Original: Japanese
Provisional Translation

Guidelines for Submission of Residue Data of Pesticides Registered Outside of Japan for the Estimation of Maximum Residue Limits in Feeds

(Director-General, Food safety and Consumers Affairs, MAFF, Japan, Notification No. 21-Syouan-11433, 2 February, 2010, Revision Date **:** 13 March, 2018.)

I. Objective

Article 3.1 of the Law Concerning Safety Assurance and Quality Improvement of Feeds (Act No. 35 of 1953; hereinafter referred to as the "Law") stipulates that the Minister of Agriculture, Forestry and Fisheries establishes the Ministerial Ordinance Concerning the Ingredient Standards for Feeds and Feed Additives (Ordinance of MAFF No. 35 of 1971) in order to ensure steady supply and the safety of foods derived from livestock through providing safe feeds. The Ordinance includes maximum residue limits (MRLs) for pesticides in cereal grains and forage/hay (hereinafter referred to as "feed") fed to livestock.

In order to ensure steady supply and the safety of foods derived from livestock, it is necessary to ensure steady supply of safe feeds, not only domestically produced but also imported. To meet this goal, the Ministry of Agriculture, Forestry and Fisheries recently formalized a system for establishing/revising import tolerances in feeding stuffs for pesticides not yet registered in Japan but only registered overseas for use on feed crops to be exported to Japan on a basis of scientific data including those specified under the requirements in the Guidelines.

These Guidelines outline the procedures and requirements for applying for the establishment and/or revision of MRLs in feeds for pesticides. As the requirements for scientific data on each pesticide should be science- and risk-based, and any future scientific developments should be taken into account, these Guidelines show the list of studies commonly required for the establishment of MRLs in feeds. They may be substituted by other study(ies) or assessment(s) that can be regarded as sufficient for estimation of MRLs.

II. Procedures for Establishment and Revision of MRLs in Feeds for Pesticides

1. Application

The Guidelines deal with those active ingredients that are newly registered or in a process of registration for use on feed crops in the United States of America, Canada, Australia, Brazil, Argentine and/or People's Republic of China *

(hereinafter referred to as "Countries").

* Countries considered may be reviewed as necessary.

Any person or company wishing to apply for the establishment/revision of MRLs for active ingredients mentioned above in feeds expected to be exported to Japan, can do so by sending a duly filled Request Form to the Animal Products Safety Division, Food Safety and Consumer Affairs Bureau, MAFF. The Request Form should be addressed to the Director-General of Food Safety and Consumers Affairs. The Request Form should accompany study reports and any other information as required in Section III-1 of the Guidelines.

If the applicant lives abroad, an appropriate contact person in Japan should be identified to deal with the application and any other process afterwards.

2. Estimation of MRLs

The submitted study reports and any other information will be reviewed by responsible officers in the Division for the estimation of an MRL in feed from the following points of view:

(1) Exportation of the feed grown with the application of the active ingredient in question;

(2) Residue concentrations in the feed; and

(3) Residue transfer from the feed to edible tissues of livestock, milk and/or eggs.

If review of the data from points (1)-(3) indicates that no risk management option is necessary, no MRL will be established for the active ingredient in the feed concerned.

If some or significant residues are expected to be found in edible tissues of livestock, milk and or eggs, draft MRLs in these foods derived from livestock will be estimated from the maximum animal burden calculated using the highest residue concentrations in feed and the maximum proportion of agricultural commodities in animal feed; animal metabolism studies; and animal feeding studies. These draft MRLs will be further considered by the Ministry of Health, Labour and Welfare for their inclusion in the so-called “Positive List”.

The Food Safety Commission will conduct risk assessment of the active ingredient in accordance with Article 24.1.5 of the Food Safety Basic Law (Act No. 48 of 2003).

MRLs for feed will be considered by the Agricultural Materials Council in accordance with Article 3.2 of the Law, taking into account the risk assessments.

In response to the Council's report, the Division will take necessary procedures for the establishment of MRLs in feeds, based on Article 3.1 of the Law.

The Food safety Commission and Council may ask for additional studies/information from the applicant if necessary.

III. Required Data

1. Data Required When Applying for Establishment/Revision of MRLs in Feed

The study reports given below are required when applying for the establishment and/or revision of MRLs. Feedingstuffs for which MRLs are to be estimated are listed in the Appendix**.

** The list includes feed crops and their portions that are fed to livestock at significant amounts in Japan. The list may be reviewed as necessary.

