Food Safety Commission

Food Safety Commission of Japan 2010

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

Establishment of Food Safety Commission

Food Safety Commission (FSC) was established on July 1, 2003, as a part of Japanese Cabinet Office, based on its founding regulation of Food Safety Basic Act (refer to the end of this brochure). Its mission was set as 'implementing science-based risk assessments in an objective, neutral and impartial manner'. As an independent risk assessor, FSC's role is different by nature from that of risk managers, such as the Ministry of Health, Labour and Welfare (MHLW), the Ministry of Agriculture, Forestry and Fisheries (MAFF), and the Consumer Affairs Agency (CAA), in that the responsibility of those risk managers are to develop administrative measures and regulations of food safety.

○ Background of setting up FSC

Food is essential to life. But, sometimes food contains undesired agents that may cause adverse health effects, or 'hazards', to consumers. No food can be free of risk, therefore it is not realistic to assume 'absolute guarantee of no risk' in food. This 'no zero-risk' concept is driven from the internationally recognized 'risk analysis' framework, in which the scientific method is used to prevent or contain food-related adverse effects under precondition of 'certain risk does exist in every food'. The analysis is organized by three elements (risk assessments, risk management, and risk communication; see page 4). According to this concept, efficient management is ensured, firstly, by scientifically assessing the probability and severity of hazard-driven adverse health effects, known as 'risks' in food. Then, the risks are minimized in accord with appropriate management plans, which have been designed based on the risk assessment.

Situations surrounding Japan's food safety have changed dramatically. For example, Japan's foodstuff imports have increased extremely in past few decades. Also, Japan has experienced the emergence of new hazards such as Bovine Spongiform Encephalopathy (BSE) and enterohemorrhagic *Escherichia coli* O157:H7, while also facing new types of food production technologies such as DNA recombination. To properly deal with all those challenges combined with heightened public concerns toward food safety at once, Food Safety Basic Act was enacted in 2003 to support new administrative plan formation in food safety.

Situation changes around food safety administration

Changes in food safety situation in Japan

- Region-to-region and international expansion of foodstuff distributions
- Emerging hazards such as *E. coli* O157:H7 and prions
- Newly developed technologies (e.g. GMO)
- Improved quality of analytical techniques for detection of environmental contaminants

Food safety crisis

- Bovine Spongiform Encephalopathy (BSE)
- Excessive pesticide residues in imported foods
- Food containing pesticides that are not registered in Japan

