

Food Safety Basic Act

(Act No. 48 of May 23, 2003)

Chapter I General Provisions

(Purpose)

Article 1 In consideration of the vital importance of precise responses to the development of science and technology, and to the progress of internationalization and other changes in the environment surrounding Japan's dietary habits, the purpose of this Act is to comprehensively promote policies to ensure food safety by establishing basic principles, by clarifying the responsibilities of the national and local governments, and food-related business operators and the roles of consumers, and establishing a basic direction for policy formulation, in order to ensure food safety.

(Definition)

Article 2 The term "Food" as used in this Act means all food and drink (excluding pharmaceutical products or quasi-pharmaceutical products specified by the Pharmaceutical Affairs Act (Act No. 145 of 1960)).

(Basic Recognition in Taking Measures for Ensuring Food Safety)

Article 3 Food safety must be ensured by taking the necessary measures based on the basic recognition that the protection of the health of our citizens is a top priority.

(Appropriate Measures at Each Stage of the Food Supply Process)

Article 4 Food safety may be affected by every element in a series of internal and external Food supply processes, from the production of agricultural, forestry, and marine products to Food sales (hereinafter referred to as the "Food Supply Process"); thus must be ensured by taking the necessary measures appropriately at each stage of the Food Supply Processes.

(Prevention of Adverse Effects on the Health of Citizens)

Article 5 Food safety must be ensured by taking the necessary measures on the basis of scientific knowledge and in sufficient consideration of international trends and the opinions of citizens with respect to ensuring Food safety, for the purpose of preventing adverse effects on the health of citizens due caused by ingestion of Food.

(Responsibilities of the National Government)

Article 6 The national government is responsible for formulating and implementing comprehensive policies to ensure Food safety on the code of basic principles for ensuring Food safety, provided in the preceding three articles (hereinafter referred to as the "Basic Principles").

(Responsibilities of Local Governments)

Article 7 Local governments are responsible, pursuant to the Basic Principles, and based on an appropriate sharing of roles with the national government, for formulating and implementing policies to ensure Food safety that suit their natural and socioeconomic characteristics of the area.

(Responsibility of Food-related Business Operators)

Article 8 (1) Business operators that produce, import, sell, or conduct other business for fertilizers, agricultural chemicals, feed, feed additives, veterinary medicines and other production materials for agriculture, forestry, or fishing industry that may have an effect on Food safety, Food (including agricultural, forestry, and marine products used as raw materials or materials), additives (those provided in Article 4, paragraph (2) of the Food Sanitation Act (Act No. 233 of 1947)), apparatus (that provided in paragraph (4) of the that Article) or containers and packaging (those provided in paragraph (5) of the that Article) (hereinafter referred to as "Food-related Business Operators") are responsible for appropriately taking the necessary measures to ensure Food safety at each stage of the Food Supply Processes. This will be done according to the code of the Basic Principles and on the basis of the recognition that they bear the primary responsibility for ensuring Food safety when conducting their business activities.

(2) In addition to what is prescribed in the preceding paragraph, Food-related Business Operators must, in conducting their business activities, make efforts to provide accurate and appropriate information concerning Food and other articles related to their own business activities on the code of the basic principles.

(3) In addition to what is prescribed in the preceding two paragraphs, Food-related Business Operators are responsible for cooperating in policies that are implemented by the national or the local governments, on the code of the Basic Principles, to ensure Food safety.

(Consumer's Role)

Article 9 Consumers are to play an active role in ensuring Food safety by endeavoring to improve their own knowledge and understanding of Food safety and by making efforts to express their opinions about policies to ensure Food

safety.

(Legislative Measures)

Article 10 The government must take legislative or financial measures and other necessary measures to implement policies to ensure Food safety.

Chapter II Basic Direction for Policy Formulation

(Implementation of Assessment of the Effect of Food on Health)

Article 11 (1) In formulating policies to ensure Food safety, assessment (hereinafter referred to as the "Assessment of the Effect of Food on Health") must be made for each policy on the effects that potentially harmful biological, chemical, or physical agents likely to be contained in Food, or conditions under which Food is likely to be placed, have on human health, through the ingestion of the Food; provided, however, that this does not apply to the following cases:

- (i) where the Assessment of the Effect of Food on Health is explicitly unnecessary in consideration of the substance of the policy.
- (ii) where the substance and degree of adverse effects on human health are clear.
- (iii) where there is no time to conduct an Assessment of the Effect of Food on Health in advance in cases where the measure is urgently necessary to prevent or restrain an adverse effect on human health.

