Provisional translation

Food Safety Commission of Japan

Decision of September 13, 2007

Revision of June 21, 2022

This English version of the Commission Decision is intended to be reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail. The FSCJ shall not be responsible for any consequence resulting from use of this English version.

Guideline for the Risk Assessment of the Effects of Food on Health for Foodborne Microorganisms and Others (Viruses, Parasites)

[1] Background

The Food Safety Commission of Japan (hereinafter referred to as "the FSCJ") established guidelines for an Assessment of the Effects of Food on Health[1] [denoting the "Assessment of the Effect of Food on Health" stipulated in Article 11, paragraph (1) of the Food Safety Basic Act (No. 48 of 2003)] for various subjects from the perspective of ensuring the fairness and transparency, based on "Basic Matters" stipulated in Article 21, paragraph (1) of this act (Decision of the Cabinet dated June 29, 2012).

Concerning the assessment of the effects of food on health for microorganisms, viruses, and parasites, the FSCJ formulated and published the "Guideline for the Risk Assessment of the Effects of Food on Health for the Foodborne Microorganisms and Others (Viruses, Parasites) in September, 2007 [Tentative Version (Japanese only), Decision of the FSCJ on September 13, 2007]."

In June 2021, FAO/WHO published the "Microbiological Risk Assessment Guidance for Food, Microbiological Risk Assessment Series 36 (MRA 36)." In response to this publication, the FSCJ decided to revise the above tentative guidelines for the purpose to ensure consistency with international assessment methods and to incorporate the latest knowledge obtained from the results of assessments conducted domestically and overseas.

[2] Purpose of this Guideline

The purpose of this guideline is to improve the fairness and transparency of the assessment clarifying the basic concept, method, and data of assessment in line with the characteristics of foodborne microorganisms (bacteria, viruses, protozoa) and parasites other than protozoa [hereinafter referred to as "Microorganisms and Others"]; and to facilitate research and discussions while pursuing consistency of assessment methods among agents, sectors and with international communities as much as possible.

[3] Definitions

The definitions of risk analysis terms related to the "Glossary of Food Safety (Japanese)"

[1] An Assessment of the Effects of Food on Health includes the following two methodologies:
- The relevant ministers hear the opinions of the FSCJ pursuant to Article 24 of the Food Safety Basic Act.
- The FSCJ conducts the assessment at its discretion on the basis of Article 23, paragraph (1), item (ii) of the Food Safety Basic Act.

published by the FSCJ, shall apply.

[4] Objective and basic concept of the assessment

The FSCJ provides risk management organizations with information on risks relating to the effects on human health caused by foodborne microbiological and other hazards and helps them to select risk management measures to reduce risks (for example, design of microbial standards in foods). That is, it provides risk management organizations with rational information to be a scientific basis for selecting a solution to minimize risks.

The assessment shall be conducted objectively and fairly based on the level of scientific knowledge reached at the time. The FSCJ will coordinate well with risk management organizations while sharing information with them. Meanwhile, the assessment shall be conducted independently and shall be functionally distinct from the risk management process.

In assessment,

- Risk assessment policy[2] should be established in consultation with risk-management organizations, risk-assessment organizations, and other related parties.
- In principle, the FSCJ shall follow a systematic approach, with the four components of "Hazard Identification (identifying hazards)," "Exposure Assessment," "Hazard Characterization (identifying adverse effects)," and "Risk Characterization," based on Codex's "Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CXG 30-1999)."
- The FSCJ shall share information with the general public, including risk management organizations and other related parties, and exchange opinions.

[5] Scope

The scope of the assessment applies to hazards of "Microorganisms and Others" in food and the toxins/metabolites produced by them.

In this guideline, food is defined as all food and drink (including water for drinking), and the assessment is conducted for a group of people affected by hazards and whose health is adversely affected.[3] The assessment shall be performed for factors in all or part of a series of food supply processes (food chain) from the production of agricultural, forestry and fishery products to food consumption after identifying the combination of hazards and foods[4] that may contain them.

[6] Consideration for assessment

When conducting the assessment, the following points should be considered as much as possible to reflect the phenomena that may occur in reality.

(i) Characteristics of "Microorganisms and Others"

- Pathogenic characteristics and strain differences of target" Microorganisms and Others"; and susceptibility to human infection and transmission.
- Dynamics: Part of "Microorganisms and Others" in foods proliferate, extinct and generate toxins during preserving and handling foods through food chains from production to consumption.

(ii) Social and environmental factors

[2] See "Working Principles for Risk Analysis for Food Safety for Application by Governments" (CXG 62-2007).
[3] For example, people living in a specific area, groups or gathering of individuals belonging to similar characteristics (occupation, age, etc.). People means "Persons residing in Japan" unless otherwise specified.
[4] The food in this text does not necessarily mean a single food.