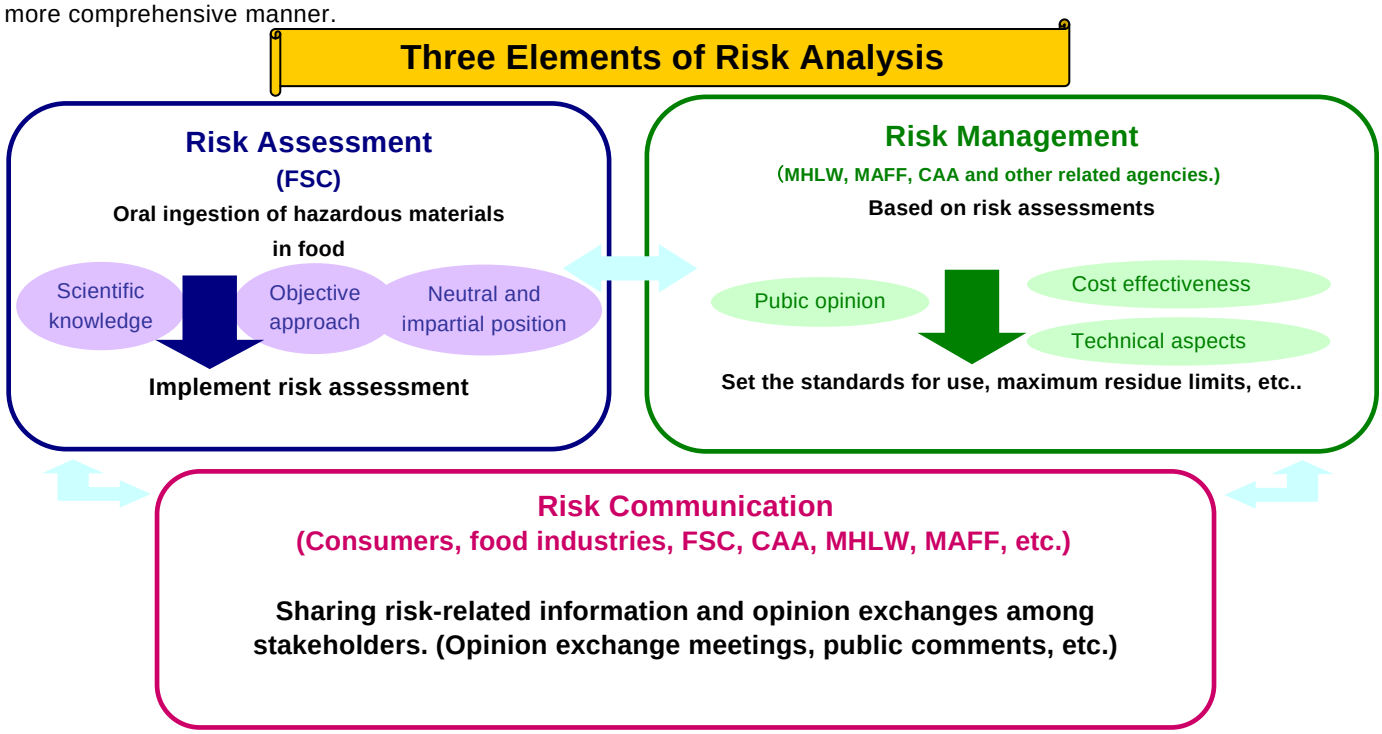
New approach to food safety

- Ensuring safety at every stage of food production; from farm to table
- Generalization of the concept (risk analysis) that there is no zero-risk in food, thus appropriate risk assessments and assessment-based regulation should be implemented
- Creation 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

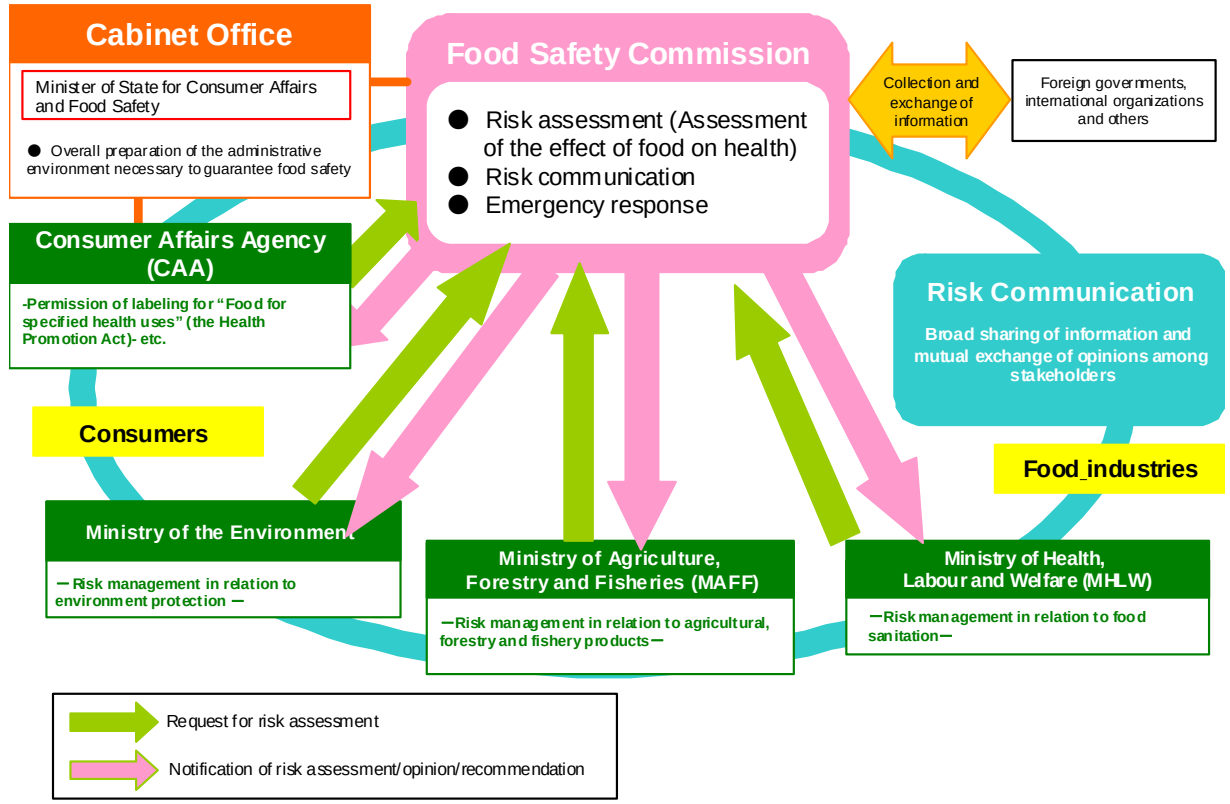
→ Establishment of the Food Safety Basic Act

