Draft 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)

Centre for Food Safety
Food and Environmental Hygiene Department
December 2012
Draft Guidelines for Technical Meeting with Trade on 20 December 2012.  
Subject to further revision.

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CHAPTER 1 INTRODUCTION

Background

1.1 The Pesticide Residues in Food Regulation (Cap. 132CM) (“the Regulation”), passed by the Legislative Council in June 2012, will come into operation and be enforced by the Food and Environmental Hygiene Department (FEHD) on 1 August 2014 after a grace period of about two years.

1.2 Schedule 1 of the Regulation sets out a list of maximum residue limits (MRLs)/ extraneous maximum residue limits (EMRLs) for specified pesticide-food pairs. The presence of any pesticide residues in food exceeding the specified MRLs/EMRLs is not permitted under the Regulation.

1.3 Schedule 2 of the Regulation sets out a list of exempted pesticides that are natural and the residues of which are identical to or indistinguishable from natural food components. These pesticides and their residues in food are exempted from the requirement of having a MRL in food under the Regulation.

1.4 With regard to a food containing pesticide residues with no specified MRLs/EMRLs in Schedule 1, the general principle is that except for exempted pesticides, import and sale is only allowed if the consumption of the food concerned is not dangerous or prejudicial to health. In deciding whether the consumption of the food concerned is dangerous or prejudicial to health, the Director of Food and Environmental Hygiene (DFEH) will conduct risk assessment taking into account the local food consumption patterns and other factors.

1.5 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 DEFH periodically and as appropriate.
The mechanism for handling proposal for revising/adding MRLs/EMRLs and exempted pesticides

1.6 Members of the trade have expressed concern on whether there will be a channel for them to comment on the existing MRLs/EMRLs, and to propose new MRLs/EMRLs and exempted pesticides for inclusion in Schedules 1 and 2 by DFEH. To this end, traders are welcomed to make proposals accompanied by sufficient supporting information to DFEH for consideration.

1.7 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, taking into account the latest international developments, consistency with the existing list, availability of relevant supporting information and reference materials for testing, and whether the limits concerned have passed the scrutiny of risk assessment based on the local food consumption patterns.

The Guide

1.8 This 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 (the Guide) is issued by the Centre for Food Safety (CFS) of the FEHD. It aims 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. It also provides answers to some of the frequently asked questions.

1.9 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.

1.10 This Guide is subject to periodic review by DFEH and may be amended or supplemented as necessary from time to time.
CHAPTER 2 DEFINITIONS

2.1 The followings are definitions of some technical terms which are useful and applicable to this Guide –

“Acceptable daily intake (ADI)” of a chemical is an estimate of the amount of a substance in food and/or drinking-water, expressed on a body-weight basis, that can be ingested daily over a lifetime without appreciable health risk to the consumer on the basis of all the known facts at the time of the evaluation. It is expressed in milligrams of the chemical per kilogram of body weight.

“Acute reference dose (ARfD)” of a chemical is an estimate of the amount of a substance in food and/or drinking-water, expressed on a body-weight basis, that can be ingested in a period of 24 hours or less without appreciable health risk to the consumer on the basis of all known facts at the time of the evaluation. It is expressed in milligrams of the chemical per kilogram of body weight.

“Aquatic products” means any product derived from any edible part of any aquatic organism, including—
(a) fish;
(b) fish roe;
(c) edible offal of fish;
(d) crustacean;
(e) mollusc (including cephalopod); and
(f) any other aquatic invertebrate animal, but does not include an amphibian, marine mammal or reptile.

“Codex Alimentarius Commission” means the body created in 1963 by the World Health Organization and the Food and Agriculture Organization to develop food standards, guidelines and related texts.

“Exempted pesticides” are substances falling under the definition of pesticide and meet one of the following criteria:
(a) the use of the pesticides does not result in residues occurring in food;
(b) the residues are identical to or indistinguishable from natural food
components; or
(c) the residues are of no toxicological significance or will not be dangerous or prejudicial to human health.

“Extraneous Maximum Residue Limits (EMRL)” means a pesticide residue arising from environmental sources (including former agricultural uses) other than the use of a pesticide directly or indirectly on the commodity, the maximum concentration of which is to be legally permitted (expressed as mg/kg) in food commodities.

