

Food Safety Commission



Food Safety Commission



Japan 2008



<http://www.fsc.go.jp/english/index.html>

Establishment of the Food Safety Commission

Food is an essential part of our daily lives, however, there are no “absolute guarantees” in food safety. The foods we consume contain not only nutrients in abundance, but also agents that may potentially cause adverse health effects (called “hazards”). No matter what the food, there is always some level of risk. Therefore, it is important that we, first, be able to scientifically assess the probability and the severity of such an adverse health effect resulting from a hazard(s) in food (called “risk”). Then, these risks should be minimized by way of appropriate management based on the assessment.

In recent decades, the circumstances surrounding the dietary habits of the people of Japan have changed considerably. Japan has begun importing an extremely large amount of foodstuffs from overseas; there has been an emergence of new hazards, such as Bovine Spongiform Encephalopathy (BSE) and enterohemorrhagic *Escherichia coli* O157:H7; and new technologies, such as recombinant DNA techniques for food productions. There has also been a spate of incidents which have threatened food safety and undermined public trust.

In order to respond adequately to these changes in circumstances and to public concern, the Food Safety Basic Law (refer to the end of this brochure) was enacted in 2003, and it was resolved to develop new administration for ensuring the safety of food. The basic principle of the law is that the protection of the health of general public in Japan is the top priority. The law clarifies the responsibilities of the state, local governments and food-related businesses from production to marketing (such as processing, wholesale, and retail). It also clarifies the roles of consumers. Furthermore, by introducing a new concept of “risk analysis”, the law also aims to comprehensively promote the guarantee of food safety.

Changes in the circumstances surrounding food safety administration

Changes in the circumstances surrounding dietary habits in Japan

- Increasing volume of international trade of food
- Changing human/animal interactions with potential for disease transmission, including *E. coli* O-157:H7, prions, etc.
- New food and agriculture technologies (recombinant DNA, etc.)
- Improvement of analytical technologies for detection of environmental contaminants, etc.

Occurrence of incidents threatening food safety

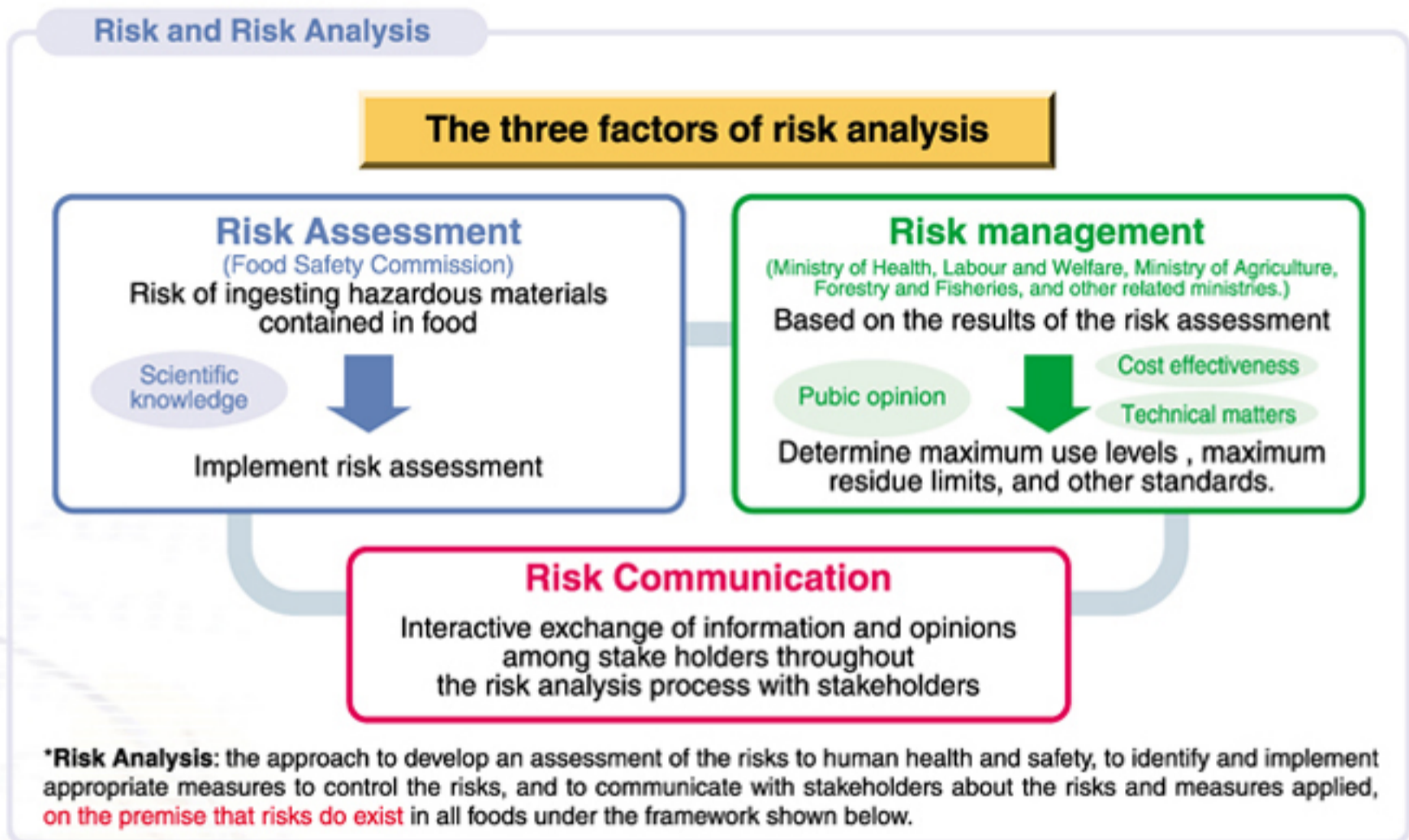
- Outbreaks of Bovine Spongiform Encephalopathy (BSE)
- Problems of pesticide residues in imported foods
- Use of unregistered pesticides within Japan

