

# **Food Sanitation Act (This amended Act will come into effect by 1 Jun 2021. (Tentative translation))**

(Act No. 233 of December 24, 1947)

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## **Chapter I General Provisions**

Article 1 The purpose of this Act is to prevent the sanitation hazards resulting from eating and drinking by enforcing the regulations and other measures necessary, from the viewpoint of public health, to ensure food safety and thereby to protect citizens' good health.

Article 2 (1) The State, prefectures, cities specified by a Cabinet Order based on the provisions of Article 5, paragraph (1) of the Community Health Act (Act No. 101 of 1947) (hereinafter referred to as "cities establishing health centers") and special wards shall take the necessary measures to disseminate the correct knowledge concerning food sanitation through educational activities and PR activities, conduct the collection, compilation, analysis, and provision of information on food sanitation, promote research on food sanitation, enhance inspection capabilities concerning food sanitation, and foster the human resources to be engaged in the improvement of food sanitation and enhance their capabilities.

(2) The State, prefectures, cities establishing health centers, and special wards shall coordinate closely with each other so that measures concerning food sanitation shall be implemented comprehensively and immediately.

(3) The State shall develop a system for conducting the collection, compilation, analysis, and provision of information on food sanitation, carrying out research,

and making inspections on food sanitation with regard to imported food, additives, apparatus and containers and packaging, and take the measures necessary to ensure international coalition. At the same time, the State shall provide prefectures, cities establishing health centers, and special wards (hereinafter referred to as "prefectures, etc.") with the technical assistance necessary for them to pursue their responsibilities as set forth in the preceding two paragraphs.

Article 3 (1) A food business operator (meaning a person or juridical person who is engaged in collecting, producing, importing, processing, cooking, storing, transporting, or selling food or additives, or producing, importing, or selling apparatus or containers and packaging, or a person or juridical person who provides food to many and unspecified persons on an ongoing basis at schools, hospitals or other facilities; the same shall apply hereinafter) shall, on the food business operator's own responsibility, endeavor to ensure the safety of the food, additives, apparatus or containers and packaging which the food business operator collects, produces, imports, processes, cooks, stores, transports, sells, provides to many and unspecified persons, or uses in business (hereinafter referred to as "food for sale, etc."), and for that purpose, the food business operator shall endeavor to obtain the knowledge and technologies necessary to ensure the safety of food for sale, etc., ensure the safety of raw materials of food for sale, etc., conduct voluntary inspections of food for sale, etc., and take other necessary measures.

(2) A food business operator shall endeavor to make a record of any necessary information such as the name of a person who has sold food for sale, etc. or the raw materials thereof to the food business operator and retain such record, within the limit necessary for preventing food sanitation hazards resulting from food for sale, etc.

(3) In order to prevent food sanitation hazards resulting from food for sale, etc., a food business operator shall endeavor to take any necessary measures appropriately and immediately, such as the provision of a record prescribed in the preceding paragraph to the State or prefectures, etc. and the disposal of the food for sale, etc. which had caused the food sanitation hazards.

Article 4 (1) The term "food" as used in this Act shall mean all food and drink; provided, however, that this term shall not include pharmaceutical products, quasi-pharmaceutical products or regenerative medicine products specified by the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960).

(2) The term "additives" as used in this Act shall mean substances which are used by being added, mixed or infiltrated into food or by other methods in the

- process of producing food or for the purpose of processing or preserving food.
- (3) The term "natural flavoring agents" as used in this Act shall mean substances obtained from animals or plants or mixtures thereof which are used for flavoring food.
- (4) The term "apparatus" as used in this Act shall mean tableware, kitchen utensils, and other machines, implements, and other articles which are used for collecting, producing, processing, cooking, storing, transporting, displaying, delivering, or consuming food or additives and which come into direct contact with food or additives; provided, however, that this term shall not include machines, implements, and other articles used for harvesting food in agriculture and fisheries.
- (5) The term "containers and packaging" as used in this Act shall mean articles which contain or wrap food or additives and are offered "as is" when delivering food or additives.
- (6) The term "food sanitation" as used in this Act shall mean sanitation concerning eating and drinking, with regard to food, additives, apparatus, and containers and packaging.
- (7) The term "business" as used in this Act shall mean the act of collecting, producing, importing, processing, cooking, storing, transporting, or selling food or additives, or the act of producing, importing, or selling apparatus or containers and packaging, in the course of trade; provided, however, that the term shall not include the business of harvesting food in agriculture and fisheries.
- (8) The term "a business person" as used in this Act shall mean a person or juridical person who is engaged in business.
- (9) The term "a registered conformity assessment body" as used in this Act shall mean a juridical person who has obtained registration from the Minister of Health, Labour and Welfare pursuant to the provisions of Article 33, paragraph (1).

## **Chapter II Food and Additives**

Article 5 Food or additives which are used for sales (including delivery other than sales to many and unspecified persons; the same shall apply hereinafter) shall be collected, produced, processed, used, cooked, stored, transported, displayed and delivered in a clean and sanitary manner.

Article 6 The following food and additives shall not be sold (including cases of being delivered but not being sold to many and unspecified persons; the same shall apply hereinafter), or collected, produced, imported, processed, used, cooked, stored, or displayed for the purpose of marketing:

- (i) Articles which have deteriorated, or are rotten, or immature; provided, however, that this shall not apply to articles which involve no risk to human health in general and are recognized as being edible;
- (ii) Articles which contain or are covered with toxic or harmful substances or are suspected to contain or be covered with such substances; provided, however, that this shall not apply to cases where the Minister of Health, Labour and Welfare specifies that such articles involve no risk to human health;
- (iii) Articles which are contaminated with pathogens or are suspected to be so, and involve a risk to human health;
- (iv) Articles which involve a risk to human health due to contamination or the addition of foreign substances or on other grounds.

Article 7 (1) When articles which have not generally been served for human consumption and have not been proved to involve no risk to human health or articles including those articles have newly come to be sold or are going to be sold as food, the Minister of Health, Labour and Welfare may prohibit the sales of such articles as food, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council, when the Minister of Health, Labour and Welfare finds it necessary to prevent food sanitation hazards.

(2) Regarding articles which have generally been served for human consumption but are served in a manner extraordinarily different from ordinary manners, the Minister of Health, Labour and Welfare may prohibit the sales of such articles as food, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council, when there is no evidence to prove that the articles involve no risk to human health and the Minister of Health, Labour and Welfare finds it necessary to prevent food sanitation hazards.

(3) In the case of serious damage to human health which is suspected to have been caused by food, and when it is suspected, from the conditions of the damage, that the food included articles which have not generally been served for human consumption and involve the risk of causing the damage, the Minister of Health, Labour and Welfare may prohibit the sales of such food, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council, when the Minister of Health, Labour and Welfare finds it necessary to prevent food sanitation hazards.

(4) When the Minister of Health, Labour and Welfare has prohibited the sales under the preceding three paragraphs, and finds that there is no risk of food sanitation hazards resulting from articles or food pertaining to the prohibition, based on an application from an interested person concerning the prohibition, or as needed, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare, the Minister of Health, Labour and Welfare shall rescind the

prohibition, in whole or in part, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council.

- (5) When the Minister of Health, Labour and Welfare has prohibited the sales under paragraphs (1) to (3), or has rescinded the prohibition, in whole or in part, under the preceding paragraph, the Minister of Health, Labour and Welfare shall issue a public notice in the official gazette.

Article 8 (1) A business person who handles food containing any ingredient or material which requires special caution from the viewpoint of preventing food sanitation hazards and which has been designated by the Minister of Health, Labour and Welfare by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council (referred to as a "designated ingredient, etc." in paragraph (3) and Article 70, paragraph (1)) (hereinafter in this paragraph referred to as "food containing designated ingredient, etc.") shall, upon obtaining information that any food containing designated ingredient, etc. handled by the business person causes or may cause human health damage, notify the relevant prefectural governor, the city mayor of the relevant city establishing health centers, or the ward mayor of the relevant special ward (hereinafter referred to as the "prefectural governor, etc.") of that information without delay pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

- (2) When there has been a notification under the preceding paragraph, the prefectural governor, etc. shall report the notified information to the Minister of Health, Labour and Welfare.

- (3) Physicians, dentists, pharmacists and other relevant persons shall endeavor to monitor human health damage suspected of being caused by the ingestion of a designated ingredient, etc. and, at the request of the relevant prefectural governor, etc. for cooperation necessary for an investigation conducted by such prefectural governor, etc. into human health damage suspected of being caused by the ingestion of a designated ingredient, etc. in order to prevent food sanitation hazards, shall endeavor to provide information on the damage or to provide other necessary cooperation.

Article 9 (1) Regarding specific food or additives which are collected, produced, processed, cooked, or stored in a specific country or region, or which are collected, produced, processed, cooked, or stored by a specific person, if, as a result of inspections under Article 26, paragraphs (1) to (3), or Article 28, paragraph (1), a considerable number of articles falling under the following food or additives are found, or it is found that articles falling under the following food or additives are likely to be included to a considerable extent, judging from the conditions of food sanitation management at a production site

or on other grounds specified by an Ordinance of the Ministry of Health, Labour and Welfare, and the Minister of Health, Labour and Welfare finds it particularly necessary to prevent food sanitation hazards resulting from that specific food or additives, considering the level of the risk to human health and other matters specified by an Ordinance of the Ministry of Health, Labour and Welfare, the Minister of Health, Labour and Welfare may prohibit the sales of said specific food or additives, or the collection, production, import, processing, use, or cooking of that specific food or additives for the purpose of marketing, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council:

- (i) Food or additives listed in each item of Article 6;
  - (ii) Food prescribed in Article 12;
  - (iii) Food or additives which do not conform to the standards established pursuant to the provisions of Article 13, paragraph (1);
  - (iv) Food in which additives are used by methods that do not conform to the criteria established pursuant to the provisions of Article 13, paragraph (1);
  - (v) Food prescribed in Article 13, paragraph (3).
- (2) When the Minister of Health, Labour and Welfare intends to issue a prohibition under the preceding paragraph, the Minister of Health, Labour and Welfare shall consult with the heads of the relevant administrative organs in advance.
- (3) When the Minister of Health, Labour and Welfare has issued a prohibition under paragraph (1), and finds that there is no risk of food sanitation hazards resulting from specific food or additives pertaining to the prohibition, based on an application from an interested person concerning the prohibition, or as needed, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare, the Minister of Health, Labour and Welfare shall rescind the prohibition, in whole or in part, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council.
- (4) When the Minister of Health, Labour and Welfare has issued a prohibition under paragraph (1), or has issued a rescission of prohibition, in whole or in part, under the preceding paragraph, the Minister of Health, Labour and Welfare shall issue a public notice in the official gazette.

