

The Food Safety Basic Law (Tentative Translation)

Law No. 48, May 23, 2003

Last amendment : No. 50. Jun 2 . 2006

Contents

- Chapter I General Provisions (Articles 1-10)
- Chapter II Basic Direction for Policy Formulation (Articles 11-21)
- Chapter III Food Safety Commission (Articles 22-38)

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 Law is to comprehensively promote policies to ensure food safety by establishing basic principles, by clarifying the responsibilities of the state, 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

“Food” as used in this Law shall mean all food and drink (excluding drugs and quasi-drugs provided by the Pharmaceutical Affairs Law (Law No. 145 of 1960)).

(Basic recognition in taking measures for ensuring food safety)

Article 3

Food safety shall be ensured by taking the necessary measures based on the simple 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 fishery products to food sales (hereinafter referred to as “food supply process”); it thus shall be ensured by taking the necessary measures appropriately at each stage of the food supply process.

(Prevention of adverse effects on the health of citizens)

Article 5

Food safety shall 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 food.

(Responsibilities of the state)

Article 6

The state shall be responsible for comprehensively formulating and implementing 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 the local governments)

Article 7

Local governments shall be responsible for formulating and implementing policies to ensure food safety that corresponds to the natural, economic, and social conditions of the area under their jurisdiction, on the code of the basic principles and on the basis of an appropriate sharing of roles with the state.

(Responsibility of food-related business operators)

Article 8

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 fishery that may have an effect on food safety, food (including agricultural, forestry, and fishery products used as raw materials or materials), additives (those provided in Article 2, paragraph 2 of the Food Sanitation Law (Law No. 233 of 1947)), apparatuses (those provided in Article 2, paragraph 4 of the said Law) or containers and packages (those provided in Article 2, paragraph 5 of the said Law) (hereinafter referred to as “food-related business operators”) shall be responsible for appropriately taking the necessary measures to ensure food safety at each stage of the food supply process. 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 the provisions of the preceding paragraph, food-related business operators shall, 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 the provisions of the preceding two paragraphs, food-related business operators shall be responsible for cooperating in policies that are implemented by the state or the local governments, on the code of the basic principles, to ensure food safety.

(Roles of consumers)

Article 9

Consumers shall 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, etc.)

Article 10

The government shall take legislative or financial measures and other necessary measures to implement policies to ensure food safety.

Chapter II Basic Directions for Policy Formulation

(Implementation of assessment of the effect of food on health)

Article 11

In formulating policies to ensure food safety, assessment (hereinafter referred to as the “assessment of the effect of food on health”) shall be made for each policy on the effects that potentially harmful biological, chemical, or physical agents in food or the condition of food have on human health, through the ingestion of the food, provided that this shall not apply to the following cases:

- (1) where the assessment of the effect of food on health is explicitly unnecessary in consideration of the contents of the measure;
 - (2) where the contents and degree of adverse effects on human health are clear;
 - (3) where there is no time to conduct an assessment of the effects of food on health in advance in cases where the measure is urgently necessary to prevent or control an adverse effect on human health.
2. In cases as cited in (3) of the preceding paragraph, the assessment of the effect of food on health shall be conducted subsequently and without delay.
3. The assessment of the effect of food on health provided in the preceding two paragraphs shall 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 nationals’ dietary habits and other circumstances)

Article 12

In formulating policies to ensure food safety, it shall 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 comment on those policies, shall 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 liable to cause serious damage to human health by food ingestion, shall be taken to prevent such damage.

(Close and mutual cooperation among related administrative bodies)

Article 15

In formulating policies to ensure food safety, close and mutual cooperation among related administrative bodies shall be made to create the necessary measures for ensuring food safety to be appropriately taken at each stage of the food supply process.

(Establishment of research and other systems)

Article 16

In formulating policies to ensure food safety, necessary measures, such as establishment of research systems, promotion of research and development, dissemination of results thereof and training of researchers, shall 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, shall be taken to appropriately and effectively implement the necessary measures for ensuring food safety in response to changes in the environment surrounding Japanese dietary habits.

(Ensuring appropriate labeling)

Article 18

In formulating policies to ensure food safety, necessary measures for accurately conveying the information on food, such as ensuring the appropriate operation of a food labeling system, shall 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 shall 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, the effects of policies on the environment shall be considered.

(Determination and publication of Basic Matters concerning implementation of measures)

Article 21

The government shall determine basic matters concerning implementation of measures (hereinafter referred to as “Basic Matters”) that are to be taken in accordance with the provisions of Articles 11 to 20.

