Provisional translation



Food Safety Commission of Japan Annual Work Program for Fiscal Year 2018 (Excerpt)

Chapter 1. Priorities in FSCJ Work Program for FY 2018

(1) Principle for FSCJ Administration

The Food Safety Commission Japan (FSCJ) will steadily and smoothly implement its affairs under the Jurisdiction, giving maximum priority to protecting the public health in accordance with basic principles of Food Safety Basic Act (Act No.48 of 2003) and basic matters prescribed by Article 21, paragraph 1 of Food Safety Basic Act (Cabinet Decision on June 29, 2012), and continue to develop and improve its assessment approaches.

(2) Matters of Priority

① Steadily implementation of risk assessment

FSCJ steadily implements risk assessment through effective collection of data, strategic research and assessment, development and use of new assessment methods in a timely and reliable manner, and strengthen the structure of FSCJ secretariat, taking into consideration the amendment direction of Food Sanitation Act such as an introduction of Positive List System for apparatus and containers/packages. In addition, FSCJ will consider the effective use of (Quantitative) Structure-Activity Relationship ((Q)SAR) in risk assessment, as was started in abroad, based on "Methods for Risk Assessments toward a new era: Effective use of (Q)SAR and Read across for toxicity evaluation of chemical substances" (Decision of the Working Group on Planning of Assessment Method on June 30, 2017). FSCJ will also continue to investigate a strategy to apply Benchmark Dose approach to risk assessments in light of the current situation in assessment organizations in abroad.

② Strategic implementation of risk communication

In order to promote public awareness on food safety based on the scientific knowledge such as assessment results, FSCJ will implement risk communication on priority basis to address issues of great public concern and interest in accordance with a report by the Expert Committee on Planning and Coordination of FSCJ, "How a risk communication should be implemented" (Conclusion of the meeting on May 28, 2015). As for strategic risk communication, FSCJ will make full use of new information and communication tools to effectively disseminate food safety related information, strengthening coordination with mass media, consumer organizations, business associations, and stakeholders.

③ Effective use of survey and research projects

To ensure appropriate risk assessments, FSCJ will proceed with survey and research projects systematically and strategically in accordance with a roadmap "On direction to promote survey and research projects for food safety securing" (Decision of the Committee on December 16, 2010, amended on March 31, 2015; hereinafter referred to as "Roadmap"), and the results from these



projects shall be promptly and effectively applied to planning of new assessment methods. In addition, proceeding of each project will be reviewed by external experts at every step to ensure its transparency.

(4) Overseas dissemination of information, participation to international meetings, and intensive cooperation with related organizations

FSCJ will intensively disseminate overseas the related information in order to make FSCJ's activity recognized overseas and consequently help enhancing FSCJ's function. Also, FSCJ sends the Commissioners, Expert Committee members and the secretariat staffs to related international meetings so as to contribute to global discussion on risk assessments and collect necessary information. FSCJ will continue its effort to enhance international cooperation through regular meetings with food safety risk assessment bodies abroad, based on the Memorandum of Cooperation as exchanged before 2017, holding discussion and information exchange. Consequently, FSCJ will discuss with relevant organizations for a renewal of the memorandum.

(5) Enhancing capacity for emergency response

FSCJ shall closely work with relevant ministries and organizations so as to continuously improving its emergency response.

Chapter 2. General management of FSCJ

(1) The Commission meeting

A regular meeting of the Commission is basically held once a week on a day which the chairperson decides with consulting the Commission. The meeting is to be fundamentally open to the public. In addition, an extraordinary meeting will be held to deal with a matter of urgency and highest priority.

- (2) Meeting of Expert Committee on Planning and Coordination Meeting of Expert Committee on Planning and Coordination for FY 2018 will be held following a schedule in Appendix 1.
- (3) Meeting of Expert Committee on the Risk Assessment

Meeting of Expert Committee will be held as necessary.

FSCJ will make its effort to implement effective survey and assessment of an issue that cannot be appropriately deliberated in an existing committee or that is to be deliberated in multiple Committees on different subjects in the following ways.

- ① In principle, FSCJ will set up a working group on relevant issue that is equivalent of an Expert Committee under the Committee.
- ② FSCJ will set up a Subcommittee under an Expert Committee.
- ③ An Expert Committee may invite expert members of other Expert Committees for survey and assessment.
- ④ FSCJ may held a joint Meeting between Expert Committees on related subjects.
- (4) Ensuring coordination between the Commission and each Expert Committee In order to achieve smooth survey and assessment at Expert Committees, the Commissioner is to attend a meeting of every Expert Committee and provide information and advises as necessary.