Principle of Risk Analysis

Food Safety Basic Act underlines how to ensure the protection of Japanese public health through food safety. The Act clarifies responsibilities of local and central governments, food-related businesses in regard to production through marketing (e.g. processing, wholesales, and retails). Consumers are also included as a stakeholder to share the responsibility of food safety. In this Act, a new concept of 'risk analysis' was introduced to promote food safety in a more comprehensive manner.



Collaboration among Government Agencies



What does Food Safety Commission do?

FSC is primarily composed of seven commissioners who are appointed based on their profound knowledge of food safety. As its subordinate structure, FSC has 12 Expert Committees that operate to either implement risk assessments on individual hazards such as food additives, pesticides and so on (11 subcommittees) or to commit to other activities such as strategic planning of assessment/emergency response/risk communication (1 subcommittee). Those core FSC activities are supported by secretariat staffers who provide operational services to the Commissioners and Expert Committee members.

Organization Chart of FSC

Food Safety Commission: Commissioners

Susumu Kumagai (Chairperson)
Hiroshi Satou (Deputy Chairperson),Yasushi Yamazoe (Deputy Chairperson),
Kunitoshi Mitsumori(Deputy Chairperson)
Katsue Ishii, Kiyoko Kamiyasuhira, Masatsune Murata

Expert Committees (Approximately 200 experts served)

- Planning

- Food additives
- Pesticides
- Veterinary medicines
- Apparatus and containers/ packages
- Chemicals and Contaminants

→ Chemical Substances

- Microorganisms and Viruses
- Prions
- Natural toxins and mycotoxins

→ Biological Materials

- Genetically modified foods
- Novel foods
- Feed, fertilizers, etc

→ Novel Foods

Secretariat

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

Main Roles of FSC

1. Risk assessment

FSC's core role is risk assessment of food-associated hazards that are potentially contained in food (e.g. food additives, pesticides and so on). According to this mission, FSC releases assessment reports, in which a risk of hazard ingestion is practically expressed in form of possibility and severity of adverse health effects under certain conditions.

Risk assessments are mostly conducted based on risk managers' requests (mainly from MAFF, MHLW and CAA) but occasionally FSC initiates a risk assessment on its own decision, the scheme called 'self-tasking assessment'. Following the notification of assessment reports to risk managers, FSC can opt to make recommendations in the name of the Prime Minister regarding effective policies that the risk managers may adopt in response to the assessment results.

2. Raising awareness through risk communication

Risk communication is a key element in appropriately controlling the risks and public health protection, targeting stakeholders including consumers to share information and exchange opinions regarding food safety. FSC emphasizes risk communication on food-related hazards that especially catches attention of the general public. The process of risk communication is also coordinated with risk managers and local governments so that the operation can be smooth and effective.

FSC's Commissioners meeting is held every Thursday to give final decision to the individual scientific assessment reports drafted by each Expert Committee, or FSC Working Group. All the meetings, except for those that discuss company's or individual's intellectual properties, are open to public to ensure transparency of their discussion and decisions. Minutes are posted on the Commission's website.

3. Emergency response

As a part of daily activity, FSC, CAA and risk managers keep close ties to each other to collect and analyze information, in preparation to minimize damages and public health protection in case of food poisoning outbreaks. In an emergency situation with potential harm to the public health, the government will work as a whole to prevent expansion and recurrence of such damage in a swift, appropriate and harmonized way. Major role of FSC in this situation is to provide scientific information or to rapidly release statement to the public through media, government PR and the internet.