(2) In cases as cited in item (iii) of the preceding paragraph, the Assessment of the Effect of Food on Health must be conducted subsequently and without delay.

(3) The Assessment of the Effect of Food on Health provided in the preceding two paragraphs must be conducted in an objective, neutral, and fair manner on the basis of the state-of-the-art scientific knowledge of the time.

(Formulation of Policies on the Basis of the Results of the Assessment of the Effect of Food on Health in Consideration of the Conditions of the Dietary Habits of Citizens and Other Circumstances)

Article 12 In formulating policies to ensure Food safety, it must be conducted for the purpose of preventing and restraining the adverse effect of Food ingestion on human health, in consideration of the dietary habits of citizens and other circumstances, and on the basis of the results of the Assessment of Effect of Food on Health if conducted in accordance with the provisions of paragraph (1) or (2) of the preceding article.

(Promotion of Exchanges of Information and Opinions)

Article 13 In formulating policies to ensure Food safety, necessary measures for

promoting the mutual exchange of information and opinions among persons or parties concerned, such as provision of information concerning the policies and the granting of opportunities to state opinion on those policies, must be taken to reflect public opinion in the formulation of the policies and to ensure the transparency and fairness of the process.

(Establishment of a System to Cope with Emergency and Other Situations)

Article 14 In formulating policies to ensure Food safety, necessary measures, such as establishment of a system to cope with or prevent emergency situations that cause or are likely to cause serious damage to human health by Food ingestion, must be taken to prevent that damage.

(Close and Mutual Coordination among Relevant Administrative Organs)

Article 15 In formulating policies to ensure Food safety, close and mutual coordination among relevant administrative organs must be made to create the necessary measures for ensuring Food safety to be appropriately taken at each stage of the Food Supply Processes.

(Establishment of Test and Research and Other Systems)

Article 16 In formulating policies to ensure Food safety, necessary measures, such as establishment of test and research systems, promotion of research and development, dissemination of results thereof and training of researchers, must be taken in consideration that efforts to improve scientific knowledge are important for ensuring Food safety.

(Collection, Arrangement, and Utilization of Internal and External Information)

Article 17 In formulating policies to ensure Food safety, necessary measures such as the collection, arrangement, and utilization of internal and external information about ensuring Food safety, must be taken to appropriately and effectively implement the necessary measures for ensuring Food safety in response to changes in the environment surrounding dietary habits of citizens.

(Ensuring Appropriate Operation of a Food Labeling System)

Article 18 In formulating policies to ensure Food safety, necessary measures for accurately transmitting the information on Food, such as ensuring the appropriate operation of a Food labeling system, must be taken in consideration that Food labeling plays an important role in ensuring Food safety.

(Education and Learning regarding Ensuring Food Safety)

Article 19 In formulating policies to ensure Food safety, necessary measures for improving knowledge and understanding of ensuring Food safety among citizens must be taken by promoting education and learning and improving public relations activities on ensuring Food safety.

(Consideration for Effects on the Environment)

Article 20 In formulating policies to ensure Food safety, it must be conducted in consideration of the effects of policies on the environment.

(Determination and Publication of Basic Matters Concerning Implementation of Measures)

Article 21 (1) The government must determine basic matters concerning implementation of measures (hereinafter referred to as "Basic Matters") that are to be taken in accordance with the provisions of Article 11 through the preceding Article.

(2) The Prime Minister must formulate a draft of Basic Matters after hearing the opinions of the Food Safety Commission and ask the Cabinet for its decision.

(3) The Prime Minister must publicize the Basic Matters without delay once the Cabinet has made its decision in accordance with the provisions of the preceding paragraph.

(4) The provisions of the preceding two paragraphs apply mutatis mutandis to the changes of the Basic Matters.

Chapter III Food Safety Commission

(Establishment)

Article 22 The Food Safety Commission (hereinafter referred to as the "Commission") is established in the Cabinet Office.