(5) Ensuring coordination with risk management agencies

FSCJ will ensure coordination with risk management agencies through Liaison Committee among Ministries and Agencies on the related problems, from the view point of consistent implementation of measures to ensure food safety.

(6) Development of the secretariat structure FSCJ will ensure necessary budget, structure and regular personnel in order to improve its assessment capacity.

Chapter 3. Implementation of Risk Assessment

- 1. Steady implementation of risk assessments requested form risk management organizations
- (1) Risk assessments requested form risk management organizations

FSCJ implements risk assessments, upon requests made by risk management organizations, effectively and strategically to complete the assessment promptly unless additional data and documents are requested or there are special reasons.

(2) Risk assessment requested from risk management organizations upon applications submitted from industries

FSCJ performs risk assessments, upon applications submitted from a company through risk management organizations, within a standard period after receiving dossiers based on the decision of the Commission, "On the standard period for a risk assessment of items applied from company through risk management organizations (Decision of the Committee on July 16, 2009)". (Generally the period is one year excluding time required for collection of additional data and documents requested by relevant Expert Committees).

(3) Risk assessments on agricultural chemicals on "Positive-list"

FSCJ performs risk assessments on agricultural chemicals on "Positive-list" according to the risk assessment guidelines for pesticides and others with Provisional Standards (Decision of the Committee on June 29, 2006).

2. Establishment of Assessment Guidelines

To facilitate FSCJ's risk assessment process and ensure its transparency, FSCJ shall establish guidelines (Assessment guidelines and Approach for assessment, etc.) for hazard-specific risk assessment on priority basis as necessary. A prompt data referring system for previous assessment reports will be introduced into the FSCJ Secretariat to improve efficiency in drafting a risk assessment report.

In FY 2018, the working group on allergens in foods will consider the assessment guideline based on a draft guideline made by the research project. As for the assessment guidelines for veterinary medicinal products and feed additives, FSCJ will proceed the discussion in the Expert Committees. Moreover, FSCJ will consider establishment of guideline for assessment of pesticides, and proceed the study on the effective use of Benchmark Dose approach or of methods that help the quantitative assessment of food poisoning-causing bacteria.



3. Self-tasking Risk Assessment: Periodical examination and consideration of hazard-items for the assessment, and the implementation

(1) Selection of hazard items for self-tasking risk assessment

Hazard items for self-tasking risk assessment in FY2018 will be selected following the schedule described in Appendix 1, based on "Items to be included in the documents to be provided to the Expert Committee on Planning and Coordination regarding the self-tasking risk assessment by FSCJ" (Decision of the Commission on May 27, 2004), and "Stance of the Expert Committee on Planning and Coordination for selecting candidates of hazard items for self-tasking risk assessment by FSCJ" (Decision of the Committee on June 17, 2004).

(2) Implementing risk assessments

For the hazard-items for self-tasking assessment on the list, selected before FY 2017 but the assessment remained incomplete, FSCJ will continue the following process for the assessments:

 Risk assessment of lead in foods, apparatus and food containers/packaging materials (Decision in FY 2008)

FSCJ proceeds discussion at relevant Expert Committees based on the examination of scientific knowledge collected by survey projects.

- ② Risk assessment of allergens in foods (Decision in FY 2015) The working group on allergens in foods will consider the assessment guideline based on a draft guideline made by the research project. The working group will start research and survey regarding eggs and milk using related scientific knowledge sorted by survey and research project. In addition, a survey and research project for scientific knowledge on barleys or wheat and Soba will be started.
- (3) Dissemination of outcome of self-tasking risk assessments

When outcome of self-tasking risk assessments become available within FY 2018, the information shall be disseminated to public in appropriate manners, e.g. convening public meetings and/or disseminating on Facebook. As for the decisions made in the procedure of hazard item selection for FY 2017 (e.g. collection of information), relevant information shall be provided to public through FSCJ's website, Facebook and others.

Chapter 4. Monitoring of Achievement of Risk Management Measures based on the Assessment

1. Monitoring of achievement of risk management measures based on the assessment

FSCJ will inspect status of achievement of risk management measures by the risk management organizations based on the risk assessment outcome by around October 2018, and will offer a recommendation or an opinion if necessary as a consequence of the inspection.