New approaches to food safety

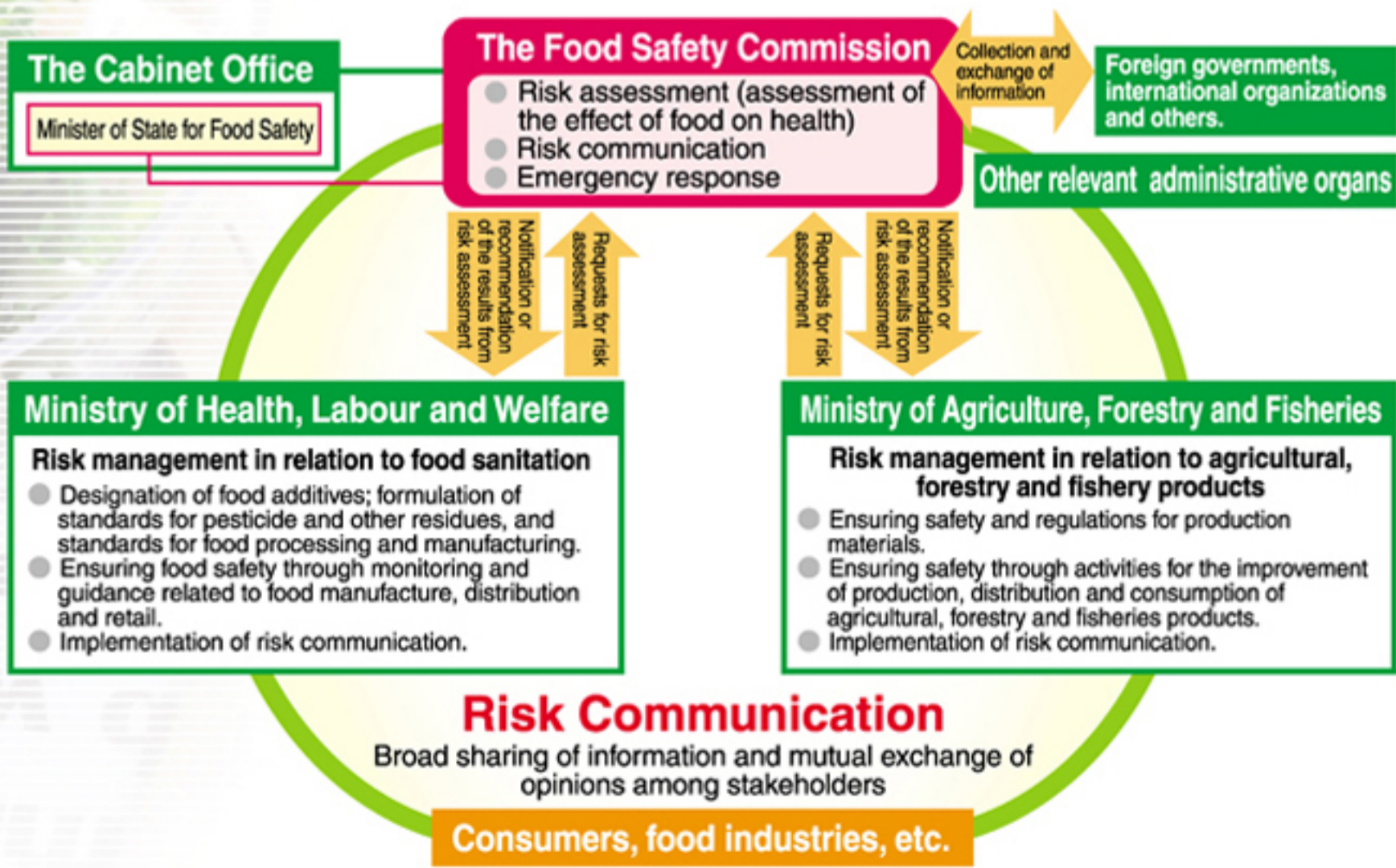
- Ensure safety at each stage from farm to table
- Universalization of the concept (risk analysis) that there are no “absolute guarantees” in food safety, that assessment should be implemented on the assumption that risks do exist, and that the risks should be adequately controlled.
- Establishment of risk assessment organizations overseas
 - French Food Safety Agency (Agence Française de Sécurité Sanitaire des Aliments: AFSSA), 1999
 - European Food Safety Authority (EFSA), 2002
 - Federal Institute for Risk Assessment, Germany (Bundesinstitut für Risikobewertung: BfR), 2002

