

Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals used outside Japan

I. Purpose

This guideline outlines the procedures required to apply for the establishment and revision of maximum residue limits (MRLs) for agricultural chemicals on/in foods, and the scope of required documents. The guideline targets agricultural chemicals - pesticides, veterinary drugs, and feed additives - that are approved in the foreign countries for foods exported to Japan. The foods include agricultural products, animal products, or seafood.

The requirements given in this document notwithstanding, it is not necessarily appropriate to require a uniform set of documents for every chemical. Also, advances in science and technology may bring new analytical and evaluation methods. Therefore, the study results and related documents given in the guideline can be replaced by other documents sufficient to conduct evaluation for establishment and revision of MRLs.

Background

The Food Sanitation Law was amended and promulgated in May 2003. Based on the amended law, the Ministry of Health, Labour and Welfare (MHLW) is going to implement a positive list system for agricultural chemicals on/in food. The system is aimed at prohibiting the distribution of foods that contain agricultural chemicals above a certain level unless MRLs for the chemicals on/in the foods are established. This system will go into effect within three years after the publication of the amended Food Sanitation Law, May 30, 2003.

In the implementation of the positive list system, Japan expects foreign countries to make requests for establishing or revising MRLs for agricultural chemicals when these chemicals are newly approved in the countries for foods exported to Japan.

For agricultural chemicals used in Japan the MHLW establishes MRLs, based on Article 11 Paragraph 1 of the Food Sanitation Law, at the time of the registrations/authorizations of the agricultural by the Ministry of Agriculture, Forestry and Fisheries (MAFF).

II. Procedures for Establishment and Revision of MRLs for Agricultural Chemicals

1. Application

Any person may apply to the Minister of Health, Labor and Welfare with Form 1 or 2 for the establishment or revision of MRLs for an agricultural chemical in the case that

the chemical is approved in a country for foods exported to Japan. The Form should be accompanied by required documents on the chemical including data as described in the section III.

If the applicant is abroad, an appropriate contact person in Japan should be identified to handle the application. The Form should be submitted to the Standards and Evaluation Division, the Department of Food Safety, MHLW.

2. Evaluation

The submitted application will first be examined by the secretariat of the Division. Then, the risk assessment on the chemical will be done by the Food Safety Commission, based on Article 24, Paragraph 1, Item 1 of the Food Safety Basic Law. Draft MRLs will be discussed at the Pharmaceutical Affairs and Food Sanitation Council, based on the Commission's assessment.

The Commission and Council may ask for additional documents/data from the applicant if necessary.

In response to the Council's report, the secretariat will take necessary procedures including the WTO notification and prepare for publication on the establishment or revision of MRLs, based on Article 11 Paragraph 1 of the Food Sanitation Law.

III. Required Documents

1. Data Sets and GLP Compliance

A. Data Sets

The data sets required when applying for the establishment and revision of MRLs are given below. Besides them, other data on safety assessment should be submitted if available.

a. Establishment of MRLs

Pesticides

A set of toxicity data and residue data given in "Data Requirements for Supporting Registration of Pesticides" - Director-General, Agricultural Production Bureau, MAFF, Japan, Notification No. 12-Nousan-8147, 24 November, 2000 - (excluding effects of aquatic animals and plants, effects on beneficial creatures other than aquatic animals and plants, and study data on water contamination). The Notice is available in English on <http://www.mhlw.go.jp/english/topics/foodsafety/residue/dl/01.pdf>

Feed additives

A set of safety data and residue data given in the "establishment of evaluation standards for feed additives" - Director General, Food Safety and Consumer Affairs Bureau, MAFF, Japan, Notification No. 4-Chiku-A-201, March 16, 1992. These documents can be replaced by documents prepared according to the VICH guideline for safety (VICH: the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products). The Notice is available in English on <http://www.mhlw.go.jp/english/topics/foodsafety/residue/dl/02.pdf>

Veterinary drugs.

Documents according to the toxicity study guidelines for given in Section 4 of the

attachment to the "practices for documents on veterinary drugs,"- Director General, Food Safety and Consumer Affairs Bureau, MAFF, Japan, Notification No. 12-33, March 31, 2000. These documents can be replaced by documents prepared according to the VICH guideline for safety. The Notice is available in English on <http://www.mhlw.go.jp/english/topics/foodsafety/residue/dl/03.pdf>

b. Revision of MRLs

Residue data on target foods - agricultural products, animal products, or seafood. If new findings on safety and residue of the applied chemical have been obtained after MRLs were established for the chemical, documents on the findings should be submitted. The applicant must have toxicity data, but the submission shall be made upon request of the MHLW.

B. GLP Compliance

In principle, studies mentioned the above "A" should comply with the GLP requirements.

If data are quoted from studies not conducted by the applicant, prior permission should be obtained from the study authors unless they have been publicized in scientific journals.

C. Language

The executive summary should be in Japanese. Other accompanying documents, such as study reports may be written in English. Documents in other languages are not acceptable.

2. Additional Data

If the MHLW determines additional study data as necessary in discussion for the establishment or revision of MRLs, the applicant may be requested to submit them.

3. Other Requirements

The following documents should be submitted.

- ✓ Information on registration/authorization of the substance in other countries*, including country names, food products for which the substance can be applied, and applicable MRLs.
- ✓ The draft MRLs that the applicant proposes to be established, and analytical methods for the chemical residue in foods (e.g., methods to monitor the chemical remaining in marketed foods).

If the chemical residue may be decomposed, migrated, or concentrated in the process of manufacturing or cooking (especially, in cereal grains and oil seeds), the submission of processing data is desirable.

If the registration of the target chemical is revoked overseas or the registration is withdrawn after Japan establishes its MRLs, the applicant should inform them to the MHLW.

Note: Australia, Canada, EU, New Zealand, the US, where the establishment of MRLs is based on toxicity data equivalent to those needed for scientific evaluation by the JMPR or JECFA.

Form 1

Minister of Health and Welfare

Date

Address of applicant
(For a corporation, principal place of business)

Name of applicant
(For a corporation, its name and the representative's name)
Seal

We hereby apply for the establishment of residue standards (MRLs) for the pesticide/veterinary drug/feed additive given below, based on Article 11 of the Food Sanitation Law.

Name of substance

(Notes)

1. Use JIS A4-size paper.
 2. Use black ink (or "SUMI"), and write in clear block letters in English or Japanese.
 3. Give the contact in Japan, if the applicant lives overseas. The seal may be replaced by the applicant's signature.
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Form 2

Date

Minister of Health and Welfare

Address of applicant
(For a corporation, principal place of business)

Name of applicant
(For a corporation, its name and the representative's name)
Seal

We hereby apply for the partial revision of the residue standards (MRLs) for the pesticide/veterinary drug/feed additive given below, based on Article 11 of the Food Sanitation Law.

Name of substance

(Notes)

1. Use JIS A4-size paper.
 2. Use black ink (or "SUMI"), and write in clear block letters in English or Japanese.
 3. Indicate the contact in Japan, if the applicant lives overseas. The seal may be replaced by the applicant's signature.
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