Past activity

A part of FSC's previous work is available at the following website:

(http://www.fsc.go.jp/english/index.html)

1. Risk assessment

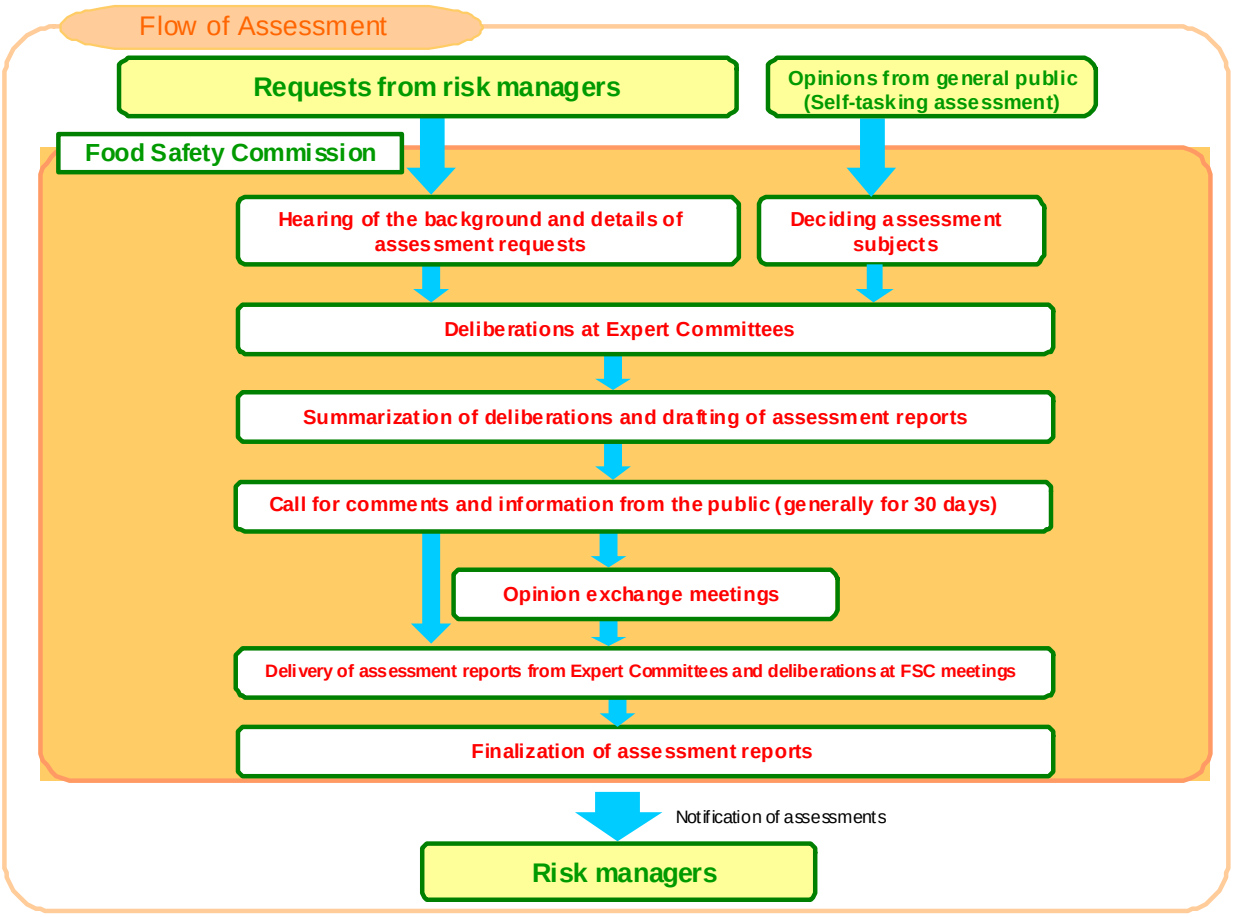
Most of FSC's risk assessments begin with risk managers' requests. In the period from July 2003 to March 2010, FSC received 1,306 assessment requests from risk managers (e.g. MHLW, MAFF, CAA, Ministry of the Environment). A total of 886 requests including FSC's 10 self-tasking assessments were completed and notified to the risk managers.