Establishment of the Food Safety Basic Law

As required by the Food Safety Basic Law, the Food Safety Commission (FSC) was established within the Cabinet Office on July 1, 2003, for the purpose of implementing risk assessment in an objective, neutral and impartial manner based on scientific knowledge. As a risk assessment entity, the FSC is independent of the risk management organizations such as the Ministry of Health, Labour and Welfare (MHLW) and the Ministry of Agriculture, Forestry and Fisheries (MAFF), which develop administrative measures and regulations in pursuit of food safety.



Links with Government Ministries



Role of the Food Safety Commission

FSC comprises seven commissioners who have professional expertise in food safety issues. Within the Commission, 14 Expert Committees have been established, 11 of which are dedicated to implementing individual risk assessments of such materials as food additives and pesticides.

Organization of the Food Safety Commission and Secretariat

Members of the Food Safety Commission

Takeshi Mikami (Chairperson)
Naoko Koizumi (Deputy Chairperson)
Taku Nagao, Masao Hirose, Kazumasa Nomura,
Keiko Hatae, Seiichi Honma

Expert Committees (composed of a total of about 250 experts)

- Planning
- Risk communication
- Emergency response

[Assessment Groups]

- Chemical Substance Assessment Groups
(Food additives, Pesticides, Veterinary medicines, Apparatus/containers and packages, Chemical substances, Contaminants and other toxins)
- Biological Materials Assessment Groups
(Microorganisms/Viruses, Prions, Natural toxins/mycotoxins, and other related agents)
- Emerging Foods Assessment Groups
(Genetically modified foods, and other related agents, Novel foods, Feed/fertilizer)

Secretariat (Director-General, Deputy Director-General, 4 Divisions, 1 Director)

- General Affairs Division
- Risk Assessment Division
- Recommendation and Public Relations Division
- Information and Emergency Response Division
- Director for Risk Communication



The Main Roles of FSC

1. Risk assessment

The Commission's most important role is the implementation of risk assessments of the effects on human health of hazardous substances that may be found in foods, which include E. coli bacteria (O157:H7), prions, food additives, and pesticides. In other words, the Commission scientifically assesses the possibility and severity of adverse effects on health covered by ingesting hazardous substances contained in foods.

The Commission assesses risk when requested by the risk management bodies, mainly the Ministry of Health, Labor, and Welfare and the Ministry of Agriculture, Forestry and Fisheries. In addition, it also determines areas where it is necessary to assess risk on its own initiative, and conducts "self-tasking assessment."

The FSC is in a position to make recommendations through the Prime Minister to the ministers of the relevant risk management bodies regarding policies to be implemented on the basis of the results of risk assessments.