2. Report from Food Safety Monitor

FSCJ request the food safety monitor to report about achievement of risk management measures based on the assessment as required, and will refer the resulted reports for a recommendation or an opinion to the risk management organizations when necessary.



Besides, FSCJ will conduct a questionnaire survey for grasping people's awareness about food safety by around January 2019.

Chapter 5. Encouraging Survey and Research Projects on Ensuring Food Safety

- 1. Promotion of researches on risk assessment methodology
- (1) Selection of research projects on risk assessment methodology

FSCJ will invite proposal from the public for research projects on the assessment methodology for FY 2019 to implement risk assessment appropriately focusing on "Accumulation of scientific knowledge required for evaluation of hazard and situation of exposure", "Elucidation of mechanisms for expression of effects" and "Establishing new methodologies for risk assessment" based on Roadmap. From the applied research proposals, FSCJ will select the projects with the higher necessity for risk assessment on a priority basis. These procedures follow the schedule described in Appendix 3. Call for research proposals shall consider open recruitment that ensures applicants from a large number of research institutes including universities, and transparency of selection procedures shall be secured by releasing a summary of the minutes.

(2) Conduct of ex-post evaluation of research projects completed in FY 2017

FSCJ will conduct ex-post evaluation of the projects that were completed in FY 2017 following the schedule described in Appendix 4. In addition, FSCJ will hold the results presentation and will publish the research result reports on FSCJ's web site.

- (3) Conduct of mid-term evaluation of research projects to be proceeding in FY 2018 FSCJ will conduct mid-term evaluation of the projects that are to be proceeding in FY 2018 following the schedule described in Appendix 4, and provide suggestions such as to revise the research plan to the chief researcher as necessary.
- (4) Practical guidance

In order to ensure proper implementation of the budget, FSCJ will give practical guidance in October 2018, mainly to persons in charge of accounting of the newly adopted subjects.

(5) Cooperation with the relevant ministries and agencies

Participating to Competitive Research Fund Liaison Conference for Concerned Government Agencies, FSCJ will exchange opinion about handling of competitive fund among others, and will revise the research related provision as necessary. For effective implementation of research, FSCJ will hold "Promotion of research on securement of food safety Liaison Meeting" (On Strengthening of Coordination and Policy Adjustment with the relevant ministries and agencies for promotion of research on securement of food safety (The relevant ministries and agencies arrangement, January 31 2005)) prior to the selection of newly adopted research projects as required, thus strengthen coordination and policy adjustment with the relevant ministries and agencies.

- 2. Promotion of survey on ensuring food safety
- (1) Selection of projects to be subjects to general survey on ensuring food safety



As for projects to be subjects to general survey on ensuring food safety of FY 2019, FSCJ will select the projects with the higher necessity for risk assessment on a priority basis focusing on "Accumulation of scientific knowledge required for evaluation of hazard and situation of exposure", "Elucidation of mechanisms for expression of effects" and "Establishing new methodologies for risk assessment" based on Roadmap following to the schedule described in Appendix 5. Call for proposals shall consider open recruitment that ensures applicants from a large number of research institutes including universities.

- (2) Disclosure of information of projects to be subject to general survey on ensuring food safety Concerning the adopted projects, FSCJ will publish the conduct plan on the web site and others and update the content as required. The results of the survey shall be opened to the public through Comprehensive Information System for Food Safety.
- 3. Conduct of follow-up evaluation of survey and research project toward "Program Evaluation"

FSCJ will conduct a follow-up evaluation of research projects and survey projects focusing on the significance of the projects, validity of management policy, and utilization of results toward program evaluation in FY 2019 and setting of a new roadmap.

Chapter 6. Promotion of risk communication

FSCJ will conduct risk communication strategically based on "Report on how should be a risk communication on food safety" (Report of Expert Committee on Planning and Coordination on My 28 2015).

- 1. Dissemination of information by various tools
- (1) Website

Through the website, FSCJ will provide the public with information about results of risk assessments, the latest news related to food safety, and schedule of the Commission, Expert Committee and public meetings.

In particular, activities of each Expert Committee shall be informed on the properly designed pages in order to make the Commission's activity well recognized. "Kids box" which is popular with those concerned with school education or parents of younger children will be published more frequently. In addition, past information provided on the website will be reorganized for make it easier to understand.

