LegCo Panel on Food Safety and Environmental Hygiene

Proposed Regulation of Pesticide Residues in Food in Hong Kong

PURPOSE

This paper consults Members on the proposed Regulation on Pesticide Residues in Food (proposed Regulation) to be made by the Director of Food and Environmental Hygiene (DFEH) under section 55 of the Public Health and Municipal Services Ordinance (Cap. 132).

BACKGROUND

- 2. At present, the import, manufacture, sale and supply of pesticides in Hong Kong are regulated by the Pesticides Ordinance (Cap. 133). Fisheries and Conservation Department (AFCD) is responsible for enforcing the relevant provisions. All pesticides intended for sale in Hong Kong must be registered with the Director of Agriculture, Fisheries and Conservation (DAFC). Except with a licence issued by DAFC, no person shall import, manufacture, sell or supply registered pesticides. While there are general provisions under Cap.132 that all food on sale for human consumption must be wholesome, unadulterated and fit for human consumption, there is currently no specific legal provision that regulates the level of pesticide residues in food.
- 3. The Centre for Food Safety (CFS) operates a food surveillance programme and regularly takes food samples to test, among others, for pesticide residues following the testing methods and standards recommended by the Codex Alimentarius Commission (Codex) 1. However, the lack of a specific legal provision governing pesticide residues in food means that a case-by-case assessment would need to be

Codex was established by the Food and Agriculture Organisation and the World Health Organisation of the United Nations in 1960s and has been the single most important international reference point for

consumers, food producers, processors, national food control agencies and the international food trade

in developing food associated standards.

made in order to substantiate that the concerned food sample is unfit for human consumption (section 54 of Cap. 132) before CFS can prosecute the food trader concerned. This also deviates from the general principle that pesticide use should be kept at a minimum possible level as recognized by Codex and developed countries. The introduction of specific regulation on pesticide residues in food is therefore considered necessary.

- 4. In November 2007, the Administration consulted Members on the same subject before launching a public consultation exercise. The proposals then were summarised as follows:
 - to define "pesticide" and other related terms in a way consistent with Codex;
 - to adopt a "positive list approach"²;
 - to adopt "maximum residue limits" (MRLs)³ and "extraneous maximum residue limits" (EMRLs)⁴ developed by Codex as the backbone;
 - to develop a "default value" for pesticide residues without specified MRLs;
 - to develop a list of "exempted substances";
 - to adopt Codex's classification of foods; and
 - to implement the new legislation with a grace period.
- 5. We have since then collected views from a wide range of stakeholders, experts and the public, and jointly organised a Regional Symposium on Regulation of Pesticide Residues in Food with the European Commission in 2009. We have also consulted the Expert Committee on Food Safety⁶. We have refined the 2007 proposed

³ Codex defines "MRL" as the maximum concentration of a pesticide residue (expressed as mg/kg) recommended by the Codex to be legally permitted in or on food and agricultural commodities.

² Under a "positive list approach", any pesticide residues without specified maximum residue limits (MRLs) in the legislation are strictly not allowed.

⁴ Codex defines "EMRL" as referring to a pesticide residue or a contaminant arising from environmental sources (including former agricultural uses) other than the use of a pesticide or contaminant substance directly or indirectly on the commodity. It is the maximum concentration of a pesticide residue or contaminant (expressed as mg/kg) that is recommended by the Codex to be legally permitted or recognized as acceptable in or on food and agricultural commodities.

⁵ Under a "default value" approach, any pesticide residues with residual level exceeding a "default value" are not allowed.

⁶ The Expert Committee on Food Safety is responsible for advising DFEH in the formulation of food safety measures, review of food safety standards in light of international practices, trends and developments, as well as risk communication strategies. The Expert Committee consists of academics, professionals, food experts, members of the trade and consumer group, and other experts.

regulatory framework in the light of the feedback received. Based on the refined framework, we have further consulted the stakeholders. Since January 2011, we have conducted a total of 14 briefings and consultation sessions to gauge the views of the stakeholders. On the basis of the views collected, the Administration has further improved the suggested regulatory framework. Details are in the consultation document at **Annex 1**.