2. The Prime Minister shall 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 shall promulgate the Basic Matters without delay once the Cabinet has made its decision in accordance with the provision of the preceding paragraph.

4. The provisions of the preceding two paragraphs shall 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”) shall be established in the Cabinet Office.

(Office duties under the jurisdiction of the Commission)

Article 23

The Commission shall take charge of the following office duties:

(1) to offer opinions to the Prime Minister in accordance with the provisions of Article 21, paragraph 2;

(2) to conduct an assessment of the effects of food on health in accordance with the provisions of the following article or at its direction;

(3) to make recommendations to related 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;

(4) 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 (2), and to make recommendations to related ministers through the Prime Minister if necessary;

(5) to examine and deliberate on important matters regarding policies to be implemented for ensuring food safety, and to give opinions to the heads of related administrative bodies if necessary;

(6) to conduct scientific research and study necessary to perform office duties cited in items (2) to (5);

(7) to plan and implement the mutual exchange of information and opinions among persons or parties concerned with respect of office duties cited in items (2) to (6); and

(8) to coordinate office duties conducted by related administrative bodies 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 (2) of the preceding paragraph, it shall notify related 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 (3) or (4) of paragraph 1, it shall publish the contents of the notification or the recommendation without delay.

4. Related ministers shall report to the Commission on policies that they have implemented on the basis of a recommendation in accordance with the provisions of (3) or (4) of paragraph 1.

(Hearing of the Commission' s opinions)

Article 24

In any of the following cases, related ministers shall hear the Commission' s opinions, provided that this shall not apply to cases that the Commission recognizes as falling under Article 11, paragraph 1 (1) or that the related minister recognizes as falling under (3) of the same paragraph:

(1) when intending to prescribe cases that are not injurious to human health as provided in the proviso of Article 6 (2) of the Food Sanitation Law (including cases where it applies mutatis mutandis in Article 62, paragraph 2 of the said Law), when intending to prohibit sales in accordance with the provisions cited in paragraphs (1) to (3) of Article 7 of the said Law or to dissolve the prohibition in accordance with Article 4 of the said Law partially or entirely, when intending to enact, amend or abolish the Ministry of Health, Labour and Welfare Ordinance provided in Article 9, paragraph 1 of the said Law, when intending to prescribe cases that are not injurious to human health as provided in Article 10 of the said Law, when intending to establish standards or specifications in accordance with the provisions of Article 11, paragraph 1 of the said Law (including cases where it applies mutatis mutandis in Article 62, paragraph 2 of the said Law) or Article 18, paragraph 1 of the said Law (including cases where it applies mutatis mutandis in Article 62, paragraph 3 of the said Law), or when intending to establish standards in accordance with the provisions of Article 50, paragraph 1 of the said Law;

(2) when intending to set, change, or abolish official specifications in accordance with the provisions of Article 1-3 of the Agricultural Chemicals Regulation Law (Law 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 the said Law, or when intending to establish or change the standards (excluding standards for determining whether falling under cases cited in Article 3, paragraph 1 (6) or (7) of the said Law) provided in Article 3, paragraph 2 of the said Law (including cases where it applies mutatis mutandis in Article 15-2, paragraph 6 of the said Law);

(3) when intending to set, change, or abolish official specifications in accordance with the provisions of Article 3 of the Fertilizer Control Law (Law No. 127 of 1950), when intending to enact, amend, or abolish the Cabinet Order provided in Article 4, paragraph 1 (4) of the said Law, 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 said Law (including cases where it applies mutatis mutandis in Article 33-2, paragraph 6 of the said Law), when intending to register or register provisionally changes of specified normal fertilizers in accordance with the provisions of Article 13-2, paragraph 2 of the said Law (including cases where it applies mutatis mutandis in Article 33-2, paragraph 6 of the said Law), 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 the said Law

(including cases where it applies mutatis mutandis in Article 33-2, paragraph 6 in the said Law)

(4) when intending to form a plan for enactment, amendment, or abolishment of the Cabinet Order provided in Article 2, paragraph 1 of the Domestic Animal Infectious Disease Control Law (Law No. 166 of 1951), when intending to enact, amend, or abolish the Ministry of Agriculture, Forestry and Fisheries Ordinance, which prescribes reported communicable diseases referred to in Article 4, paragraph 1 of the said Law, or when intending to form a plan for enactment, amendment, or abolishment of the Cabinet Order provided in Article 62, paragraph 1 of the said Law;

(5) when intending to designate feed additives in accordance with the provisions of Article 2, paragraph 3 of the Law Concerning Safety Assurance and Quality Improvement of Feed (Law 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 the said Law, or when intending to prohibit manufacture, import, sales, or use in accordance with the provisions of Article 23 of the said Law;