2. Promoting risk communication

Risk communication is an inseparable part of the risk management framework for the protection of public health. Through risk communication, information and opinions are shared among stakeholders including consumers. Along with conducting risk communication on matters related to risk assessments in areas of high public concern, the FSC also plays a supporting role by collaborating with the risk communication conducted by risk management bodies.

FSC strives to ensure transparency, by, in principle, making the Commission's meetings (in principle held every Thursday) and the meetings of the Expert Committees open to the public, and by posting the minutes of all meetings on the Commission's website.

Risk assessment activities and public meetings conducted by FSC

○ Risk assessment activities → 538 items (July 1, 2003 to February 29, 2008)

○ Public meetings → 315 meetings (July 1, 2003 to February 29, 2008)

Following are the key themes for the meetings which have been planned and hosted by FSC.

- Risk assessment related to measures against BSE in Japan
- Risk assessment related to methylmercury in seafood
- Genetically modified foods
- Drug-resistant bacteria
- Avian influenza
- Risk assessment related to foods for specified health uses containing soy-isoflavone
- *Shokuiku* (Food education)



3. Responses to emergency situations

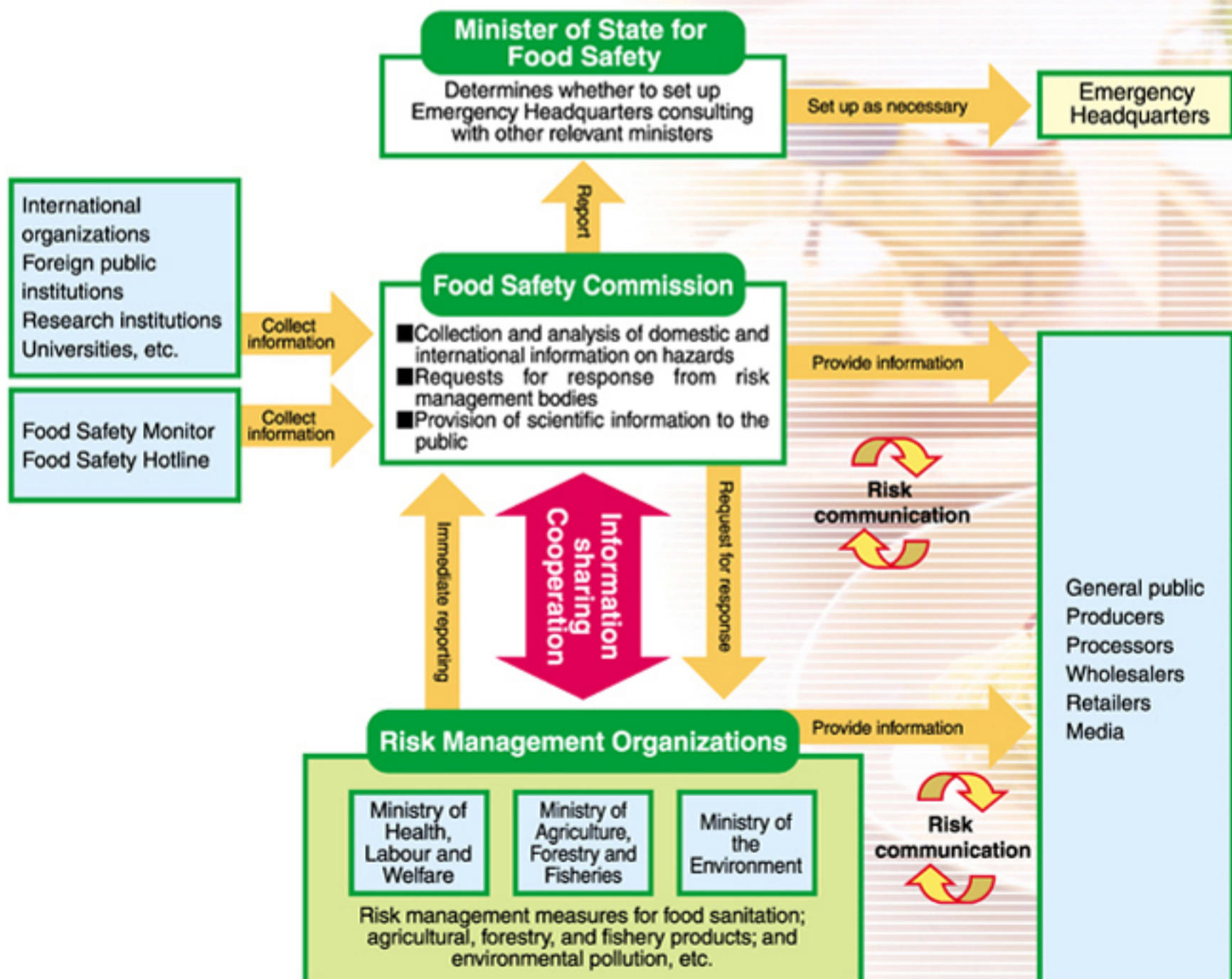
Through regular close coordination, the FSC and other risk management organizations collect and analyze information on the occurrence of foodborne illnesses, striving to prevent damage and minimize risk to public health.