“Food” includes—
(a) drink;
(b) ice;
(c) chewing gum and other products of a similar nature and use;
(d) smokeless tobacco products; and
(e) articles and substances used as ingredients in the preparation of food, but does not include—
(f) live animals or live birds, other than live aquatic products;
(g) fodder or feeding stuffs for animals, birds or aquatic products; or
(h) medicine as defined by section 2(1) of the Pharmacy and Poisons Ordinance (Cap. 138) or Chinese herbal medicine or proprietary Chinese medicine as defined by section 2(1) of the Chinese Medicine Ordinance (Cap. 549).

“Good Agricultural Practice (GAP)” in the use of pesticides includes the nationally authorised safe uses of pesticides under actual conditions necessary for effective and reliable pest control. It encompasses a range of levels of pesticide applications up to the highest authorised use, applied in a manner which leaves a residue which is the smallest amount practicable.

• Authorised safe uses are determined at the national level and include nationally registered or recommended uses, which takes into account public and occupational health and environmental safety considerations.

• Actual conditions include any stage in the production, storage,
transport, distribution and processing of food commodities and animal feed.

“Highest residue (HR)” is the highest residue level (expressed as mg/kg) in a composite sample of the edible portion of a food commodity when a pesticide has been used according to maximum GAP conditions. The HR is estimated as the highest of the residue values (one from each trial) from supervised trials conducted according to the maximum GAP conditions, and includes residue components defined for estimation of dietary intake.

“Highest residue – processed (HR-P)” is the highest residue in a processed commodities calculated by multiplying the HR of the raw agricultural commodity by the corresponding processing factor.

“Maximum Residue Limit (MRL)” means the maximum concentration of a pesticide residue (expressed as mg/kg) to be legally permitted in food commodities.

“Pesticide” means—
(a) any substance intended for preventing, destroying, attracting, repelling or controlling any pest (including any unwanted species of plants, animals, birds or aquatic products) during the production, storage, transport, distribution or processing of—
   (i) food, agricultural commodities; or
   (ii) fodder or feeding stuffs for animals, birds, or aquatic products;
(b) any substance which may be administered to animals, birds or aquatic products for the control of ectoparasities;
(c) any substance intended for use as a plant growth regulator, defoliant, desiccant, fruit thinning agent or sprouting inhibitor; and
(d) any substance applied to crops before or after harvest to protect them from deterioration during storage or transport, but does not include—
   (e) fertilizers;
   (f) nutrients for plants, animals, birds, aquatic products;
   (g) food additives; or
(h) drugs for animals, birds, or aquatic products.

“Pesticide residue” means any substance present in food resulting from the use of pesticide, and includes any derivatives and impurities of toxicological significance.

“Primary food commodity” means a product in, or nearly in, its natural state that—
(a) is intended for processing into food for sale; or
(b) can serve as food without further processing.

“Processing factor” for a specified pesticide residue, commodity and food process is the residue level in the processed product divided by the residue level in the starting commodity, usually a raw agricultural commodity.

“Processed food” means the product, resulting from the application of physical, chemical or biological processes to a “primary food commodity” intended for direct sale to the consumer, for direct use as an ingredient in the manufacture of food or for further processing. “Primary food commodities” treated with ionizing radiation, washed, sorted or submitted to similar treatment are not considered to be “processed foods”.

“Residue definition (for compliance with MRLs)”, in relation to a pesticide, means the combination of the pesticide and its derivatives or related compounds to which the MRL applies.

“Residue definition (for estimation of dietary intake)”, in relation to a pesticide, means the combination of the pesticide, and its metabolites, impurities and degradation products to which the STMR and HR apply.

“Safety reference values” are established by international bodies (e.g. JMPR) and national authorities to ensure the safety of pesticide residue in food. The ADI and ARfD are two commonly used safety reference values for assessing the risk of chronic and acute adverse health effects of pesticide residues, respectively.
“Supervised trials” for estimating MRLs are scientific studies in which pesticides are applied to crops or animals according to specified conditions intended to reflect commercial practice after which harvested crops or tissues of slaughtered animals are analysed for pesticide residues. Usually specified conditions are those which approximate existing or proposed GAP.