(6) when intending to enact, amend, or abolish the Ministry of Health, Labour and Welfare Ordinance provided in Article 6, Article 9, Article 13, paragraph 1 (3), or Article 14, paragraph 6 (2) or (3) of the Abattoirs Law (Law 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 the said Law;

(7) when intending to enact, amend, or abolish the Ministry of Health, Labour and Welfare Ordinance provided in Article 4, paragraph 2 (limited to the part pertaining to the provisions of paragraph 1 (1) to (3) of the said article) of the Waterworks Law (Law No. 177 of 1957);

(8) when intending to give approval for drugs, quasi-drugs, or medical instruments for the purpose of use for animals (hereinafter referred to as “veterinary medicine, etc.”) in accordance with the provisions of Article 14, paragraph 1 of the Pharmaceutical Affairs Law or the provisions of the said paragraph applied in accordance with the provisions of Article 83, paragraph 1 of the said Law, when intending to give approval for veterinary medicine, etc. in accordance with the provisions of Article 14-3, paragraph 1 of the said law (including cases where it applies mutatis mutandis in Article 20, paragraph 1 of the said Law; the same shall apply hereunder) or the provisions of the said paragraph applied in accordance with the provisions of Article 83, paragraph 1 of the said Law, when intending to conduct a re-examination of veterinary medicine, etc. in accordance with the provisions of Article 14-4, paragraph 1 of the said Law (including cases where it applies mutatis mutandis in Article 19-4, the same shall apply hereunder) or the provisions of the said paragraph applied in accordance with the provisions of Article 83, paragraph 1 of the said Law, when intending to conduct re-assessment of veterinary medicine, etc. in accordance with the provisions of Article 14-6, paragraph 1 of the said Law (including cases where it applies mutatis mutandis in Article 19-4 of the said Law; the same shall apply hereunder) or the provisions of the said paragraph applied in accordance with the provisions of Article 83, paragraph 1 of the said Law, when intending to give approval for veterinary medicine, etc. in accordance with the provisions of Article 19-2, paragraph 1 of the said Law or the provisions of the said paragraph applied in accordance with the provisions of Article 83, paragraph 1 of the said Law, or when intending to enact, amend, or abolish the Ministry of Agriculture, Forestry and Fisheries Ordinance provided in Article 83-5, paragraph 1 of the said Law or the provisions of Article 14, paragraph 2 (3) of the said Law applied in accordance with the provisions of Article 83, paragraph 1 of the said Law;

(9) 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 Agricultural Land Soil Pollution Prevention Law (Law No. 139 of 1970) or the Cabinet Order provided in Article 3, paragraph 1 of the said Law (limited to those that prescribe conditions 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);

(10) when intending to enact, amend, or abolish the Ministry of Health, Labour and Welfare Ordinance provided in Article 11, Article 15, paragraph 4 (2) or (3), paragraph (6) or Article 19 of the Poultry Slaughtering Business Control and Poultry Meat Inspection Law (Law No. 70 of 1990);

(11) when intending to erase or exclude the name of additives in accordance with the provisions of Article 2-2, paragraph 1 of Supplementary Provisions of The Law Concerning Amendments to the Food Sanitation Law and the Nutrition Improvement Law (Law No. 101 of 1995).

(12) when intending to form a plan for enactment, amendment, or abolishment of the Cabinet Order provided in Article 6, paragraph 1 of the Law Concerning Special Measures against Dioxins (Law No. 105 of 1999);

(13) when intending to enact, amend, or abolish the Ministry of Health, Labour and Welfare Ordinance provided in Article 7, paragraph 1 or 2 of the Law concerning Special Measures against Bovine Spongiform Encephalopathy (Law No. 70 of 2002); and

(14) in addition to those cited 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 related ministers as falling under Article 11, paragraph 1 (3)), related ministers shall report such 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, related ministers may hear the Commission's opinions if they are recognized as necessary for formulating policies to ensure food safety.

(Request for submission of materials, etc.)

Article 25

The Commission may request that the heads of related administrative bodies submit materials, opinions, and explanations and provide other necessary cooperation, if it is recognized to be necessary for performing office duties 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 of Japan (Law No. 89 of 1896), enterprises and other private bodies, prefectural experimental and research institutes, or persons of learning and experience, if it is recognized to be necessary for performing office duties under its jurisdiction.

(Request in an emergency)

Article 27

The Commission may request that the research institutes of related national administrative bodies 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 liable to cause serious damage concerning ensuring food safety.