KEY FEATURES OF THE PROPOSED REGULATION

Objectives

- 6. The proposed Regulation aims to strengthen the regulation of pesticide residues in food to achieve the following objectives -
 - (a) better protect public health;
 - (b) facilitate effective regulation; and
 - (c) promote harmonisation between local and international standards.

In striving to achieve the above objectives, the Administration is mindful of the need to maintain stable supply of food in Hong Kong.

To adopt Codex's definition of "pesticides" and other related terms

7. The main structure of the proposed Regulation has taken reference from that of Codex. It defines terms such as "pesticide", "pesticide residue", "MRL" and "EMRL" in a way consistent with Codex. This will promote harmonisation of local and international standards.

To regulate pesticide residues by a list of MRLs/EMRLs

8. The proposed Regulation will specify in its First Schedule a list of MRLs/EMRLs for certain pesticide-food pairs (i.e. the maximum concentration of specified pesticide residues permitted in specified food commodities). The presence of any of these pesticide residues in food at levels exceeding the MRLs/EMRLs will contravene the proposed Regulation.

9. The formulation of the list of MRLs/EMRLs is based primarily on the available standards recommended by Codex, supplemented by standards of the Mainland and other major food exporting countries to Hong Kong (the USA and Thailand). These standards will further be scrutinised by conducting risk assessment to ensure that the proposed standards are adequate to protect public health in Hong Kong, taking into account the heavy reliance of Hong Kong on imported food. Such an approach will strike a balance between protecting public health and maintaining stable supply of food in Hong Kong.

To adopt Codex's classification of foods

10. As Codex standards form the backbone of the local set of standards for pesticide residues in food, we have also adopted Codex's food classification system for consistency. This has the added benefit of adopting the uniform nomenclature used in international markets.

Pesticide residues with no specified MRL/EMRL in the proposed Regulation

11. With regard to pesticide-food pairs for which no MRL/EMRL has been specified in the proposed Regulation, the general principle is that except for exempted substances, import and sale of the concerned food will be prohibited unless DFEH is satisfied that the detected level of pesticide residue is not dangerous or prejudicial to health. In coming to his decision, DFEH will conduct risk assessment.

To establish a list of exempted substances

- 12. To facilitate the trade to use pesticides that are natural and the residues of which are identical to or indistinguishable from natural food components, it is proposed to specify a list of exempted substances in the Second Schedule of the proposed Regulation. An exempted substance must fall 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 pose any public health risk.
- 13. Such a list of exempted substances is not available from Codex, but we have made reference to the lists adopted by major food exporting countries to Hong Kong in drawing up our own.

To update the lists of MRLs/EMRLs and exempted substances regularly

14. As new pesticides and new applications on crops keep emerging, the lists of MRLs/EMRLs and exempted substances specified in the proposed Regulation will be updated by DFEH regularly.

To set up a mechanism for application for adding/revising MRLs and exempted substances

- 15. We propose to set up a mechanism where a person may apply to DFEH for adding a new MRL to the First Schedule or revising an existing MRL therein, or adding an exempted substance to the Second Schedule. Similar trade facilitation measures are commonly found in overseas jurisdictions ⁷. The purpose is to cater for pesticide-food pairs or pesticides respectively that have been found to be acceptable from public health perspective in other jurisdictions but not yet included in the local lists of MRL / exempted substances.
- 16. Applications must be accompanied by sufficient information. Application fee will be charged on the basis of full-cost recovery and will not be refundable.
- 17. The proposed Regulation will provide that DFEH may approve the application if he is satisfied, among other things, that the level of residue is not dangerous or prejudicial to health. In coming to his decision, DFEH will conduct risk assessment. DFEH would revise the lists of MRLs and exempted substances regularly by incorporating MRLs/exempted substances approved during the period.

Canada, the EU, Japan and the USA have adopted a similar regulatory measure of import tolerance for pesticide residues in food.

