Provisional Translation

The Food Safety Commission
(Decision of the Committee on December 16, 2010)
Revised on August 27, 2019

Strategic direction for promoting research and survey to ensure food safety

1. Background

In accordance with Article 23, paragraph (1), item (6) of the Food Safety Basic Act, the Food Safety Commission of Japan (hereinafter referred to as "the Committee") shall be in charge of conducting scientific research and survey (hereinafter referred to as "the research-survey") necessary for risk assessments of food-related hazards on human health (hereinafter referred to as "risk assessments") defined in Article 11, paragraph (1) of the Food Safety Basic Act. Accordingly, the Committee has implemented "Research Program for Risk Assessment on Food Safety" (hereinafter referred to as "research program") and "Survey Program on Food Safety" (hereinafter referred to as "survey program").

The Committee was established as an independent organization to conduct science-based risk assessments in an objective, neutral, and impartial manner, after identifying the first BSE case in Japan, with the recognition that the protection of public health is the top priority. The Committee is functionally separated from risk management organizations which are responsible for regulations, guidelines etc.

To conduct risk assessment accurately, the Committee needs to make constant efforts to accumulate the latest scientific findings in a structured manner and to develop and improve its risk assessment methodologies.

In particular, with the globalization of foods and advances in analysis methods and techniques, it is necessary to have discussions focusing on previously unidentified risks and the related substances with their quantities. It is also indispensable to take into consideration the application of the latest scientific technologies including genome-editing technologies in a food sector, which are rapidly developed both domestically and internationally.

Moreover, with the rapid advancement of information technologies, it is required to collect and integrate scientific data with its effective utilization and application, since the volume of scientific information available for risk assessments is increasing and new approaches to risk assessment methodologies, including *in silico* assessment methods,[*1] are under development.

Furthermore, next future issues might be to conduct risk assessments with consideration of food consumption patterns and consumers' physiological and nutritional characteristics and to develop a risk assessment method with consideration of diversity of high-risk groups and benefits from food consumption.

Under such circumstances, it becomes more and more important to conduct the research-survey systematically and strategically and utilize its results effectively for the Committee to conduct accurate and globally-harmonized risk assessments promptly. Thereby, risk assessments conducted by the Committee are expected to further contribute to strengthening food safety both domestically and internationally.

It has been nearly nine years since the Committee established "Strategic direction for promoting research and survey to ensure food safety" (hereinafter referred to as "the Roadmap") in December 2010. It aimed to promote the systematic and strategic implementation of the research-survey, based on the indication from the Cabinet Office Administrative Project Reviews and the Ministry of Finance (MOF) Annual Budget Expenditure Review of FY2010. In this situation, the Committee decided to revise the Roadmap to clarify and define overall research and survey directions to be followed for the next five years with an eye to 10 years ahead, while the Committee continues paying attention to domestic and international progress of scientific research to obtain effective results to conduct risk assessments.

The Roadmap is to be revised depending on the future progress of the domestic and international research-survey when it is needed.

2. Direction of the research-survey

The research-survey conducted by the Committee is intended to obtain results which can be utilized at each step of risk assessment.

Risk assessments conducted by the Committee are based on "CAC/GL 62-2007: Working Principle for Risk Analysis for Food Safety for Application by Governments" (hereinafter referred to as "the working principle"), which is an international agreement at the Codex Alimentarius Commission (CAC). According to the working principle, risk assessment should incorporate the four steps of risk assessment, i.e. hazard identification, hazard characterization, exposure assessment, and risk characterization.

To achieve results that can be utilized at each of the four steps in risk assessment, the research-survey conducted by the Committee focuses on accumulation of scientific findings necessary for hazard characterization and exposure assessment, elucidation of mechanisms of human health effects, and establishment of a new assessment methodology, etc.

(1) Accumulation of scientific findings necessary for hazard characterization and exposure assessment

According to the working principle, risk assessment of food-related matters should be based on scientific data most relevant to the national context and should use available quantitative information to the greatest extent possible. At the same time, the working principle mentions that risk assessment may also take into account qualitative information.

It is also necessary to keep paying attention to food materials having no history of use in foods in consideration of global food situation and advances in food technology.

Hence, the Committee aims to conduct risk assessment promptly on the basis of the latest scientific findings with highly specialized experts and systems.

① The research-survey for accumulating scientific findings and knowledge needed for hazard characterization and exposure assessments including estimation of amount of exposure: development of sophisticated estimation techniques and the estimation method using biomarkers.

② The research-survey for accumulating and analyzing scientific findings and knowledge needed for risk assessments in order to support cutting-edge technologies (genome editing technology, nano-technology, etc.) regarding food development, manufacturing and processing, raw materials for food apparatus, containers, and packages and production of food additives.

(2) Elucidation of expression mechanism of effects on human health

It is an essential subject at the step of “hazard characterization” to elucidate expression mechanism of effects on human health regarding each hazard. Particularly regarding hazards derived from Japanese food culture, the Committee needs to lead a research on expression mechanism of effects on human health and to disseminate its outcome, as there is often no information available in the other countries. It is also important to conduct a research considering a realistic exposure level in accordance with the actual situation of Japanese dietary habits.

Hence, the Committee aims to conduct risk assessments based on steady scientific evidence

and to make the assessment results widely acceptable to the people in Japan as well as in other countries, by conducting the research-survey below.

① Research-survey for elucidating expression mechanism of effects on human health regarding hazards derived from Japanese dietary habits.

