

**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)**

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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.

1.2 Schedule 1 to 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 to the Regulation sets out a list of exempted pesticides. 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 or sale is only allowed if the consumption of the food concerned is not dangerous or prejudicial to health.

1.5 As new pesticides and new applications on crops keep emerging, the list of MRLs/EMRLs in Schedule 1 and the list of exempted pesticides in Schedule 2 to the Regulation will be updated by the Director of Food and Environmental Hygiene (DFEH) 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 The 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 procedures 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 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 provision 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 relevant 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 take 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 ectoparasites;
- (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”, also known as health-based guidance values, are established by international bodies (e.g., The Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Meeting on Pesticide residues (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) and 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 (<http://www.cfs.gov.hk>), 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 *in duplicates* (preferably in electronic format, hard copies may be requested when necessary) 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.
 - For proposals related to group MRL/EMRL, or MRL/EMRL for a minor crop, proponents should follow the latest recommendations from the Food and Agriculture Organization of the United Nation (FAO) or Codex in providing data on the representative commodity
- (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 Chemical Abstract Service (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 the 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 JMPR or other competent authorities)
- (c) Analytical methods —
 - the source and availability of reference materials, 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 number(s) 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 *in duplicates* (preferably in electronic format, hard copies may be requested when necessary) 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: pesticide_proposal@fehd.gov.hk

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: pesticide_proposal@fehd.gov.hk

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 website of CFS (<http://www.cfs.gov.hk>).

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 form 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 using 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 technical documents and data are required for submitting a proposal?

The documentation required is specified in Section 3.3 of the Guide. 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 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 incorporate suitable 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 scrutiny of 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: pesticide_proposal@fehd.gov.hk

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 has also issued user guidelines in related to the interpretation of the Regulation, as well as guidelines on food classification specifying the necessary information of food classification which is applicable to the Regulation.

In addition, you may obtain the full version of the Regulation at the website of the Bilingual Laws Information System operated by the Department of Justice (<http://www.legislation.gov.hk>).



請將建議表格連同有關文件送交：

香港金鐘道66號
金鐘道政府合署43樓
食物環境衛生署
食物安全中心
電話號碼：2867 5699
傳真號碼：2893 3547
電郵地址：pesticide_proposal@fehd.gov.hk

Please send the proposal form together with relevant documents to :

Centre for Food Safety
Food and Environmental Hygiene Department
43/F Queensway Government Offices,
66 Queensway, Hong Kong
Tel. No. : 2867 5699
Fax No. : 2893 3547
Email address : pesticide_proposal@fehd.gov.hk

《食物內除害劑殘餘規例》(第 132CM 章) 中
增加或修訂最高殘餘限量 / 最高再殘餘限量 / 增加獲豁免除害劑的建議書
Proposal for addition or revision of maximum residue limit (MRL)/
extraneous maximum residue limit (EMRL)/ addition of an exempted pesticide under the
Pesticide Residues in Food Regulation (Cap. 132CM)

提交建議書須知 Notice to Submission of Proposal	
(1)	在填寫本建議表格前，請參閱《食物內除害劑殘餘規例》(第 132CM 章)各項條文及本《指引》的資料。 You are advised to read the provisions of the Pesticide Residues in Food Regulation, Cap. 132CM and the information in this Guide before completing this proposal form.
(2)	如建議書內提供的資料(包括聯絡資料)有所變更，請盡快通知本辦事處。 Please notify this office as soon as possible should there be any change of information provided in the proposal (including contact information).
(3)	任何人提供明知失實的資料或文件或罔顧實情地提供失實的資料或文件，即屬犯罪。 It will be an offence if a person provides information or a document that the person knows is false or recklessly provides information or a document that is false.
(4)	請保留已填妥的建議表格副本，以供日後參考。 Please keep a copy of this completed proposal form for future reference.

