

# Food Sanitation Act

(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 his/her own responsibility, endeavor to ensure the safety of the food, additives, apparatus or containers and packaging which he/she 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, he/she shall endeavor to obtain the knowledge and technologies necessary to ensure the safety 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 said 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 or quasi-pharmaceutical products specified by the Pharmaceutical Affairs Act (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 he/she 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 he/she 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 said damage, that said food included articles which have not generally been served for human consumption and involve the risk of causing said 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 he/she finds it necessary to prevent food sanitation hazards.

(4) In the case where the Minister of Health, Labour and Welfare has prohibited the sales under the preceding three paragraphs, he/she shall rescind said prohibition, in whole or in part, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council, when he/she finds that there is no risk of food sanitation hazards resulting from articles or food pertaining to said prohibition, based on an application from an interested person concerning said prohibition, or as needed, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

(5) In the case where 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, he/she shall issue a public notice in

the official gazette.

Article 8 (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, in the case where, 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, 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 said specific food or additives for the purpose of marketing, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council, when he/she finds it particularly necessary to prevent food sanitation hazards resulting from said 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:

- (i) Food or additives listed in each item of Article 6;
  - (ii) Food prescribed in Article 10;
  - (iii) Food or additives which do not conform to the standards established pursuant to the provisions of Article 11, 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 11, paragraph (1);
  - (v) Food prescribed in Article 11, paragraph (3).
- (2) When the Minister of Health, Labour and Welfare intends to issue a prohibition under the preceding paragraph, he/she shall consult with the heads of the relevant administrative organs in advance.
- (3) In the case where the Minister of Health, Labour and Welfare has issued a prohibition under paragraph (1), he/she shall rescind said prohibition, in whole or in part, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council, when he/she finds that there is no risk of food sanitation hazards resulting from specific food or additives pertaining to said prohibition, based on an application from an interested person concerning said prohibition, or as needed, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.
- (4) In the case where 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, he/she shall issue a public notice in the official gazette.

Article 9 (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 and organs of livestock and 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 attached which have been issued by a governmental organization of an exporting country, and which certify that they are not the meat or organs of livestock and 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 said livestock meat, etc. have been sent from a governmental organization of said countries via a telecommunications line to a computer (with an input-output

device) used by the Ministry of Health, Labour and Welfare and has been recorded in a file on said computer.

Article 10 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 11 (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 1-2, paragraph (1) of the Agricultural Chemicals Control 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 Pharmaceutical Affairs Act 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 said substances in said food.

Article 12 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 remaining in food, 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 Pharmaceutical Affairs Act and are to be used only for animals (hereinafter referred to as "agricultural chemicals, etc." in this Article) as the standard concerning the ingredients of food set forth in paragraph (1), or when he/she finds it necessary, he/she may request the Minister of Agriculture, Forestry and Fisheries to provide data concerning the ingredients of the agricultural chemicals, etc. or offer other necessary cooperation.

Article 13 (1) Regarding food for which the criteria for the methods of production or processing have been established pursuant to the provisions of Article 11, paragraph (1) and which are specified by a Cabinet Order, when a person who intends to produce or process such food by way of a comprehensive sanitation management and production process (meaning a production or processing process in which measures to prevent food sanitation hazards are taken comprehensively for production or processing methods and sanitation management methods; the same shall apply hereinafter) (including persons who intend to produce or process such food in foreign countries) makes an application, the Minister of Health, Labour and Welfare may grant approval for producing or processing such food by way of the comprehensive sanitation management and production process, for each type of food such person intends to produce or process and for each production or processing facility.

(2) When production or processing methods and sanitation management methods in a comprehensive sanitation management and production process pertaining to an application prescribed in the preceding paragraph do not conform to the criteria specified by an Ordinance of the Ministry of Health, Labour and Welfare, the Minister of Health, Labour and Welfare shall not grant approval under the same paragraph.