To dovetail with registration of pesticides for use on local food crops

- 18. There is a need to introduce suitable measures to ensure that a newly registered pesticide for use on local food crops under Cap. 133 would be properly regulated under the proposed Regulation.
- 19. We propose that DAFC shall collect, for the purpose of application for registration of pesticide under Cap.133, any information relevant to the proposed Regulation for consideration of setting up MRLs or adding exempted substances. We further propose to empower DFEH in the proposed Regulation to obtain from DAFC such information.
- 20. On the basis of the information submitted by the applicant, DFEH would advise DAFC whether the pesticide in question could be regulated by way of setting up a MRL or adopted as an exempted substance in the proposed Regulation. If so, DFEH would amend the First or Second Schedule in the proposed Regulation to incorporate the new standard.
- 21. DAFC would decide whether to approve the registration of the pesticide, having regard to DFEH's advice and other relevant considerations under Cap. 133.
- 22. Application fee will be charged on the basis of full-cost recovery as if the applicant is applying for adding MRLs or exempted substances under the proposed Regulation and will not be refundable.

Penalty

- 23. It would be an offence to import, manufacture or sell for human consumption any food containing
 - (a) pesticide residue at a level exceeding that specified in First Schedule of the proposed Regulation; or
 - (b) pesticide not specified in the First or Second Schedule of the proposed Regulation, or though so specified, but are found in other kinds of food, i.e. not in the stated pesticide-food pairs, unless DFEH is satisfied that the detected level will not be dangerous or prejudicial to health.

The maximum penalty for contravention will be a fine at level 5 (\$50,000) and imprisonment for six months. This is in line with the penalty for selling food which is unfit for human consumption under section 54 of Cap.132.

Statutory defences

- 24. We have provided statutory defences under the proposed Regulation. At present, section 71 of Cap. 132 stipulates conditions under which warranty may be pleaded by the defendant as defence in any proceedings for an offence under the relevant part of the Ordinance. This would also be applicable to the offences under the proposed Regulation. For example, a vendor charged under the proposed Regulation may produce evidence such as invoices to demonstrate that the food concerned is in the original state as obtained from the supplier without any further treatment and the supplier's earlier confirmation of safe food supply.
- 25. In addition, section 70 of Cap.132 provides that if the defendant could prove that the contravention was due to the act or default of some other person, and that he has used all due diligence to secure that the provisions in question were complied with, he may plead this as a defence. Again, this is applicable to offences under the proposed Regulation.

Grace period

26. To allow sufficient time for the trade to comply with the proposed Regulation, we propose that there should be a two-year grace period prior to the commencement of the proposed Regulation. During this period, CFS will provide briefings, training and guidelines for different sectors to familiarise them with the proposed Regulation.

Improvement over the proposed regulatory framework in 2007

27. The updated proposed framework described in paragraphs 6 to 26 above has improved over the one in 2007 in the following aspects -

- The "positive list (a) modified "positive list approach": approach" in the 2007 framework is a strict arrangement with no allowance for the use of pesticides outside the list of MRLs The modified "positive list approach" now and EMRLs. proposed provides that where pesticide residues are found outside the list, it will be prohibited unless DFEH is satisfied that the level of residue will not be dangerous or prejudicial to health. In coming to his decision, DFEH will conduct risk assessment. Risk assessment is a science-based approach. Compared with the "positive list approach", the modified "positive list approach" is more flexible. The Expert Committee on Food Safety supports such an approach as it is science-based and in line with international developments on regulation of pesticide residues in food. Accordingly, there is no need to develop a "default value" since this has been taken care of by risk assessment;
- (b) applications for adding/revising MRLs and exempted substances: to ensure that the lists of MRLs and exempted substances are up-to-date, we now propose to allow food traders to apply to DFEH to add a new MRL or revise an existing MRL, or to add an exempted substance under the proposed Regulation. The proposed Regulation will provide that DFEH may approve the application if he is satisfied, among other things, that the level of residue is not dangerous or prejudicial to health. In coming to his decision, DFEH will conduct risk assessment; and
- (c) dovetailing mechanism between Cap. 133 and the proposed Regulation: to ensure that a newly registered pesticide for use on local food crops under Cap. 133 is properly regulated under the proposed Regulation, we now propose to introduce an arrangement whereby AFCD will require applicants for pesticide registration under Cap. 133 to provide sufficient information for the purpose of setting up the corresponding MRLs or exempted substances. Such information would be passed to DFEH to facilitate the latter's processing of the application of adding new MRL or exempted substances in the proposed Regulation. We would empower DFEH in the proposed Regulation to obtain from DAFC such information.