The FSC has prescribed procedures to respond appropriately to all kinds of emergency situations caused by food-related hazards such as foodborne illnesses, and periodically conducts simulated emergency response training.

Furthermore, in the event of a food-related emergency, a whole-of-government response will be appropriately and swiftly implemented to prevent the spread and reoccurrence of the hazard; and accurate and easy-to-understand information will be swiftly provided to the public through the media, government publication and the website.

Based on other systems, whole-of-government responses will be taken in the event of disasters, acts of bioterrorism or other emergency situations in which citizens will suffer substantial damage.

Role of the Food Safety Commission in Emergencies



FSC Activities in Fiscal 2007

Detailed descriptions of the following activities are available at FSC website (<http://www.fsc.go.jp/english/index.html>).

1. Risk assessment activities

FSC received requests for risk assessment for 952 items from MHLW, MAFF, and the Ministry of the Environment in the four and a half years from its establishment; completed assessments for 538 items, and submitted its opinion to the risk management bodies.

Assessments Implemented by Expert Committees

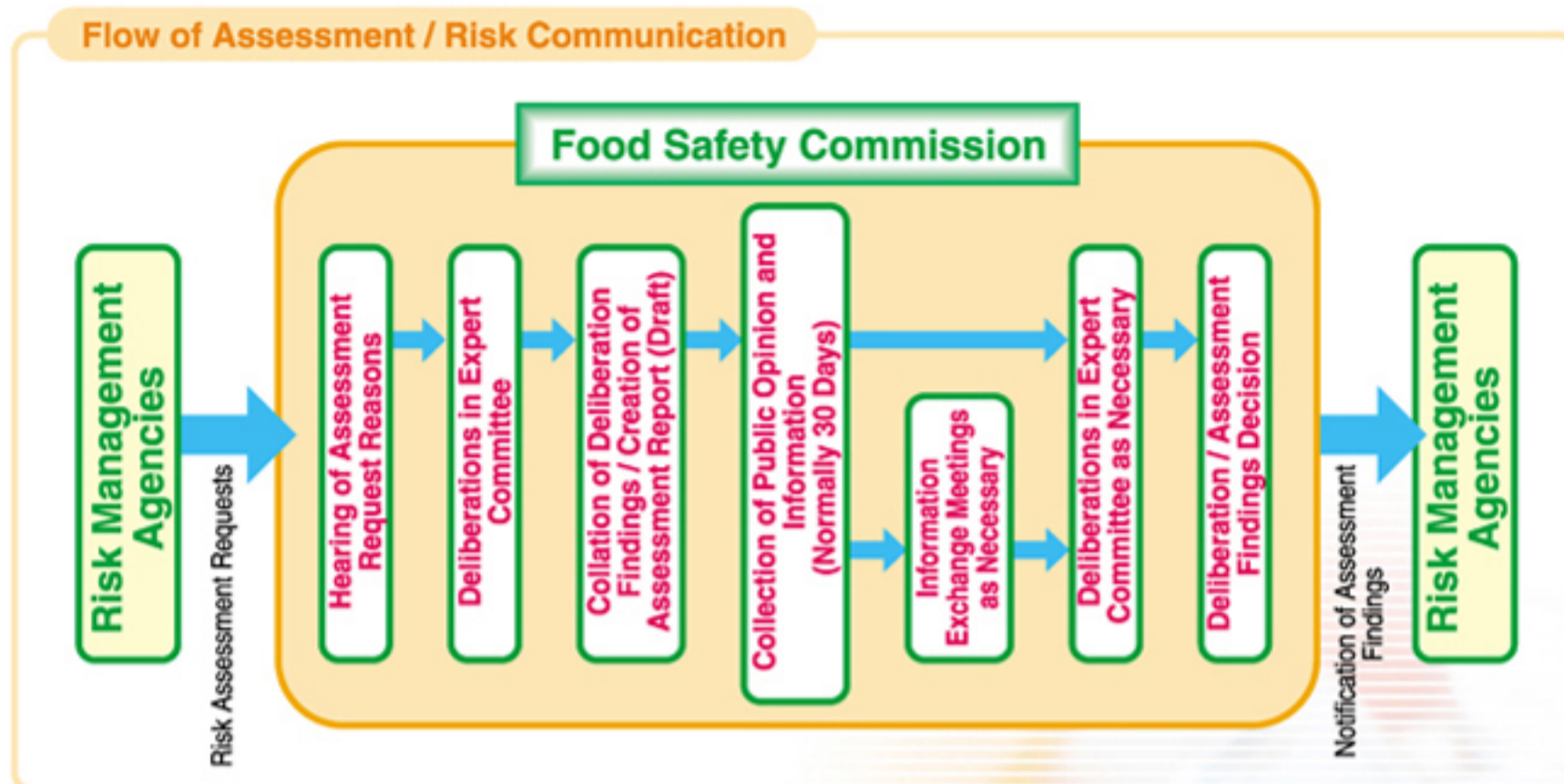
(July 1, 2003 to February 29, 2008)