(3) A person who intends to obtain approval under paragraph (1) shall submit a written application attached with data concerning test results of food which he/she produced or processed through said comprehensive sanitation management and production process and other data, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.



- (4) When a person who has obtained approval under paragraph (1) (referred to as a "person obtaining approval" in the following paragraph) intends to change part of the comprehensive sanitation management and production process pertaining to said approval, he/she may apply for approval for the change. In this case, the provisions of the preceding two paragraphs shall apply mutatis mutandis.
- (5) In cases falling under any of the following items, the Minister of Health, Labour and Welfare may rescind, in whole or in part, the approval under paragraph (1) which a person obtaining approval has obtained:
- (i) When production or processing methods and sanitation management methods in a comprehensive sanitation management and production process pertaining to said approval have become unconformable to the criteria specified by an Ordinance of the Ministry of Health, Labour and Welfare set forth in paragraph (2);
  - (ii) When a person obtaining approval has changed part of the comprehensive sanitation management and production process pertaining to said approval without obtaining approval under the preceding paragraph;
  - (iii) When the Minister of Health, Labour and Welfare has found it necessary and has requested a person obtaining approval who produces or processes food through a comprehensive sanitation management and production process pertaining to said approval in a foreign country (referred to as a "person obtaining approval for production in a foreign country" in the following item) to submit a necessary report, but no report has been made or a false report has been made;
  - (iv) When the Minister of Health, Labour and Welfare has found it necessary and has intended to have ministry officials carry out inspections of food, books and documents, and other articles at production or processing facilities, offices, warehouses, and other locations of a person obtaining approval for production in a foreign country, but the inspections have been refused, obstructed or evaded.
- (6) The provisions of this Act or orders based on this Act shall apply to the production or processing of food through a comprehensive sanitation management and production process pertaining to the approval under paragraph (1) by deeming it to be the production or processing of food through methods that conform to the criteria set forth in Article 11, paragraph (1).
- (7) A person who intends to obtain the approval under paragraph (1) or the approval for change under paragraph (4) shall pay a fee specified by a Cabinet Order by taking into consideration the actual costs of the assessment.

Article 14 (1) An approval under paragraph (1) of the preceding Article shall, unless it is renewed at an interval of not less than three years as specified by a

Cabinet Order (hereinafter referred to as a "valid period" in this Article), cease to be effective upon the expiration of such period.

- (2) The provisions of paragraphs (2) and (3) of the preceding Article shall apply mutatis mutandis to a renewal set forth in the preceding paragraph.
- (3) In the case where an application for renewal under paragraph (1) has been filed, when the disposition for the application has not been completed by the expiration date of the valid period, the approval then in force shall remain in force even after the expiration of the valid period until the disposition is completed.
- (4) In the case set forth in the preceding paragraph, when an approval has been renewed, the valid period of the approval shall start from the day following the expiration date of the valid period for the former approval.
- (5) A person who intends to obtain a renewal of the approval under paragraph (1) shall pay a fee specified by a Cabinet Order by taking into consideration the actual costs of the assessment.

### **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, in the case where, 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, 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 said specific apparatus or containers and

packaging in business, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council, when he/she finds it particularly necessary to prevent the food sanitation hazards resulting from said 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:

- (i) Apparatus or containers and packaging prescribed in the preceding paragraph;
  - (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.
- (2) When the Minister of Health, Labour and Welfare intends to issue a prohibition under the preceding paragraph, he/she shall consult with the heads of the relevant administrative organs in advance.
- (3) The provisions of Article 8, 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 containers and packaging shall not be produced by methods that do not conform to such criteria.

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

Article 19 (1) From the viewpoint of public health, the Minister of Health, Labour and Welfare may establish the necessary criteria for the labeling of food or additives to serve for the purpose of marketing, or apparatus or containers and packaging for which the standards or criteria have been established pursuant to the provisions of paragraph (1) of the preceding Article, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation

Council.