(Functions under the Jurisdiction)

Article 23 (1) The Commission takes charge of the functions listed in the following items:

(i) to state opinions to the Prime Minister in accordance with the provisions of Article 21, paragraph (2).

(ii) to conduct an Assessment of the Effects of Food on Health in accordance with the provisions of the following article or at its direction.

(iii) to make recommendations to relevant ministers through the Prime Minister about policies to be implemented for ensuring Food safety on the basis of the results of the Assessment of the Effect of Food on Health which was conducted in accordance with the provisions of the preceding item.

(iv) to monitor the implementation conditions of policies that are implemented

on the basis of the results of the Assessment of the Effect of Food on Health, which was conducted in accordance with the provisions of item (ii), and to make recommendations to relevant ministers through the Prime Minister if necessary.

- (v) to study and deliberate on important matters regarding policies to be implemented for ensuring Food safety, and to state opinions to the heads of relevant administrative organs if necessary.
 - (vi) to conduct scientific research and study necessary to perform functions cited in items (ii) through (v).
 - (vii) to plan and implement the mutual exchange of information and opinions among persons or parties concerned with respect of functions cited in items (ii) through (vi).
 - (viii) to coordinate functions conducted by relevant administrative organs regarding the mutual exchange of information and opinions among persons or parties concerned with respect to ensuring Food safety.
- (2) When the Commission conducts the Assessment of the Effect of Food on Health in accordance with the provisions of item (ii) of the preceding paragraph, it must notify relevant ministers of the results of the assessment without delay.
- (3) When the Commission has given notification in accordance with the provisions of the preceding paragraph or made a recommendation in accordance with the provisions of item (iii) or (iv) of paragraph (1), it must publicize the matters of the notification or the contents of the recommendation without delay.
- (4) Relevant ministers must report to the Commission on policies that they have implemented on the basis of a recommendation in accordance with the provisions of item (iii) or (iv) of paragraph (1).

(Hearing of the Commission's opinions)

Article 24 (1) In any of the following cases, relevant ministers must hear the Commission's opinions; provided, however, that this does not apply to cases that the Commission recognizes as falling under Article 11, paragraph (1), item (i) or that the relevant minister recognizes as falling under item (iii) of the same paragraph:

- (i) when intending to specify cases that involves no risk to human health as provided in the proviso of Article 6, paragraph (2) of the Food Sanitation Act (including as applied *mutatis mutandis* pursuant to Article 62, paragraph (2) of that Act), when intending to prohibit the sales in accordance with the provisions cited in paragraphs (1) through (3) of Article 7 of that Act or to rescind the prohibition in whole or in part in accordance with the provision of paragraph (4) of that Article, when intending to enact, amend or abolish the

- Ministry of Health, Labor and Welfare Order provided in Article 9, paragraph (1) of that Act, when intending to specify cases as having no risk to human health as provided in Article 10 of that Act, when intending to establish criteria or standards in accordance with the provisions of Article 11, paragraph (1) of that Act (including as applied mutatis mutandis pursuant to Article 62, paragraph (2) of that Act), when intending to specify substances as clearly having no risk to human health or the quantity as having no risk to human provided Article 11, paragraph (3) of that Act, when intending to establish criteria or standards in accordance with the provisions of Article 18, paragraph (1) of that Act (including as applied mutatis mutandis pursuant to Article 62, paragraph (3) of that Act), or when intending to establish standards in accordance with the provisions of Article 50, paragraph (1) of that Act.
- (ii) when intending to set, change, or abolish official specifications in accordance with the provisions of Article 1-3 of the Agricultural Chemicals Control Act (Act No. 82 of 1948), when intending to designate or change the designation of specified agricultural chemicals in accordance with the provisions of Article 2, paragraph (1) of that Act, or when intending to establish or change the standards (excluding standards for determining whether falling under cases cited in Article 3, paragraph (1), item (vi) or (vii) of that Act) provided in Article 3, paragraph (2) of that Act (including cases as applied mutatis mutandis pursuant to Article 15-2, paragraph (6) of that Act).
- (iii) when intending to set, change, or abolish official specifications in accordance with the provisions of Article 3 of the Fertilizer Regulation Act (Act No. 127 of 1950), when intending to enact, amend, or abolish the Cabinet Order provided in Article 4, paragraph (1), item (iv) of that Act, when intending to register or register provisionally specified normal fertilizers in accordance with the provisions of Article 7, paragraph (1) or Article 8, paragraph (3) of the that Act (including as applied mutatis mutandis pursuant to Article 33-2, paragraph (6) of that Act), when intending to register or register provisionally changes of specified normal fertilizers in accordance with the provisions of Article 13-2, paragraph (2) of that Act (including as applied mutatis mutandis pursuant to Article 33-2, paragraph (6) of that Act), or when intending to register or register provisionally changes of specified normal fertilizers, or to abolish registrations or provisional registrations in accordance with the provisions of Article 13-3, paragraph (1) of that Act (including as applied mutatis mutandis pursuant to Article 33-2, paragraph (6) in that Act).
- (iv) when intending to form a plan for enactment, amendment, or abolishment of the Cabinet Order provided in Article 2, paragraph (1) of the Act on