“Supervised trials median residue (STMR)” is the expected residue level (expressed as mg/kg) in the edible portion of a food commodity when a pesticide has been used according to maximum GAP conditions. The STMR is estimated as the median of the residue values (one from each trial) from supervised trials conducted according to maximum GAP conditions.

“Supervised trials median residue – processed (STMR-P)” is the expected residue in a processed commodity calculated by multiplying the STMR of the raw agricultural commodity by the corresponding processing factor.
CHAPTER 3 SUBMISSION OF PROPOSAL

3.1 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.

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).

3.2 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 (to be added), or obtained from—

Risk Assessment Section,
Centre for Food Safety,
Queensway Government Offices,
66 Queensway,
Hong Kong

Documentation and information required

3.3 Every section on the proposal form must be completed, with relevant supporting information and documentation as detailed below —

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)

(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.

(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))

(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).

3.4 A checklist of documentation required to be submitted with the proposal is provided at **Appendix II**.

**Submission of proposal**

3.5 The completed proposal form, together with the required documentation as specified in paragraph 3.3 and checklist at **Appendix II**, can be submitted in person/ by mail/ by email/ by facsimile to —

Risk Assessment Section,
Centre for Food Safety,
Queensway Government Offices,
66 Queensway,
Hong Kong

Facsimile: (852) 2893 3547
Email: *(to be added)*

3.6 No fee is required for submission of a proposal.

3.7 Acknowledgement of receipt will be issued via post or e-mail to the proponent in 10 calendar days.
CHAPTER 4  ENQUIRIES

4.1  Enquiry related to the submission of proposal may be addressed to —

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 added)
CHAPTER 5  FREQUENTLY ASKED QUESTIONS

5.1 How to obtain relevant food consumption data in Hong Kong if the proponent would like to conduct preliminary risk assessment on the proposed MRLs/EMRLs?

The Food and Environmental Hygiene Department (FEHD) has conducted Hong Kong's largest scale and most comprehensive food consumption survey for collecting information on food consumption patterns of the general public. Such information provides useful data for the evaluation of potential risks associated with food. Details of the survey can be found at the following website: http://www.cfs.gov.hk/english/programme/programme_firm/programme_fcs.html

The trade may also refer to the GEMS/Food Consumption Cluster Diets for a rough estimate of the consumption pattern of different food commodities. The GEMS/Food Consumption Cluster Diets data is available at the following website: http://www.who.int/foodsafety/chem/gems/en/index1.html

5.2 Will a fee be charged for submitting a proposal to DFEH for adding a new MRL/EMRL or revising an existing MRL/EMRL, or adding an exempted pesticide in Schedules 1 and 2 to the Regulation?

No fee is required for submitting a proposal to DFEH for adding a new MRL/EMRL or revising an existing MRL/EMRL, or adding an exempted pesticide in Schedules 1 and 2 to the Regulation.

5.3 Is it necessary to submit separate proposals for the same pesticide with more than one pesticide-food pair?

For proposal on MRLs concerning the same pesticide with more than one pesticide-food pair, submission of only one proposal suffices. For example, if the proponent wishes to suggest revising the MRLs of cyhalothrin in rice and plums, the proponent may submit the two proposed MRLs on just one proposal form.
However, for proposals concerning more than one pesticide or exempted pesticide, separate proposal forms should be submitted, one for each additional pesticide/exempted pesticide.

5.4 What type of technical documents and data are required for submitting a proposal?

The documentation required is specified in Section 3.3 of the Guideline for Submission of a MRL/EMRL or Exempted Pesticide Proposal. However, there have been concerns on whether the food trade or importers who are interested in submitting proposal of a new MRL/EMRL or exempted pesticide would possess all the information required, especially proprietary data such as supervised trial data which are often generated and owned by pesticide companies. Such information is desirable but not essential, except for establishing a brand new MRL/EMRL currently not in force anywhere in the world. If the concerned MRL/EMRL or exempted pesticide has already been adopted by Codex or is currently in force in other places, the food trade or importers may provide relevant evaluation reports from the Joint Food and Agriculture Organization/World Health Organization Meeting on Pesticide residues (JMPR) or the concerned competent authorities to support the proposal in lieu of the original toxicological and field-trial data.