(2) Facebook

According to guidelines for submission in "Managerial regulations for FSCJ official Facebook" (Decision by the Director of the FSCJ secretariat in May 2017), FSCJ will conduct timely and appropriate dissemination about the various information such as; Health hazard information that requires flexible responses, Reminder to take caution against seasonal issues, Publication of scientific knowledge related to food safety.

When necessary, a news translated in English will be disseminated.



(3) E-mail Newsletter

FSCJ will publish e-mail newsletter which consists of "Weekly Report" and "Reading Matters". In the "Weekly News", the activities of the Commission, Expert Committee and/or Public Meetings will be briefly reported, and a plain explanation of useful information related with food safety will be put on "Reading Matters".

(4) Blog

The articles written in "Reading Matters" and other information regarding food safety will be distributed through writing on FSCJ's weblog.

(5) Booklet and other paper media

Based on the Management Situation Report of the Commission, the annual performance of the Commission is clearly summarized in a booklet to widely disseminate to the public.

Revising the brochure of FSCJ, "Food Safety Commission" both Japanese edition and English edition, FSCJ will distribute it at the public meeting and other occasions to have a relationship with stakeholders.

(6) YouTube

FSCJ will put the scene of "Advanced Lecture; Risk Assessment" which is a lecture course opened in order to promote public awareness of scientific knowledge on food safety, and of "Study workshop on food safety for every one" as motion pictures. As for the information that is easier to understand if it is described by a motion picture, FSCJ will consider making a content for a motion picture.

2. Promotion of public awareness of scientific knowledge on "Food Safety"

For the purpose of effectively diffusing the scientific knowledge on food safety among general consumers, FSCJ holds the following open lectures. One is a lecture for a wide range of consumers on the basic knowledge of science related to food safety; "Study workshop on food safety for everyone", and the other is a lecture opened to food-related business operator and researchers for promoting better understanding food safety risk assessment; "Advanced Lecture; Risk Assessment". These two lectures are held separately in different places including the provinces. Besides, in the case where excessive consumption of a specific food is a matter of concern, FSCJ will spread adequately the related scientific knowledge to the population with higher consumption of relevant food considering the better way to disseminate the information.

As for opinion exchange meeting except the above mentioned lectures, the meetings will be held to those concerned with school education as a priority target. Especially, in order to enhance the ripple effect, FSCJ will establish procedures with which local public entities can easily held an opinion exchange meeting, improve the contents of lectures, and prepare and provide the teaching materials that are easier to utilize on site.

FSCJ also will revise the technical glossary of food safety terminology as necessary, and will start to prepare a subtext on food safety for use in teaching by those concerned with school education.



In addition, FSCJ will respond to consultations and questions from consumers through "Food Safety Dial". FSCJ will share information provided through "Food Safety Dial" or from Food Safety Monitors with risk management organizations as initial risk information, and make efforts to effectively utilize it for securing food safety. Information regarding important questions will be disseminated through FSCJ's website, Facebook and others.

- 3. Establishment of a network for cooperation with relevant organizations and parties
- (1) Cooperation with risk management organizations

FSCJ will hold "Risk communication Liaison Conference for Concerned Government Agencies" basically every other week for more effective implementation of risk communication in cooperation with risk management organizations. Close information exchange and arrangement between risk management organizations is also implemented.

(2) Cooperation with local public entities

Maximally utilizing the information network with persons in charge of food safety at local public entities, FSCJ will share various information and documents regarding food safety. Moreover, FSCJ will hold a liaison conference with local public entities for the purpose of more effective implementation of risk communication (either co-organized or organized by local public entity alone).

- (3) Cooperation with mass media, consumer parties, business operator parties, relevant professional organizations (Establishment of system for smooth exchange of information)
 Regularly exchanging opinions, FSCJ strengthen the cooperation with mass media, consumer parties, business operator parties, and relevant professional organizations.
 In particular with consumer parties, business operator parties, relevant professional organizations, FSCJ will co-organize opinion exchange meetings or dispatch a lecturer based on their demands.
- (4) Cooperation with academic societies

As cooperation with academic societies is effective to spread scientific knowledge of food safety, FSCJ will continue to offer lectures by a member of the Commission and an exhibition booth in the meetings of relevant societies. Upon implementing such a cooperation, the academic field to be prioritized shall be clarified, and the organic linkage of the abovementioned lecture by a member of the Commission and the exhibition booth in a meeting of relevant academic society shall be considered toward further strengthening of cooperation with academic societies.