28. The proposed framework at **Annex 1** has addressed many of the concerns raised by the stakeholders during the briefing and consultation sessions held since January 2011 referred to in paragraph 5 above. At **Annex 2** is our initial response to the concerns raised.

WAY FORWARD

29. The Administration will embark on a two-month public consultation exercise in mid July. Subject to the views received, the Administration plans to table the proposed Regulation at the Legislative Council towards the end of 2011.

ADVICE SOUGHT

30. Members are invited to comment on the proposals above.

Centre for Food Safety
Food and Environmental Hygiene Department
Food and Health Bureau
July 2011

Consultation Document

Refined Regulatory Framework for Pesticide Residues in Food in Hong Kong

Centre for Food Safety
Food and Environmental Hygiene Department
Food and Health Bureau
July 2011

CONTENTS

		Page
Chapter 1	Introduction	3
Chapter 2	Situation in Hong Kong and International Practice	4-5
Chapter 3	The Refined Regulatory Framework	6-13
Chapter 4	Views Sought	14-15
Annex I	Preliminary List of Pesticides to be Included in the Proposed Regulation	16-20
Annex II	Principles in interpreting MRLs/EMRLs in respect of dried, dehydrated, concentrated, processed or compounded food	21
Annex III	Preliminary List of Exempted Substances to be Included in the Proposed Regulation	22-24

CHAPTER 1 INTRODUCTION

- 1.1 The use of pesticides and other chemicals has become a common agricultural practice to enhance and stabilise crop yield, protect the nutritional integrity of food, facilitate storage to assure year-round supplies, and provide attractive and appealing food products. The proper use of pesticides is beneficial to public health to protect crops from contamination by natural toxins and harmful microorganisms.
- 1.2 Notwithstanding the beneficial effects, the use of pesticides and its resultant residues requires careful monitoring and regulation. Small amounts of pesticide residues may remain in the crops or animal food. Exposure to pesticide residues in food is an issue that is of considerable concern to consumers, food producers, academics and government agencies.
- 1.3 The adverse health effects of pesticides depend on the nature of the pesticide, as well as the amount and duration of individual exposure. Excessive exposure to some pesticides may cause acute adverse health effects¹.
- 1.4 Most of the international regulatory authorities and the Mainland authority have already introduced statutory control on pesticide residues in food. To better protect public health, facilitate effective regulation and promote harmonisation between local and international standards, there is a genuine need to introduce a regulatory framework on pesticide residues in food in Hong Kong.

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¹ For example, methamidophos and triazophos may affect the nervous system.

CHAPTER 2 SITUATION IN HONG KONG AND INTERNATIONAL PRACTICE

Food supplies in Hong Kong

2.1 Most of the fruit and vegetable supplied in Hong Kong are imported from countries or areas around the world. In 2010, about 33% of fresh and semi-processed fruits, vegetables and cereals were imported from the Mainland, 30% from Thailand and about 13% from the United States of America (USA), with each of the rest of the other countries contributing to less than 5% of the total annual import.² Local production accounted for only 2.5% of fresh vegetables consumed in 2010.³

Current regulatory control on the use of pesticides

- At present, the import, manufacture, sale and supply of pesticides in Hong Kong are regulated by the Pesticides Ordinance (Cap. 133). The Agriculture, Fisheries and Conservation Department (AFCD) is responsible for enforcing the relevant provisions. All pesticides intended for sale in Hong Kong must be registered with the Director of Agriculture, Fisheries and Conservation (DAFC). Except with a licence issued by DAFC, no person shall import, manufacture, sell or supply registered pesticides. While there are general provisions under Cap.132 that all food on sale for human consumption must be wholesome, unadulterated and fit for human consumption, there is currently no specific legal provision that regulates the level of pesticide residues in food.
- 2.3 The Centre for Food Safety (CFS) operates a food surveillance programme and regularly takes food samples to test, among others, for pesticide residues following the testing methods and standards recommended by the Codex Alimentarius Commission (Codex)⁴. However, the lack of a specific legal provision governing the level of pesticide residues in food means that a case-by-case assessment would need to be made in order to substantiate that the concerned food sample is unfit for human consumption (section 54 of Cap. 132) before CFS can prosecute the food trader concerned. This also deviates from the general principle that pesticide use should be kept at a minimum possible level as recognized by Codex and developed countries. The introduction of specific regulation on pesticide residues in food is therefore considered necessary.