5.5 How long will it take for the proponent to be informed of the result of his proposal?

DFEH will consider the proposals on a case-by-case basis and suitably incorporate the proposals received in the next updating exercise of Schedules 1 and 2, taking into account the latest international developments, consistency with the existing list, availability of relevant supporting information and reference materials for testing, and whether the limits concerned could pass the risk assessment.

5.6 Will FEHD also accept overseas proposals?

FEHD will accept and handle overseas proposals in the same way as the local ones.
5.7 Which office will be responsible for receiving and handling the proposal and who should the proponent contact for further information?

The Risk Assessment Section of CFS will be responsible for receiving and handling the proposals. Any enquiries could be addressed to:

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 added)

5.8 Is there any provision for appeal in the event that DFEH decides not to accept the proposal?

DFEH will assess each proposal based on the statutory guidelines and objective scientific analysis, with the aim to ensure food safety and protect public health. The decision of DFEH is therefore considered final and no appeal mechanism is provided.

5.9 Are there any other guidelines relating to the Regulation published by FEHD?

Other than this guide on proposal for revising/ adding MRLs/EMRLs and adding exempted pesticides, FEHD will also issue a guidance document on food classification specifying the necessary information of food classification which is applicable to the Regulation, as well as an user guidelines in related to the interpretation of the Regulation.
In addition, you may obtain the full version of the Regulation at the following link [to be added].

Centre for Food Safety
Food and Environmental Hygiene Department
December 2012
Proposal for addition or revision of maximum residue limit (MRL) / extraneous maximum residue limit (EMRL) / addition of an exempted pesticide under the Pesticide Resides in Food Regulation (Cap. 132CM)

Notice to Submission of Proposal

(1) You are advised to read the provisions to the Pesticide Resides in Food Regulation, Cap. 132CM and the information in this Guide before completing this proposal form.

(2) Please notify this office as soon as possible should there be any change of information provided in the proposal (including contact information).

(3) It will be an offence if a person provides information or a document that the person knows is a false or recklessly provides information or a document that is false.

(4) Please keep a copy of this completed proposal form for future reference.
## Part A 
### (Please fill in Part A(1) if submission is made by a Body Corporate)

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<td>Name of Authorised Person:</td>
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<td>Business Registration No. (for body corporate registered in Hong Kong):</td>
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<td>Office Address:</td>
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<td>Telephone No.:</td>
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### (Please fill in Part A(2) if submission is made by an Individual)

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## Part (2) A(2)

### 聯絡人資料

**Particulars of Contact Person**

Please provide details of a contact person for future contact purpose. No need to complete if information is the same as in Part A.

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<tr>
<th>中文姓名</th>
<th>Name in Chinese</th>
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<td>地址</td>
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## Part (3) A(3)

### 通訊語言選擇

**Choice of Correspondence Language**

Please tick the appropriate box.

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<th>I would use Chinese for my future correspondence.</th>
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<td>本人以英文為日後的通訊語言。</td>
<td>I would use English for my future correspondence.</td>
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### 乙部(1) Part B(1)

**Purpose of Submission of Proposal**

**For the Trade Meeting on 20 December 2012. Subject to further revision.**

**Please state the purpose of submission of proposal**

(Example: for importation of a specific food item for sale)

*If necessary, please provide the above information in separate sheets with supporting documents attached when necessary.*

---

### 乙部(2) Part B(2)

**Proposal for change of**

(Please tick in one box only.)

- [ ] Add to Schedule 1 a MRL or EMRL of the pesticides residues of a pesticide that is listed in Schedule 1 in relation to a food

- [ ] Add to Schedule 1 a MRL or EMRL of the pesticides residues of a pesticide that is not listed in Schedule 1 in relation to a food

- [ ] Revise a MRL or EMRL listed in Schedule 1

- [ ] Add an exempted pesticide to Schedule 2
<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Residue Definition</th>
<th>Description of Food</th>
<th>Current Maximum Residue Limit (MRL) (mg/kg)</th>
<th>Proposed Maximum Residue Limit (MRL) (mg/kg)</th>
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Draft Guidelines for Technical Meeting with Trade on 20 December 2012.
Subject to further revision.