Article 10 (1) The meat, bones, milk, organs, and blood of livestock (meaning livestock prescribed in Article 3, paragraph (1) of the Slaughterhouse Act (Act No. 114 of 1953) and others specified by an Ordinance of the Ministry of Health, Labour and Welfare; the same shall apply hereinafter) which have or are suspected to have any of the diseases listed in item (i) or item (iii), have any of the disorders listed in item (i) or item (iii), or have died, or the meat, bones, and organs of poultry (meaning poultry prescribed in Article 2, item (i) of the

Poultry Slaughtering Business Control and Poultry Meat Inspection Act (Act No. 70 of 1990) and others specified by an Ordinance of the Ministry of Health, Labour and Welfare; the same shall apply hereinafter) which have or are suspected to have any of the diseases listed in item (ii) or item (iii), have any of the disorders listed in item (ii) or item (iii), or have died shall not be sold as food, or be collected, processed, used, cooked, stored, or displayed as food for the purpose of marketing, except for cases specified by an Ordinance of the Ministry of Health, Labour and Welfare; provided, however, that this shall not apply to the meat, bones, and organs of dead livestock or poultry which the ministry officials find as involving no risk to human health and as being edible.

(i) Diseases or disorders listed in each item of Article 14, paragraph (6) of the Slaughterhouse Act;

(ii) Diseases or disorders listed in each item of Article 15, paragraph (4) of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act;

(iii) Diseases or disorders other than those listed in the preceding two items which are specified by an Ordinance of the Ministry of Health, Labour and Welfare.

(2) The meat, milk and organs of livestock, and, the meat and organs of poultry, and, products thereof specified by an Ordinance of the Ministry of Health, Labour and Welfare (hereinafter referred to as "livestock meat, etc." in this paragraph) shall not be imported as food for the purpose of marketing, unless they have certificates or their copies attached which have been issued by a governmental organization of an exporting country, and which certify that they are not the meat, milk or organs of livestock, or, the meat or organs of poultry, or, products thereof which have or are suspected to have any of the diseases listed in each item of the preceding paragraph, have any of the disorders listed in each item of the same paragraph, or have died, and which contain other matters specified by an Ordinance of the Ministry of Health, Labour and Welfare (hereinafter referred to as "matters regarding sanitation" in this paragraph); provided, however, that this shall not apply to livestock meat, etc. imported from countries specified by an Ordinance of the Ministry of Health, Labour and Welfare, for which matters regarding sanitation concerning the livestock meat, etc. have been sent from a governmental organization of those countries via a telecommunications line to a computer (with an input-output device) used by the Ministry of Health, Labour and Welfare and have been recorded in a file on the computer.

Article 11 (1) The food and additives specified by an Ordinance of the Ministry of Health, Labour and Welfare as requiring the taking of measures to control particularly important processes in order to prevent food sanitation hazards shall not be imported for the purpose of marketing, unless they have been

produced or processed in the countries or regions or facilities specified by the Minister of Health, Labour and Welfare as reliably taking those measures.

- (2) The food and additives specified by an Ordinance of the Ministry of Health, Labour and Welfare as requiring certification of the conditions of food sanitation management at a production site in order to check that they do not fall under any of the food and additives listed in the items of Article 6 and to check other matters specified by an Ordinance of the Ministry of Health, Labour and Welfare shall not be imported for the purpose of marketing, unless they have certificates or their copies attached which have been issued by a governmental organization of an exporting country and which contain the relevant matters.

Article 12 Additives (excluding natural flavoring agents and articles that have generally been served for human consumption and that are used as additives) and preparations and food containing additives shall not be sold, or be produced, imported, processed, used, stored, or displayed for the purpose of marketing, except for cases that the Minister of Health, Labour and Welfare specifies as having no risk to human health by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council.

Article 13 (1) From the viewpoint of public health, the Minister of Health, Labour and Welfare may establish the criteria for the methods of producing, processing, using, cooking, or preserving food or additives to be served for the purpose of marketing, or may establish standards for the ingredients of food or additives to be served for the purpose of marketing, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council.

- (2) When the criteria or standards have been established pursuant to the provisions of the preceding paragraph, food or additives shall not be produced, processed, used, cooked, or preserved using methods that do not conform to such criteria; food or additives that do not conform to such criteria shall not be sold or imported; and food or additives that do not conform to such standards shall not be produced, imported, processed, used, cooked, preserved, or sold.

- (3) Food in which substances that are the ingredients of agricultural chemicals (meaning agricultural chemicals prescribed in Article 2, paragraph (1) of the Agricultural Chemicals Regulation Act (Act No. 82 of 1948), hereinafter the same shall apply in the following Article), substances that are used by being added, mixed or infiltrated into feed (meaning feed prescribed in Article 2, paragraph (2) of the Act on Safety Assurance and Quality Improvement of Feed (Act No. 35 of 1953)) or are used by other methods for feed for the purpose of providing it for usage specified by an Ordinance of the Ministry of Agriculture, Forestry and Fisheries based on Article 2, paragraph (3) of the same Act, and



pharmaceutical products that are prescribed in Article 2, paragraph (1) of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices and are to be used for animals (including substances chemically generated from such substances and excluding substances that the Minister of Health, Labour and Welfare specifies as clearly having no risk to human health) remain in a quantity exceeding the quantity that the Minister of Health, Labour and Welfare specifies as having no risk to human health by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council shall not be produced, imported, processed, used, cooked, preserved, or sold for the purpose of marketing; provided, however, that this shall not apply to cases where standards concerning the ingredients of food under paragraph (1) have been established with regard to the residual limit of those substances in that food.

Article 14 When the Minister of Health, Labour and Welfare intends to establish a quantity limit for substances (including substances chemically generated from such substances) that are the ingredients of the agricultural chemicals, feed additives prescribed in Article 2, paragraph (3) of the Act on Safety Assurance and Quality Improvement of Feed, and pharmaceutical products that are prescribed in Article 2, paragraph (1) of the Act on Securing Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices and are to be used only for animals (hereinafter referred to as "agricultural chemicals, etc." in this Article) remaining in food as the standard concerning the ingredients of food set forth in paragraph (1) of the preceding Article, or when the Minister of Health, Labour and Welfare intends to designate the edible scope of meat, milk and other products of the target animals (meaning the target animals prescribed in Article 14, paragraph (2), item (iii) (b) of the same Act after replacing the relevant terms pursuant to the provisions of Article 83, paragraph (1) of the same Act) in which regenerative medicine products that are prescribed in Article 2, paragraph (9) of the same Act and are to be used only for animals (hereinafter referred to as "animal regenerative medicine products" in this Article) have been used, or when the Minister of Health, Labour and Welfare finds it necessary, the Minister of Health, Labour and Welfare may request the Minister of Agriculture, Forestry and Fisheries to provide data concerning the ingredients of the agricultural chemicals, etc. or concerning the component cells, transgenes and other materials specified by an Ordinance of the Ministry of Health, Labour and Welfare of the animal regenerative medicine products, or to offer other necessary cooperation.

### **Chapter III Apparatus and Containers and Packaging**

Article 15 Apparatus and containers and packaging used in business shall be clean and sanitary.

Article 16 Apparatus or containers and packaging which contain or are covered with toxic or harmful substances and involve a risk to human health, or apparatus or containers and packaging which touch food or additives and have a harmful effect on them and involve a risk to human health shall not be sold, nor be produced or imported for the purpose of marketing, nor be used in business.

Article 17 (1) Regarding specific apparatus or containers and packaging which are produced in a specific country or region, or are produced by a specific person, if, as a result of inspections under Article 26, paragraphs (1) to (3), or Article 28, paragraph (1), a considerable number of articles falling under the following apparatus or containers and packaging are found, or it is found that articles falling under the following apparatus or containers and packaging are likely to be included to a considerable extent, judging from the conditions of food sanitation management at a production site or on other grounds specified by an Ordinance of the Ministry of Health, Labour and Welfare, and the Minister of Health, Labour and Welfare finds it particularly necessary to prevent the food sanitation hazards resulting from that specific apparatus or containers and packaging, considering the level of the risk to human health and other matters specified by an Ordinance of the Ministry of Health, Labour and Welfare, the Minister of Health, Labour and Welfare may prohibit the sales of said specific apparatus or containers and packaging, the production or import of said specific apparatus or containers and packaging for the purpose of marketing, or the use of that specific apparatus or containers and packaging in business, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council:

(i) Apparatus or containers and packaging prescribed in the preceding Article;

(ii) Apparatus or containers and packaging which do not conform to the standards established pursuant to the provisions of paragraph (1) of the following Article.

(iii) Apparatus or containers and packaging violating paragraph (3) of the following Article.

(2) When the Minister of Health, Labour and Welfare intends to issue a prohibition under the preceding paragraph, the Minister of Health, Labour and Welfare shall consult with the heads of the relevant administrative organs in advance.

(3) The provisions of Article 9, paragraphs (3) and (4) shall apply mutatis

mutandis to the case where a prohibition under paragraph (1) has been issued. In this case, the term "food or additives" in paragraph (3) of the same Article shall be deemed to be replaced with "apparatus or containers and packaging."

Article 18 (1) From the viewpoint of public health, the Minister of Health, Labour and Welfare may establish standards for the apparatus or containers and packaging, or the raw materials thereof to serve for the purpose of marketing or to be used in business, or establish the criteria for the production methods thereof, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council.

(2) When the standards or criteria have been established pursuant to the provisions of the preceding paragraph, the apparatus or containers and packaging which do not conform to such standards shall not be sold, nor be produced or imported for the purpose of marketing, nor be used in business; raw materials which do not conform to such standards shall not be used; and the apparatus or containers and packaging shall not be produced by methods that do not conform to such criteria.

(3) Apparatus or containers and packaging shall not be made of raw materials which are those of materials specified by a Cabinet Order by taking into consideration the impact on public health of the elution or leaching of their components into food and for which the maximum levels at which their component substances (excluding substances chemically generated from such component substances) are permitted to be contained in apparatus or containers and packaging produced using those raw materials or are permitted to migrate by elution or leaching into food from apparatus or containers and packaging produced using those raw materials, are not specified in the standards established in paragraph (1); provided, however, that this shall not apply to cases where apparatus or containers and packaging have been processed so as to eliminate the risk of those substances migrating by eluting or leaching into food beyond the maximum levels specified by the Minister of Health, Labour and Welfare as involving no risk to human health by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council (excluding cases where those substances are used in such part of the apparatus or containers and packaging as come into contact with food).

