Provisional translation

The Food Safety Commission

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Procedure for Risk Assessment of Agricultural Chemicals for which provisional standards are established

1. Basic approach

1) The Ministry of Health, Labour and Welfare (MHLW) plans to request for the assessment of food safety risks to human health (hereinafter referred to as "risk assessment") based on the "positive list system for agricultural chemicals remaining in foods" introduced by the MHLW (MHLW Notification November 28, 2005, Director Notice Syoku-An No. 1128001) in the next five years. Under the plan, total of 758 substances including pesticides, veterinary medicines and feed additives (hereinafter referred to as "agricultural chemicals") will be assessed, and on average, 150 substances per year.

   In order to efficiently conduct such a large number of assessments on agricultural chemicals, for which provisional standards are established, the Food Safety Commission of Japan (FSCJ) will provisionally establish the evaluation procedure referring to the current risk assessment methods and evaluate the toxicity etc.

2) For the agricultural chemicals categorized in either of the following two types, risk assessment will be conducted under the current risk assessment method/procedure with toxicological, metabolism and residual studies (hereinafter referred to as "toxicity studies")

   ・Substances determined by international risk assessment agencies as for which the ADI cannot be set.

   ・Substances ingested in relatively large amount through food by general population (hereinafter referred to as "priority substances").

3) International harmonization on risk assessment (i.e., requirements for toxicity testing) for agricultural chemicals is in progress and existing overseas risk assessments are also utilizable. In principle, when conducting the risk assessment, results from the previous risk assessments conducted in overseas shall be utilized, if they are available, along with those conducted in Japan.

Upon conducting the risk assessment of a substance that has been previously evaluated in Japan and/or overseas, information such as the previous risk assessment results shall be utilized. Furthermore, new scientific findings obtained after the completion of the previous assessment and information on actual usage of the substance would be comprehensively discussed in order to reflect time elapsed after the previous assessment and intake characteristics in Japan.

4) If new important toxicity findings such as carcinogenicity is identified in the process of risk assessment, these findings shall be used.

2. Implementation of risk assessment

Risk assessment of agricultural chemicals for which provisional standards are set will be conducted according to the following two assessment procedures.

1) Assessment procedures for priority substances

① Risk assessment method

Risk assessment of priority substances shall be conducted using toxicity studies as described in ②.

② Data and/or information to be used for the risk assessment (i.e., toxicity data) of the applied substance shall be based on the following guidelines:

・For the substance categorized as a pesticide:

"Guidelines on establishing and revising residue standards concerning agricultural chemicals used overseas", Notification No. 0205001, issued on February 5, 2004 by Director-General, Department of Food Safety, Ministry of Health, Labour and Welfare (MHLW), and "Data requirements for registration of agricultural chemicals", Notification No. 12-Nousan-8147, issued on November 24, 2000 by Director-General, Agricultural Production Bureau, Ministry of Agriculture, Forestry and Fisheries (MAFF)

・For the substance categorized as a veterinary medicine:

"Practices for documents on veterinary drugs", Notification No. 12-33, issued on March 31, 2000 by Director-General, Food Safety and Consumer Affairs Bureau, MAFF.

・For the substance categorized as a feed additive:

"Establishment of evaluation standards for feed additives", Notification No. 4-Chiku-A-201, issued on March 16, 1992 by Director-General, Food Safety and Consumer Affairs Bureau, MAFF.

③ Requirement of additional data and/or information

A) When the FSCJ judges that toxicity studies and/or information submitted are insufficient for the risk assessment, the FSCJ will request for additional data and/or information to the MHLW indicating the time limit. Upon setting the time limit, the FSCJ shall take into consideration the reasonable time period necessary to conduct the tests and prepare data and/or information.

B) In response to the request from the FSCJ, the MHLW shall take effort to collect additional data and/or information and submit them within the time limit.
When the additional data and/or information are not submitted from the MHLW within the time limit, the FSCJ will judge that the assessment is unable to be undertaken.

2) Assessment procedures for agricultural chemicals not categorized as priority substances

① Risk assessment method

To implement the risk assessment for agricultural chemicals not categorized as priority substances, the FSCJ will comprehensively review previous assessments conducted both in Japan and overseas for their backgrounds, toxicity studies that served as the basis for the assessment, and the scientific findings accumulated over the years since the completion of the previous assessment.

Provided that following criteria A) and B) are met, and it is judged appropriate to conduct the assessment, the risk assessment shall be implemented by establishing acceptable daily intake (ADI) or other methods.

In case where there exist several assessment reports that fulfill the criteria, the FSCJ shall analyze these assessment reports and comprehensively conduct risk assessment.

A) An appropriate assessment methodology such as the establishment of an ADI, must be adopted considering intended use of the applied substance.

When evaluating the validity of the assessment methodology, background of the establishment of the provisional standard for the applied substance and risk management measures shall be considered.