| Description of proposed pesticide |

| Schedule 2, Proposed Exempted Pesticide |

| Common name of pesticide (ISO or BSI) |

| Chemical name(s) (IUPAC) |

| Type of pesticide (e.g. insecticide) |

| Place where the pesticide is registered |

| Usage of pesticide (e.g. corn) |

| Other information |

### 部分(1) Part C(1)

**Particulars of the Pesticide**

(請以英文及中文提供所需資料，如適用)

(Please provide information in English and Chinese, if applicable)

### 部分(2) Part C(2)

**Particulars of Food Commodity concerned**

(請以英文及中文提供所需資料，如適用)

(Please provide information in English and Chinese, if applicable)

Note: For proposal of new exempted pesticide, please skip this Part.

### 註釋

BSI = British Standards Institution

ISO = International Standardization Organization

IUPAC = International Union of Pure and Applied Chemistry

**Note:** If the proposal includes a new exempted pesticide, please skip this part.
### Part D

#### Technical Information of the Pesticide and Food-pair concerned

(The proponent shall provide the following **mandatory** information in separate sheets with supporting literature)

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<tr>
<td>Item No.</td>
<td>Description of Information</td>
</tr>
</tbody>
</table>
| 1 | 現時或預計有關食品在本港市面供應的情況  
The current or anticipated availability of the food concerned in Hong Kong |
| 2 | 有關除害劑的相關毒性數據和安全參考值  
The toxicological data and safety reference values of the pesticide concerned |
| 3 | 由受監督田間試驗所得的除害劑殘餘數據  
Residue data obtained from supervised trials on crops |
| 4 | 除害劑的分析方法和是否有可供使用的分析參考標準  
The analytical methods of the pesticide residues concerned and the information on availability of analytical reference standards |
| 5 | 食品法典委員會或海外司法管轄區是否已就有關除害劑制定最高殘餘限量或最高再殘餘限量  
Whether the relevant MRL or EMRL of the pesticide residues concerned have been established by the Codex Alimentarius Commission or jurisdiction outside Hong Kong, if applicable |
| 6 | 海外司法管轄區是否豁免就有關除害劑制定最高殘餘限量  
Whether the pesticide concerned has been allowed to be used in food without any limit on the amount of the concentration of its residue being imposed by any jurisdiction outside Hong Kong, if applicable |
| 7 | 其他相關資料  
(例如除害劑加工及處理研究報告)  
Other related information  
(e.g. results of processing studies of the pesticides) |
Part E(1)

請注意：戊部(1)只適用於公司及合夥申請，如屬個人申請，請填寫戊部(2)。

Attention: Part E(1) is applicable to body corporate and partnership. If the applicant is an individual, please complete Part E(2).

聲明 Declaration

本人

（中文正楷）

(English Name in Block Letters)

香港身份證/其他身份證明文件號碼

Hong Kong Identity Card/Other Proof of Identity No.

□

受

Proprietor

董事

Director

獲正式授權的負責人

Responsible person duly authorised by the Company

現謹此作出以下聲明：

of the above business and hereby declare that:

本人獲正式授權代表上述公司/合夥提出此項申請和作出聲明，並完全明白表格夾附的《用途聲明》。

I am duly authorised to make this proposal and declaration on behalf of the above-named body corporate/partnership and fully understand the “Statement of Purpose” as attached.

(a)

本人聲明，盡本人所知所信，根據本建議書表格中所提供的資料，包括夾附所有文獻中的資料，皆為完整及真確。

(b)

I declare that the information provided under this proposal form is, including those in the supporting literatures, to the best of my knowledge and belief, true and complete.

署名：

Signature: ____________________________

職銜：

Position held: ____________________________

公司印章：

Company Chop: ____________________________

(適用於公司申請 applicable to body corporate)

日期 Date: ____________________________

□ 請在適當的方格內填上「 ✔」號。 Please tick the appropriate box.
Draft Guidelines for Technical Meeting with Trade on 20 December 2012.
Subject to further revision.

Part E(2)

Attention: Part E(2) is applicable to individual application. If the applicant is a body corporate and partnership, please complete Part E(1).