#### **Chapter IV Labeling and Advertising**

Article 19 (1) From the viewpoint of accurately communicating to general consumers information on apparatus or containers and packaging that is necessary for public health, the Prime Minister may establish necessary criteria for the labeling of apparatus or containers and packaging for which

standards or criteria have been established pursuant to the provisions of paragraph (1) of the preceding Article, by hearing the opinions of the Consumer Commission.

- (2) Apparatus or containers and packaging for which the criteria for labeling have been established pursuant to the provisions of the preceding paragraph shall not be sold, displayed for the purpose of marketing, nor used in business, without labeling which conforms to such criteria.
- (3) Criteria for the labeling of food and additives for the purpose of marketing shall be subject to the Food Labeling Act (Act No. 70 of 2013).

Article 20 False or exaggerated labeling or advertising, which may cause harm to public health regarding food, additives, apparatus, or containers and packaging, shall not be used.

### **Chapter V Japanese Standards of Food Additives**

Article 21 Regarding additives for which the criteria and standards have been established pursuant to the provisions of Article 13, paragraph (1) and additives for which the criteria have been established pursuant to the provisions of Article 4, paragraph (1) of the Food Labeling Act, the Minister of Health, Labour and Welfare and the Prime Minister shall compile the Japanese Standards of Food Additives to contain the relevant criteria and standards.

### **Chapter VI Monitoring and Guidance**

Article 21-2 The State and prefectures, etc. shall work together in mutual coordination to ensure that their monitoring or guidance related to food sanitation (hereinafter referred to as "monitoring and guidance") will be implemented comprehensively and promptly, in order to prevent persons who have been or are suspected to have been poisoned by food, additives, apparatus, or containers and packaging (hereinafter referred to as "persons poisoned by food, etc.") from appearing across wide areas or increasing and to prevent any violations pertaining to this Act or orders or dispositions based on this Act with regard to food, additives, apparatus, or containers and packaging distributed widely.

Article 21-3 (1) The Minister of Health, Labour and Welfare may establish a wide-area cooperating council consisting of the State, prefectures, etc. and other relevant organizations pursuant to an Ordinance of the Ministry of Health, Labour and Welfare (hereinafter each referred to as a "council" in this

Article and Article 66), in order to ensure the development of a system for coordination and cooperation in the implementation of monitoring and guidance.

- (2) A council may include as its members prefectures, etc. other than the member prefecture, etc. of the council and other persons deemed necessary by the council, when the council finds it necessary.
- (3) The members of a council shall respect the results of discussions concerning the matters agreed upon at the council meetings.
- (4) In addition to what is prescribed in the preceding three paragraphs, the matters necessary for the operation of a council shall be specified by the council.

Article 22 (1) The Minister of Health, Labour and Welfare and the Prime Minister shall establish guidelines concerning the monitoring and guidance to be implemented by the State and prefectures, etc. (hereinafter referred to as the "guidelines").

- (2) The guidelines shall define the following matters:
  - (i) Basic policies concerning the implementation of monitoring and guidance;
  - (ii) Matters concerning items for which monitoring and guidance shall be implemented intensively;
  - (iii) Matters concerning a system for implementing monitoring and guidance;
  - (iv) Matters concerning the ensuring of mutual coordination and cooperation between the State, prefectures, etc. and other relevant organizations in the implementation of monitoring and guidance.
  - (v) Other important matters concerning the implementation of monitoring and guidance.
- (3) When the Minister of Health, Labour and Welfare and the Prime Minister have established or revised the guidelines, they shall publicize it and notify prefectural governors, etc. of such guidelines without delay.

Article 23 (1) Every fiscal year, the Minister of Health, Labour and Welfare shall establish a plan concerning the monitoring and guidance to be implemented by the State regarding the following fiscal year's import of food, additives, apparatus, and containers and packaging (hereinafter referred to as the "imported food monitoring and guidance plan"), based on the guidelines.

- (2) The imported food monitoring and guidance plan shall define the following matters:
  - (i) Matters concerning items for which monitoring and guidance shall be implemented intensively, judging from circumstances at the productions sites and other circumstances;
  - (ii) Matters concerning guidance on the implementation of voluntary sanitation

- management for business persons engaged in import;
- (iii) Other matters needed for the implementation of monitoring and guidance.
- (3) When the Minister of Health, Labour and Welfare has established or revised the imported food monitoring and guidance plan, the Minister of Health, Labour and Welfare shall publicize it without delay.
- (4) The Minister of Health, Labour and Welfare shall publicize the implementation of the imported food monitoring and guidance plan.

Article 24 (1) Every fiscal year, a prefectural governor, etc. shall establish plans concerning the following fiscal year's monitoring and guidance to be implemented by that prefecture, etc. (hereinafter referred to as "prefectural plans for the monitoring of and guidance on food sanitation"), based on the guidelines.

- (2) Prefectural plans for the monitoring of and guidance on food sanitation shall define the following matters:
- (i) Matters concerning items for which monitoring and guidance shall be implemented intensively;
- (ii) Matters concerning guidance on the implementation of voluntary sanitation management for food business operators;
- (iii) Matters concerning the ensuring of coordination and cooperation with the State and other relevant organizations including other prefectures, etc. in the implementation of monitoring and guidance;
- (iv) Other matters needed for the implementation of monitoring and guidance.
- (3) Prefectural plans for the monitoring of and guidance on food sanitation shall be established by taking into consideration the situation of facilities established by food business operators in areas of that prefecture, etc., actual conditions of food sanitation hazards, and other circumstances of the areas.
- (4) When a prefectural governor, etc. has established or revised prefectural plans for the monitoring of and guidance on food sanitation, the prefectural governor, etc. shall publicize it and report it to the Minister of Health, Labour and Welfare and the Prime Minister, without delay, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare and a Cabinet Office Ordinance.
- (5) A prefectural governor, etc. shall publicize the implementation of prefectural plans for the monitoring of and guidance on food sanitation, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare and a Cabinet Office Ordinance.

## **Chapter VII Inspections**

Article 25 (1) Food or additives specified by a Cabinet Order for which standards have been established pursuant to the provisions of Article 13, paragraph (1),

or apparatus or containers and packaging specified by a Cabinet Order for which standards have been established pursuant to the provisions of Article 18, paragraph (1) shall not be sold, displayed for the purpose of marketing, nor used in business, unless they have labeling specified by an Ordinance of the Ministry of Health, Labour and Welfare attached which certifies that they have received inspections by the Minister of Health, Labour and Welfare, a prefectural governor, or a registered conformity assessment body in accordance with a classification specified by a Cabinet Order and have passed the inspections.

- (2) A person who intends to receive inspections by the Minister of Health, Labour and Welfare pursuant to the provisions of the preceding paragraph shall pay a fee specified by the Minister of Health, Labour and Welfare by taking into consideration the actual costs of the assessment, and a person who intends to receive inspections by a registered conformity assessment body pursuant to the provisions of the preceding paragraph shall pay a fee specified by the registered conformity assessment body by obtaining approval from the Minister of Health, Labour and Welfare by taking into consideration the actual costs of the assessment.
- (3) A fee set forth in the preceding paragraph which has been paid by a person who intends to receive inspections by the Minister of Health, Labour and Welfare shall be deemed to be income of the Treasury and a fee set forth in the preceding paragraph which has been paid by a person who intends to receive inspections by a registered conformity assessment body shall be deemed to be income of the registered conformity assessment body.
- (4) In addition to what is prescribed in the preceding three paragraphs, the matters necessary for inspections set forth in paragraph (1) and the measures to be taken when passing the inspections shall be specified by a Cabinet Order.
- (5) No request for examination may be made against the results of inspections set forth in paragraph (1).

Article 26 (1) When a prefectural governor has found food, additives, apparatus or containers and packaging listed in the following items, and finds, in light of the capabilities, etc. for conducting inspections of a person who produced or processed them, that food, additives, apparatus or containers and packaging which the person produced or processed are likely to continue to fall under those listed in the following items and finds it necessary to prevent food sanitation hazards, the prefectural governor may, following requirements and procedures specified by a Cabinet Order, order the person to receive inspections by the prefectural governor or a registered conformity assessment body regarding the relevant food, additives, apparatus or containers and packaging:

- (i) Food or additives listed in Article 6, item (ii) or item (iii);
  - (ii) Food or additives which do not conform to standards established pursuant to the provisions of Article 13, paragraph (1);
  - (iii) Food for which additives are used in methods that do not conform to the criteria established pursuant to the provisions of Article 13, paragraph (1);
  - (iv) Food prescribed in Article 13, paragraph (3);
  - (v) Apparatus, or containers and packaging prescribed in Article 16;
  - (vi) Apparatus, or containers and packaging which do not conform to standards established pursuant to the provisions of Article 18, paragraph (1);
  - (vii) Apparatus or containers and packaging violating Article 18, paragraph (3).
- (2) When the Minister of Health, Labour and Welfare finds it necessary to prevent food sanitation hazards, the Minister of Health, Labour and Welfare may order a person who imports food, additives, apparatus or containers and packaging of the same type as those produced or processed by a person who has produced or processed food, additives, apparatus or containers and packaging listed in each item of the preceding paragraph or food prescribed in Article 12 to receive inspections by the Minister of Health, Labour and Welfare or a registered conformity assessment body regarding the relevant food, additives, apparatus or containers and packaging.
- (3) When the Minister of Health, Labour and Welfare finds it necessary to prevent food sanitation hazards, the Minister of Health, Labour and Welfare may order a person who imports food, additives, apparatus or containers and packaging which are found likely to fall under those listed in each item of paragraph (1) or food prescribed in Article 12, judging from circumstances at production sites and other circumstances, to receive inspections by the Minister of Health, Labour and Welfare or a registered conformity assessment body regarding the relevant food, additives, apparatus or containers and packaging.
- (4) A person who has received an order under the preceding three paragraphs shall not sell the relevant food, additives, apparatus or containers and packaging, display them for the purpose of marketing, nor use them in business until the person receives the relevant inspections and receives notice of the results thereof.
- (5) A notice set forth in the preceding paragraph which is to be made by a registered conformity assessment body shall be made through the prefectural governor or the Minister of Health, Labour and Welfare who has ordered the person to receive the relevant inspections.
- (6) A person who intends to receive inspections by the Minister of Health, Labour and Welfare pursuant to the provisions of paragraphs (1) to (3) shall pay a fee specified by the Minister of Health, Labour and Welfare by taking into consideration the actual costs of the assessment, and a person who intends to



receive inspections by a registered conformity assessment body pursuant to the provisions of paragraphs (1) to (3) shall pay a fee specified by the registered conformity assessment body, by obtaining approval from the Minister of Health, Labour and Welfare, by taking into consideration the actual costs of the assessment.