- (2) Food, additives, 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.

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 11, paragraph (1) and additives for which the criteria have been established pursuant to the provisions of Article 19, paragraph (1), the Minister of Health, Labour and Welfare shall compile the Japanese Standards of Food Additives to contain said criteria and standards.

### **Chapter VI Guidelines and Plans for Monitoring and Guidance**

Article 22 (1) The Minister of Health, Labour and Welfare shall establish guidelines concerning the monitoring of and guidance on food sanitation to be implemented by the State and prefectures, etc. (hereinafter such monitoring and guidance shall be referred to as "monitoring and guidance" and such guidelines shall be 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) Other important matters concerning the implementation of monitoring and guidance.

(3) When the Minister of Health, Labour and Welfare has established or revised the guidelines, he/she shall publicize it 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, he/she 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, mayor of a city establishing health centers, or head of a special ward (hereinafter referred to as a "prefectural governor, etc.") shall establish plans concerning the following fiscal year's monitoring and guidance to be implemented by said 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 securing of coordination between said prefecture, etc. and other relevant administrative organs including neighboring prefectures, etc.;
  - (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 said prefecture, etc., actual conditions of food sanitation hazards, and other circumstances of said areas.
- (4) When a prefectural governor, etc. has established or revised prefectural plans for the monitoring of and guidance on food sanitation, he/she shall publicize it and report it to the Minister of Health, Labour and Welfare, without delay, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.
- (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.

## 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 11, 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 said 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 said 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 said inspections shall be specified by a Cabinet Order.

(5) No appeal under the Administrative Appeal Act (Act No. 160 of 1962) may be entered against the results of inspections set forth in paragraph (1).

Article 26 (1) In the case where a prefectural governor has found food, additives, apparatus or containers and packaging listed in the following items, and when he/she 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, he/she may, following requirements and procedures specified by a Cabinet Order, order the person to receive inspections by said prefectural governor or a registered conformity assessment body regarding said 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 11, 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 11, paragraph (1);
  - (iv) Food prescribed in Article 11, 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).
- (2) When the Minister of Health, Labour and Welfare finds it necessary to prevent food sanitation hazards, he/she 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 10 to receive inspections by the Minister of Health, Labour and Welfare or a registered conformity assessment body regarding said food, additives, apparatus or containers and packaging.
- (3) When the Minister of Health, Labour and Welfare finds it necessary to prevent food sanitation hazards, he/she 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 10, 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 said food, additives, apparatus or containers and packaging.
- (4) A person who has received an order under the preceding three paragraphs shall not sell said food, additives, apparatus or containers and packaging, display them for the purpose of marketing, nor use them in business until he/she receives said 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 said 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 said 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 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 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 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 implement monitoring and guidance, pursuant to the prefectural plans for the monitoring of and guidance on food sanitation.
- (3) The Minister of Health, Labour and Welfare shall have food sanitation inspectors implement monitoring and guidance pertaining to the import of food, additives, apparatus or containers and packaging, pursuant to the imported food monitoring and guidance plan.
- (4) In addition to what is prescribed in the preceding three paragraphs, 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.

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) In the case where 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 said 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 said 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 previous 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, he/she 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 79), 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), he/she 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 said 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 said 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 said 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 uncomformable to any of the items of Article 33, paragraph (1), he/she 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, he/she 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) No person other than a registered conformity assessment body shall use labeling or advertising or conduct any other acts which may cause people to mistake the operation he/she 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 he/she 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 10, 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 him/her 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 by himself/herself.

- (2) In the case where 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, when 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 his/her supervision at said 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 said 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 his/her supervision at said 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;
- (iii) A person who has completed prescribed courses at training institutes for food sanitation supervisors registered by the Minister of Health, Labour and Welfare;
- (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 the Minister of Health, Labour and Welfare.
- (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 he/she 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 himself/herself, notify the name of the food sanitation supervisor or the fact that he/she 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 his/her facility within 15 days. The same shall apply when he/she 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 said food or additives.