甲部 <u>Part A</u> <p style="text-align: center;">提交建議人士/公司資料 Particulars of Person/Company Submitting the Proposal</p>	
甲部(1) Part A(1) (如由公司提交建議，請填寫甲部(1)) (Please fill in Part A(1) if submission is made by a Body Corporate)	
公司名稱(中文)： Name of Corporation in Chinese:	
公司名稱(英文)： Name of Corporation in English:	
獲授權人姓名(中文)： Name of Authorised Person in Chinese:	獲授權人姓名(英文)： Name of Authorised Person in English:
商業登記號碼(如為香港登記的公司)： Business Registration No. (for body corporate registered in Hong Kong):	
辦事處地址(中文)： Office Address in Chinese:	
辦事處地址(英文)： Office Address in English:	
電話號碼： Telephone No.:	傳真號碼： Fax. No.:
電郵地址： Email Address:	
甲部(2) Part A(2) (如由個人提交建議，請填寫甲部(2)) (Please fill in Part A(2) if submission is made by an Individual)	
中文姓名： Name in Chinese:	
英文姓名： Name in English:	
香港身份證 / 其他身份證明文件號碼 (如適用)： Hong Kong Identity Card/Other Proof of Identity No. (if applicable):	
通信地址(中文)： Correspondence Address in Chinese:	
通信地址(英文)： Correspondence Address in English:	
電話號碼： Telephone No.:	傳真號碼： Fax. No.:
電郵地址： Email Address:	

甲部(3) Part A(3)

聯絡人資料

Particulars of Contact Person

(請提供一位聯絡人的詳細資料，以作將來聯絡用途。如與甲部(1)資料相同，則無須填寫。)

Please provide details of a contact person for future contact purpose. You are not required to complete this part if the information is the same as that in Part A(1).

中文姓名：

Name in Chinese:

英文姓名：

Name in English:

電話號碼：

Telephone No.:

流動電話號碼：

Mobile Phone No.:

辦事處地址(中文)：

Office Address in Chinese:

辦事處地址(英文)：

Office Address in English:

傳真號碼：

Fax No.:

電郵地址：

Email Address:

甲部(4) Part A(4)

通訊語言選擇

Choice of Correspondence Language

(請在適當方格內加上「✓」號。)(Please tick the appropriate box.)

本人擬以

I would use

☐

中文

Chinese

☐

英文

English

為日後的通訊語言。

for my future correspondence.

<p>乙部(1) Part B(1)</p> <p style="text-align: center;">提交建議書的目的 Purpose of Submission of Proposal</p>
<p>請說明提交建議書的目的 (例如進口某食品以供出售)</p> <p>Please state the purpose of submission of proposal (e.g., for importation of a specific food item for sale)</p> <p>如有需要，請另紙提供上述資料，並一併提交所需佐證文件。 Please provide the above information in separate sheets with supporting documents attached when necessary.</p>
<p>乙部(2) Part B(2)</p> <p style="text-align: center;">建議更改項目 Proposal for change (只限在一個方格內加上「✓」號。)(Please tick in one box only.)</p>
<p>依據《食物內除害劑殘餘規例》(第 132CM 章)， Pursuant to the Pesticide Residues in Food Regulation, Cap. 132CM,</p>
<p><input type="checkbox"/> (a) 於附表 1 中為附表 1 所列的除害劑增加關乎某食物的除害劑殘餘最高殘餘限量/最高再殘餘限量 to add to Schedule 1 an MRL/EMRL of the pesticide residues of a pesticide that is listed in Schedule 1 in relation to a food</p>
<p><input type="checkbox"/> (b) 於附表 1 中為附表 1 沒有列出的除害劑增加關乎某食物的除害劑殘餘最高殘餘限量/最高再殘餘限量 to add to Schedule 1 an MRL/EMRL of the pesticide residues of a pesticide that is not listed in Schedule 1 in relation to a food</p>
<p><input type="checkbox"/> (c) 修訂附表 1 所列的最高殘餘限量/最高再殘餘限量 to revise an MRL/EMRL listed in Schedule 1</p>
<p><input type="checkbox"/> (d) 於附表 2 中增加獲豁免除害劑 to add an exempted pesticide to Schedule 2</p>

乙部(3) Part B(3)

建議修訂 / 增加的項目詳情

Particulars of revision/ addition items

(只限在一個方格 ☐ 內加上「✓」號並在該欄填上擬修訂 / 增加的項目詳情。)(Please tick in one box ☐ only and provide the particulars of revision/ addition items.)