(7) The provisions of paragraphs (3) to (5) of the preceding Article shall apply *mutatis mutandis* to inspections set forth in paragraphs (1) to (3).

Article 27 A person who intends to import food, additives, apparatus or containers and packaging to serve for the purpose of marketing or to use in business shall make a notification to the Minister of Health, Labour and Welfare on a case-by-case basis, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

Article 28 (1) The Minister of Health, Labour and Welfare, the Prime Minister, or a prefectural governor, etc. may, when it is found to be necessary, request a business person or other relevant persons to submit the necessary report, or have their officials visit places for business, offices, warehouses, and other places, inspect food, additives, apparatus or containers and packaging to serve for the purpose of marketing or to use in business, business facilities, books and documents, and other articles, and remove food, additives, apparatus or containers and packaging to serve for the purpose of marketing or to use in business, without charge, within the limit necessary for using them for the purpose of testing.

(2) The Minister of Health, Labour and Welfare or a prefectural governor, etc. shall, when having their officials conduct on-site inspections, or remove articles pursuant to the provisions of the preceding paragraph, have them carry their identification and produce it at the request of relevant persons.

(3) The authorities prescribed in paragraph (1) shall not be construed as having been granted for criminal investigation.

(4) The Minister of Health, Labour and Welfare, the Prime Minister, or a prefectural governor, etc. may entrust affairs concerning the testing of food, additives, apparatus or containers and packaging that have been removed pursuant to the provisions of paragraph (1) to a registered conformity assessment body.

Article 29 (1) The State and prefectures shall set up the necessary facilities for inspections where inspections under Article 25, paragraph (1) or Article 26, paragraphs (1) to (3) (hereinafter referred to as "product inspections") and affairs concerning the testing of food, additives, apparatus or containers and packaging that have been removed pursuant to the provisions of paragraph (1)

of the preceding Article are to be carried out.

- (2) Cities establishing health centers and special wards shall set up the necessary facilities for inspections where the business affairs concerning the testing of food, additives, apparatus or containers and packaging that have been removed pursuant to the provisions of paragraph (1) of the preceding Article are to be carried out.
- (3) The matters necessary for food sanitation inspection facilities of prefectures, etc. shall be specified by a Cabinet Order.

- Article 30 (1) The Minister of Health, Labour and Welfare, the Prime Minister, or a prefectural governor, etc. shall appoint food sanitation inspectors from among their officials to have them enforce the authority thereof prescribed in Article 28, paragraph (1) and perform the duties of guidance on food sanitation.
- (2) A prefectural governor, etc. shall have food sanitation inspectors appointed by the prefectural governor, etc. implement monitoring and guidance, pursuant to the prefectural plans for the monitoring of and guidance on food sanitation.
  - (3) The Prime Minister shall, pursuant to the guidelines, have food sanitation inspectors appointed by the Prime Minister implement monitoring and guidance pertaining to the labeling or advertising of food, additives, apparatus, and containers and packaging.
  - (4) The Minister of Health, Labour and Welfare shall have food sanitation inspectors appointed by the Minister of Health, Labour and Welfare implement monitoring and guidance pertaining to the import of food, additives, apparatus, and containers and packaging, pursuant to the imported food monitoring and guidance plan.
  - (5) In addition to what is prescribed in the preceding each paragraph, the qualifications of food sanitation inspectors and other matters necessary for food sanitation inspectors shall be specified by a Cabinet Order.

### **Chapter VIII Registered Conformity Assessment Bodies**

Article 31 A person who intends to obtain registration as a registered conformity assessment body shall pay a fee specified by a Cabinet Order by taking into consideration the actual costs of the assessment and apply for registration with the Minister of Health, Labour and Welfare, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

Article 32 A juridical person falling under any of the following items may not obtain registration as a registered conformity assessment body:

- (i) A juridical person who has been sentenced to a fine or severer punishment for violation of this Act or any disposition based on this Act or whose officer

in charge of its business has been sentenced to a fine or severer punishment for violation of this Act or any disposition based on this Act, before the expiration of a period of two years since the person served out the sentence or ceased to be subject to the sentence;

- (ii) A juridical person who has had its registration rescinded pursuant to the provisions of Article 43, before the expiration of a period of two years since the date of said rescission;
- (iii) A juridical person whose business is to be conducted by an officer who has been an officer in charge of the business of the juridical person pertaining to the rescission of registration under Article 43 within 30 days prior to the date of said rescission, before the expiration of a period of two years since the date of said rescission.

Article 33 (1) When a person who has applied for registration under Article 31 (hereinafter referred to as an "applicant for registration" in this paragraph) conforms to all the requirements listed as follows, the Minister of Health, Labour and Welfare shall register that person. In this case, the procedures necessary for registration shall be specified by an Ordinance of the Ministry of Health, Labour and Welfare:

- (i) A person shall possess the machines, implements, and other facilities listed in column 2 of the appended table respectively for each type of product inspection listed in column 1 of the same table, product inspections shall be conducted by a person who has the knowledge and experience that conform to the conditions listed in column 3 of the same table, and the number of such persons shall exceed the number listed in column 4 of the same table;
- (ii) Measures to ensure the credibility of product inspections listed as follows shall be taken:
  - (a) Full-time supervisors shall be placed for each type of product inspection at departments conducting inspections;
  - (b) Documents concerning management of the operation of product inspections and the securing of accuracy shall be prepared;
  - (c) A specialized department shall be established for managing the operation of product inspections and ensuring accuracy in accordance with what is written in the documents listed in (b);
- (iii) An applicant for registration shall not fall under any of the following as a person governed by a business person who sells food, additives, apparatus, or containers and packaging for which product inspections under Article 25, paragraph (1) or Article 26, paragraphs (1) to (3) shall be received, or who produces, imports, processes, or displays such articles for the purpose of marketing, or uses such articles in business (hereinafter referred to a "business person subject to inspections" in this item and in Article 39,

paragraph (2)):

- (a) If an applicant for registration is a stock company, a business person subject to inspections shall be its parent corporation (meaning parent corporations prescribed in Article 879, paragraph (1) of the Companies Act (Act No. 86 of 2005));
  - (b) More than half of the officers of an applicant for registration (in the case of a partnership corporation (meaning partnership corporations prescribed in Article 575, paragraph (1) of the Companies Act), personnel in charge of its business) shall be officers or employees of a business person subject to inspections (including those who have been officers or employees of the business person subject to inspections in the past two years);
  - (c) Representative officers of an applicant for registration shall be officers or employees of a business person subject to inspections (including those who have been officers or employees of the business person subject to inspections in the past two years).
- (2) Registration shall be made by entering the following matters in the registry:
- (i) The date of registration and registration number;
  - (ii) The name of the registered conformity assessment body, the name of its representative, and the location of its principal office;
  - (iii) Types of product inspections which the registered conformity assessment body shall conduct;
  - (iv) The name and the location of the office where the registered conformity assessment body shall conduct product inspections.

Article 34 (1) Registration as a registered conformity assessment body shall, unless it is renewed at an interval of not less than three years as specified by a Cabinet Order, cease to be effective upon the expiration of such period.

(2) The provisions of Article 31 to the preceding Article shall apply *mutatis mutandis* to the renewal of registration set forth in the preceding paragraph.

Article 35 (1) A registered conformity assessment body shall conduct product inspections without delay, when requested, except for cases where there are justifiable grounds not to do so.

(2) A registered conformity assessment body shall conduct product inspections fairly by a method that conforms to the technical criteria specified by an Ordinance of the Ministry of Health, Labour and Welfare.

Article 36 (1) When a registered conformity assessment body intends to newly establish or abolish an office where it conducts product inspections or intends to change the locations thereof, it shall notify the Minister of Health, Labour and Welfare by one month prior to the day when the establishment, abolition,

or change is scheduled.

- (2) A registered conformity assessment body shall, when there has been any change to the matters listed in Article 33, paragraph (2), items (ii) and (iv) (limited to the parts pertaining to the name of the office), notify the Minister of Health, Labour and Welfare to that effect without delay, and, when intending to change the matters listed in item (iii) of the same paragraph, notify the Minister of Health, Labour and Welfare to that effect by one month prior to the day when the change is scheduled.

Article 37 (1) A registered conformity assessment body shall establish rules concerning the operation of product inspections (hereinafter referred to as "operational rules") and apply for approval from the Minister of Health, Labour and Welfare prior to the initiation of the operation of product inspections. The same shall apply when it intends to change the rules.

- (2) Operational rules shall define methods for conducting product inspections, fees concerning product inspections, and other matters specified by an Ordinance of the Minister of Health, Labour and Welfare.
- (3) When the Minister of Health, Labour and Welfare finds that operational rules for which he/she has granted approval under paragraph (1) have become inappropriate for conducting product inspections fairly, the Minister of Health, Labour and Welfare may order the registered conformity assessment body to change the operational rules.

Article 38 A registered conformity assessment body shall not suspend, in whole or in part, the operation of product inspections nor abolish the operation of product inspections without obtaining the approval of the Minister of Health, Labour and Welfare.

Article 39 (1) Within three months after the end of each business year, a registered conformity assessment body shall prepare an inventory of property, balance sheet, profit and loss statement or income and expenditure account statement, and business report of the business year (including an electromagnetic record (any record which is prepared by electronic, magnetic, or any other means unrecognizable by natural perceptive function, and is used for data-processing by a computer; hereinafter the same shall apply in this Article) in cases where electromagnetic records are prepared instead of those paper documents; referred to as "financial statements, etc." in the following paragraph and Article 89), and maintain them at the office for a period of five years thereafter.

- (2) A business person subject to inspections and any other interested person may make the following requests at any time within the business hours of a

registered conformity assessment body. However, when making a request set forth in item (ii) or item (iv), they shall pay fees specified by the registered conformity assessment body:

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

Article 40 (1) Officers, employees of a registered conformity assessment body or those who formerly held such positions shall not disclose secrets which have come to their knowledge concerning the operation of product inspections or the business affairs entrusted to them pursuant to the provisions of Article 28, paragraph (4) (referred to as "entrusted affairs" in the following paragraph).