Name of Expert Committee	Existing requests	Self tasks by FSC	Total	Assessment completed	Collecting public comment	In Progressed
Food Additives	83	0	83	64	3	16
Pesticides	384	0	384	148	9	227
including positive list items	133	0	133	47	4	82
including residues in soft drinks	93	0	93	8	1	84
Veterinary Medicines	252	0	252	160	6	86
including Positive List system	75	0	75	21	3	51
Chemical / Contaminant Substances	51	0	51	11	7	33
including residues in soft drinks	48	0	48	9	7	32
Apparatus/Containers and Packages	4	0	4	4	0	0
Microorganisms /Viruses	3	1	4	3	0	1
Prions	11	2	13	11	0	2
Natural Toxins/Mycotoxins, and other toxins.	3	0	3	3	0	0
Genetically Modified organisms, and other related agents	69	0	69	60	0	9
Novel Foods	66	0	66	54	0	12
Feed/Fertilizer, and other related agents.	23	0	23	19	0	4
including positive list items	5	0	5	2	0	3
Joint meeting of Veterinary Medicine and Feed/Fertilizer	2	0	2	1	0	1
Joint meeting of Novel Foods and Food Additives	1	0	1	0	0	1
Total	952	3	955	538	25	392

Note

1. "In Progress" includes items currently being discussed, those requiring the submission of additional information, and those pending discussion.
2. If the risk management agencies back down on their request, it will be subtracted from "Existing requests" numbers.
3. the items which are under consideration after the deadlines of public comment are included in "Collecting public comment."

Flow of Assessment / Risk Communication



○ Self tasking assessment

In addition to the risk assessments requested from risk management bodies, FSC conducts similar assessment on its own initiative whenever the Commission regards it as necessary to do so—the most recent example of which are “Microorganisms” related to some foodborne diseases as well as “Beef/beef organs imported to Japan.”

The guideline for the assessment of microorganisms has been developed with the result of opinion exchange meetings taken into account; the current focus has been shifted onto “*Campylobacter jejuni/coli* in livestock, especially chicken.”

With regard to the import of beef/beef organs, the Commission has launched a new assessment program in 2007 by sending a questionnaire to 14 countries that have exported the product to Japan FY2003 to FY2006 (except the U.S. and Canada for which the risk assessment was previously completed).

Furthermore, as regards the assessments of which results were delivered to risk management bodies, the Commission also follows up on the matters whether its advice has been appropriately reflected in policies to ensure food safety.

○ Development of evaluation guidelines

FSC is also engaged in developing a guideline for each hazard/substance to provide information on the policy of risk assessments, the material/data to be submitted for assessment, and the assessment procedure, as appropriate. To date nine guidelines have been released, including several “Guidelines for safety assessment standards for genetically modified (GM) foods” developed based on various viewpoints of food categories and processes. We expect another new guideline to be completed soon on GM foods (microorganisms).