Assessments Implemented by Expert Committees

(July1,2003 to March 31,2010)

Name of Expert Committee	Existing requests *1	fiscal 2009 *2	Self tasks by FSC	Total	Assessment complete	fiscal 2009	Collecting public comment *3	In Progressed *4
Food additives	100	8	0	100	88	11	3	9
Pesticides	528	53	0	528	305	63	17	206
Positive list items	209	20	0	209	109	25	11	89
Residues in soft drinks	93	0	0	93	20	3	1	72
MRLs in feeds	2	2	0	2	0	0	0	2
Veterinary medicines	285	31	0	285	242	25	11	32
Positive list system	65	2	0	65	43	10	2	20
Chemicals and contaminants	55	1	2	57	36	7	0	21
Residues in soft drinks	48	0	0	48	29	5	0	19
Apparatus and containers/packages	13	6	0	13	4	0	0	9
Microorganisms /viruses	4	0	1	5	5	1	0	0
Prions	11	0	2	13	19	8*5	0	2
Natural toxins/mycotoxins	4	0	2	6	4	0	0	2
Genetically modified foods	107	23	0	107	90	18	1	16
Novel foods	69	7	1	70	62	8	0	8
Feed,fertilizers,etc	127	45	0	127	30	4	3	94
Positive list items	77	42	0	77	6	2	1	70
Undecided*6	0	0	1	1	0	0	0	1
Joint meeting of Feed/fertilizer and Microorganisms /viruses	1	0	0	1	1	0	0	0
Joint meeting of Novel foods and Food additives	1	0	0	1	0	0	0	1
Working group for food-related choking incidents	1	1	0	1	0	0	1	0
Total	1306	175	9	1315	886	145	36	401

Note
1. If the risk management agencies back down on their requests, it will be subtracted from "Existing requests" numbers.
2. Fiscal 2009 is from April 2009 to March 2010.
3. The items which are under consideration after the deadlines of collecting puplic comments are included in "Collecting puplic comment."
4."In Progress" includes items currently being discussed, those requiring submission of additional information and those pending discussion
5. In terms of the assesment of "Beef/beef organs imported to Japan," which is a self task by FSC, the number of countries whose assesment has been done is included. (As of Feb. 25 2010, 8 countries are already done.)
6. The expert committee to deal with "Aluminum, " which was chosen as a self task by FSC on March 18 2010, has not yet been decided and FSC is now gathering information which is necessary for the assesment.



○ Self-tasking assessment

Besides risk assessments requested by risk managers, FSC also takes initiative to conduct assessments, so-called 'self-tasking risk assessment.' Recent examples of self-tasking assessments include 'food-borne pathogenic microorganisms', 'lead in food, apparatus and containers/packages', and 'beef/beef offal imported to Japan from countries with no BSE report.'

Assessment of '*Campylobacter jejuni* and *Campylobacter coli* in chicken' has been completed as a part of 'food-borne pathogenic microorganisms,' and FSC has been also discussing the feasibility of carrying other three combinations of microorganisms/foods. For the assessment of 'beef/beef offal imported to Japan from countries with no BSE report', questionnaires to collect necessary information for the assessment has been sent to 14 countries with previous records of beef/beef offal exported to Japan (2003-2006) plus Korea. Presently, assessments of 8 countries have been completed (March 2010) and the remaining countries are under way. In order to conduct the assessment of 'lead in food, apparatus and containers/packages', FSC has set up a working group and assessment report has been drafted but still under deliberation.

Future self-tasking assessments include mycotoxins such as 'ochratoxin', 'deoxynivalenol/nivalenol' and 'arsenic in food' for fiscal 2008. In the next year of fiscal 2009, 'trans fatty acids' and 'aluminium' are already chosen for the assessment subjects.

After completion of self-tasking assessments, FSC continues to monitor how its assessments are actually reflected on risk managers' policy setting as ensuring food safety is the major focus of self-tasking assessment.

○ Assessment guidelines

To facilitate the smooth deliberations of risk assessment, FSC guidelines have been developed to outline the basic principle of dossier/data submission and procedures for food-related risk assessment. To date, 11 guidelines have been developed (e.g. 'guidelines of safety assessment standards for genetically modified (GM) foods') and are used for assessments.

○ Fact sheets

FSC's fact sheets are outlined information/data sheet of concerned hazards. They are drafted based on the latest scientific knowledge from those international bodies' various risk assessments and research results available at the time of publication. Additional data are periodically added to the existing published fact sheets such as those on 'acrylamide in processed food', 'growth hormone for cattle', 'potassium bromate', 'trans fatty acids', 'effects of excessive vitamin A intake', 'Q fever' and 'the effects of alcoholic drink intake for pregnant women on fetus.' FSC is committed to continuously collect and analyze latest knowledge so that the information is relayed to the general public in a timely manner.