- Domestic Animal Infectious Diseases Control (Act No. 166 of 1951), when intending to enact, amend, or abolish the Ministry of Agriculture, Forestry and Fisheries Order, which prescribes notifiable infectious diseases referred to in Article 4, paragraph (1) of that Act, or when intending to form a plan for enactment, amendment, or abolishment of the Cabinet Order provided in Article 62, paragraph (1) of that Act.
- (v) when intending to designate feed additives in accordance with the provisions of Article 2, paragraph (3) of the Act on Safety Assurance and Quality Improvement of Feeds (Act No. 35 of 1953), when intending to establish, amend, or abolish standards or specifications in accordance with the provisions of Article 3, paragraph (1) of that Act, or when intending to prohibit manufacture, import, sales, or use in accordance with the provisions of Article 23 of that Act.
- (vi) when intending to enact, amend, or abolish the Ministry of Health, Labor and Welfare Order provided in Article 6, Article 9, Article 13, paragraph (1), item (iii), or Article 14, paragraph (6), item (ii) or (iii) of the Slaughterhouse Act (Act No. 114 of 1953), or when intending to form a plan for enactment, amendment, or abolishment of the Cabinet Order provided in Article 14, paragraph (7) of that Act.
- (vii) when intending to enact, amend, or abolish the Ministry of Health, Labor and Welfare Order provided in Article 4, paragraph (2) (limited to the part pertaining to the provisions of paragraph (1), items (i) through (iii) of that article) of the Water Supply Act (Act No. 177 of 1957).
- (viii) when intending to give approval for pharmaceutical products, quasi-pharmaceutical products, or medical instruments for the purpose of use for animals (hereinafter referred to as "veterinary medicine, etc.") pursuant to the provisions of Article 14, paragraph (1) of the Pharmaceutical Affairs Act or the provisions of that paragraph as applied pursuant to the provisions of Article 83, paragraph (1) of that Act following the deemed replacement of terms, when intending to give approval for veterinary medicine, etc. pursuant to the provisions of Article 14-3, paragraph (1) of that Act (including as applied *mutatis mutandis* pursuant to Article 20, paragraph (1) of the Act; the same applies hereinafter) or the provisions of that paragraph as applied pursuant to the provisions of Article 83, paragraph (1) of that Act following the deemed replacement of terms, when intending to conduct a re-examination of veterinary medicine, etc. pursuant to the provisions of Article 14-4, paragraph (1) of that Act (including as applied *mutatis mutandis* pursuant to Article 19-4; the same applies hereinafter) or the provisions of that paragraph as applied pursuant to the provisions of Article 83, paragraph (1) of that Act following the deemed replacement of terms, when intending to conduct re-assessment of veterinary medicine, etc. pursuant to