- Eating and behavioral habits in the target group
- Sanitary conditions and others when handling food that affect the potential of cross-contamination risk

(iii) Susceptibility to hazards

- Differences in susceptibility in the target population
- Various interactions after ingestion between the host (human) and target "Microorganisms and Others" *in vivo* as well as the toxin and metabolites produced by them (for example, interaction with the immune system).

[7] Type of risk assessment

To estimate the frequency and severity of the adverse effects on human health from the target "Microorganisms and Others," risk assessments can be the following: 1. qualitative assessments, 2. semi-quantitative assessments, and 3. quantitative risk assessments, or the combination of any of them. The type of risk assessment should be selected depending on the purpose of the assessment as well as the quality and quantity of data.

1. Qualitative risk assessments

Qualitative risk assessments are descriptive or categorical treatments such as "very low," "low," "moderate," or "high" of data or results.

2. Semi-quantitative risk assessments

Semi-quantitative risk assessments provide an intermediary level between the numerical evaluations of quantitative assessments and the textual evaluation of qualitative risk assessments. Risks are categorized by relative magnitude and are allotted to qualitative estimate categories in the form of weights or scores.[5]

3. Quantitative risk assessments

Quantitative risk assessments treat variables and results related to risk estimation numerically. There are deterministic risk assessments and probabilistic risk assessments. Deterministic risk assessments present results in mean values, percentile values, etc. Probabilistic risk assessments present results in probability distributions. To quantify and explain relationships between factors affecting exposures, mathematical models are applied in quantitative risk assessments using logical tests and conditional statements.

[8] Structure of risk assessment

Risk assessment, in principle, shall be conducted in accordance with a systematic approach, including the four components described above [4].

1. Hazard identification (identifying hazards)

Hazard identification is conventionally the first step in "Risk Assessment." The purpose of hazard identification is to identify "Microorganisms and Others," which potentially pose concern of adverse health effects relating to foods, and the toxins and metabolites generated by them. Important well-known information should be provided regarding the relationship and interactions of hazards, foods (including inherent natures, environmental factors, and condition of products) and hosts (the group of population) as well as the causal relationship between these factors and human disease.

[5] Semi-quantitative assessment assigns numbers to each category of qualitative description. For example, it shows the result of summing up the points, expressing numbers out of 10.

2. Exposure assessment

In exposure assessment, the probability and magnitude of human exposure to hazards via food consumption is evaluated from the available information by a qualitative, semi-quantitative, or quantitative method, or a combination of any of these methods.

In this step, the behaviors of "Microorganisms and Others" and the sources of exposure shall be analyzed, as they survive, proliferate, decrease, or extinct in foods, depending on conditions. In many cases, exposure assessment depends on concept models and mathematical models to estimate exposure at the time of consumption because normally it is not possible to obtain detailed data related to the exposure, such as the frequency and level of contamination of the hazards in food at the time of consumption and the intake. For this reason, various mathematical models are proposed, and predictive microbiology models are utilized in international microbiological risk assessments as well.

Further, depending on the purpose of the evaluation and the quality and quantity of the data, exposure assessment is, in some cases, limited to searching for methods to quantify or minimize exposure.

3. Hazard characterization (identifying adverse effects)

In hazard characterization (identifying adverse effects), the nature of the adverse effects associated with hazards that may present in food is estimated by a qualitative, semi-quantitative, or quantitative method, or a combination of any of these methods. Basically, the factors to be considered are: the host (human) related to the onset of foodborne disease (age, underlying diseases, immune state, etc.), potential pathogenicity of hazards (toxicity, infection/invasion mechanism, transmissibility, strain diversity, antimicrobial resistance, etc.), food characteristics, dose-response relationship, etc. Hazard characteristics (identifying adverse effects) can be iterative as component of risk assessment or as stand-alone process. A dose-response relationship model shall be used to assess hazards quantitatively.

4. Risk characterization

Risk characterization is the final step in "Risk Assessment." Based on the results of hazard identification, exposure assessment and hazard characterization, the occurrence probability and severity, including uncertainties, of known or potential adverse health effects in a given population are estimated by a qualitative, semi-quantitative, or quantitative method, or a combination of these methods.

(1) The objective of risk characterization is to achieve the following:

(i) To estimate risk integrating the results of exposure assessment and hazard characterization

Risk estimation presents the following two cases:
-absolute risk estimates (e.g. the number of food poisoning cases due to the hazards under assessment in a food product per 100,000 population); and
-relative risk estimates (e.g. estimates of risk reduction effect by implementing various risk management measures)

(ii) To provide answers to the questions asked in the assessment

For example, the questions include the following:

- Estimation of current risk
- Comparison of the impact of each factor in food chain on risk
- Risk estimation to establish Appropriate Level of Protection (ALOP)
- Impact of risk management measures on risk
- Evaluation on equivalence of impact of overseas and Japanese risk management measures

(2) Risk characterization work includes:

(i) To estimate the frequency and severity of adverse effects on health that may occur in the target population by a qualitative, semi-quantitative, or quantitative method, or a combination of these methods.