(2) Officers or employees of a registered conformity assessment body who are engaged in the operation of product inspections or entrusted affairs shall be deemed to be officials engaged in public duties by laws and regulations when the penal provisions prescribed by the Penal Code (Act No. 45 of 1907) or other laws and regulations are applied.

Article 41 When the Minister of Health, Labour and Welfare finds that a registered conformity assessment body has become unconformable to any of the items of Article 33, paragraph (1), the Minister of Health, Labour and Welfare may order the registered conformity assessment body to take necessary measures to make it conformable to these provisions.

Article 42 When the Minister of Health, Labour and Welfare finds that a registered conformity assessment body has violated the provisions of Article 35, or that product inspections by a registered conformity assessment body, labeling under Article 25, paragraph (1), or a statement of notice under Article 26, paragraph (4) are not appropriate, the Minister of Health, Labour and Welfare may order the registered conformity assessment body to conduct product inspections or take necessary measures to improve its methods of product inspections or other operational methods.

Article 43 The Minister of Health, Labour and Welfare may, when a registered conformity assessment body falls under any of the following items, rescind the registration thereof, or order the suspension of the operation of product inspections, in whole or in part, for a specified period:

- (i) When a registered conformity assessment body has violated the provisions of this Chapter;
- (ii) When a registered conformity assessment body now falls under Article 32, item (i) or item (iii);
- (iii) When a registered conformity assessment body has conducted product inspections without following the operational rules approved under Article 37, paragraph (1);
- (iv) When a registered conformity assessment body has violated an order issued under Article 37, paragraph (3), or the preceding two Articles;
- (v) When a registered conformity assessment body has rejected a request under each item of Article 39, paragraph (2), without justifiable grounds;
- (vi) When a registered conformity assessment body has obtained registration under Article 33, paragraph (1), by wrongful means.

Article 44 A registered conformity assessment body shall keep books, record matters concerning product inspections specified by an Ordinance of the Ministry of Health, Labour and Welfare, and retain them, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

Article 45 In any of the following cases, the Minister of Health, Labour and Welfare shall issue a public notice of the relevant matters in official gazettes:

- (i) When the Minister of Health, Labour and Welfare has granted registration under Article 33, paragraph (1);
- (ii) When registration of a registered conformity assessment body has ceased to be effective pursuant to the provisions of Article 34, paragraph (1);
- (iii) When there has been a notification under Article 36, paragraph (1) or paragraph (2);
- (iv) When the Minister of Health, Labour and Welfare has granted approval under Article 38;
- (v) When the Minister of Health, Labour and Welfare has rescinded registration or ordered the suspension of product inspections under Article 43.

Article 46 (1) A person other than a registered conformity assessment body shall not use labeling or advertising or conduct any other acts which may cause people to mistake the operation the person conducts for a product inspection.

- (2) The Minister of Health, Labour and Welfare may order a person other than a registered conformity assessment body to take measures not to cause people to mistake the operation the person conducts for a product inspection.

Article 47 (1) The Minister of Health, Labour and Welfare may have a registered conformity assessment body make a report on its operation or financial situation, or have the ministry officials visit offices or places of business of a registered conformity assessment body to inspect its operational situation or books, documents and other articles, or question relevant persons, to the extent necessary for the enforcement of this Act.

- (2) The provisions of Article 28, paragraphs (2) and (3) shall apply mutatis mutandis to cases set forth in the preceding paragraph.

### **Chapter IX Business**

Article 48 (1) A business person who produces or processes dairy products, additives specified by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 12, or other food or additives requiring special consideration with regard to sanitation in the process of production or processing and which are specified by a Cabinet Order shall place a full-time food sanitation supervisor for each facility to have the food sanitation supervisor supervise the production or processing in a sanitary manner; provided, however, that this shall not apply to facilities which the business person supervises as a food sanitation supervisor in person.

- (2) If a business person conducts production or processing businesses for which full-time food sanitation supervisors are required under the preceding paragraph at two or more facilities, and those facilities lie next to each other, one food sanitation supervisor shall be sufficient for those two or more facilities, notwithstanding the provisions of the preceding paragraph.

- (3) A food sanitation supervisor shall supervise persons who are engaged in the production or processing of food or additives pertaining to the food sanitation supervisor's supervision at the relevant facility so that there should be no violations pertaining to this Act nor orders or dispositions based on this Act with regard to such food or additives.

- (4) In addition to what is prescribed in the preceding paragraph, a food sanitation supervisor shall take the necessary care and state the necessary opinions to the business person with regard to sanitation management methods at the relevant facility and other matters concerning food sanitation, in order to prevent any violations pertaining to this Act or orders or dispositions based on this Act and prevent food sanitation hazards, with regard to food or additives pertaining to the food sanitation supervisor's supervision at the



relevant facility.

- (5) When placing a food sanitation supervisor at a facility, a business person shall respect the stated opinions of the food sanitation supervisor pursuant to the provisions of the preceding paragraph.
- (6) No person other than those falling under any of the following items may be a food sanitation supervisor:
  - (i) A physician, dentist, pharmacist, or veterinarian;
  - (ii) A person who has graduated from a university under the School Education Act (Act No. 26 of 1947), a university under the old University Ordinance (Imperial Ordinance No. 388 of 1918) or a vocational training school under the old Vocational Training School Ordinance (Imperial Ordinance No. 61 of 1903) after completing a course in medical science, dentistry, pharmacy, veterinary medicine, animal science, fisheries science, or agricultural chemistry (including persons who have completed such course and have completed the junior course of a specialist university under the same Act);
  - (iii) A person who has completed prescribed courses at training institutes for food sanitation supervisors registered by a prefectural governor;
  - (iv) A person who has graduated from a high school or secondary education school under the School Education Act or a secondary school under the old Secondary School Ordinance (Imperial Ordinance No. 36 of 1943) or a person who is deemed to have equal or greater academic ability than the above-mentioned persons pursuant to an Ordinance of the Ministry of Health, Labour and Welfare and who has been engaged in sanitation management of the production or processing of food or additives for three years or more at production or processing businesses for which full-time food sanitation supervisors are required under paragraph (1), and who has completed courses of training sessions registered by a prefectural governor.
- (7) A person who possesses the qualifications of a food sanitation supervisor due to falling under item (iv) of the preceding paragraph may become a food sanitation supervisor only at a facility of the same type of production or processing business as the one where the person has been engaged in food management work for three years or more.
- (8) A business person prescribed in paragraph (1) shall, when placing a food sanitation supervisor or becoming one in person, notify the name of the food sanitation supervisor or the fact that the business person has become a food sanitation supervisor and other matters specified by an Ordinance of the Ministry of Health, Labour and Welfare to the prefectural governor of the location of the facility of the business person within 15 days. The same shall apply when the business person has changed food sanitation supervisors.

Article 49 Necessary matters concerning registration of training institutes under

paragraph (6), item (iii) of the preceding Article or training sessions under item (iv) of the same paragraph shall be specified by a Cabinet Order, and subjects and other necessary matters concerning courses at training institutes under item (iii) of the same paragraph and courses of training sessions under item (iv) of the same paragraph shall be specified by an Ordinance of the Ministry of Health, Labour and Welfare.

Article 50 (1) The Minister of Health, Labour and Welfare may establish the necessary criteria concerning measures to prevent toxic or harmful substances from getting mixed into food or additives in the process of the production or processing of the food or additives.

(2) When criteria have been established pursuant to the provisions of the preceding paragraph, a business person (excluding poultry slaughterers prescribed in Article 6, paragraph (1) of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act) shall observe them.

Article 51 (1) The Minister of Health, Labour and Welfare shall, by an Ordinance of the Ministry of Health, Labour and Welfare, establish criteria for the following matters pertaining to the sanitary management of facilities for businesses (excluding businesses producing apparatus or containers and packaging and businesses of poultry slaughtering prescribed in Article 2, paragraph (5) of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act (referred to as "poultry slaughtering businesses" in Article 54 and Article 57, paragraph (1))) and pertaining to other measures necessary for public health (hereinafter referred to as "measures necessary for public health in the Article"):

(i) Matters concerning the maintenance of the cleanliness of the interior and exterior of such facilities, and extermination of rats and insects and other general sanitation management;

(ii) Matters concerning efforts to control processes that are particularly important to prevent food sanitation hazards (in the case of small business persons (excluding business persons who produce apparatus or containers and packaging and poultry slaughterers prescribed in Article 6, paragraph (1) of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act; the same shall apply in the following paragraph) and other business persons specified by a Cabinet Order, efforts accommodating the characteristics of the food handled by such business persons).

(2) A business person shall establish and comply with measures necessary for public health in accordance with the criteria established pursuant to the provisions of the preceding paragraph and pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

- (3) A prefectural governor, etc. may, by a Prefectural Ordinance, establish necessary provisions concerning measures necessary for public health, provided that such provisions are not in violation of the criteria established pursuant to the provisions of paragraph (1).

Article 52 (1) The Minister of Health, Labour and Welfare shall, by an Ordinance of the Ministry of Health, Labour and Welfare, establish criteria for the following matters pertaining to the sanitary management of facilities for businesses producing apparatus or containers and packaging and pertaining to other measures necessary for public health (hereinafter referred to as "measures necessary for public health" in this Article):

- (i) Matters concerning the maintenance of the cleanliness of the interior and exterior of such facilities, and other general sanitation management;
  - (ii) Matters concerning efforts to appropriately manage production necessary to prevent food sanitation hazards.
- (2) A business person who produces apparatus or containers and packaging shall take measures necessary for public health in accordance with the criteria established pursuant to the provisions of the preceding paragraph (in the case of business persons who produce apparatus or containers and packaging made only of raw materials of materials other than those specified by a Cabinet Order as prescribed in Article 18, paragraph (3), limited to the matters listed in item (i) of the preceding paragraph).
- (3) A prefectural governor, etc. may, by a Prefectural Ordinance, establish necessary provisions concerning measures necessary for public health, provided that such provisions are not in violation of the criteria established pursuant to the provisions of paragraph (1).

Article 53 (1) A person who sells, or produces or imports for the purpose of marketing, apparatus or containers and packaging made of raw materials of materials specified by a Cabinet Order as prescribed in Article 18, paragraph (3) shall, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare, explain to the counterparty of the sales of the apparatus or containers and packaging handled by such person that the relevant apparatus or containers and packaging handled by such person fall under any of the following items:

- (i) Such apparatus or containers and packaging have been made of raw materials which are those of materials specified by a Cabinet Order as prescribed in Article 18, paragraph (3) and which all conform to the standards established pursuant to the provisions of paragraph (1) of the same Article;
- (ii) Such apparatus or containers and packaging have been processed as

prescribed in the proviso of Article 18, paragraph (3).