- (2) Prefectures may establish the necessary criteria concerning public health measures to be taken such as for maintaining the cleanliness of the interior and exterior of business facilities (excluding poultry slaughtering businesses prescribed in Article 2, item (v) of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act) and for exterminating rats and insects, etc., by a Prefectural Ordinance.
- (3) When the criteria set forth in the preceding two paragraphs have been established, 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 From the viewpoint of public health, prefectures shall establish the necessary criteria for facilities for restaurant businesses or other businesses which have an extraordinary impact on public health (excluding poultry slaughtering businesses prescribed in Article 2, item (v) of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act) and which are specified by a Cabinet Order, for each type of business, by a Prefectural Ordinance.

Article 52 (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 he/she finds that the business facilities of the person conform to the criteria under the preceding Article; provided, however, that he/she 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 his/her approval rescinded pursuant to the provisions of Articles 54 to 56, before the expiration of a period of two years since the date of said rescission;
  - (iii) A juridical person who has persons falling under any of the preceding two items among the officers 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 53 (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 said 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 said 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 54 In the case where a business person has violated any of the provisions of Article 6, Article 9, Article 10, Article 11, paragraph (2) or paragraph (3), Article 16, Article 18, paragraph (2), or Article 20, or where a business person has violated any prohibition under Article 8, paragraph (1) or Article 17, paragraph (1), the Minister of Health, Labour and Welfare or a prefectural governor may order the business person or his/her officials 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.

Article 55 (1) In the case where a business person has violated any of the provisions of Article 6, Article 9, Article 10, Article 11, paragraph (2) or paragraph (3), Article 16, Article 18, paragraph (2), Article 19, paragraph (2), Article 20, Article 25, paragraph (1), Article 26, paragraph (4), Article 48, paragraph (1) or Article 50, paragraph (3), where a business person has violated any prohibition under Article 7, paragraphs (1) to (3), Article 8, paragraph (1) or Article 17, paragraph (1), where a business person now falls under any of Article 52, paragraph (2), item (i) or item (iii), or where 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) In the case where 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 9, paragraph (2), Article 10, Article 11, paragraph (2) or paragraph (3), Article 16, Article 18, paragraph (2), Article 26, paragraph (4), or Article 50, paragraph (3), or where a business

person has violated any prohibition under Article 7, paragraphs (1) to (3), Article 8, 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 56 In the case where a business person has violated any criteria under Article 51 with regard to his/her business facilities, a prefectural governor may order that person to develop and improve the facilities, rescind the approval under Article 52, paragraph (1), prohibit the business in whole or in part, or suspend the business for a specified period.

### **Chapter X Miscellaneous Provisions**

Article 57 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 62, 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 62, paragraphs (1) and (3));
- (iii) Expenses needed for the approval of a business under Article 52, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 62, paragraph (1));
- (iv) Expenses needed for disposal under Article 54 (including the cases where it is applied mutatis mutandis under Article 62, paragraphs (1) and (3));
- (v) Expenses needed for autopsies of corpses under Article 59, paragraph (1) or paragraph (2) (including the cases where it is applied mutatis mutandis under Article 62, 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 58 (1) A physician who has diagnosed a person who has been or is suspected to have been poisoned by food, additives, apparatus, or containers and packaging (hereinafter referred to as a "person poisoned by food, etc.") or 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 he/she finds that there have been persons poisoned by food, etc., he/she shall make a report to the prefectural governor, etc. immediately and conduct an investigation, pursuant

to a Cabinet Order.

- (3) In the case where 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, he/she shall make a report to the Minister of Health, Labour and Welfare immediately.
- (4) When a director of a health center has conducted an investigation under paragraph (2), he/she 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, he/she shall make a report to the Minister of Health, Labour and Welfare, pursuant to a Cabinet Order.