聲明 Declaration

本人

(中文姓名)

(English Name in Block Letters)

香港身份證/其他身份證明文件號碼

Hong Kong Identity Card/Other Proof of Identity No.

I hereby declare that:

(a) 本人提出此項申請和作出聲明，並完全明白表格所附的《用途聲明》。

I make this proposal and declaration and fully understand the “Statement of Purpose” as attached.

(b) 本人聲明，盡本人所知所信，根據本建議書表格中所提供的資料，包括附有所有文獻中的資料，皆為完整及真確。

I declare that the information provided under this proposal form is, including those in the supporting literatures, to the best of my knowledge and belief, true and complete.

簽署：

Signature: ____________________________

申請人姓名：

Name of the Applicant: ____________________________

日期：

Date: ____________________________
Statement of Purpose

(under the Personal Data (Privacy) Ordinance)

Purpose of Collection

1. The personal data you provide are mainly for use within this Department but they may also be disclosed to other Government bureaux and departments or other parties (including the general public) for the purposes mentioned in paragraph 1 above. Apart from this, the personal data may only be disclosed to those parties where you have given prior consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance.

Classes of Transferees

2. You have a right of access and correction with respect to personal data as provided for in Sections 18 and 22 and Principle 6 of Schedule 1 to the Personal Data (Privacy) Ordinance. Your right of access includes the right to obtain a copy of your personal data. A fee may be imposed for complying with a data access request.

Enquiries

4. Enquiries concerning the personal data provided, including making requests for access and corrections, should be addressed to:

Risk Assessment Section
Centre for Food Safety, Food and Environmental Hygiene Department
43/F, Queensway Government Offices, 66 Queensway, Hong Kong
Tel. No.: 2867 5699
Draft Guidelines for Technical Meeting with Trade on 20 December 2012.
Subject to further revision.

<table>
<thead>
<tr>
<th>Checklist of documents to be submitted for the proposal for addition or revision of maximum residue limit (MRL)/extraneous maximum residue limit (EMRL)/addition of an exempted pesticide</th>
<th>Provided</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A Proposal Form &amp; Checklist</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A1 One set of duly completed and signed proposal form (Proposal for addition or revision of maximum residue limit (MRL)/extraneous maximum residue limit (EMRL)/addition of an exempted pesticide)</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>A2 This checklist duly completed</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td><strong>B Technical information concerning the proposal</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Part I: Proposal of revising/adding MRLs/EMRLs of pesticides already included in Schedule 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B1 The purpose of the proposal (e.g. for importation of a specific food item)</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>B2 The current or anticipated availability of the food concerned in Hong Kong (e.g. trade data and import statistics, if any)</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>B3 A description of the food commodity concerned (product name, Codex food code, product of origin, etc.)</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>B4 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)</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>B5 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.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>B6 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.</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
| B7 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 | ☐ | ☐ |
Checklist of documents to be submitted for the proposal for addition or revision of maximum residue limit (MRL)/extraneous maximum residue limit (EMRL)/addition of an exempted pesticide

- 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:

<table>
<thead>
<tr>
<th>B8</th>
<th>A description of the pesticide concerned, including but not limiting to the following —</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>identity (common/chemical/trade names; physical and chemical properties, etc.)</td>
</tr>
<tr>
<td></td>
<td>intended use (herbicide, fungicide, insecticide, etc.)</td>
</tr>
<tr>
<td></td>
<td>applicable types of crops and agricultural commodities (e.g. cereals, fruits, vegetables etc.)</td>
</tr>
<tr>
<td></td>
<td>use pattern (amount, frequency and time of application presented in Good Agricultural Practice (GAP))</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B9</th>
<th>Toxicological profile of the pesticide concerned, including but not limiting to the following —</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>summary of the toxicological studies being reviewed</td>
</tr>
<tr>
<td></td>
<td>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)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B10</th>
<th>Analytical methods —</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>the source and availability of reference standards, including the parent and metabolites as stated in the residues definition, are also required. Two independent sources with contact details of the suppliers, such as address, website, contact numbers and email address, are preferable</td>
</tr>
</tbody>
</table>

### 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:

| B11 | 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) |

Please ✓ in only one box for each item:

- Provided
- Not Applicable