② Research-survey on adverse effect mechanisms resulting from ingestion of foods, which are normally considered to be harmless, in a particular group

③ Research-survey for examining validation of extrapolation toxicological findings in animal experiments to health effects on humans

④ Research-survey for elucidating expression mechanism of effects on human health regarding food-related microbiological and chemical hazards

(3) Use of new methods for risk assessment

Regarding risk assessments of chemical substances, it is required to introduce and use new assessment methods including “Threshold of Toxicological Concern: TTC” [*2], which is under discussion or used in Europe, the United States of America and International organizations. Taking into account the tremendous development of information technologies, it is necessary to collect, integrate, and use scientific data for risk assessment effectively. It is also important to conduct a research to discuss on risk assessment methods incorporating the point of view of risk-benefit.

Regarding animal experiments, taking into account animal-welfare[*3], the Committee should address the following issues: improvement of the methods of animal experiments from the point of view of the standard concept of animal experiments “Three R Principles”[*4], and development and introduction of alternative methods of animal experiments such as *in vitro* and *in silico* assessment methods.

It is also important to disseminate risk assessment results to the people adequately to spread accurate understanding.

Therefore, the Committee aims to conduct internationally-harmonized risk assessments quickly and appropriately, through the following research-survey.

① Research-survey for introduction of new risk assessment methods, taking into account the domestic and overseas trends

② Research-survey for use of preexisting toxicity data into risk assessment of the other chemicals

③ Research-survey for introduction of new risk assessment methods from the standpoints of "3R principles" and/or for improvement of experimental methods

④ Research-survey for the correct understanding and its dissemination to the people

3. Implementation of research program and survey program

Research and survey program shall be operated based on "Implementation of Research Program for Risk Assessment on Food Safety by Food Safety Commission" (Decision of the Research-Survey Project Planning and Coordination Committee on February 7, 2011) and "Implementation of Survey Program on Food Safety by Food Safety Commission" (Decision of the Research-Survey Project Planning and Coordination Committee on February 7, 2011), respectively.

Every fiscal year, the Committee shall formulate priority subjects for the research and survey program for the next fiscal year and select projects from the public based on the priority subjects.

When selecting projects, the Committee shall consider effective and efficient coordination of the research-survey with a view of a short, middle and long term application of the findings, so that the research-survey can maximally provide scientific findings and information necessary for risk assessments. For instance, a survey project may collect necessary knowledge from information possessed by domestic and foreign research organizations or from various scientific literature, and thus proceed mechanism analysis or establishment of new risk assessment methods.

To conduct the research and survey program efficiently and effectively, the Committee shall exchange information intensively with domestic and foreign research organizations, as well as ensure close coordination with other research and survey projects under jurisdiction of other ministries.

4. Evaluation of research and survey program

(1) Evaluation of research and survey projects

Regarding research projects, prior and interim evaluation and ex-post evaluation shall be conducted at Prior and Interim Evaluation Sub-Committee and Ex-post Evaluation Sub-Committee of the Research-Survey Planning Committee respectively, based on "Guideline for evaluation of FSCJ Research Program for Risk Assessment on Food Safety" (Decision of the Research-Survey Project Planning and Coordination Committee on February 7, 2011).

Regarding survey projects, ex-post evaluation shall be conducted at Ex-post Evaluation Sub-Committee of the Research-Survey Planning Committee, based on “Guideline for evaluation of FSCJ Survey Program on Food Safety” (Decision of the Research-Survey Project Planning Committee on June 4, 2013). Moreover, the Program Evaluation Sub-Committee of the Research-Survey Planning Committee shall conduct a follow-up survey and evaluation on use of the findings obtained from the research-survey in risk assessments.

(2) Evaluation of research program and survey program

Regarding the research and survey program, the Program Evaluation Sub-Committee of the Research-Survey Planning Committee shall conduct an overall program evaluation including an evaluation of the degree of achievement and secondary outcomes of the research and survey program as a whole. The Committee shall use the evaluation results for improvement of the program in general.

5. Utilization of results of the research-survey

The Committee attempts utilization of results of the research-survey at each risk assessment procedure and shares the results with the related ministries and agencies. The Committee makes the results open to the public and promotes its dissemination and a wide range of uses or the results via the official website and presentation meetings. Regarding research findings, the Committee additionally considers the possibility of publication via widely distributed and peer-reviewed academic journals.

*1: *in silico* assessment methods
Methods to predict and evaluate action, safety and effectiveness of chemical substances, particularly involving computer models, based on data accumulated.

*2: Threshold of Toxicological Concern: TTC
Science-based pragmatic tool to determine a threshold of every group of food-related chemicals, which are classified by those toxicological levels estimated based on their chemical structures. It is based on a concept that there is a threshold of exposure value that can be presumed to present no appreciable human health risk.

*3: Animal Welfare
Internationally accepted concept for animal welfare that appeals the “five freedoms”: i) Freedom from starvation and thirst, ii) Freedom from pain, injury or disease, iii) Freedom

from fear and suffering, iv) Freedom from physical discomfort and heat stress, and v) Freedom to behave normally.

*4: Three R principle

A principle for animal experiments, composing the following three philosophies.

- Replacement: To replace the use of animals with alternative techniques, as far as the experiment achieves the scientific aim.
- Reduction: To reduce the number of animals used to a minimum, as far as the experiment achieves the scientific aim.
- Refine: To refine the way experiments are carried out, to make sure animals suffer as little as possible, as far as the experiment fulfill the scientific necessity.