- (2) A person who sells, or produces or imports for the purpose of marketing, raw materials which are used for apparatus or containers and packaging and which are those of materials specified by a Cabinet Order as prescribed in Article 18, paragraph (3) shall endeavor to provide necessary explanations pursuant to an Ordinance of the Ministry of Health, Labour and Welfare, upon receipt of a request for confirmation that the raw materials conform to the standards established pursuant to the provisions of paragraph (1) of the same Article from a person who produces apparatus or containers and packaging using the raw materials.

Article 54 Prefectures shall, by a Prefectural Ordinance, establish criteria necessary from the viewpoint of public health for facilities for businesses which have an extraordinary impact on public health (excluding poultry slaughtering businesses) and which are specified by a Cabinet Order, by taking into consideration the criteria specified by an Ordinance of the Ministry of Health, Labour and Welfare.

Article 55 (1) A person who intends to conduct businesses prescribed in the preceding Article shall obtain approval from the prefectural governor pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

- (2) In the case set forth in the preceding paragraph, the prefectural governor shall grant approval when the prefectural governor finds that the business facilities of the person conform to the criteria under the preceding Article; provided, however, that the prefectural governor may decline to grant approval when the person who intends to conduct businesses prescribed in the preceding Article falls under any of the following items:

(i) A person who has been punished for violation of this Act or any disposition based on this Act, before the expiration of a period of two years since the person served out the sentence or ceased to be subject to the sentence;

(ii) A person who has had the person's approval rescinded pursuant to the provisions of Articles 59 to 61, before the expiration of a period of two years since the date of the rescission;

(iii) A juridical person who has persons falling under any of the preceding two items among the officers in charge of its business.

- (3) A prefectural governor may attach the necessary conditions such as a valid period of not less than five years to the approval set forth in paragraph (1).

Article 56 (1) When there has been an inheritance, merger, or split related to a person who has obtained the approval set forth in paragraph (1) of the preceding Article (hereinafter referred to as an "approved business person" in

this Article) (limited to an inheritance, merger, or split for succeeding the relevant business), an heir (when there are two or more heirs and one particular heir has been selected as the successor of the business by consent of all the heirs, such selected heir), a juridical person surviving the merger, a juridical person established by the merger, or a juridical person succeeding to the relevant business by the split shall succeed to the status of the approved business person.

- (2) A person who has succeeded to the status of the approved business person pursuant to the provisions of the preceding paragraph shall notify the prefectural governor to that effect without delay, with a document proving such fact.

Article 57 (1) A person who intends to conduct a business (excluding the businesses prescribed in Article 54, those which have a minor impact on public health and are specified by a Cabinet Order, and poultry slaughtering businesses) shall notify the relevant prefectural governor in advance of the name and the location of the person's business office and other matters specified by an Ordinance of the Ministry of Health, Labour and Welfare, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

- (2) The provisions of the preceding Article shall apply mutatis mutandis to persons who have made a notification pursuant to the provisions of the preceding paragraph. In this case, the terms "person who has obtained the approval set forth in paragraph (1) of the preceding Article" and "approved business person" in paragraph (1) of the same Article shall be deemed with "person who has made a notification pursuant to the provisions of paragraph (1) of the following Article" and "notifying business person", respectively; and the term "approved business person" in paragraph (2) of the same Article shall be deemed to be replaced with "notifying business person."

Article 58 (1) When a business person falls under any of the following items and recalls any food or additives collected, produced, imported, processed or sold by the business person, or any apparatus or containers and packaging produced, imported or sold by the business person (excluding cases where such recall is made due to an order under paragraph (1) or (2) of the following Article and cases specified by an Ordinance of the Ministry of Health, Labour and Welfare and a Cabinet Office Ordinance as involving no risk of food sanitation hazards), such business person shall notify the relevant prefectural governor of the commencement and status of such recall, without delay, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare and a Cabinet Office Ordinance.

- (i) The case where the business person has violated or is likely to violate any of

the provisions of Article 6, Article 10 to Article 12, Article 13, paragraph (2) or paragraph (3), Article 16, Article 18, paragraph (2) or paragraph (3), or Article 20;

(ii) The case where the business person has violated or is likely to violate any prohibition under Article 9, paragraph (1) or Article 17, paragraph (1).

(2) When there has been a notification under the preceding paragraph, the prefectural governor shall report the matters related to the notification to the Minister of Health, Labour and Welfare or the Prime Minister pursuant to an Ordinance of the Ministry of Health, Labour and Welfare and a Cabinet Office Ordinance.

Article 59 (1) When a business person has violated any of the provisions of Article 6, Article 10 to Article 12, Article 13, paragraph (2) or paragraph (3), Article 16 or Article 18, paragraph (2) or paragraph (3), or when a business person has violated any prohibition under Article 9, paragraph (1) or Article 17, paragraph (1), the Minister of Health, Labour and Welfare or a prefectural governor may order the business person or the officials of the Minister or the prefectural governor to dispose of the food, additives, apparatus, or containers and packaging, or order the business person to take any other necessary measures to eliminate the food sanitation hazards.

(2) When a business person has violated the provisions of Article 20, the Prime Minister or a prefectural governor may order the business person or the officials of the Minister or the prefectural governor to dispose of the food, additives, apparatus, or containers and packaging, or order the business person to take any other necessary measures to eliminate the food sanitation hazards caused by the false or exaggerated labeling or advertising.

Article 60 (1) When a business person has violated any of the provisions of Article 6, Article 8, paragraph (1), Article 10 to Article 12, Article 13, paragraph (2) or paragraph (3), Article 16, Article 18, paragraph (2) or paragraph (3), Article 19, paragraph (2), Article 20, Article 25, paragraph (1), Article 26, paragraph (4), Article 48, paragraph (1), Article 50, paragraph (2), Article 51, paragraph (2), Article 52, paragraph (2) or Article 53, paragraph (1), when a business person has violated any prohibition under Article 7, paragraphs (1) to (3), Article 9, paragraph (1) or Article 17, paragraph (1), when a business person now falls under any of Article 55, paragraph (2), item (i) or item (iii), or when a business person has violated any conditions under paragraph (3) of the same Article, a prefectural governor may rescind the approval under paragraph (1) of the same Article, prohibit the business in whole or in part, or suspend the business for a specified period.

(2) When a business person (limited to a person or juridical person who imports

food, additives, apparatus, or containers and packaging) has violated any of the provisions of Article 6, Article 8, paragraph (1), Article 10, paragraph (2), Article 11, Article 12, Article 13, paragraph (2) or paragraph (3), Article 16, Article 18, paragraph (2) or paragraph (3), Article 26, paragraph (4), Article 50, paragraph (2), Article 51, paragraph (2), Article 52, paragraph (2) or Article 53, paragraph (1), or when a business person has violated any prohibition under Article 7, paragraphs (1) to (3), Article 9, paragraph (1) or Article 17, paragraph (1), the Minister of Health, Labour and Welfare may prohibit the business in whole or in part, or suspend the business for a specified period.

Article 61 When a business person has violated any criteria under Article 54 with regard to the business person's business facilities, a prefectural governor may order that person to develop and improve the facilities, rescind the approval under Article 55, paragraph (1), prohibit the business in whole or in part, or suspend the business for a specified period.

#### **Chapter X Miscellaneous Provisions**

Article 62 The Treasury shall bear half of the following expenses of the prefectures or cities establishing health centers pursuant to a Cabinet Order:

- (i) Expenses needed for removal under Article 28, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3));
- (ii) Expenses needed to place food sanitation inspectors under Article 30, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3));
- (iii) Expenses needed for the approval of a business under Article 55, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 68, paragraph (1));
- (iv) Expenses needed for disposal under Article 59 (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3));
- (v) Expenses needed for autopsies of corpses under Article 64, paragraph (1) or paragraph (2) (including the cases where it is applied mutatis mutandis under Article 68, paragraph (1));
- (vi) Expenses needed for lawsuits concerning the enforcement of this Act and compensation to be paid as a result of the lawsuits.

Article 63 (1) A physician who has diagnosed a person poisoned by food, etc. or has examined a corpse thereof shall notify the director of the nearest health center to that effect immediately.

(2) When the director of a health center has received a notification set forth in

the preceding paragraph or in other cases where the director of a health center finds that there have been persons poisoned by food, etc., the director of a health center shall make a report to the prefectural governor, etc. immediately and conduct an investigation, pursuant to a Cabinet Order.

- (3) When a prefectural governor, etc. has received a report from the director of a health center pursuant to the provisions of the preceding paragraph, and when there have been or are likely to be more persons poisoned by food, etc. than specified by an Ordinance of the Ministry of Health, Labour and Welfare, or in other cases specified by an Ordinance of the Ministry of Health, Labour and Welfare, the prefectural governor, etc. shall make a report to the Minister of Health, Labour and Welfare immediately.
- (4) When the director of a health center has conducted an investigation under paragraph (2), the director of a health center shall make a report to the prefectural governor, etc. pursuant to a Cabinet Order.
- (5) When a prefectural governor, etc. has received a report under the preceding paragraph, the prefectural governor, etc. shall make a report to the Minister of Health, Labour and Welfare, pursuant to a Cabinet Order.

Article 64 (1) A prefectural governor, etc. may, when it is found to be necessary to investigate the cause of death, submit the corpse of a person who has died of a disease that was or is suspected to have been caused by food, additives, apparatus, or containers and packaging to be autopsied with the consent of the bereaved family.

- (2) In the case set forth in the preceding paragraph, when the cause of death is not clear without autopsying a corpse and a prefectural governor, etc. finds it is likely to cause serious public sanitation hazards eventually, the prefectural governor, etc. may submit the corpse to be autopsied after notifying the bereaved family, even without obtaining the consent thereof.
- (3) The provisions of the preceding two paragraphs shall not preclude compulsory dispositions under the Rules on Criminal Procedure.
- (4) When autopsying a corpse pursuant to the provisions of paragraph (1) or paragraph (2), care shall be taken to pay respect to the deceased.

Article 65 If there have been or are likely to be more persons poisoned by food, etc. than specified by an Ordinance of the Ministry of Health, Labour and Welfare, or if persons poisoned by food, etc. have appeared or are likely to appear across wide areas, and it is urgent to prevent food sanitation hazards, the Minister of Health, Labour and Welfare may request prefectural governors, etc. to investigate the causes of food poisoning and report the investigation results, within a fixed time limit.