Chapter 7. Emergency response framework

1. Emergency response

When a food safety emergency occurs, FSCJ shall closely work with concerned administrative organs so as to promptly provide relevant scientific and toxicological information to relevant ministries and organizations and to public, based on "Guidelines for Emergency Response of FSCJ" (Decision of the Commission on April 21 2005. Hereafter refer to as the Guideline").



2. Maintenance and improvement of emergency response system

FSCJ should be prepared for any emergency situation to occur at any time. FSCJ should maintain or improve the networks for emergency situation to occur, should organize a practical emergency drill for quick collection of related scientific knowledge and for emergency response. The Expert Committee on Planning and Coordination is responsible for reviewing and updating preparedness and emergency procedures of FSCJ through the experience of actual emergency response or of the practical emergency drill. When necessary, the Committee shall revise the Guideline.

3. Food safety emergency drill

In 2018, practical training programs should be provided to the Secretariat's staff-members in consecutive months from April to November. In addition, the annual drill on food safety emergency response should be held in December, to be followed by a wrap-up to review and improve FSCJ's capacity to effective response to future events.

Chapter 8. Collection, review, and utilization of relevant information for ensuring food safety

FSCJ collects scientific information and data relevant to ensuring food safety on a daily basis, through publishes by international organizations, foreign government agencies and papers in academic journals, as well as through Food Safety Dials.

The collected information is adequately organized and analyzed so as to be ready to respond to the needs from public and risk management organizations. FSCJ accumulates the information in a webbased database called the "Comprehensive Information System for Food Safety" and reports in the Commission meetings, thus disseminates the information to public and share the information with risk management organizations.

FSCJ also promote commonization of hazard information, and shear of the hazard information with concerned ministries and agencies.

In addition, FSCJ will ensure the networks with relevant experts or professional organs from whom professional information can be obtained for emergency situation to occur, in order to utilize professional knowledge of the experts in food safety risk assessment or in emergency response.

Chapter 9. Promotion of international cooperation

(1) Dispatchment of the Commissioner and a staff of FSCJ secretariat to relevant international meetings

In 2018, FSCJ will dispatch the Commissioner, a member of Expert Committee and a staff of FSCJ secretariat to relevant international meetings that are held as follows.

May 2018	Prion 2018
June	The 86th Meeting of The Joint FAO/WHO Expert Committee on Food Additives (JECFA)



June	The 25th Meeting of The Joint OECD Working Group on novel foods and feeds
August	Visit the U.S.A. for inspection of Bio-Regulations
September	Joint FAO/WHO Meeting on Pesticide Residues (JMPR)
September	EFSA's third scientific conference
September	The 6th regular meeting with EFSA
September	The Global Summit on Regulatory Science (GSRS) 2018
March 2019	The Society of Toxicology

In addition, FSCJ will dispatch the Commissioners or others to other international meetings that come to be held as necessary.

(2) Invitation of researchers and experts from abroad

FSCJ invites researchers and experts on food safety from abroad in order to fulfill the scientific knowledge for establishing measures to ensure food safety.

(3) Strengthening of cooperation with foreign organizations for food safety

FSCJ will strength its cooperation with foreign organizations for food safety, dispatching the staffs as personnel exchange and implementing information exchange regarding the risk assessment. Also FSCJ makes an efforts to participate in an international joint evaluation. Regular meeting will be convened with risk assessment bodies abroad, i.e. European Food Safety Authority (EFSA) and Food Safety Australia New Zealand (FSANZ), Autoridade de Segurança Alimentar e Económica (ASAE), Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES), and Bundesinstitut fur Risikobewertung (BfR) based on the Memorandum of Cooperation as exchanged so far. FSCJ also proceed with investigation for strengthening cooperation with Technical University of Denmark (DTU) in accordance with the Memorandum of Cooperation signed in March 2018.. In addition, FSCJ proceed the construction of information exchange or cooperation with other foreign governmental organs such as Food and Drug Administration (FDA), as necessary.

(4) Dissemination abroad of information

FSCJ will provide up-to-date information on its activities including risk assessment reports, results from comprehensive survey to ensure food safety, research results on risk assessment methodology, and relevant matters, in English pages of its website.

FSCJ publishes a quarterly journal in English, "Food Safety-The Official Journal of Food Safety Commission of Japan" that contains research papers on food safety and English translation of risk assessment report for dissemination of information toward inside and outside the country.