(如有需要，請另紙提供下述資料)

(Please provide the information in separate sheets when necessary)

《食物內除害劑殘餘規例》(第 132CM 章)

Pesticide Residues in Food Regulation, Cap. 132CM

附表 1 第 1 部的最高殘餘限量

Schedule 1, Part 1, Maximum Residue Limits (MRLs)

	項 (如適用) Item (If applicable)	除害劑 Pesticide	殘餘物定義 Residue Definition (如與目前除害劑 殘餘物定義不同，請填寫此欄) (Please fill in this column if it is different from existing pesticide residue definition)	食物描述 Description of Food	現時最高殘餘 限量 (毫克 / 公斤) Current Maximum Residue Limit (MRL) (mg/kg) (如適用) (If applicable)	建議最高 殘餘限量 (毫克 / 公斤) Proposed Maximum Residue Limit (MRL) (mg/kg)
<input type="checkbox"/>						

附表 1 第 2 部的最高再殘餘限量

Schedule 1, Part 2, Extraneous Maximum Residue Limits (EMRLs)

	項 (如適用) Item (If applicable)	除害劑 Pesticide	殘餘物定義 Residue Definition (如與目前除害劑 殘餘物定義不同，請填寫此欄) (Please fill in this column if it is different from existing pesticide residue definition)	食物描述 Description of Food	現時最高 再殘餘限量 (毫克 / 公斤) Current Extraneous Maximum Residue Limit (EMRL) (mg/kg) (如適用) (If applicable)	建議最高 再殘餘限量 (毫克 / 公斤) Proposed Extraneous Maximum Residue Limit (EMRL) (mg/kg)
<input type="checkbox"/>						

附表 2 建議的獲豁免除害劑 Schedule 2, Proposed Exempted Pesticide	
	建議的除害劑的描述 Description of proposed pesticide
<input type="checkbox"/>	

丙部(1) Part C(1) 除害劑的詳細資料 Particulars of the Pesticide (請以中、英文提供所需資料，如適用) (Please provide information in English and Chinese, if applicable)	
除害劑的通用名稱(ISO 或 BSI) Common name of pesticide (ISO or BSI)	
化學名稱(IUPAC) Chemical name(s) (IUPAC)	
除害劑類別 (例如除蟲劑) Type of pesticide (e.g., insecticide)	
除害劑註冊地點 Place where the pesticide is registered	
除害劑的施用對象(例如:玉米) Usage of pesticide (e.g., corn)	
其他資料 Other information	

註：英國標準局 BSI = British Standards Institution
 NOTE: 國際標準化組織 ISO = International Standardization Organization
 理論化學和應用化學聯會 IUPAC = International Union of Pure and Applied Chemistry

丙部(2) Part C(2) 相關食物的詳細資料 Particulars of Food Commodity concerned (請以中、英文提供所需資料，如適用) (Please provide information in English and Chinese, if applicable) 註：如擬建議增加獲豁免除害劑，不用填寫此部分。 Note: For proposal of new exempted pesticide, please skip this Part.	
食物名稱 Name of food commodity	
食品的學名(如適用) Scientific name of product, if available	
擬輸往香港的食物原產地 Place of origin of food commodity intended for export to Hong Kong	
食物加工研究報告 Reports of available food processing studies	
其他資料 Other information	

丁部 Part D

除害劑及其相關“除害劑－食物”組合的技術資料
Technical Information of the Pesticide and Pesticide-Food Pair Concerned

(提交建議者應另紙提供下列**必須**的資料，並提交佐證文獻)
(The proponent shall provide the following **mandatory** information in separate sheets with supporting literature)

項目編號 Item No.	資料詳情 Description of Information	參考文件編號 Reference No.
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	相關除害劑的毒性數據和安全參考值 The toxicological data and safety reference values of the pesticide concerned	
3	對農作物進行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	相關除害劑殘餘的分析方法和是否有可供使用的分析參照標準 The analytical methods of the pesticide residues concerned and the information on availability of analytical reference standards	
5	食品法典委員會或香港以外司法管轄區是否已就相關除害劑殘餘制定最高殘餘限量/最高再殘餘限量(如適用) Whether the relevant MRL/EMRL of the pesticide residues concerned have been established by the Codex Alimentarius Commission or jurisdiction outside Hong Kong, if applicable	
6	相關除害劑是否獲香港以外司法管轄區准許在食物中使用，並且對其殘餘物的含量沒有任何限制(如適用) 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 (例如除害劑加工研究結果) Other related information (e.g., results of processing studies of the pesticides)	

戊部(1) 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)
I _____

香港身份證/ 其他身份證明文件號碼 _____ () am
Hong Kong Identity Card/ Other Proof of Identity No. _____

- ☐ 東主
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:

- (a) 本人獲正式授權代表上述公司 / 合夥提出此項建議和作出聲明，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.

- (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，包括佐證文獻的資料，皆為真實及完整。
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 : _____

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.

戊部(2) Part E(2)

請注意：戊部(2)只適用於個人申請，如屬公司及合夥申請，請填寫戊部(1)。

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

聲明 Declaration

本人

I

(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.