² Census and Statistics Department. Hong Kong Merchandise Trade Statistics - Imports December 2010.

http://www.afcd.gov.hk/english/agriculture/agr hk/agr hk.html

³ Agriculture, Fisheries and Conservation Department. Agriculture in HK. Available from:

⁴ Codex, established by the Food and Agriculture Organization and the World Health Organization of the United Nations in 1960s, is the single most important reference point for consumers, food producers, processors, national food control agencies and the international food trade in developing food associated standards.

International practice

2.4 Regulation of pesticide residues in food is well developed in the international arena. Statutory regulation on pesticide residues in food has been introduced in major jurisdictions such as Australia, the European Union, Japan, the Mainland, New Zealand, Singapore and the USA. We have made reference to the practices in these jurisdictions in formulating the refined regulatory framework in Chapter 3.

CHAPTER 3 THE REFINED REGULATORY FRAMEWORK

Background

- 3.1 To address growing concern about safe use of pesticide in food, the Government conducted a public consultation exercise on a proposal for regulatory framework for pesticide residues in food in November 2007. The key features of the proposed regulatory framework then were summarised as follows:
 - to define "pesticide" and other related terms in a way consistent with Codex;
 - to adopt a "positive list approach"⁵;
 - to adopt "maximum residue limits" (MRLs) ⁶ and "extraneous maximum residue limits" (EMRLs) ⁷ developed by Codex as the backbone;
 - to develop a "default value" for pesticide residues without specified MRLs and a list of "exempted substances";
 - to adopt Codex's classification of foods; and
 - to implement the new Regulation with a grace period.

Under a "positive list approach", any pesticide residues without specified maximum residue limits (MRLs) in the legislation are strictly not allowed.

⁶ Codex defines "MRL" as the maximum concentration of a pesticide residue (expressed as mg/kg) recommended by the Codex Alimentarius Commission to be legally permitted in or on food and agricultural commodities.

Odex defines "EMRL" as referring to a pesticide residue or a contaminant arising from environmental sources (including former agricultural uses) other than the use of a pesticide or contaminant substance directly or indirectly on the commodity. It is the maximum concentration of a pesticide residue or contaminant (expressed as mg/kg) that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on food and agricultural commodities.

⁸ Under a "default value" approach, any pesticide residues with residual level exceeding a "default value" are not allowed.

We have since then collected views from a wide range of stakeholders, experts, and the public, and conducted a Regional Symposium on Regulation of Pesticide Residues in Food, jointly organized with the European Commission in 2009. We have also consulted the Expert Committee on Food Safety⁹. We have refined the 2007 proposed regulatory framework in the light of the feedback received. Based on the refined framework, we have further consulted the stakeholders. Since January 2011, we have conducted a total of 14 briefings and consultation sessions to gauge the views of the stakeholders. On the basis of the views collected, the Government has further improved the proposed regulatory framework.

Objectives of refined regulatory framework

- 3.3 The refined regulatory framework aims to strengthen the regulation of pesticide residues in food to achieve the following objectives -
 - (a) better protect public health;
 - (b) facilitate effective regulation; and
 - (c) promote harmonisation between local and international standards.
- 3.4 In striving to achieve the above objectives, the Government is mindful of the need to maintain a stable supply of food in Hong Kong. To achieve the above objectives, we propose that DFEH should make a Regulation on Pesticide Residues in Food (the proposed Regulation) under section 55 of the Public Health and Municipal Services Ordinance (Cap. 132).

To adopt Codex's definition of "pesticides" and other related terms

3.5 The main structure of the framework has taken reference from that of Codex. Definition of terms such as "pesticide", "pesticide residue", "MRL" and "EMRL" in the proposed Regulation is consistent with those of Codex. This will promote harmonisation of local and international standards.

