

Provisional translation

Food Safety Commission of Japan (FSCJ)

October 4, 2022

Revised version of the FSCJ decision dated July 16, 2009

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.

Standard Processing Period for Risk Assessment of the Effect of Food on Health Regarding Applications Submitted from Industries

For the risk assessment regarding applications submitted from industries, conducted upon request from risk management organizations, the standard processing period (i.e. standard period of time to be typically needed between the date of an assessment request by the risk management organization and the date of notification of assessment result, hereinafter referred to as “standard processing period”) is established as below;

1. The standard processing period

For risk assessments regarding applications submitted from industries via risk management organizations, the FSCJ shall endeavor to notify the assessment result within one year from the date it receives the explanation of an assessment request from the risk management organization at a Commission meeting; provided, however, that this does not apply to the active substances that the Minister of Agriculture, Forestry and Fisheries designates the scope of agricultural chemicals and gives public notice that a person must undergo reevaluations by the Minister for the relevant designated agricultural chemicals, in accordance with Article 8, paragraph (1) of the Agricultural Chemicals Regulation Act (Act No. 82 of 1948).

2. Determination of the time period

The following periods shall not be included in the time period stipulated in 1, above.

- 1) When the FSCJ secretariat (hereinafter referred to as the “secretariat”) identifies that data and/or information provided in an application is not sufficient for risk assessment in the

preliminary review, the secretariat may request additional data and/or information from the risk management organization. In the case in which a written request for additional data and/or information is issued by the FSCJ, the time period for the risk management organization to prepare and submit the data and/or information to the FSCJ shall not be included in the standard processing period.

- 2) When the Commission or Expert Committees identify that data and/or information provided in an application is not sufficient for risk assessment during their discussions, they may request additional data and/or information from the risk management organization. In the case in which a written request for additional data and/or information is issued by the FSCJ, the time period for the risk management organization to prepare and submit the data and/or information to the FSCJ shall not be included in the standard processing period.

3. Submission of additional data and/or information

In principle, the FSCJ shall request the risk management organization to submit the additional data and/or information stipulated within one year from the date of the request. However, in the case in which the applicant has justification for the delay of submission (i.e. due to the nature of the additional data and/or information), the applicant may submit the reason for delay to the FSCJ via the risk management organization.

4. Termination of the risk assessment

When the additional data and/or information are not submitted within the time limit stipulated without justifiable reasons and the FSCJ will find it difficult to implement the risk assessment, the FSCJ shall notify that effect as an assessment to the risk management organization.

5. Status of achievement

Once a year, the secretariat shall report to the Commission the status of achievement for the standard risk assessment period.

Supplementary provisions

1. This decision shall enter into force from January 1, 2010.
2. The FSCJ shall endeavor to observe the standard processing period for the all risk assessments regarding the applications submitted from industries by the end of the fiscal year 2012.