Article 66 In the case prescribed in the preceding Article, the Minister of Health, Labour and Welfare shall, when the Minister of Health, Labour and Welfare finds it necessary, hold a council meeting where the Minister of Health, Labour and Welfare shall ensure closer cooperation between relevant organizations, etc. by sharing necessary information on the investigation of the causes of food poisoning and the results thereof and shall endeavor to ensure that discussions will take place on measures necessary to prevent persons poisoned by food, etc. from appearing across wide areas or increasing.

Article 67 (1) Prefectures, etc. shall endeavor to provide the necessary advice, guidance and other assistance to food business operators in order to prevent food poisoning and improve food sanitation in the region.

(2) Prefectures, etc. shall appoint food sanitation promotion leaders from among those who enjoy the public's confidence and who have the enthusiasm, knowledge and experience for the improvement of food sanitation, in order to promote the voluntary activities of food business operators concerning the improvement of food sanitation.

(3) A food sanitation promotion leader shall cooperate with the measures set by prefectures, etc., provide consultation for food business operators, and perform other activities such as giving advice to such persons, with regard to sanitation management methods for facilities for restaurant businesses and other matters concerning food sanitation.

Article 68 (1) The provisions of Article 6, Article 9, Article 12, Article 13, paragraphs (1) and (2), Articles 16 to 20 (excluding Article 18, paragraph (3)), Articles 25 to 61 (excluding Article 51, Article 52, paragraph (1), item (ii) and paragraph (2), and Article 53), and Articles 63 to 65 shall apply mutatis mutandis to toys designated by the Minister of Health, Labour and Welfare as those likely to harm the health of infants when they touch such toys. In this case, the term "Additives (excluding natural flavoring agents and articles that have generally been served for human consumption and are used as additives)" in Article 12 shall be deemed to be replaced with "Chemically synthesized compounds (meaning substances obtained by causing a chemical reaction other than a degradation reaction to elements or compounds by chemical means) intended to be used as additives for toys."

(2) The provisions of Article 6, and Article 13, paragraphs (1) and (2) shall apply mutatis mutandis to the cleaning agents used for cleaning vegetables, fruits, or tableware.

(3) The provisions of Articles 15 to 18, Article 25, paragraph (1), Articles 28 to 30, Article 51, Articles 54, Article 57 and Articles 59 to 61 shall apply mutatis mutandis to cases where food is provided to many and unspecified persons on

an ongoing basis at schools, hospitals or other facilities.

Article 69 In order to prevent food sanitation hazards, the Minister of Health, Labour and Welfare, the Prime Minister and a prefectural governor shall endeavor to clarify the situation of food sanitation hazards by publicizing the name, etc. of a person who has violated this Act or any disposition based on this Act.

Article 70 (1) When the Minister of Health, Labour and Welfare intends to specify cases having no risk to human health prescribed in the proviso of Article 6, item (ii) (including cases where it is applied *mutatis mutandis* under Article 68, paragraphs (1) and (2)), intends to prohibit the sales under Article 7, paragraphs (1) to (3) or rescind the prohibition in whole or in part under paragraph (4) of the same Article, intends to designate a designated ingredient, etc. pursuant to the provisions of Article 8, paragraph (1), intends to establish, revise, or abolish the Ordinance of the Ministry of Health, Labour and Welfare set forth in Article 10, paragraph (1), intends to specify cases having no risk to human health prescribed in Article 12, intends to establish the criteria or standards prescribed in Article 13, paragraph (1) (including cases where it is applied *mutatis mutandis* under Article 68, paragraphs (1) and (2)), intends to specify substances clearly having no risk to human health or the quantity of the substances having no risk to human health prescribed in Article 13, paragraph (3), intends to establish the criteria or standards prescribed in Article 18, paragraph (1) (including cases where it is applied *mutatis mutandis* under Article 68, paragraphs (1) and (3)), intends to specify the quantity of the substances having no risk to human health prescribed in the proviso of Article 18, paragraph (3), intends to establish or revise the imported food monitoring and guidance plan prescribed in Article 23, paragraph (1), intends to establish the criteria prescribed in Article 50, paragraph (1), or intends to establish, revise, or abolish the Ordinance of the Ministry of Health, Labour and Welfare set forth in Article 51, paragraph (1), Article 52, paragraph (1) or Article 54, the Minister of Health, Labour and Welfare shall publicize the purpose, contents, and other necessary matters to canvass widely for citizens' opinions; provided, however, that this shall not apply when it is urgent for food sanitation hazards to be prevented and that there is no time to canvass widely for citizens' opinions in advance.

(2) When a prefectural governor, etc. intends to establish or revise prefectural plans for the monitoring of and guidance on food sanitation prescribed in Article 24, paragraph (1), the prefectural governor, etc. shall publicize the purpose, contents, and other necessary matters to canvass widely for residents' opinions.

(3) In the case set forth in the proviso of paragraph (1), the Minister of Health, Labour and Welfare shall canvass widely for citizens' opinions subsequently and without delay.

(4) The provisions of paragraph (1) and the preceding paragraph shall apply mutatis mutandis when the Prime Minister intends to establish the criteria for labeling prescribed in Article 19, paragraph (1) (including cases where it is applied mutatis mutandis under Article 68, paragraph (1)) and when the Minister of Health, Labour and Welfare and the Prime Minister intend to establish or revise guidelines.

Article 71 In order to reflect citizens' or residents' opinions in the measures concerning food sanitation and to promote the exchange of information and opinions between relevant persons, the Minister of Health, Labour and Welfare, the Prime Minister and a prefectural governor, etc. shall publicize the implementation of the measures and canvass widely for citizens' or residents' opinions.

Article 72 (1) In the case prescribed in the main clause of Article 70, paragraph (1), the Minister of Health, Labour and Welfare shall consult with the Prime Minister in advance.

(2) When the Prime Minister intends to establish the criteria for labeling prescribed in Article 19, paragraph (1) (including cases where it is applied mutatis mutandis under Article 68, paragraph (1)), the Prime Minister shall consult with the Minister of Health, Labour and Welfare in advance.

(3) When the Minister of Health, Labour and Welfare has established the criteria or standards prescribed in Article 18, paragraph (1) (including cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3)) or Article 13, paragraph (1) as applied mutatis mutandis under Article 68, paragraph (1) or (2), or when the Minister of Health, Labour and Welfare finds it necessary, the Minister of Health, Labour and Welfare may request the Prime Minister to establish the criteria for labeling prescribed in Article 19, paragraph (1) (including cases where it is applied mutatis mutandis under Article 68, paragraph (1)).

Article 73 The Minister of Health, Labour and Welfare and the Prime Minister shall endeavor to ensure mutual close cooperation, including the exchange of necessary information, in order to prevent the sanitation hazards resulting from eating and drinking.

Article 74 deleted

Article 75 deleted

Article 76 The term "prefectural governor" in Article 48, paragraph (8), Article 55, Article 56, paragraph (2) (including cases where it is applied mutatis mutandis in Article 57, paragraph (2)), Article 57, paragraph (1), Article 58, Article 59, Article 60, paragraph (1), Article 61 and Article 69 shall be deemed to be replaced with "city mayor" for cities establishing health centers and "ward mayor" for special wards; provided, however, that this shall not apply to any disposition specified by a Cabinet Order concerning businesses specified by a Cabinet Order.

Article 77 In addition to what is prescribed in the main clause of the preceding Article, affairs which are specified as those to be determined by prefectures in this Act and are specified by a Cabinet Order shall be determined by designated cities set forth in Article 252-19, paragraph (1) of the Local Autonomy Act (Act No. 67 of 1947) (hereinafter referred to as "designated cities") or by core cities set forth in Article 252-22, paragraph (1) of the same Act (hereinafter referred to as "core cities") from designated cities or core cities (hereinafter referred to as "designated cities, etc.") pursuant to a Cabinet Order. In this case, the provisions of this Act concerning prefectures shall apply to designated cities, etc. as the provisions concerning designated cities, etc.

Article 78 (1) A person who is dissatisfied with the determination concerning a request for examination on a disposition made by the head of a local public entity (excluding prefectures; the same shall apply in the following paragraph) pursuant to the provisions of this Act (limited to a disposition pertaining to item 1 legally delegated affairs prescribed in Article 2, paragraph (9), item (i) of the Local Autonomy Act (referred to as "item 1 legally delegated affairs" in the following paragraph and the following Article)) may make a request for re-examination to the Minister of Health, Labour and Welfare (the Prime Minister in cases involving a disposition under Article 59, paragraph (2) (including cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3)); the same shall apply in the following paragraph).

(2) If the head of a local public entity has delegated the authority to make dispositions pertaining to item 1 legally delegated affairs among the affairs to be determined by the head pursuant to the provisions of this Act to an official serving as the head's subsidiary organ or to the head of an administrative organ under the control of the head, and a determination is made on a request for re-examination made under Article 255-2, paragraph (2) of the Local Autonomy Act against a disposition made by such official or head of the

administrative organ with the delegated authority, a person who is dissatisfied with the determination may make a request for further examination to the Minister of Health, Labour and Welfare pursuant to the provisions of Article 252-17-4, paragraphs (5) to (7) of the same Act.

Article 79 (1) Affairs that are to be determined by prefectures pursuant to the provisions of Article 25, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3)), Article 26, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 68, paragraph (1)), Article 28, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3)), Article 30, paragraph (2) (excluding the part pertaining to monitoring and guidance accompanying the approval of a business prescribed in Article 54 (limited to businesses specified by a Cabinet Order by taking into consideration the status of distribution of food or additives) and including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3)), Article 59 (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3)), Article 63 (including the cases where it is applied mutatis mutandis under Article 68, paragraph (1)), and Article 64, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 68, paragraph (1)) shall be deemed to be item 1 legally delegated affairs.

(2) Affairs that are to be determined by cities establishing health centers or special wards pursuant to the provisions of Article 28, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3)), Article 30, paragraph (2) (excluding the part pertaining to monitoring and guidance accompanying the approval of a business prescribed in Article 54 (limited to businesses specified by a Cabinet Order by taking into consideration the status of distribution of food or additives) and including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3)), Article 59 (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3)), Article 63 (including the cases where it is applied mutatis mutandis under Article 68, paragraph (1)), and Article 64, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 68, paragraph (1)) shall be deemed to be item 1 legally delegated affairs.