The Expert Committee on Food Safety is responsible for advising DFEH in the formulation of food safety measures, review of food safety standards in light of international practices, trends and developments, as well as risk communication strategies. The Expert Committee consists of academics, professionals, food experts,

To regulate pesticide residues by a list of MRLs/EMRLs

- 3.6 The proposed Regulation will specify in its First Schedule a list of MRLs/EMRLs for certain pesticide-food pairs (i.e. the maximum concentration of specified pesticide residues permitted in specified food commodities). The presence of any of these pesticide residues in food at levels exceeding the MRLs/EMRLs will contravene the proposed Regulation.
- 3.7 The formulation of the list of MRLs/EMRLs is based primarily on the available standards recommended by Codex, supplemented by related standards of the Mainland and other major food exporting countries to Hong Kong (the USA and Thailand). These standards will further be scrutinised by conducting risk assessment to ensure that they are adequate to protect public health in Hong Kong. This approach is considered pragmatic, taking into account the heavy reliance of Hong Kong on imported food. Such an approach will strike a balance between protecting public health and maintaining stable supply of food in Hong Kong.
- 3.8 The proposed list of pesticides to be included in the proposed regulation is at Annex I. The full list of proposed MRLs/EMRLs is available at CFS's website¹⁰. This is a preliminary list as CFS is updating the MRLs/EMRLs according to the latest changes in the international standards.
- 3.9 Some general principles in interpreting the MRLs/EMRLs in respect of dried, dehydrated, concentrated, processed or compounded food are at <u>Annex II</u>.

To adopt Codex's classification of foods

3.10 As Codex standards form the backbone of the refined regulatory framework, we have also adopted Codex's food classification system for consistency. This has the added benefit of adopting the uniform nomenclature used in international markets.

Pesticide residues with no specified MRL/EMRL in the proposed Regulation

3.11 With regard to pesticide-food pairs for which no MRL/EMRL has been specified in the proposed Regulation, the general principle is that except for exempted substances, import and sale of the concerned food will be prohibited unless DFEH is satisfied that the detected level of pesticide residue is not dangerous or prejudicial to health. To this end, DFEH will conduct risk assessment, taking into account a host of factors including safety reference values¹¹ and local situation.

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

Safety reference values refer to acceptable daily intake for chronic toxicity and acute reference dose for acute toxicity.

To establish a list of exempted substances

- 3.12 To facilitate the trade to use pesticides that are natural and the residues of which are identical to or indistinguishable from natural food components, it is proposed to specify a list of exempted substances in the Second Schedule of the proposed Regulation. Exempted substances must fall 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 pose any public health risk.
- 3.13 Such a list of exempted substances is not available from Codex, but we have made reference to the lists adopted by major food exporting countries to Hong Kong in drawing up our own. The proposed list of exempted substances in Hong Kong is at <u>Annex III</u>.

To update the lists of MRLs/EMRLs and exempted substances regularly

3.14 As new pesticides and new applications on crops keep emerging, the lists of MRLs/EMRLs and exempted substances specified in the proposed Regulation will be updated by DFEH regularly.

To allow application for revising/adding MRLs and exempted substances

3.15 Import tolerance is a trade facilitation measure commonly found in overseas jurisdictions¹². The purpose is to cater for pesticide-food pairs or pesticides respectively that have been found to be acceptable from public health perspective in other jurisdictions but not yet included in the local lists of MRL / exempted substances. We propose to adopt a similar measure which would allow a person to apply to DFEH for adding a new MRL to the First Schedule or revising an existing MRL therein, or adding an exempted substance to the Second Schedule of the proposed Regulation. Application fee will be charged on the basis of full-cost recovery and will not be refundable.

Canada, the EU, Japan and the USA have adopted a regulatory measure of import tolerance for pesticide residues in food.