()

現謹此聲明：

hereby declare that:

- (a) 本人提出此項建議和作出聲明，並完全明白夾附的“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，在本建議表格提供的資料，包括佐證文獻的資料，皆為真實及完整。

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 : _____

用途聲明

Statement of Purpose

(根據《個人資料(私隱)條例》)(向資料當事人展示或提供)

(under the Personal Data (Privacy) Ordinance) (to be displayed or provided to data subjects)

收集資料的目的

Purpose of Collection

1. 你所提供的個人資料，食物環境衛生署(“本署”)食物安全中心會用作處理於《食物內除害劑殘餘規例》(第132CM 章) 附表 1 或附表 2 修訂/增加最高殘餘限量 / 最高再殘餘限量或增加獲豁免除害劑的建議。個人資料的提供，純屬自願。如果你不提供充分的資料，我們未必能夠處理你的建議，或在有需要時提供協助。

The personal data are provided by individuals to the Centre for Food Safety, Food and Environmental Hygiene Department (“this Department”) for the purposes of handling of proposal for addition or revision of maximum residue limit (MRL)/ extraneous maximum residue limit (EMRL)/ addition of an exempted pesticide as listed in Schedule 1 or Schedule 2 to the Pesticide Residues in Food Regulation, Cap. 132CM. The provision of personal data is voluntary. If you do not provide sufficient information, we may not be able to handle the proposal or provide assistance to you where appropriate.

資料受讓人類別

Classes of Transferees

2. 你所提供的個人資料，主要供本署內部使用，但也可能為上文第 1 段所述目的向其他政府決策局和部門或有關各方(包括一般市民)披露。此外，本署如要披露資料，只可向你已事先同意的有關各方披露，或在《個人資料(私隱)條例》允許的情況下披露。

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.

查閱個人資料

Access to Personal Data

3. 《個人資料(私隱)條例》第 18 及第 22 條以及附表 1 第 6 原則訂明，你有權查閱及改正個人資料，包括有權取得你的個人資料的文本。本署應查閱要求而提供資料時，可能會收取費用。

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.

查詢

Enquiries

4. 有關所提供個人資料的查詢(包括要求查閱及改正資料)，請送交：

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

香港金鐘道 66 號金鐘道政府合署 43 樓
食物環境衛生署食物安全中心
風險評估組
電話號碼：2867 5699

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

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		Provided	<u>Not</u> Applicable
		Please ✓ in only one box for each item	
<u>A</u>	<u>Proposal Form & Checklist</u>		
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)	<input type="checkbox"/>	
A2	This checklist duly completed	<input type="checkbox"/>	
<u>B</u>	<u>Technical information concerning the proposal</u>		
<u>Part I: Proposal of revising/adding MRLs/EMRLs of pesticides already included in Schedule 1</u>			
B1	The purpose of the proposal (<i>e.g., for importation of a specific food item</i>)	<input type="checkbox"/>	
B2	The current or anticipated availability of the food concerned in Hong Kong (e.g., trade data and import statistics, if any)	<input type="checkbox"/>	
B3	A description of the food commodity concerned (product name, Codex food code, product of origin, etc.)	<input type="checkbox"/>	
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)	<input type="checkbox"/>	
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.	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>
B7	Analytical methods of the pesticide residues concerned, the associated method validation data and source of related reference standards — <ul style="list-style-type: none"> 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 	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>

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		Provided	Not Applicable
		Please ✓ in only one box for each item	
	<ul style="list-style-type: none"> 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, LOQ and quality control requirements as well as method validation data including precision and recovery 	<input type="checkbox"/>	<input type="checkbox"/>
Part II: Proposal of adding MRLs/EMRLs of pesticides NOT included in Schedule 1 Information required <u>in addition to</u> those listed in <u>Part I</u> :			
B8	A description of the pesticide concerned, including but not limiting to the following — <ul style="list-style-type: none"> 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 the Good Agricultural Practice (GAP)) 	<input type="checkbox"/> 	<input type="checkbox"/>
B9	Toxicological profile of the pesticide concerned, including but not limiting to the following — <ul style="list-style-type: none"> 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 JMPR or other competent authorities) 	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
B10	Analytical methods — <ul style="list-style-type: none"> the source and availability of reference materials, 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 	<input type="checkbox"/>	<input type="checkbox"/>
Part III: Proposal of adding exempted pesticides to Schedule 2 Information required <u>in addition to</u> those listed in <u>Part I and Part II</u> , 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)	<input type="checkbox"/>	<input type="checkbox"/>