Article 80 (1) The authority of the Minister of Health, Labour and Welfare specified by this Act may be delegated to the directors of the Local Bureaus of Health and Welfare, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

(2) The authority delegated to the directors of the Local Bureaus of Health and Welfare pursuant to the provisions of the preceding paragraph may be

delegated to the chiefs of the Local Welfare Bureau Branches, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

- (3) The Prime Minister shall delegate the authority under this Act (excluding the authority specified by a Cabinet Order) to the Secretary General of the Consumer Affairs Agency.

## **Chapter XI Penal Provisions**

Article 81 (1) A person who falls under any of the following items shall be punished by imprisonment with work for a period not exceeding three years or a fine not exceeding three million yen:

- (i) A person who has violated the provisions of Article 6 (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (2)), Article 10, paragraph (1), or Article 12 (including the cases where it is applied mutatis mutandis under Article 68, paragraph (1));
  - (ii) A person who has violated the prohibition under Article 7, paragraphs (1) to (3);
  - (iii) A business person who has not obeyed an order issued by the Minister of Health, Labour and Welfare or a prefectural governor (a city mayor or ward mayor when replacing the terms pursuant to the provisions of Article 76; hereinafter the same shall apply in this item) pursuant to the provisions of Article 59, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3)) or an order issued by the Prime Minister or a prefectural governor pursuant to the provisions of Article 59, paragraph (2) (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3)) (including those who provide food prescribed in Article 68, paragraph (3)), or a business person who has conducted business in violation of a disposition under Article 60 (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3)).
- (2) A person who has committed any of the crimes set forth in the preceding paragraph may be cumulatively punished both by imprisonment with work and a fine in light of the circumstances.

Article 82 (1) A person who has violated the provisions of Article 13, paragraph (2) (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (2)) or paragraph (3), Article 16 (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3)), Article 19, paragraph (2) (including the cases where it is applied mutatis mutandis under Article 68, paragraph (1)), Article 20 (including the cases where it is applied mutatis mutandis under Article 68, paragraph (1)), or

Article 55, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 68, paragraph (1)) shall be punished by imprisonment with work for a period not exceeding two years or a fine not exceeding two million yen.

- (2) A person who has committed any of the crimes set forth in the preceding paragraph may be cumulatively punished both by imprisonment with work and a fine in light of the circumstances.

Article 83 A person falling under any of the following items shall be punished by imprisonment with work for a period not exceeding one year or a fine not exceeding one million yen:

- (i) A person who has violated the provisions of Article 10, paragraph (2), Article 11, Article 18, paragraph (2) (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3)) or paragraph (3), Article 25, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3)), Article 26, paragraph (4) (including the cases where it is applied mutatis mutandis under Article 68, paragraph (1)), and Article 63, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 68, paragraph (1));
- (ii) A person who has violated the prohibition under Article 9, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 68, paragraph (1)) or Article 17, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3));
- (iii) A person who has disclosed secrets which have come to the person's knowledge concerning the person's duties in violation of Article 40, paragraph (1);
- (iv) A person who has violated the criteria under Article 54 (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3)) or who has violated the conditions under Article 55, paragraph (3) (including the cases where it is applied mutatis mutandis under Article 68, paragraph (1));
- (v) A business person who has not obeyed an order issued by a prefectural governor (a city mayor or ward mayor when replacing the terms pursuant to the provisions of Article 76) pursuant to the provisions of Article 61 (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3)) (including those who provide food prescribed in the same paragraph), or a person who has conducted business in violation of a disposition under Article 61 (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3)).

Article 84 Officials or employees of a registered conformity assessment body

which has violated an order of the suspension of business under Article 43 shall be punished by imprisonment with work for a period not exceeding one year or a fine not exceeding one million yen.

Article 85 A person falling under any of the following items shall be punished by a fine not exceeding 500 thousand yen:

- (i) A person who has refused, obstructed or evaded on-site inspections by officials or removal under Article 28, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3));
- (ii) A person who has not made a report under Article 28, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (3)) or who has made a false report;
- (iii) A person who has not made a notification under Article 27, Article 48, paragraph (8) (both including the cases where it is applied mutatis mutandis under Article 68, paragraph (1)), Article 57, paragraph (1) or Article 58, paragraph (1) or who has made a false notification;
- (iv) A person who has violated an order under Article 46, paragraph (2).

Article 86 Officials or employees of a registered conformity assessment body who have committed any of the following violations shall be punished by a fine not exceeding 500 thousand yen:

- (i) When a registered conformity assessment body has abolished the whole operation of product inspections without obtaining approval under Article 38;
- (ii) When a registered conformity assessment body has not recorded matters prescribed in Article 44, has made false record, or has failed to retain books in violation of the same Article;
- (iii) When a registered conformity assessment body has not made a report under Article 47, paragraph (1) or has made a false report;
- (iv) When a registered conformity assessment body has refused, obstructed or evaded inspections under Article 47, paragraph (1), has not given answers to questions under the same paragraph, or has given false answers.

Article 87 When a food sanitation supervisor has neglected the food sanitation supervisor's duties under Article 48, paragraph (3), and when there have been acts falling under violations set forth in Articles 81 to 83 with regard to food or additives pertaining to the food sanitation supervisor's supervision at the relevant facility, the food sanitation supervisor shall be punished by a fine as prescribed in the respective Articles in light of the manner of such acts; provided, however, that this shall not apply when the food sanitation supervisor is the person who has committed such acts.



Article 88 When a representative of a juridical person, an agent, an employee or any other worker of a juridical person or person, in connection with the business of such juridical person or person, has committed an act in violation of the provisions listed in the following items, not only shall the offender be punished but also the juridical person shall be punished by a fine prescribed in the relevant respective items or the individual shall be punished by a fine prescribed in the respective Articles; provided, however, that this shall not apply when the individual shall be punished by a fine as a food sanitation supervisor pursuant to the provisions of the preceding Article:

- (i) Article 81 or Article 82 (limited to the part pertaining to the provisions of Article 13, paragraph (2) (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (2)) or paragraph (3), Article 19, paragraph (2) (including the cases where it is applied mutatis mutandis under Article 68, paragraph (1)), and Article 20 (including the cases where it is applied mutatis mutandis under Article 68, paragraph (1))) A fine not exceeding 100 million yen;
- (ii) Article 82 (excluding the part pertaining to the provisions of Article 13, paragraph (2) (including the cases where it is applied mutatis mutandis under Article 68, paragraphs (1) and (2)) or paragraph (3), Article 19, paragraph (2) (including the cases where it is applied mutatis mutandis under Article 68, paragraph (1)), and Article 20 (including the cases where it is applied mutatis mutandis under Article 68, paragraph (1))), Article 83, or Article 85 A fine prescribed in the respective Articles.

Article 89 A person who has not maintained financial statements in violation of Article 39, paragraph (1), or has not recorded matters to be recorded in financial statements, has made a false record, or has refused a request under each item of Article 39, paragraph (2) without justifiable grounds shall be punished by a non-penal fine not exceeding 200 thousand yen.

Appended Table (Re: Article 33)

|                             |                          |   |      |
|-----------------------------|--------------------------|---|------|
| Physicochemical inspections | 1. Centrifugal separator | A person shall fall under any of the following items: | Four |
|-----------------------------|--------------------------|---|------|

|   |  |
|---|--|
| <p>2. Water purifying apparatus</p>   | <p>(i) A person who has graduated from a university (excluding a junior college) under the School Education Act, a university under the old University Ordinance, or a vocational training school under the old Vocational Training School Ordinance after completing a course in medical science, dentistry, pharmacy, veterinary medicine, animal science, fisheries science, agricultural chemistry, or applied chemistry, or a course relevant to these, and has experience of being engaged in the operation of physicochemical inspections for one year or more;</p> |
| <p>3. Deep freezer</p>  | <p>(ii) A person who has graduated from a junior college or a vocational high school under the School Education Act after completing a course in industrial chemistry or a course relevant to this, and has experience of being engaged in the operation of physicochemical inspections for three years or more;</p>   |
| <p>4. Homogenizer</p>   | <p>(iii) A person who has equal or greater knowledge and experience than those listed in the preceding two items.</p>  |
| <p>5. Gas chromatograph</p>   |  |
| <p>6. Gas chromatograph mass spectrometer (limited to those which conduct inspections of agricultural chemicals remaining in food that are prescribed in Article 2, paragraph 1 of the Agricultural Chemicals Regulation Act)</p> |  |

|                             |  |  |       |
|-----------------------------|--|--|-------|
|                             | 7. Atomic absorption photometer<br>8. High performance liquid chromatograph  |  |       |
| Bacteriological inspections | 1. Centrifugal separator<br>2. Water purifying apparatus<br><br>3. Deep freezer<br><br>4. Homogenizer<br><br>5. Dry heat sterilizer<br>6. Optical microscope<br>7. Autoclave<br>8. Incubator | A person shall fall under any of the following items:<br>(i) A person who has graduated from a university (excluding a junior college) under the School Education Act, a university under the old University Ordinance, or a vocational training school under the old Vocational Training School Ordinance after completing a course in medical science, dentistry, pharmacy, veterinary medicine, animal science, fisheries science, agricultural chemistry, or biology, or a course relevant to these, and has experience of being engaged in the operation of bacteriological inspections for one year or more;<br>(ii) A person who has graduated from a junior college or a vocational high school under the School Education Act after completing a course in biology or a course relevant to this, and has experience of being engaged in the operation of bacteriological inspections for three years or more;<br>(iii) A person who has equal or greater knowledge and experience than those listed in the preceding two items. | Four  |
| Inspections using animals   | 1. Centrifugal separator   | A person shall fall under any of the following items:  | Three |

|  |  |  |
|--|--|--|
|  | <p>2. Water purifying apparatus</p> <p>3. Deep freezer</p> <p>4. Homogenizer</p> | <p>(i) A person who has graduated from a university (excluding a junior college) under the School Education Act, a university under the old University Ordinance, or a vocational training school under the old Vocational Training School Ordinance after completing a course in medical science, dentistry, pharmacy, veterinary medicine, animal science, fisheries science, agricultural chemistry, or biology, or a course relevant to these, and has experience of being engaged in the operation of inspections using animals for one year or more;</p> <p>(ii) A person who has graduated from a junior college or a vocational high school under the School Education Act after completing a course in biology or a course relevant to this, and has experience of being engaged in the operation of inspections using animals for three years or more;</p> <p>(iii) A person who has equal or greater knowledge and experience than those listed in the preceding two items.</p> |
|--|--|--|