<Studies related to feed crops>

(1) Plant Metabolism Studies

Plant metabolism study(ies) on the feed crop(s) to be considered for MRLs should be conducted in accordance with the "Data Requirements for Supporting Registration of Pesticides" (Director-General, Agricultural Production Bureau, MAFF, Japan, Notification No. 12-Nousan-8147, 24 November, 2000. hereinafter referred to as "Notification").

The Notice is available in English at the URL below:
http://www.mhlw.go.jp/english/topics/foodsafety/residue/dl/01.pdf

If there is no study on the concerned feed crop(s), study(ies) on the botanically related crops may be submitted in lieu of the required data after consultation with the Division.

(2) Feed Crop Supervised Residue Trials

Feed crop supervised residue trials should be conducted in accordance with the Notification and in Countries. It is desirable that the supervised residue trials include decline studies.

If a by-product of agricultural commodity is used as feed in Japan, a processing study

should also be conducted.

<Studies on livestock>

(3) Livestock Metabolism Studies

Livestock metabolism study(ies) should be conducted in accordance with OECD Test Guideline 503 “Metabolism in Livestock”.

(4) Livestock Feeding Studies

Livestock Feeding Study(ies) should be conducted in accordance with OECD Test Guideline 505 “Residues in Livestock”.

< Other necessary studies>

(5) Storage Stability Studies

Storage stability study(ies) should be conducted in accordance with OECD Test Guideline 506 “Stability of Pesticide Residues in Stored Commodities”.

(6) Information on Analytical Method(s) for (1)-(5)

Detailed information on analytical method(s) for residues of the active ingredient in the feed crops in question and, if necessary, in foods derived from farm animal shall be submitted.

(7) Toxicity Studies

Toxicity studies (excluding those on toxic effects on aquatic animals and plants, effects on beneficial organisms other than aquatic animals and plants, and study on water contamination) and studies indicating residue situations (excluding study on fate in soil) should be conducted in accordance with the Notification.

(8) Label of the Pesticide Product

The officially approved label(s) or draft label(s) of a product(s) containing the active ingredient that is to be used on a feed crop(s) expected to be exported to Japan shall be submitted. The label or draft label should clearly indicate the approved or planned use pattern of the product.

(9) Information on Registration in the Countries

Information on the registration of the active ingredient in the Countries, e.g., country

name, applicable MRLs in that country, shall be submitted.

2. GLP Compliance

In principle, studies mentioned in Section 1 should be conducted in compliance with the GLP requirements.

If submitted study was not conducted or commissioned by the applicant, prior permission shall be obtained from the study authors unless they have been publicly available in scientific literature.

3. Submission of Study Reports

The monograph of the studies specified in Section 1, (1)-(7) shall be submitted both electronically, e.g., in CD-ROM, and in printed form. The monograph should be in Japanese. However, if it is not possible to submit it in Japanese, the English text may be acceptable upon consultation with the Division.

Individual reports of the studies specified in Section1, (1)-(6) shall be submitted electronically, e.g., in CD-ROM.

The monograph and study reports in languages other than Japanese or English are not acceptable.

IV. Other Requirements

1. Additional Requirements

If the Division determines additional study data are necessary for the establishment or revision of MRLs, the applicant may be requested to submit them.

2. Conditions of Registration in the Countries

If the registration of an active ingredient for which import tolerances have been established in Japan is revoked or withdrawn in the Country(ies), the applicant shall immediately inform the Division of this fact.
For an active ingredient in a process of registration, the applicant shall submit the approved label to the Division immediately after it is approved.

3. Revision or Correction of Data Set

If any of submitted study report or monograph is revised or corrected, the applicant

shall submit the revised/corrected study report or monograph to the Division and a note indicating the revision/correction and the reason thereof.

Request Form

Date

Director-General of Food Safety and Consumers Affairs

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 [revision] of MRLs in feeds for the pesticide given below, in accordance with Article 3.1 of the Law Concerning Safety Assurance and Quality Improvement of Feeds (Act No. 35 of 1953).

Name of substance

(Notes for applicants)

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

Appendix: List of feedstuffs

CROP	FEEDSTUFF
Barley	grain
Brewer's grain	dried
Wheat	grain
Wheat	milled byproducts
Oat	grain
Oat	hay and straw
Rye	grain
Rye	hay and straw
Rice	bran/pollard
Rice	straw
Corn, (field and pop)	grain
Corn gluten	feed
Corn gluten	meal
Corn, field	milled byproducts
Corn, field	hominy meal
Distiller's grain	dried
Beet, sugar	dried pulp
Sorghum, grain	grain
Sorghum, grain	stover
Soybean	seed
Soybean	meal
Soybean	okara
Soybean	hulls
Rape	meal
Palm	kernel meal
Sesame seed	meal
Alfalfa	hay and meal
Vetch	hay
Grass	hay