

**A Guide to the Proposal for
Addition or Revision of
Maximum Residue Limits (MRLs) and
Extraneous Maximum Residue Limits (EMRLs) and
Addition of Exempted Pesticides under the
Pesticide Residues in Food Regulation (Cap. 132CM)**

**Technical Meeting
20 December 2012**



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Chapter 1

Introduction

Introduction

- ✿ Background
- ✿ The mechanism for handling proposal for revising/adding MRLs/EMRLs and exempted pesticides
- ✿ The Guide
 - ✿ Purpose and disclaimers

Background

- ✿ As new pesticides and new applications on crops keep emerging, the lists of MRLs/EMRLs in Schedule 1 and exempted pesticides in Schedule 2 in the Regulation will be updated by DFEH periodically and as appropriate.

Mechanism for handling proposal for revising/adding MRLs/EMRLs and exempted pesticides (1)

- ✿ Members of the trade expressed concern on whether there will be a channel for them to –
 - ✦ comment on the existing MRLs/EMRLs; and
 - ✦ propose new MRLs/EMRLs and exempted pesticides for inclusion in Schedules 1 and 2 by DFEH.
- ✿ Traders are welcomed to make proposals accompanied by sufficient supporting information to DFEH for consideration.

Mechanism for handling proposal for revising/adding MRLs/EMRLs and exempted pesticides (2)

- ✿ DFEH will consider the proposals on a case-by-case basis and suitably incorporate the proposals received in Schedules 1 and/or 2 in the next updating exercise.

Objectives of the Guide

- ✿ To provide general information and to set out the procedure and essential documentations necessary for submission of proposals for addition or revision of MRLs/EMRLs or addition of exempted pesticides under the Regulation.
- ✿ To provide answers to some of the frequently asked questions.

Disclaimers

- ✿ This Guide is provided for information only. It does not have the force of law and should not be interpreted in any manner which would override the provision of the Regulation. In case of inconsistency, the statutory provisions will prevail. This Guide should not be regarded as legal advice. If you need legal advice, please contact your own lawyer.
- ✿ This Guide is subject to periodic review by DFEH and may be amended or supplemented as necessary from time to time.

Chapter 2

Definitions

Definitions

- ✿ Key terms extracted from the Regulation :
 - ✿ Section 2 – Interpretation; and
- ✿ Other technical terms related to interpretation of the Regulation
 - ✿ e.g., acceptable daily intake (ADI), supervised trials median residue (STMR), etc.

Chapter 3

Submission of Proposal

Submission of Proposal (1)

- ✿ Any person may propose to DFEH:
 - a) to add to Schedule 1, in relation to a food, a MRL/EMRL of a pesticide that is listed in Schedule 1;
 - b) to add to Schedule 1, in relation to a food, a MRL/EMRL of a pesticide that is not listed in Schedule 1;
 - c) to revise a MRL/EMRL listed in Schedule 1; or
 - d) to add a pesticide to Schedule 2.

Submission of Proposal (2)

- ✿ The proponent should state clearly in Part B(2) & B(3) of the proposal form, on which of the items ((a), (b), (c) and/or (d)) above that he/she wishes to make a proposal.
- ✿ Each proposal form should contain proposal(s) on **one pesticide only**.
- ✿ Proposal(s) for additional pesticide(s) should be made on separate proposal form(s).

Submission of Proposal (3)

- ✿ The proposal should be made in the name of a person or a body corporate, and must be made in the specified form at **Appendix I**.
- ✿ The proposal form can also be downloaded from the CFS website or obtained from CFS by writing.

Part I: Proposal of revising/adding MRLs/EMRLs of pesticides already included in Schedule 1

- a) The current or anticipated availability of the food concerned in Hong Kong (e.g., trade data and import statistics, if any)
- b) A description of the food commodity concerned (product name, Codex food code, product of origin, etc.)
- c) Whether the relevant MRL/EMRL of the pesticide-food pair concerned has been established by Codex or any place outside Hong Kong. If applicable, provide the relevant MRL/EMRL, including the residue definition and relevant supporting documents (e.g., decision documents adopted/issued by Codex or other competent authorities)

Part I: Proposal of revising/adding MRLs/EMRLs of pesticides already included in Schedule 1

- d) Data obtained from relevant supervised trials, particularly those related to the establishment of the MRL/EMRL or exemption from the MRL/EMRL establishment, including the Highest Residue (HR), the Supervised Trials Median Residue (STMR), etc.

