

Standard office processing period related to establishment of Maximum Residue Limits for Agricultural Chemicals

In establishment of Maximum Residue Limits (MRLs) for Agricultural Chemicals such as pesticides, the Cabinet Office food safety commission has conducted risk assessment for health effects on people. The Ministry of Health, Labor and Welfare has conducted establishment of MRLs based on the evaluation results and so on.

With regard to items requested by the *applicant, the standard office processing period to the setting or revision of MRLs from the notification of the results of food health effects assessment from the Cabinet Office food safety commission, is made as follows.

I. Covered range

MRLs based on the following cases shall be covered;

- i) In case of the requests for the establishment of MRLs of pesticides from the Ministry of Agriculture, Forestry and Fisheries
- ii) In case of the requests of the opinion for veterinary drugs from the Minister of Agriculture, Forestry and Fisheries to the Minister of Health, Labor and Welfare, based on the Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical devices
- iii) In case of the requests of the opinion for feed additives from the Minister of Agriculture, Forestry and Fisheries to the Minister of Health, Labor and Welfare, based on the of the Act on Safety Assurance and Quality Improvement of Feeds law on securing feed safety and improving quality.
- iv) In case of requests for establishment of MRLs based on “Guideline for Application for Establishment and Revision of MRLs for Agricultural Chemicals used outside Japan”.

* Applicant for I-i), I-ii), and I-iii) are Minister of Agriculture, Forestry and Fisheries or Ministry of Agriculture, Forestry and Fisheries. Applicant for I-iv) is the applicant in “Guideline for Application for Establishment and Revision of MRLs for Agricultural Chemicals used outside Japan”.

II. Standard office processing period

We shall attempt to set or revise MRLs concerning the item, within one year from the date of notification of the assessment of food health effect from the Cabinet Office food safety

commission.

III. Calculation of the periods

The periods of time specified in II shall not include the period of time described in the following:

- i) The period to require for the preparation and submission of the additional documents for establishment of MRLs, when Ministry of Health, Labor and Welfare request the applicant to submit additional documents due to deficiencies.
- ii) The period to restart the procedures for establish of MRLs, when the applicant requests the Ministry of Health, Labor and Welfare to suspend the procedures.
- iii) The period of agreement as the exclusion of standard office processing period between the Ministry of Health, Labor and Welfare and the applicant (except i) and ii).

IV. Application Period

Application period shall be applied by the notification of the results of food health effects assessment, from the Food Safety Commission.