2. Risk communication

Risk communication by FSC aims at communicating with stakeholders on risk assessment outcomes or other information related to food safety through opinion exchange and other methods. Commonly used communication practices include the followings:

○ Opinion exchange meetings on risk assessment results

Once a draft risk assessment report is finalized, by usual procedure, FSC seeks public comments on assessment outcomes. Additionally, in some cases FSC holds opinion exchange meetings with stakeholders (e.g. consumers and industry participants) to offer direct commentaries about assessments, especially when the assessed subject is of high concern by general public. In fiscal 2009, FSC held opinion exchange meetings on subjects such as 'Campylobacter, the food-poisoning bacteria' and 'Beef and beef offal imported to Japan from countries with no BSE report.'

'Science cafe' is another type of opinion exchange meeting where participants can freely exchange opinions about basic science as is the foundation of risk assessment. Under international program, FSC invites experts from overseas to host seminars on international trend and the latest knowledge of selected hazards.

Junior Food Safety Commission

This summer event is one of FSC's ways of risk communication with general public, specifically targeting 5th or 6th graders at elementary schools and their parents.

Core concept of this event is FSC's recognition that kids are the future key players of food safety. Participants are also given opportunity to learn basics about food safety from FSC Commissioners while having fun. Their mock deliberation takes place in the real FSC meeting room, and the event has been continued since 2007.

FSC opinion exchange meetings

Previously, FSC has held 386 opinion exchange meetings (March 2010, occasionally co-hosted with other agencies).

Followings are the key themes of past meetings:

- BSE countermeasures in Japan,
- Methylmercury in seafood,
- Genetically modified foods (GMO),
- Cadmium consumption from food,
- Food-borne pathogenic microorganisms,
- 'Foods for specified health uses' with soy-isoflavones,
- Food derived from somatic cell cloned livestock,
- Beef/beef offal imported from countries with no BSE reports.

Science cafe

○ Opinion exchange meetings co-hosted by FSC and local governments

Some opinion exchange meetings are held by co-host of FSC and other agencies including local governments. Under this scheme, FSC has held workshops and small casual meetings In fiscal 2009, partly supported by local governments and local risk communicators who completed specialized lectures given by FSC. In addition, FSC sends Commissioners as a lecturer to local governments or other stakeholders' meetings to give seminars about roles and basic idea of risk assessment by FSC.

○ Food Safety Hotline

Food Safety Hotline was set up as a tool for general public to gain information on or express their opinions about food safety. Among the information communicated through this hot line, frequently asked questions and their answers are gathered and posted on the website to help the understanding of general public. In fiscal 2009, a total of 655 calls were made through this hot line. Among the received questions, the major topics included somatic cell-cloned cattle and edible oil containing high diacylglycerol.

○ Food Safety Monitors

This monitor system was created by FSC to gather wide variety of food safety-related information through daily lives of 470 citizens chosen as 'food safety monitors'. Their tasks include submitting comments on risk management policies of their living areas, periodically answering to the monitoring questionnaire by FSC, and communicating important information from FSC to their locals. Through this system, FSC can generally recognize public awareness of and concerns about food safety. Calls for new monitors are annual basis and made commonly around January through February.

○ Promoting web contents

Website is an important tool for FSC to distribute latest information about hot topics at the time, such as BSE, Avian influenza, and food-poisoning incidents. Targeting more active readers, FSC e-mail newsletters (e-magazines) are sent weekly to distribute general information of FSC's 'now', and general introduction to those who are not familiar with FSC's activities can be made by FSC brochures, kid's leaflet, FSC food safety glossaries, and the quarterly journal 'Food Safety'.

As an aid to enhancing food safety education for school students, FSC recently published a side reader text book targeting middle school students, titled 'Food safety from a scientific perspective'. The DVD called 'Let's think about food safety - food additives and residual agricultural chemicals' for elementary school pupils was also released on the same perspective.

○ Comprehensive Information System for Food Safety

'Comprehensive Information System for Food Safety' is a database system operated by FSC. Through this system, information gathered by FSC can be shared by general viewers.

