

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.

Assessment guide for “the assessment using reports by international/national risk assessment organization(s)”

Pesticides with established in-food provisional standards have been assessed for their health effects, when digested through food, in accordance with the “Procedure for Risk Assessment of Agricultural Chemicals, for which provisional standards are established” (adopted by the Food Safety Commission of Japan (FSCJ) on 29th June, 2006) and the following guide:

1. Basic concept of this guide

- (1) FSCJ recognized limitations on data available for the evaluations when only referring to the risk assessment reports of international organization and/or national regulatory authorities, such as Joint FAO/WHO Meeting of Pesticide Residue (JMPR), EFSA (EU), EPA (United States of America), APVMA (Australia), and Health Canada (Canada). This assessment process is called “the assessment using reports by international/national risk assessment organizations”. This shortage stems from more supple data generally submitted by Japanese applicants for the registration of agricultural chemical. Therefore, to bridge these gaps, an assessment with such limitations should be handled by insightful evaluators of high-quality expertise and well-experience background. When an assessment is conducted by using reports of international/national risk assessment organizations, it is basically conducted by the Expert Committee on Pesticides, because of their rich experiences. If necessary, each pesticide committee can contribute to assessment.

- (2) Regarding the handling of individual test results reported by international/national organizations, mentioned above, as parts of their assessment reports, only those pieces of data that are comparable in quality and interpretation to the Japanese applicants’ data for registration will be taken into consideration at the Expert Committee. If not, the Expert

Committee will mainly value their toxicity data and its assessment circumstances. If there are inconsistencies among test results and their interpretations by multiple international organizations, the Expert Committee will compare and closely examine them, then decide the most appropriate set of data for the situation. This process is also applied for a risk assessment.

2. Process of “the assessment using reports by international/national risk assessment organizations”

(1) At “the assessment using reports by international/national risk assessment organizations”, the Expert Committee will need similar types of studies for pesticides applied for registration in Japan. These include animal and plant metabolism studies, acute toxicity study, subacute toxicity study, chronic toxicity study, carcinogenicity study, reproductive/development toxicity studies, genotoxicity studies for the assessment.

(2) The Expert Committee will check data quality including the studies conducted in compliance with GLP described in (1). Only qualified data will be used for the assessment.

(3) With a confirmation of the data for use to be satisfactory for conditions (1) and (2), above, the Expert Committee will proceed to conduct assessment by using those results of international/national risk assessment organizations.

(4) When a full-set of studies described in (1) are not available, the Expert Committee will comprehensively determine whether “the assessment using reports by international/national risk assessment organizations” is still doable by using the referable report(s).

(5) The Expert Committee will describe the reasons why the studies used for the assessment were applicable, along with the studies’ results. When there is a discrepancy between the Expert Committee conclusion and that of other risk assessment organizations’ “the assessment using reports by international/national risk assessment organizations”, the basis of such gaps will be also described.

3. Preparation for the assessment

(1) Preparation of data for the assessment

The secretariat of the Expert Committee on Pesticides will prepare a draft risk assessment report based on reports by international/national risk organizations. This draft should be accompanied by a concisely organized point of discussion paper on items ① ~ ③ below. If available data of that moment from the reports are not enough, the need will be deliberated at the Expert Committee on Pesticides, then ask submission of related reference(s) to the risk assessment organizations.

① Risk assessment policy, chemical structure, mechanism of pesticide, and its application purpose.

② Summary of study results, including the risk assessment report(s) that are referred to, types of

study, and their qualities.

- ③ Other information to contribute to the assessment, if any, such as results of metabolism studies in animals and plants (kinetics, residues, major metabolites/degradates, etc.), major toxicity, target organs, potential neurotoxicity/carcinogenicity/reproductive and developmental toxicity, or genotoxicity, then a summary of assessment by international/national risk assessment organization such as an additional safety factor.