- the provisions of Article 14-6, paragraph (1) of that Act (including as applied mutatis mutandis pursuant to Article 19-4 of that Act; the same applies hereinafter) or the provisions of that paragraph as applied pursuant to the provisions of Article 83, paragraph (1) of that Act following the deemed replacement of terms, when intending to give approval for veterinary medicine, etc. pursuant to the provisions of Article 19-2, paragraph (1) of that Act or the provisions of that paragraph as applied pursuant to the provisions of Article 83, paragraph (1) of that Act following the deemed replacements of terms, or when intending to enact, amend, or abolish the Ministry of Agriculture, Forestry and Fisheries Order provided in Article 83-5, paragraph (1) of that Act or the provisions of Article 14, paragraph (2), item (iii) of that Act as applied pursuant to the provisions of Article 83, paragraph (1) of that Act following the deemed replacement of terms.
- (ix) when intending to form a plan for the enactment, amendment, or abolishment of the Cabinet Order (limited to those that designate substances contained in agricultural land soil, which are feared to become the source of the production of agricultural crops, and livestock that are feared to be harmful to human health) provided in Article 2, paragraph (3) of the Act to Prevent Soil Contamination on Agricultural Land (Act No. 139 of 1970) or the Cabinet Order provided in Article 3, paragraph (1) of that Act (limited to those that prescribe requirements for areas where the agricultural lands are understood to be used for the production of agricultural crops and livestock that are feared to be harmful to human health or where the fear thereof is understood to be conspicuous).
 - (x) when intending to enact, amend, or abolish the Ministry of Health, Labor and Welfare Order provided in Article 11, Article 15, paragraph (4), item (ii) or (iii), paragraph (6) or Article 19 of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act (Act No. 70 of 1990).
 - (xi) when intending to erase or exclude the name of additives pursuant to the provisions of Article 2-2, paragraph (1) of Supplementary Provisions of The Act for Partial Amendment of the Food Sanitation Act and the Nutrition Improvement Act (Act No. 101 of 1995).
 - (xii) when intending to form a plan for enactment, amendment, or abolishment of the Cabinet Order provided in Article 6, paragraph (1) of the Act on Special Measures against Dioxins (Act No. 105 of 1999).
 - (xiii) when intending to enact, amend, or abolish the Ministry of Health, Labor and Welfare Order provided in Article 7, paragraph (1) or (2) of the Act on Special Measures Concerning Bovine Spongiform Encephalopathy (Act No. 70 of 2002).
 - (xiv) beyond what is set forth in the preceding items, cases provided by the Cabinet Order.

- (2) In cases falling under the proviso of the preceding paragraph (limited to cases recognized by the relevant ministers as falling under Article 11, paragraph (1), item (iii)), relevant ministers must report that fact to the Commission and hear its opinions within a certain period of time after the formulation of policies to ensure the safety of the Food.
- (3) In addition to cases provided in paragraph (1), relevant ministers may hear the Commission's opinions if they are recognized as necessary for formulating policies to ensure Food safety.

(Request of Document Submission)

Article 25 The Commission may request that the heads of relevant administrative organs submit materials, opinions, and explanations and provide other necessary cooperation, if it is recognized to be necessary for performing functions under its jurisdiction.

(Entrustment of Investigation)

Article 26 The Commission may entrust necessary investigations to incorporated administrative agencies, juristic persons incorporated in accordance with the provisions of Article 34 of the Civil Code (Act No. 89 of 1896), enterprises and other private bodies, prefectural test and research institutes, or persons with relevant expertise, if it is recognized to be necessary for performing functions under its jurisdiction.

(Request in an Emergency)

- Article 27 (1) The Commission may request that the test and research institutes of relevant national administrative organs conduct an investigation, analysis, or examination necessary for the Assessment of the Effect of Food on Health if it is recognized to be necessary for coping with emergency situations that cause or are likely to cause serious damage concerning ensuring Food safety.
- (2) If the test and research institutes of relevant national administrative organs receive a request from the Commission in accordance with the provisions of the preceding paragraph, they must promptly implement the requested research, analysis, or examination.
- (3) The Commission may request that relevant ministers make a demand under Article 13, paragraph (1) of the Incorporated Administrative Agency, National Institute of Health and Nutrition Act (Act No. 180 of 1999) or a request in accordance with the provisions of Article 12, paragraph (1) of the Incorporated Administrative Agency, Food and Agricultural Materials Inspection Center Act (Act No. 183 of 1999), Article 18, paragraph (1) of the Incorporated Administrative Agency, National Agriculture and Food Research Organization Act (Act No. 192 of 1999), Article 13, paragraph (1) of the Incorporated

Administrative Agency, National Institute for Agro-Environmental Sciences Act (Act No. 194 of 1999), or Article 15, paragraph (1) of the Incorporated Administrative Agency, Fisheries Research Agency Act (Act No. 199 of 1999), if it is recognized to be necessary for coping with emergency situations that cause or are likely to cause serious damage to the ensuring of Food safety.