Article 59 (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, he/she 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 60 In the case where 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 where persons poisoned by food, etc. have appeared or are likely to appear across wide areas, and when 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 61 (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 62 (1) The provisions of Article 6, Article 8, Article 10, Article 11, paragraphs (1) and (2), Articles 16 to 20, Articles 25 to 56, and Articles 58 to 60 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 10 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 11, 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, and Articles 54 to 56 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 63 In order to prevent food sanitation hazards, the Minister of Health, Labour and Welfare 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 64 (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 62, 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 establish, revise, or abolish the Ordinance of the Ministry of Health, Labour and Welfare set forth in Article 9,

paragraph (1), intends to specify cases having no risk to human health prescribed in Article 10, intends to establish the criteria or standards pursuant to the provisions of Article 11, paragraph (1) (including cases where it is applied mutatis mutandis under Article 62, 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 11, paragraph (3), intends to establish the criteria or standards pursuant to the provisions of Article 18, paragraph (1) (including cases where it is applied mutatis mutandis under Article 62, paragraphs (1) and (3)), intends to establish the criteria pursuant to the provisions of Article 19, paragraph (1) (including cases where it is applied mutatis mutandis under Article 62, paragraph (1)), intends to establish or revise the guidelines pursuant to the provisions of Article 22, paragraph (1), intends to establish or revise the imported food monitoring and guidance plan prescribed in Article 23, paragraph (1), or intends to establish the criteria pursuant to the provisions of Article 50, paragraph (1), he/she 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 canvass widely for citizens' opinions in advance.

- (2) When a prefectural governor, etc. has established or revised prefectural plans for the monitoring of and guidance on food sanitation prescribed in Article 24, paragraph (1), he/she shall publicize the purpose, contents, and other necessary matters 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.

Article 65 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 and a prefectural governor, etc. shall publicize the implementation of said measures and canvass widely for citizens' or residents' opinions.

Article 66 The term "prefectural governor" in Article 48, Articles 52 to 56, and Article 63 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 67 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 68 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) 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 Article) may make a request for re-examination to the Minister of Health, Labour and Welfare.

Article 69 (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 62, paragraphs (1) and (3)), Article 26, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 62, paragraph (1)), Article 28, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 62, paragraphs (1) and (3); the same shall apply hereinafter), Article 30, paragraph (2) (excluding the part pertaining to monitoring and guidance accompanying the approval of a business prescribed in Article 51 (limited to restaurant businesses and other sales businesses that are specified by a Cabinet Order) and including the cases where it is applied mutatis mutandis under Article 62, paragraphs (1) and (3); the same shall apply hereinafter), Article 54 (including the cases where it is applied mutatis mutandis under Article 62, paragraphs (1) and (3); the same shall apply hereinafter), Article 58, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 62, paragraph (1)), and Article 59, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 62, paragraph (1); the same shall apply hereinafter) 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), Article 30, paragraph (2), Article 54, Article 58 (including the cases where it is applied mutatis mutandis under Article 62, paragraph (1)), and Article 59, paragraph

(1) shall be deemed to be item 1 legally delegated affairs.

Article 70 (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.

### **Chapter XI Penal Provisions**

Article 71 (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 62, paragraphs (1) and (2)), Article 9, paragraph (1), or Article 10 (including the cases where it is applied mutatis mutandis under Article 62, 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 66) pursuant to the provisions of Article 54 (including those who provide food prescribed in Article 62, paragraph (3)), or a business person who has conducted business in violation of a disposition under Article 55 (including the cases where it is applied mutatis mutandis under Article 62, 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 72 (1) A person who has violated the provisions of Article 11, paragraph (2) (including the cases where it is applied mutatis mutandis under Article 62, paragraphs (1) and (2)) or paragraph (3), Article 16 (including the cases where it is applied mutatis mutandis under Article 62, paragraphs (1) and (3)), Article 19, paragraph (2) (including the cases where it is applied mutatis mutandis under Article 62, paragraph (1)), Article 20 (including the cases where it is applied mutatis mutandis under Article 62, paragraph (1)), or