3. Food safety emergency response

There were several occasions FSC took emergency responses in fiscal 2009, including H1N1 influenza and *Escherichia coli* O157 food poisoning. In those cases, FSC's reactions are to gather scientific aspect of the incident and to release relevant scientific information to the general public as a part of risk communication. Occasionally, a Chairperson's comment may be released to directly deliver the massage of scientific perspective to the citizens.

In order to be appropriately prepared for such occasions, FSC periodically conducts emergency response trainings. Through this training, FSC aims to gain new knowledge and skills of managing emergency situation, via providing appropriate scientific information and advices to avoid concerned hazards to the public, thus collectively strengthening emergency response strategy by FSC.

4. Survey and research programs

○ Survey and examination program

Other FSC's activities include survey and examination programs, which enable FSC to collect data necessary to conduct risk assessments or other activities. Through this survey program, extensive information search and analytical examinations are available over a variety of food hazards. FSC so far conducted 13 survey and examination programs during fiscal 2009.

○ Research and development program

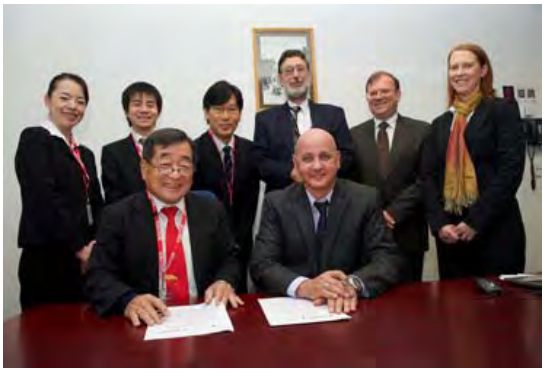
To support science-based risk assessments, FSC provides grants for research and development studies. Each year, specific categories to be enhanced due to high demand are selected and granted financial support for 3 years based on relevancy judged by FSC. For instance of fiscal 2009, FSC has offered 22 grants for research and development studies.

5. Internationalization

FSC signed a Memorandum of Cooperation (MOC) with the European Food Safety Authority (EFSA)*1 in December 2009 and with the Food Standards Australia New Zealand (FSANZ)*2 in July 2010. These memorandums contain basic agreement on cooperating in 'collection, analysis and sharing of technical data' as well as sharing 'views and expertise of data collection methodologies.'

FSC has built cooperative relationship with EFSA and FSANZ via exchanging latest knowledge and inviting experts in past years, and these relationships will be further strengthened by signed MOC and corresponding periodical meetings. Other regions/countries are also treated as a partner of food safety as well, and these relationships will be likewise continued.

Signing with EFSA (December 2009 at Parma)



Signing with FSANZ (July 2010 at Canberra)

*1 The European Food Safety Authority (EFSA) is an assessment body which is independent from the European Commission (EC) and provides scientific recommendations about food safety to the EC. It deals with risk assessment of all kinds of food.

*2 The Food Standards Australia New Zealand (FSANZ) is a bi-national agency which develops and administers food standards in Australia and New Zealand. It has a department which deals with scientific risk assessment.

The Food Safety Basic Act

Main features of the Food Safety Basic Act

1. Principles (Articles 3-5)

Ensuring safety of food:

(1) Take all actions under the basic understanding that the protection of Japanese general public is the top priority.
(2) Those principles should be applied to all the stages from production to consumption.
(3) All actions should be based on scientific knowledge while paying enough attention to the international trends and opinions of Japanese public.

2. Roles and responsibilities of related parties (Articles 6-9)

○ Responsibilities of central and local governments
- Those parties should share roles appropriately to ensure food safety.

○ Responsibilities of food-related business operators
- Take all actions in an appropriate way under the recognition that those parties have primary responsibilities for ensuring food safety.
- Strive to provide accurate and appropriate information.
- Cooperate to the actions taken by central and local governments.

○ Roles of consumers
- Nurture knowledge and understanding, and do utmost to express opinions on policies.

3. Basic Directions (Articles 11-21)

Adoption of risk analysis approach (Articles 11-13)
○ Implementation of risk assessments (assessment of the adverse health effect of food on health)
○ Formulation of policies based on risk assessments
○ 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 appropriate operation of the labeling system
○ Promotion of education and learning
○ Consideration for effects on the environment

Formulation of basic plans for FSC actions/activities (Article 21)

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