○ Fact sheets

In addition to conducting risk assessments, FSC publishes “fact sheets”, or outlined information/data, for concerned materials based on the latest scientific knowledge. They are designed to summarize the information based on various risk assessments conducted by international bodies and research results available at the time.

In FY 2007, FSC made public through its internet website new fact sheets on “potassium bromate” and “growth-promoting hormone products for cattle” and updated those regarding “acrylamide” and “trans-fatty acids”

FSC is committed to continuously collect and analyze latest news of food safety issues so as to provide relevant and readable information for the general public in a timely manner..



2. Risk communication activities

In collaboration with risk management bodies, FSC exchanges information and opinions with stakeholders including consumers through nation-wide meetings for sharing results of risk assessments and other relevant information on food safety.

Many different views exist, however, as to why and how risk communication should be held; still many issues remain to be resolved for its improved role. To this end, the Risk Communication Expert Committee developed a new strategy entitled “Improving Food Safety Risk Communication” in November 2006, which proposed some areas of consideration:

- (1) Role of risk communication,
- (2) How to provide information and ensure transparency in deliberation process,
- (3) Cooperation with local governments,
- (4) Collaboration with foreign authorities, and
- (5) Promotion of good nutrition education.

- “Improving Food Safety Risk Communication” (November 2006)

http://www.fsc.go.jp/senmon/risk/riskcom_kaizen.pdf

○ Training leaders for food safety in local communities

In FY2006, FSC launched a new education program entitled “Community Food Safety Leader Development Course” to heighten awareness of food safety in local communities. In collaboration with local governments, representatives of FSC give public talk about food safety issues and provide basic instruction of risk communication during the course.

Since FY2007, FSC has held nation-wide extra training course targeted at the students who participated in the abovementioned course, so that they may step up to skillful risk communicators in local communities. With the cooperation of the participants of these courses, the FSC will continue to help provide them with information needed for the promotion of food safety risk communication activities in local communities.

○ Food Safety Hotline

The “Food Safety Hotline” was established to receive information, inquiries and opinions related to food safety from general public. Frequently asked questions are posted on the website in a Q&A format .

In 2007(Jan-Dec), the hotline received 937 inquiries about such matters as BSE, trans-fatty acids and other hazardous agents.

Food Safety Hotline
Phone +81-3-5251-9220 or +81-3-5251-9221
10:00-17:00, Monday-Friday
(excluding public holidays and the year-end and new-year period)

○ Food Safety Monitors

In order to accept a wide scope of public opinion on food safety issues, FSC calls for “food safety monitors” made up of 470 volunteers from various regions in Japan. They are requested to submit questionnaires and reports, and provide information to help FSC to recognize public awareness of food safety. The monitors may be also requested to cooperate with FSC to provide information for local community. FSC looks for new monitors around January to February each year.

○ Other activities

FSC uses its website to update information in an easy-to-understand format on such topics as BSE, Avian influenza, and other foodborne illnesses. The Commission also began providing information through its e-mail newsletters (FSC e-magazine). In addition, it also publishes brochures that introduce the Commission's activities, leaflets for children, glossaries on food safety, and the quarterly journal "Food Safety" (in general, four publications a year); and produced the DVD "Ki ni naru shokuhin tenkabutsu (Worrisome Food Additives)", "Risk communication tool "Nani wo tabetara yoinoka? Kangaeru tame no hinto" –issho ni kangaeyou, shoku no anzen- ("Tips on Thinking About Food Safety" –Let's Think Together About Food Safety-)."



○ Providing information via Comprehensive Information System for Food Safety

The "Comprehensive Information System for Food Safety" is a database of information on food safety held by FSC. The database can be accessed through the Commission's website, and a range of information can be searched from a menu screen as shown in the next page (in Japanese).

3. Responses to emergency situations

The Commission developed procedures for responding to large-scale food safety emergency situations, carrying out simulated emergency response training sessions using the scenario of a large-scale foodborne illness. In fiscal 2007, the FSC conducted tabletop simulation drills in union with risk management agencies, namely the Ministry of Health, Labor, and Welfare; the Ministry of Agriculture, Forestry and Fisheries; and the Ministry of the Environment. Through these drills, it strengthened frameworks for responding to emergency situations.

When the frozen food poisoning case occurred in January 2008, government bodies responded in unison. The FSC coordinated with related agencies to provide accurate information based on scientific knowledge through its website, and conducted risk assessments on the pesticides ascribed as the cause of the food poisoning.