2. If the research institutes of related national administrative bodies receive a request from the Commission in accordance with the provisions of the preceding paragraph, they shall promptly implement the requested research, analysis, or examination.

3. The Commission may request that related ministers make a demand in accordance with the provisions of Article 13, paragraph 1 of the Incorporated Administrative Agency, National Institute of Health and Nutrition Law (Law No. 180 of 1999) or a request in accordance with the provisions of Article 12, paragraph 1 of the Incorporated Administrative Agency, Center for Food Quality, Labeling and Consumer Services Law (Law No. 183 of 1999), Article 18, paragraph 1 of the Incorporated Administrative Agency, National Agriculture and Food Research Organization Law (Law No. 192 of 1999), Article 13, paragraph 1 of the Incorporated Administrative Agency, National Institute for Agro-Environmental Sciences Law (Law No. 194 of 1999), or Article 15, paragraph 1 of the Incorporated Administrative Agency, Fisheries Research Agency Law (Law No. 199 of 1999), if it is recognized to be necessary for coping with emergency situations that cause or are liable to cause serious damage to the ensuring of food safety.

(Organization)

Article 28

The Commission shall be organized by seven commission members.

2. Three out of the seven Commission Members shall be part-time members.

(Appointment of Commission Members)

Article 29

With approval from both Houses, the Prime Minister shall appoint Commission Members who have superior insight into ensuring food safety.

2. In spite of the provisions of the preceding paragraph, the Prime Minister may appoint Commission Members who have qualifications as provided in the preceding paragraph, if he/she cannot obtain approval on the appointment from both Houses 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 cases falling under the preceding paragraph, the Prime Minister shall obtain subsequent approval from both Houses at the first Diet session after the relevant appointment. If the Prime Minister cannot obtain subsequent approval from both Houses in such a case, the Prime Minister shall immediately dismiss the Commission Member.

(Term of the Commission Member)

Article 30

The term of the Commission Member shall be three years, provided that the term of a substitute Commission Member shall be the remaining term of his/her predecessor.

2. The Commission Member may be reappointed.
3. If the term of the Commission Member has expired, the relevant Commission Member shall perform his/her duties until a successor is appointed.

(Dismissal of the Commission Member)

Article 31

With approval from both Houses, the Prime Minister may dismiss the Commission Member if the Commission member is recognized as being incapable of performing his/her duties due to physical or mental disability or if recognized as constituting a violation of his/her official obligations or other delinquency inappropriate for a Commission Member.

(Service of the Commission Member)

Article 32

The Commission Member shall not disclose secrets that he/she has come to know through his/her duties. The same shall apply even after he/she leaves the office.

2. The Commission Member, while in office, shall not serve as an officer of a political party or other political association or actively take part in political movements.
3. The full-time Commission Member, while in office, shall not engage in another job for remuneration, run a commercial enterprise, or conduct any other business for the purpose of financial gain except where he/she has received permission from the Prime Minister.

(Allowance of the Commission Member)

Article 33

The salary of the Commission Member shall be provided by a separate law.

(Chairperson)

Article 34

The position of Chairperson shall be established in the Commission and the Chairperson shall be appointed by full-time Commission Members by a mutual vote among the Commission Members.

2. The Chairman shall administrate the duties of the Commission and shall represent the Commission.
3. In the event that the Chairperson has an accident, the full-time Commission Member who has been designated in advance by the Chairperson shall perform the duties of the Chairperson.

(Meeting)

Article 35

The Commission shall be assembled by the Chairperson.

2. The Commission shall not hold a meeting nor make any decisions without the attendance of the Chairperson and at least three Commission Members.
3. The proceedings of the Commission shall be determined by the majority of attendees, and in cases in which the Commission is evenly divided, it shall be as determined by the Chairperson.
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 shall be deemed to be the Chairperson.

(Expert Commission Member)

Article 36

The Commission may request an Expert Commission Member to examine and deliberate on specialized matters.

2. The Prime Minister shall appoint the Expert Commission Member from persons of learning and experience.
3. The Expert Commission Member shall be dismissed at the completion of the examination and deliberation of the relevant specialized matters.
4. The Expert Commission Member shall serve on a part-time basis.

(Secretariat)

Article 37

The Commission shall establish the Secretariat to deal with clerical work.

2. The Secretariat shall have the necessary officials as well as the Secretary-General.
3. The Secretary-General shall administer the duties of the Secretariat at the behest of the Chairperson.

(Delegation to Cabinet Order)

Article 38

In addition to matters provided in this Chapter, necessary matters regarding the Commission shall be provided by Cabinet Order.

Chapter IV Additional Clauses

Abbreviation