Original: Japanese
Provisional Translation

Attachment on Shokuan No. 0205001, 5 February 2004
(Last revised by Seishoku No. 1030001, 30 October 2019)

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.

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[1] Paragraph 1 of the Food Sanitation Act, 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, Labour and Welfare with Form 1 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
- information on registration/authorization of the substance in the standard reference country*, 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
- Information on proper usage direction of the chemical (e.g., product label).

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

If the applicant is abroad, an appropriate contact person in Japan should be identified to handle the application. The Form should be submitted to Agricultural and Veterinary Chemical Residue Office, Food Safety Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW.

2. Evaluation

The submitted application will first be examined by the Secretariat. Then,

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[1] Article 11 has been amended into Article 13 on 1 June 2020.

the risk assessment on the chemical will be done by the Food Safety Commission (FSC), based on Article 11, Paragraph 1 and Article 24, Paragraph 1, Item 1 of the Food Safety Basic Act. The secretariat will prepare draft MRLs based on the Commission's assessment and take necessary procedures including discussion at the Pharmaceutical Affairs and Food Sanitation Council, the WTO notification and preparation for publication on the establishment or revision of MRLs, based on Article 11 Paragraph 1 of the Food Sanitation Act.

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

3. Withdrawal

In the case of withdrawing the application, the applicant should ask the secretariat to withdraw the application with Form 2.

III. Required Documents

1. Data Sets

The data sets required when applying for the establishment and revision of MRLs are given below A - C. Besides them, other data on safety assessment should be submitted if available. In principle, it is not necessary to submit the documents that have been evaluated by FSC, and these documents can be submitted in response to the secretariat requests.

In the case of requesting the setting of the standard which is identical to Codex standards, in principle, it is not necessary to submit the residue data for the chemical in the agricultural products, livestock products and fishery products.

A. Pesticides

a. Toxicity data

Toxicity data given in "human effect" in "Data Requirements for Registration of Pesticides" - Notification No. 30-shouan-6278[2], 29 March

[2] The notice is available at http://www.acis.famic.go.jp/eng/shinsei/index.htm

2019 by Director-General, Food Safety and Consumer Affairs Bureau, MAFF .

b. Metabolism and residue data

Plant metabolism data and residue data of agricultural crops is given in the notification. For pesticides that are expected to migrate into livestock, should submit the livestock metabolism and residue data.

For the number of testing fields in residue data to agricultural crops, although it is desirable to meet the requirements of the standard reference country, it at least should meet the requirements described by the notification.

Information on the analytical method used in the crop residual studies should be submitted. Regarding the analytical parts of sample used in the crop residual studies, it is desirable to be consistent with the analytical parts described in "Specifications and Standards for Food and Food Additives" (Public Notice No. 370 of Ministry of Health and Welfare, 1965).If the analytical parts of sample differ from those described in the public notice, information such as conversion factor based on food processing studies should be submitted.

In the case of referring MRLs on commodity group, residual studies of the crops based on the setting of the standard in the standard reference country should be submitted.

For pesticides that are expected to migrate into livestock, information on residue data for livestock and Maximum Dietary Burden (MDB) should be submitted.

B. Feed additives

Safety data and residue data is given in the "establishment of evaluation standards for feed additives" - Notification No. 4-Chiku-A-201[3], 16 March 1992 by Director-General of Livestock Industry Bureau and Director-General of Fisheries Agency, MAFF. 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

[3] The Notice is available in English on http://www.mhlw.go.jp/english/topics/foodsafety/residue/dl/02.pdf

Registration of Veterinary Medicinal Products).

C. Veterinary drugs.

Documents according to the guidelines of testing method on toxicity study etc. is given in the attachment 2 to the "practice for legal-related Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices" - Notification No. 12-A-418[4], 31 March 2000 by Director of the National Veterinary Assay Laboratory. These documents can be replaced by documents prepared according to the VICH guideline.

2. GLP Compliance

In principle, studies mentioned the above "1" should comply with the GLP requirements. When GLP certification is not obtained, documents which confirm GLP-comparable accuracy control etc. has been performed should be submitted. If data is 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.

3. Language

The executive summary should be based on pesticide abstract on the notification No. 3012-shouan Nousan-6278 or OECD dossier and should be in Japanese or in English. However, summary on study results on human effect, plant and animal metabolism should be in Japanese only. The summary of residue data also should be submitted separately. When documents are in a language except for Japanese or English, the translation should be attached.

4. Additional Data

If the MHLW judges that additional data or information is necessary for the establishment or revision of MRLs, the applicant may be requested to submit them. If the secretariat requests the applicant to submit the additional data and documents etc., the related data should be submitted

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[4] The Notice is available in English on
http://www.mhlw.go.jp/english/topics/foodsafety/residue/dl/03.pdf

within the deadline. If data is not submitted without reasons, the secretariat may deem that the applicant has withdrawn the application.

5. Other Requirements

If the chemical residue may decompose, decrease, migrate or concentrate in the process of manufacturing or cooking (especially, in cereal grains and oil seeds), the submission of processing data is desirable.

If MRLs are changed or the registration of the target chemical is revoked or withdrawn in the standard reference country during/after Japanese process to establish its MRLs, the applicant should inform them to the secretariat with all the information available.

Form 1

Minister of Health, Labour 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. Write in clear block letters.
3. Give the contact in Japan, if the applicant lives overseas. The seal may be replaced by the applicant's signature.

Form 2

Date

Minister of Health, Labour 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 withdraw the applications 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 (Date of the application)
Name of crop (Reason of withdrawal)

(Notes)
1. Use JIS A4-size paper.
2. Write in clear block letters.
3. Indicate the contact in Japan, if the applicant lives overseas. The seal may be replaced by the applicant's signature.