- 3.16 Applications must be accompanied by sufficient information, such as the current or anticipated availability of the concerned food product in Hong Kong, relevant toxicological data and safety reference values of the concerned pesticide, pesticide supervised field trial data, pesticide residue data, analytical methods, information on availability of analytical reference standards, reports of food processing studies, and relevant information if MRLs have been established by Codex or overseas jurisdictions or exemption from establishing MRL for the concerned pesticide has been granted by overseas jurisdictions.
- 3.17 Upon receiving the application, DFEH will conduct risk assessment. The proposed Regulation will provide that DFEH may approve the application if he is satisfied, among other things, that the level of residue is not dangerous or prejudicial to health. For applications related to MRLs, DFEH may set up or revise an MRL with the same or different limits from the overseas MRL cited by the applicant. For applications related to exempted substances, DFEH may add the pesticide concerned into the list of exempted substances.
- 3.18 DFEH would revise the lists of MRLs and exempted substances regularly by incorporating all MRLs/exempted substances approved during the period.

To dovetail with registration of pesticides for use on local food crops

- 3.19 To ensure that a newly registered pesticide for use on local food crops under Cap. 133 would be properly regulated under the proposed Regulation, there is a need to introduce a dovetailing mechanism.
- 3.20 We propose that DAFC shall collect, for the purpose of application for registration of pesticide under Cap. 133, any information relevant to the proposed Regulation for consideration of setting up MRLs or adding exempted substances. We would empower DFEH in the proposed Regulation to obtain from DAFC such information. On the basis of the information submitted by the applicant, DFEH would advise DAFC whether the pesticide in question could be regulated by way of setting up a MRL or adopted as an exempted substance in the proposed Regulation. If so, DFEH would amend the First or Second Schedule in the proposed Regulation to incorporate the new standard.
- 3.21 DAFC will decide whether to approve the registration of the pesticide, having regard to DFEH's advice and other relevant considerations under Cap. 133.

3.22 Application fee will be charged on the basis of full-cost recovery as if the applicant is applying for adding MRLs or exempted substances under the proposed Regulation and will not be refundable.

Penalty

- 3.23 It would be an offence to import, manufacture or sell for human consumption any food containing
 - (a) pesticide residue at a level exceeding that specified in the First Schedule of the proposed Regulation; or
 - (b) pesticide not specified in the First or Second Schedule of the proposed Regulation, or though so specified, but are found in other kinds of food, i.e., not in the stated pesticide food pairs, unless the DFEH is satisfied that the detected level will not be dangerous or prejudicial to health.

The maximum penalty for contravention will be a fine at level 5 (\$50,000) and imprisonment for six months. This is in line with the penalty for selling food which is unfit for human consumption under section 54 of Cap.132.

Statutory defences

- 3.24 Section 71 of Cap. 132 stipulates conditions under which warranty may be pleaded by the defendant as defence in any proceedings for an offence under the relevant part of the Ordinance. This would also be applicable to the offences under the proposed Regulation. For example, a vendor charged under the proposed Regulation may produce evidence such as invoices to demonstrate that the food concerned is in the original state as obtained from the supplier without any further treatment and the supplier's earlier confirmation of safe food supply.
- 3.25 In addition, section 70 of Cap.132 provides that if the defendant could prove that the contravention was due to the act or default of some other person, and that he has used all due diligence to secure that the provisions in question were complied with, he may plead this as a defence. Again, this is applicable to offences under the proposed Regulation.

Legislative timetable

3.26 We plan to table the proposed Regulation at the Legislative Council towards the end of 2011.

Grace period

3.27 To allow sufficient time for the trade to comply with the proposed Regulation, we propose that there should be a two-year grace period prior to the commencement of the proposed Regulation. During this period, CFS will provide briefings, training and guidelines for different sectors to familiarise them with the proposed Regulation.