- e) Reports of relevant food processing studies if available, including known or published processing factors for the pesticide concerned, e.g., after washing, peeling, juicing, cooking, etc.

Part I: Proposal of revising/adding MRLs/EMRLs of pesticides already included in Schedule 1

- f) Analytical methods of the pesticide residues concerned, the associated method validation data and source of related reference standards —
- ⊕ For those pesticides with MRLs listed under the Regulation, the submission of specific analytical method is still needed as the residue definition or the food matrices involved may not be the same
 - ⊕ If the same analytical method is used for analysis of the pesticide with the same residue definition in different crops, the analytical method should be submitted with a list of the crops it is applicable
 - ⊕ The crop residue analysis report should include, but not limited to: information of the analytes (including CAS numbers), applicable foods (and food portions analysed), principle and limitation of the method, reagent and apparatus required, sample preparation and cleanup procedure, instrumentation parameters, calibration method, limit of quantitation (LOQ) and quality control requirements as well as method validation data including precision and recovery

Part II: Proposal of adding MRLs/EMRLs of pesticides NOT included in Schedule 1

Information required in addition to those listed in Part I:

- a) A description of the pesticide concerned, including but not limiting to the following —
- ✦ identity (common/ chemical/ trade names; physical and chemical properties, etc.)
 - ✦ intended use (herbicide, fungicide, insecticide, etc.)
 - ✦ applicable types of crops and agricultural commodities (e.g., cereals, fruits, vegetables, etc.)
 - ✦ use pattern (amount, frequency and time of application presented in Good Agricultural Practice (GAP))

Part II: Proposal of adding MRLs/EMRLs of pesticides NOT included in Schedule 1

- b) Toxicological profile of the pesticide concerned, including but not limiting to the following —
- ✦ summary of the toxicological studies being reviewed
 - ✦ the critical toxicological endpoint(s) of concern identified, the safety factors applied during the derivation of safety reference values, and the safety reference values (including acceptable daily intake and/or acute reference dose, where appropriate, established by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) or competent authorities)
- c) Analytical methods —
- ✦ the source and availability of reference standards, including the parent and metabolites as stated in the residues definition. Two independent sources with contact details of the suppliers, such as address, website, contact numbers and email address, are preferable

Part III: Proposal of adding exempted pesticides to Schedule 2

Information required in addition to those listed in Part I and Part II, as appropriate:

- a) For proposal of exempted pesticide, information on whether the pesticide concerned has been allowed to be used in food by any place outside Hong Kong without any limit on the amount of the concentration of its residue should be provided, together with relevant supporting documents (e.g., decision documents adopted/ issued by the competent authorities)

Submission of Proposal (4)

- ✿ The completed proposal form, together with the required documentation and checklist (Appendix II), can be submitted in person/ by mail/ by email/ by facsimile.
- ✿ No fee is required for submission of a proposal .
- ✿ Acknowledgement of receipt will be issued via post or e-mail to the proponent in 10 calendar days.

Chapter 4

Enquiries

Enquiries

Risk Assessment Section,
Centre for Food Safety

Address: 43/F, Queensway Government Offices,
66 Queensway, Hong Kong

Telephone no.: (852) 2867 5699

Facsimile: (852) 2893 3547

Email: To be confirmed

Chapter 5

Frequently Asked Questions

Appendices

- ✿ I : Proposal form
- ✿ II: Checklist of Documents to be Submitted

Way Forward

- ✿ The draft guidelines can be downloaded from the website of CFS:

http://www.cfs.gov.hk/english/whatsnew/whatsnew_fstr/whatsnew_fstr_21_Pesticide.html

- ✿ Please send your comments/suggestion on the draft guidelines are welcome before 31 January 2013

- ✿ Email: ra_admin@fehd.gov.hk

- ✿ Fax: (852) 2893 3547

End