(ii) To compare independent epidemiological data showing the association between factors related to hazards (e.g. frequency and level of contamination of a certain pathogen) and disease; and to estimate the expected risk in the case that possible countermeasures are implemented.

(iii) To provide the documented necessary information for setting ALOP, on the basis of the outcome of the above (i) and (ii).

The FSCJ shall conduct risk assessment based on scientific data that are most appropriate under the circumstances and should provide the risk management organizations with the "best estimate"[6] of risk excluding bias as much as possible while considering uncertainties and variability that affect the results of the assessment. The FSCJ should also clarify the reason for the selected metrics as the best method of estimating risk, including the average value of risk, maximum likelihood estimation [7] and other metrics, and share it with the risk management organizations. When the bias cannot be eliminated, the FSCJ should explain the bias and its reasons, as well as the level of uncertainty of each data and its effect on the evaluation results.

[9] Simplified structure of risk assessment

In principle, the risk shall be assessed in accordance with the above four components: "Hazard Identification (identifying hazards)," "Exposure Assessment," "Hazard Characterization (identifying adverse effects)," and "Risk Characterization." However, in cases of the following from (1) to (7), the FSCJ will use the methods simplifying the contents of these four components as necessary and present the evaluation results.

(1) Time constraints such as urgent agents that need to be assessed.

(2) Opinions and advice are requested.

(3) Discussions for legal consistency.

(4) Agents already fully reviewed by the risk management organizations.

(5) Risk estimation by epidemiological methods is appropriate.

(6) To use the results of the exposure assessment as the conclusion is appropriate.

(7) To evaluate using data of similar feature foods is possible.

Even in such cases, as a general rule, the assessment should be processed based on the four components, and the following steps from (i) to (iv) should be undertaken.

(i) To confirm purpose and scope of the assessment,
(ii) To confirm and organize data provided and collected,
(iii) To confirm and obtain missing data (request to risk management organizations and others, or

[6] In the best estimate results, the estimated values are not necessarily point estimates, but may be mean values and distributions in some cases.
[7] Maximum likelihood estimation (MLE) is a statistical method of estimating a point of the parameters of a probability distribution (the method to estimate as a single value for characteristic values such as mean and/or variance of a population).

collect at FSCJ's discretion), and
(iv) To discuss.

[10] Use of the document

The FSCJ collects materials/data according to the characteristics of hazards, foods, and human populations to be assessed, and uses them for its assessment.

1. Ensuring the accuracy and reliability of data

The data should be relevant to the food products subject to the assessment and should be as highly representative as possible in the population subject to the assessment. To ensure the accuracy and reliability of the data, the FSCJ shall use data, wherever possible, from peer-reviewed published scientific papers and data published by public organizations including risk management organizations. Meanwhile, unpublished data and data belonging to related stakeholders shall be also used in the assessment if deemed appropriate.

2. Ensuring data transparency

The FSCJ will strive to ensure transparency by clarifying the source of the data. If there are multiple data with different characteristics, it should be noted that priority or order to be considered should be defined (e.g. Quantitative data should be given priority. Semi-quantitative or qualitative data can be used sequentially, if unavoidable).

3. Policy for lack of data

Discrepancy between the required data and available data affect the reliability and estimation of the assessment. Meanwhile, presenting the evaluation results based on available data under the changed assessment method shall be possible after consultation with the risk management organizations (e.g. changing from quantitative to semi-quantitative or qualitative, or changing the scope of assessment from the entire food chain to a stage where the data are relatively available).

In the event that the materials submitted by the risk management organizations are insufficient for the assessment, the FSCJ shall request the additional materials. A predictive microbiology can be used to fill data gaps at each stage of the food chain under the assessment. Further, in case there is no available data or it is desired to supplement the obtained data, the opinions of experts may be taken into account.

[11] Review of assessment

The assessment will be reviewed as appropriate in the case that the necessity arises to revise the various assessment results and methods considering the latest scientific knowledge and trends of international standards.

[12] Review of the guideline

This guideline will be reviewed when deemed necessary, for example, new findings about evaluation methods are obtained, considering trends of international standards as well as domestic and international scientific knowledge.

References

1) Tentative translation: “Glossary of Food Safety” (Japanese) http://www.fsc.go.jp/yougoshu.html

2) PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK ASSESSMENT (Codex: CXG 30-1999)

3) WORKING PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY FOR APPLICATION BY GOVERNMENTS (Codex: CXG 62-2007)

~~4)~~ Joint FAO/WHO (JEMRA): Microbiological Risk Assessment Guidance for Food. MICROBIOLOGICAL RISK ASSESSMENT SERIES 36 (June, 2021)