

Provisional translation

Food Safety Commission of Japan Annual Steering Plan for Fiscal Year 2010 (Excerpt)

Risk assessment

1. Steady implementation of risk assessments requested by risk managers

FSC's core principle is to conduct science-based risk assessments in an objective, neutral and impartial manner. FSC urges risk managers that request risk assessments to provide necessary dossiers in timely manner, and the submitted dossier is examined in details while adhering to the following points.

(1) Assessment requests made during FY 2009

These assessments are expected to be done by the end of FY 2010. When timely completion is difficult due to such reasons as data inadequacy or absence of assessment guidelines, this assessment timeline is not applied. The Expert Committee may halt assessments in case of data inadequacy and wait for responsible risk managers to submit additional data to close the information gap.

(2) Assessments requested by risk managers in connection with applications received from private companies (Company-related assessments)

For assessments in this category, FSC strives to complete assessments within a year after submission of data, based on 'guideline of standardized assessment terms for company-related risk assessment' (FSC notification, July 16, 2009).

(3) Assessment of substances regulated by the positive list system

Substances in this category include pesticides, veterinary drugs and feed additives. Basically these substances must undergo the assessment of FSC to establish their residue limits, otherwise, distribution of foods that contain such substances above a certain level is prohibited. This system is called the positive list system. Presently FSC sees several possibilities of improvement for this category. Specifically, improvement measures such as streamlining of pesticide assessment process, pre-submission screening of prepared dossiers, and prompt and smooth assessment deliberation should be realized by FSC. Cooperation between relevant expert committees is essential to ensure this process.



(4) Assessment of the categories that expect positive list introduction

Food packaging and containers are included in this category. FSC will continue to closely collaborate with risk managers, and plan ahead to coordinate smooth risk assessment after introduction of the system.

(5) Risk assessment for soft drink standards

FSC should continue to prioritize items for assessment, and then conduct risk assessment in orderly fashion according to the plan.

2. Risk assessment guidelines

To standardize the contents of assessment and to secure the transparency of risk assessment deliberation, FSC develops assessment guidelines for each hazard. Guidelines in process of creation include those for pesticides, veterinary drugs, feed additives and apparatus/food container and package. To finalize those guidelines, necessary procedures should be promptly taken. The products of relevant FSC's grant researches may be reflected on the guidelines.

3. Risk assessment on FSC's own initiative, so-called 'self tasking assessment'

Currently, several self-tasking assessments are committed by FSC. Assessment titles, status and the year of selection are described below.

- Risk assessments of food-poisoning microorganism (selected in FY 2004) The assessment of 'Campylobacter jejuni and Campylobacter coli in chicken' was completed in 2009. Assessments of three high-priority items (*E.coli* O-157, *Salmonella* Enteritidis, Noroviruses) will be promptly conducted based on the assessment principles set by 'the Risk assessment guideline for food-borne pathogenic microorganisms (provisional edition)'.
- Risk assessment of beef and beef offal imported to Japan from countries with no BSE report (selected in FY 2007)
 The work has been completed for eight countries out of 14 countries concerned. Assessments of other six countries will be followed up as necessary data becomes available at the Prion Expert Committee.
- Risk assessment of lead in food, apparatus and containers/packages (selected in FY 2008)
 This assessment is under way at the FSC Lead WG of Expert Committee for Chemicals and



Contaminants.

• Risk assessment of deoxynivalenol and nivalenol and risk assessment of ochratoxin A (selected in FY 2008)

These assessments will be implemented at the Expert Committee for Mycotoxin/Natural toxins.

Selected self-tasking assessments for fiscal 2009, FSC will continue to collect and analysis the information (e.g. aluminum and trans-fatty acids).

4. FSC monitoring of implementation of regulatory polices taken up by risk managers after FSC's assessment

After completion of assessment, FSC carries out a follow-up monitoring of risk managers' regulatory actions based on the risk assessments notified by FSC. For fiscal 2010, FSC will implement monitoring survey of this kind twice. FSC is also endowed with the right to issue recommendations based assessment results and other opinions to the risk managers. Monitoring results are also to be summarized (October 2010 and April 2011) and reported at FSC meetings.

5. Promoting researches that contribute to the improvement of risk assessment techniques

FSC provides competitive grant programs for researches of assessment methodologies to promote science-based risk assessment.

Promoting risk communication

1. Opinion exchange meetings to communicate risk assessment outcomes

To foster public understanding of FSC's risk assessment, FSC hosts opinion exchange meetings in various locations and styles. Meetings are assigned for selected assessment items based on the following points and 'the guideline for implementation and review of opinion exchange meetings':

- Items that especially catch public attention,
- Items that require the detailed explanation of their scientific concept and assessment processes.