Article 52, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 62, 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 73 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 9, paragraph (2), Article 18, paragraph (2) (including the cases where it is applied mutatis mutandis under Article 62, paragraphs (1) and (3)), Article 25, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 62, paragraphs (1) and (3)), Article 26, paragraph (4) (including the cases where it is applied mutatis mutandis under Article 62, paragraph (1)), and Article 58, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 62, paragraph (1));
- (ii) A person who has violated the prohibition under Article 8, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 62, paragraph (1)) or Article 17, paragraph (1) (including the cases where it is applied mutatis mutandis under Article 62, paragraphs (1) and (3));
- (iii) A person who has disclosed secrets which have come to his/her knowledge concerning his/her duties in violation of Article 40, paragraph (1);
- (iv) A person who has violated the criteria under Article 51 (including the cases where it is applied mutatis mutandis under Article 62, paragraphs (1) and (3)) or who has violated the conditions under Article 52, paragraph (3) (including the cases where it is applied mutatis mutandis under Article 62, paragraph (1));
- (v) 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 66) pursuant to the provisions of Article 56 (including the cases where it is applied mutatis mutandis under Article 62, paragraphs (1) and (3); the same shall apply hereinafter) (including those who provide food prescribed in the same paragraph), or a person who has conducted business in violation of a disposition under Article 56.

Article 74 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 75 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);
- (ii) A person who has not made a report under Article 28, paragraph (1) or who has made a false report;
- (iii) A person who has not made a notification under Article 27 or Article 48, paragraph (8) (both including the cases where it is applied mutatis mutandis under Article 62, paragraph (1)) or who has made a false notification;
- (iv) A person who has violated an order under Article 46, paragraph (2).

Article 76 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 77 When a food sanitation supervisor has neglected his/her duties under Article 48, paragraph (3), and when there have been acts falling under violations set forth in Articles 71 to 73 with regard to food or additives pertaining to his/her supervision at said facility, he/she 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 78 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 71 or Article 72 (limited to the part pertaining to the provisions of Article 11, paragraph (2) (including the cases where it is applied mutatis mutandis under Article 62, paragraphs (1) and (2)) or paragraph (3), Article 19, paragraph (2) (including the cases where it is applied mutatis mutandis under Article 62, paragraph (1)), and Article 20 (including the cases where it is applied mutatis mutandis under Article 62, paragraph (1)) ? A fine not exceeding 100 million yen;
- (ii) Article 72 (limited to the part pertaining to the provisions of Article 11, paragraph (2) (including the cases where it is applied mutatis mutandis under Article 62, paragraphs (1) and (2)) or paragraph (3), Article 19, paragraph (2) (including the cases where it is applied mutatis mutandis under Article 62, paragraph (1)), and Article 20 (including the cases where it is applied mutatis mutandis under Article 62, paragraph (1)), Article 73, or Article 75 ? A fine prescribed in the respective Articles.

Article 79 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
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2. Water purifying apparatus	(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;
3. Deep freezer	(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;
4. Homogenizer	(iii) A person who has equal or greater knowledge and experience than those listed in the preceding two items.
5. Gas chromatograph 6. Gas chromatograph mass spectrometer (limited to those which conduct inspections of agricultural chemicals remaining in food that are prescribed in Article 1-2, paragraph 1 of the Agricultural Chemicals Control Act)	

	7. Atomic absorption photometer 8. High performance liquid chromatograph		
Bacteriological inspections	1. Centrifugal separator 2. Water purifying apparatus  3. Deep freezer  4. Homogenizer  5. Dry heat sterilizer 6. Optical microscope 7. Autoclave 8. Incubator	A person shall fall under any of the following items: (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; (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; (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>
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