(Organization)

- Article 28 (1) The Commission is organized by seven commission members.
(2) Three out of the seven Commission Members are part-time members.

(Appointment of Commission Members)

- Article 29 (1) Commission Members are appointed by the Prime Minister upon obtaining consent of both houses of Diet from among persons who have excellent knowledge and experience of ensuring Food safety.
(2) Notwithstanding the provisions of the preceding paragraph, the Prime Minister may appoint Commission Members who have qualifications as provided in the preceding paragraph, if the Prime Minister cannot obtain consent of the appointment from both houses of Diet due to the Diet's closing or the dissolution of the House of Representatives in cases where the term of the Commission Members has expired or a vacancy for a Commission Member arises.
(3) In the case referred to in the preceding paragraph, the Prime Minister must obtain subsequent approval of both houses of Diet at the first Diet session after the relevant appointment. If the Prime Minister cannot obtain subsequent approval of both houses of Diet in that case, the Prime Minister must immediately dismiss the Commission Member.

(Term of Office of Commission Members)

- Article 30 (1) The term of office of the Commission Member is three years; provided, however, that the term of a substitute Commission Member is the remaining term of that member's predecessor.
(2) The Commission Member may be reappointed.
(3) When the terms of office of the Commission Member expire, those Commission Members are to perform their duties continuously until their successors are appointed.

(Dismissal of Commission Members)

- Article 31 With consent of both houses of Diet, the Prime Minister may dismiss the Commission Member if the Commission member is recognized as being incapable of performing their duties due to physical or mental disability or as constituting a violation of their obligations in the course of their duties or

other delinquency inappropriate for a Commission Member.

(Discipline of Commission Members)

Article 32 (1) The Commission Member must not divulge any secrecy which becomes known to them in course of their duties. The same applies after their retirement.

(2) During the term of office, the Commission Member must not be an officer of a political party or other political bodies nor engage in political movements actively.

(3) During the term of office, the full-time Commission Member must not engage in other jobs with remuneration, run business for profit purposes or operate other businesses seeking for monetary interest except a case in which they are permitted by the Prime Minister.

(Salary of Commission Members)

Article 33 The salary of the Commission Member is provided for in a separate Act.

(Chairperson)

Article 34 (1) The position of Chairperson is established in the Commission and the Chairperson is appointed by Commission Members by a mutual vote among the full-time Commission Members.

(2) The Chairperson presides over the affairs of the Commission and represent it.

(3) In the event that the Chairperson has an accident, the full-time Commission Member who has been designated in advance by the Chairperson performs the duties of the Chairperson.

(Meeting)

Article 35 (1) The Chairperson convenes a meeting of the Commission.

(2) The Commission may not hold a meeting nor make any resolutions without the attendance of the Chairperson and at least three Commission Members.

(3) Decisions of the Commission are made by the majority of attendees, and in the case of tie, the Chairperson makes a decision.

(4) With respect to the application of the provisions of paragraph (2) about cases in which the Chairperson is in an accident, the Committee Member provided in paragraph (3) of the preceding article is deemed to be the Chairperson.

(Expert Commission Member)

Article 36 (1) The Commission may request an Expert Advisor to study and deliberate on specialized matters.

(2) The Prime Minister appoints the Expert Advisor from among persons with

relevant expertise.

- (3) The Expert Advisor is to be dismissed upon termination of the study and deliberation of the relevant specialized matters.
- (4) The Expert Advisor is to be part-time.

(Secretariat)

Article 37 (1) The secretariat is established in the Commission for the purpose of dealing with functions of the Commission.

- (2) The secretariat has a secretary-general and necessary staffs.
- (3) The secretary-general controls the matters of the secretariat by following instructions of the Chairperson.

(Delegation to a Cabinet Order)

Article 38 In addition to what is provided for in this Chapter, necessary matters concerning the Commission is prescribed by a Cabinet Order.