2. Prompt information and consultation service as to food safety risk assessments and food safety-related issues



In order to promptly provide accurate information in easily understandable way, FSC monitors the public's interest and effectiveness of FSC's past risk communication. The information distribution tools used by FSC include website, free e-mail newsletters, quarterly journal, brochures, and food safety glossary book. FSC engages in increasing number of registered recipients for e-mail newsletter. In addition, potential improvements can be expected regarding website such as expanding web contents, swift update, and close collaboration with e-mail newsletters. Pages about assessment status and assessment outcomes should be especially reader-friendly. Visually-assisted materials and movies are also expected to facilitate efficient communication with public about assessment concept, processes, and outcomes. Items with high public concerns are discussed based on the severity at round table conference, with the participation of various stakeholders including media and consumer groups. Other effort opportunity includes elaborate cooperation with media representatives through the timely delivery of press releases by e-mail or courteous response, and to the request of media coverage interview.

FSC frequently receives questions from outside through its food safety hotline. Those questions should be properly handled, and the information gained through this hot line is made into Q&A-style presentation on the website. Along with the comments received from food safety monitors, all the information is available for the risk managers..

3. Public education on scientific knowledge and science-based way of thinking about food safety

FSC sends lecturers to local governments and educational institutions, and hosts educational gathering with school children.

4. Assisting risk communicator's training session

FSC provided lecture programs for participants wishing to become a risk communicator by FY2009. The communicators are given opportunities to assist opinion exchange meetings to promote local-level risk communication. Audience is allowed to take part in discussion.

5. Food safety monitoring activity

Currently, 470 individuals are registered as FSC food safety monitors. FSC encourages these monitors to report information related to risk management policies developed based on FSC's assessment. Information about daily-basis food safety concerns is also welcomed. Monitors are also asked to take active roles in delivering food safety information to the locals. Regional food safety



monitors' meetings are annually hosted by FSC.

6. Cooperative relations with other ministries/agencies and local governments on risk communication

Bi-monthly information exchange meetings among risk managers and consumer agency are the venue for intra-governmental risk communication, and FSC's risk communication officer is among the regular participants of this meeting. Other cooperative activities of FSC regarding risk communication include jointly operated opinion exchange meetings with related government agencies.

To closely cooperate with local governments, FSC holds liaison conferences with local entities (e.g. prefecture, health center-establishing city including government decreed cities and other core cities/wards). Via those entities, information from FSC can be transferred to the local consumer groups and residents. The educated communicators can also join in FSC's opinion exchange meetings co-hosted by local government at FSC's request.

Information collection, process and utilization to secure food safety

1. Prompt collection and dissemination of latest, accurate food safety-related information

FSC's roles in information service include the collection of domestic and international food safety-related information under cooperation with risk managers and consumer's agency. The collected information is unified under the FSC's web-based database called 'Comprehensive Information System for Food Safety', so that the other food safety-related agencies can also use this database and comprehensively share the information.

At the same time, registered information is used by FCS to update fact sheets, or to be used for self-tasking assessment. When a food crisis occurs, rapid and precise response is a key for a successful management of situation. In preparation for such a prompt response, condensed hazard information is created and updated on a daily basis.

2. Promoting international cooperation

Experts from FSC attend international conferences such as Codex committees and OECD task force conferences. FSC also invites distinguished researchers and experts from overseas under FSC's international invitation program to gain scientific up-to-date knowledge contributing to food safety-related policy setting. Periodical meetings with international agencies such as EFSA and



FSANZ are aimed at aligning and cooperation.

3. Networking with external experts

For FSC, networking with external experts and professional associations is important in an effort to prepare for future risk assessment and emergency responses. The current scope of networking includes partners like Japan Dietetic Association, the Japan Medical Association, Japan Pharmaceutical Association, and Japan Veterinary Medical Association.

Response under food safety crisis

1. Emergency response training

Each year, FSC sets a simulated emergency situation and carries emergency training to test the practicality of response plan and seek possible improvement.

2. Developing emergency response plan

FSC responds to an emergency situation according to 'the Commission's emergency response guideline.' This guideline will be reviewed as necessary based on the evaluation of the emergency training by the Expert Committee for Planning.

In case of an emergency situation, the major role of FSC is to release scientific knowledge which is needed by the public in each situation. For this purpose FSC takes responsive measures by means of announcing Commission Chairperson's comments, publishing fact sheets and Q&A and/or implementing self-tasking or requested risk assessments of high priority. FSC can also issue opinions to risk managers and will be committed to promote cooperation with Consumer's Agency and other ministerial agencies.

Survey and examination program regarding food safety measures

FSC provides grants to carry survey on a specific type of food safety status. For FY 2010, FSC plans to widely publicize grant opportunity to encourage more research companies to apply for it. The survey subjects are to be selected by June 2010. Final outcome will appear on the website, thus made viewable for the public. The process to call for and select applications is also open to the public. The exception for this open information system is the information that contains private or corporative intellectual properties. In that case, the information will be withheld from the public view.