4. Survey and research programs

○ Survey and examination programs

FSC conducts surveys and examinations necessary for carrying out its risk assessment and other duties. It manages extensive surveys for information of food safety and analytical examinations related to a variety of food hazards. The FSC conducted 15 research programs during fiscal 2007.

○ Research and development programs

For the purpose of promoting science-based risk assessments, the FSC has been conducting a competitive grant program for research and development to contribute to the formulation of risk assessment techniques. The priorities for research areas are specified in advance by FSC and applications are then invited and preliminarily reviewed. The FSC conducted 25 research and development programs during fiscal 2007.

Comprehensive Information System for Food Safety

Documented Information and Information on Hazards

Information on food safety	Domestic and overseas information on food safety collected by FSC
Information on meetings	Agenda, handouts, minutes, etc. on meetings of the FSC and Expert Committees
Information on research and surveys	Information on surveys and research conducted by the FSC
Fact sheets	Fact sheets published by FSC
Q&A	Comments to the Food Safety Hotline, reports received from Food Safety Monitors, and associated comments from government ministries
Glossary	Terms related to food safety
Database cross-referencing	Cross-referencing of terms from the above six areas

Food risk assessment and management measures

Search by assessed item	Detailed information of FSC risk assessments, the status of measures implemented by relevant government ministries, and related information by item assessed.
Search by keyword	

Information categorized into food safety themes

Search by theme	Information held by FSC or other government ministries for each key theme related to food safety (BSE, etc.)
Search by keyword	

The Food Safety Basic Law

Main features of the Food Safety Basic Law

1. Basic Principles Articles 3-5

To ensure the safety of food:

- (1) Make efforts on the basis of the basic recognition that protecting the health of general public in Japan is the top priority.
- (2) Ensure safety at each stage, from the production to the consumption of food.
- (3) Make efforts on the basis of scientific knowledge and in consideration of international trends and the opinion of general public in Japan.

2. Roles and Responsibilities of Related Parties Articles 6-9

- Responsibilities of the state and local governments
 - To make efforts to ensure the food safety on the basis of an appropriate sharing of roles.
- Responsibilities of food-related business operators
 - To recognize that they have a primary responsibility for ensuring food safety, and to appropriately take necessary measures.
 - To make efforts to provide accurate and appropriate information.
 - To cooperate in policies implemented by the control and local governments.
- Roles of consumers
 - To endeavor to improve their knowledge and understanding, and to express opinions on the policies.

3. Basic Direction Articles 11-21

Adoption of risk analysis approach

Articles 11-13

- Implementation of risk assessment (assessment of the adverse health effect of food on health)
- Formulation of policies based on the results of the risk assessment
- Promotion of risk communication

Articles 14-20

- Response to emergency situations
- Close and mutual cooperation among relevant administrative bodies
- Establishment of experiment and research systems
- Collection of internal and external information
- Ensuring the appropriate operation of a labeling system
- Promotion of education and learning
- Consideration for the effects on the environment

Formulation of the basic matters for implementation of measures Article 21

4. Establishment of the Food Safety Commission (implementation of risk assessments etc.) Articles 22-38

The Food Safety Basic Law (Tentative Translation)

Law No. 48, May 23, 2003/12/15
Last amendment: No. 8, March 30, 2007

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, National Food and Agricultural Materials Inspection Center 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 financially 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



We welcome your opinions and questions-from concerns and doubts about the safety of food, to the provision of information.

Food Safety Hotline **+81-3-5251-9220** or **+81-3-5251-9221**

- Hotline Hours: 10:00-17:00, Monday-Friday
(closed public holidays and the year-end and new-year period)

Opinions and questions can be also be sent by email. Please access the email address from the website.

Food Safety Commission website **<http://www.fsc.go.jp/english/index.html>**



■ **Transport**

- * 3-minute walk from the "Akasaka-Mitsuke Station" on the Tokyo Metro Ginza & Marunouchi Lines.
- * 6-minute walk from the "Nagatacho Station" on the Tokyo Metro Namboku and Hanzomon Lines.
Leave from Exit 8, and proceed along Gaien Street toward Tameike-Sanno. On left.
- * 8-minute walk from the "Nagatacho Station" on the Tokyo Metro Yurakucho Line.
Leave from exit 1, and proceed toward the Official Residence of the President of the House of Councilors and the Embassy of Mexico.

■ **Contact information**

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