishing health centers or a special ward, through both the director of the health center concerned and the mayor of the city or ward 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 through the director of the health center having jurisdiction over the location of the business office.

## **Chapter 6. Miscellaneous Provisions**

[Notification of Poisoned Persons or Their Corpses]

**Article 22.** Notification by a medical doctor under the provisions of Article 27 of the Law (including cases where such provisions are applied based on Article 29 Paragraph 1 of the Law) 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 foods, additives, apparatus, containers/packages, or toys listed in each of Subparagraph (1) through (4) of Article 26-4.).

(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.

[Reports of Food Poisoning]

**Article 23.** The report under the provisions of Article 7 Paragraph 1 of the Cabinet Order shall cover a calendar month and be accompanied by a food-poisoning incident card prepared on the basis of Form No. 14, for each food poisoning incident.

2. The report prescribed in the preceding Paragraph shall be submitted by the end of the month following the month when the notification prescribed in the preceding Article has been made.

[Reports on Investigation Results Concerning Food-Poisoning Incidents]

**Article 24.** The report under the provisions of Article 7 Paragraph 3 of the Cabinet Order shall cover a calendar month and consist of investigation results concerning food-poisoning incidents on the basis of Form No.15.

2. The report prescribed in the preceding Paragraph shall be accompanied by the food-poisoning incident card attached to the report prescribed in Paragraph 1 of the preceding Article and submitted by the 20th of the month following the month when the report prescribed in Paragraph 1 of preceding Article was received .

[Toys Which May be Injurious to Human Health by Infants' Contact]

**Article 25.** The toys prescribed in Article 29 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 26.** The authority of the Minister of Health, Labour and Welfare prescribed in Article 19-8, Article 19-12 and Article 19-16 of the Law pursuant to the Provision of the Article 29-6 Paragraph 1 of the Law shall be transferred to the directors of the Local Bureau of Health and Welfare.