In the above case, upon reviewing the background of the establishment of the provisional standard, following points, for example, shall be considered.

・Provisional standard was set as “not detected” or

・Provisional standard was set as “the limit of quantification or limit of detection.”

B) Appropriate tests such as toxicity studies have been conducted based on the adopted methodology.

② Data and/or information for risk assessment

A) In the case where the data and/or information used for the assessment fulfill certain requirements indicated in C), following documents shall be submitted.

(a) Risk assessments implemented by the Japanese government.
(b) Risk assessments implemented by international risk assessment organizations and foreign government organizations.

B) In addition to the risk assessments listed in A), in the case where the data and/or information used for the assessment fulfill certain requirements indicated in C), utilize the following documents. Note that in (a) to (d), it must be confirmed by the MHLW and/or MAFF that the summary reports of toxicity studies are described to the documents appropriately. Only those approved are adopted. However, the above may not apply to the cases where toxicity studies are also submitted.
(a) For pesticides, summary report from the applicants that is required upon pesticide registration and other relevant documents.
(b) For veterinary medicine, a summary application document for marketing approval of a new veterinary medicinal product and other relevant documents.
(c) Abstract prepared by an applicant for designation of a new feed additive and other relevant documents.
(d) When import tolerance (i.e., maximum residue limits that is based on uses of agricultural chemicals registered by the government in order to allow food import) is requested by foreign governments and industries, summary application documents submitted by the applicants and other relevant documents.
(e) Results from the studies on toxicity, metabolism and residues on the applied chemical, and relevant scientific papers that can elaborate scientific findings obtained after the implementation of the risk assessment report.

C) In principle, certain requirements as described in the above A) and B) demand the respective documents to include appropriate evaluation results of all the toxicity studies necessary according to the guidelines given below.

・For the substance categorized as a pesticide as described in B). (a) :
"Guidelines on establishing and revising residue standards concerning agricultural chemicals used overseas", Notification No. 0205001, issued on February 5, 2004 by Director-General, Department of Food Safety, MHLW, and "Data requirements for registration of agricultural chemicals", Notification No. 12-Nousan-8147, issued on November 24, 2000 by Director-General, Agricultural Production Bureau, MAFF.

・For the substance categorized as a veterinary medicine as described in B).(b):
"Practices for documents on veterinary drugs", Notification No. 12-33, issued on March 31, 2000 by Director-General, Food Safety and Consumer Affairs Bureau, MAFF.

・For the substance categorized as a feed additives as described in B).(c) :
"Establishment of evaluation standards for feed additives", Notification No. 4-Chiku-A-201, issued on March 16, 1992 by Director-General, Food Safety and Consumer Affairs Bureau, MAFF.

However, based on this procedure, the specific requirements will be decided by the relevant expert committees responsible for the risk assessment of the applied substance. When evaluation results for part of the toxicity studies are missing, relevant supporting explanation accompanied by adequate considerations needs to be provided.

③ Requirement of additional data and/or information

A) When the FSCJ identifies that toxicity studies are insufficient for the risk assessment, the FSCJ will request for additional data and/or information to the MHLW indicating the time limit. Upon setting the time limit, the FSCJ shall take into consideration the reasonable period necessary to conduct the tests and prepare data and/or information.

B) In response to the request from the FSCJ, the MHLW shall take effort to collect additional data and/or information and submit them within the time limit.
In case where the additional data and /or information are not submitted from the MHLW within the time limit, the FSCJ will judge that the assessment is unable to be undertaken.

3. Notification of the assessment result

1) The FSCJ shall promptly notify the risk assessment result to the MHLW when it is summarized. Upon notifying the assessment result based on the assessment procedure 2. 2), the FSCJ shall clearly indicate that the assessment of the applied substance was conducted using the existing assessment reports.
2) When it is judged that the risk assessment cannot be implemented based on the given procedure of 2. 1) ③ and 2. 2) ③, the FSCJ shall notify the assessment result to that effect to the MHLW.
3) Following the notification of the assessment result such as that of an ADI from the FSCJ, the MHLW shall calculate the dietary intake of the agricultural chemicals and promptly review the provisional standards. The reviewed standards shall be reported to the FSCJ in a written form.
4) The FSCJ can state its opinion as necessary after confirming the exposure level indicated in the report from the MHLW.

4. Others

1) When new scientific findings are acquired on the agricultural chemicals of concern after the implementation of the risk assessment (e.g. new toxicological study) and it may influence the assessment result, re-evaluation will be considered by the FSCJ.
2) When the positive list system was introduced, any one of the following measures was taken to each agricultural chemical.
   ・Provisional standards are established
   ・A certain limit is determined（generally called “uniform limit”, the amount below which a substance is regarded not to pose adverse health effects)
   ・Designated as substances not subject to the positive list system (generally called “exempted substance”, substances that will not pose adverse health effects)
   For agricultural chemicals other than those with provisional standards, the risk assessments will be conducted with different procedures.