Improvement over the proposed regulatory framework in 2007

- 3.28 The updated proposed framework described in paragraphs 3.3 to 3.27 above has improved over the one in 2007 in the following aspects -
 - (a) modified "positive list approach": The "positive list approach" in the 2007 framework is a strict arrangement with no allowance for the use of pesticides outside the lists of MRLs and EMRLs. The modified "positive list approach" now proposed provides that where pesticide residues are found outside the list, it will be prohibited unless DFEH is satisfied that the level of residue will not be dangerous or prejudicial to In coming to his decision, DFEH will conduct risk assessment. Risk assessment is a science-based approach. Compared with the "positive list approach", the modified "positive list approach" is more The Expert Committee on Food Safety supports such an flexible. approach as it is science-based and in line with international developments regulation of pesticide residues on Accordingly, there is no need to develop a "default value" since this has been taken care of by risk assessment;
 - (b) applications for adding/revising MRLs and exempted substances: to ensure that the lists of MRLs and exempted substances are up-to-date, we now propose to allow food traders to apply to DFEH to add a new MRL or revise an existing MRL, or to add an exempted substance under the proposed Regulation. The proposed Regulation will provide that DFEH may approve the application if he is satisfied, among other things, that the level of residue is not dangerous or prejudicial to health. In coming to his decision, DFEH will conduct risk assessment; and

- (c) dovetailing mechanism between Cap. 133 and the proposed Regulation: to ensure that a newly registered pesticide for use on local food crops under Cap. 133 is properly regulated under the proposed Regulation, we now propose to introduce an arrangement whereby AFCD will require applicants for pesticide registration under Cap. 133 to provide sufficient information for the purpose of setting up the corresponding MRLs or exempted substances. Such information would be passed to DFEH to facilitate the latter's processing of the application of adding new MRL or exempted substances in the proposed Regulation. We would empower DFEH in the proposed Regulation to obtain from DAFC such information.
- 3.29 We are satisfied that the refined regulatory framework is an improvement over the 2007 proposal since it is more flexible, comprehensive and caters more to the updated situation on the pesticide front in the local and international arena.

CHAPTER 4 VIEWS SOUGHT

- 4.1 Salient features of the refined regulatory framework, as set out in Chapter 3, are summarised as follows:
 - to define "pesticide" and other related terms in a way consistent with Codex;
 - to provide a list of MRLs/EMRLs, to adopt MRLs/EMRLs recommended by Codex as the backbone as well as the Codex's classification of foods;
 - to prohibit the import and sale of the concerned food for which no MRL/EMRL has been specified, unless DFEH is satisfied that the detected level will not be dangerous or prejudicial to health;
 - to provide a list of exempted substances;
 - to accept applications for adding/revising MRLs and exempted substances:
 - to dovetail the proposed Regulation with the registration of pesticides for use on food crops under the Pesticides Ordinance (Cap. 133); and
 - to commence the proposed Regulation after a two-year grace period.
- 4.2 The Government invites you to let us have your views on the refined regulatory framework. Please send your comments by letter, facsimile or e-mail to the Centre for Food Safety before 19 September 2011:

Centre for Food Safety

(Attn.: Consultation on Pesticide Residues in Food)

Food and Environmental Hygiene Department

43/F, Queensway Government Offices,

66 Queensway, Hong Kong

Facsimile: (852) 2893 3547

E-mail address: pesticide_consultation@fehd.gov.hk

Enquiry tel. no.: (852) 2867 5699

4.3 The Government will take the views received into consideration before finalising the proposed Regulation.

4.4 Any person submitting views and comments should be aware that the Government may publish all or part of the views and comments received and disclose the identity of the source in such manner as the Government considers appropriate, unless he/she requests any part of the views and comments and/or his/her identity be treated in confidence.

Annex I

Preliminary List of Pesticides to be Included in the Proposed Regulation (Note: The list is being updated and subject to change)

- 1-Naphthaleneacetic acid
 2-(Thiocyanomethyl-thio) benzothiazole (TCMTB)
 2,4-D
 2-methyl-4-chlorophenoxyace
- 4. 2-methyl-4-chlorophenoxyacetic acid (MCPA)
 5. 2-Phenylphenol
- 6. 4-(2, 4-Dichlorophenoxy) butyric acid
- Abamectin
 Acephate
 Acequinocyl
 Acetamiprid
- 12. Acibenzolar-S-methyl
- 13. Acifluorfen14. Alachlor15. Aldicarb

11. Acetochlor

- 16. Aldrin and Dieldrin
- 17. Alpha-Naphthaleneacetamide
- 18. Ametryn
- 19. Aminoethoxyvinylglycine (Aviglycine)
- 20. Aminopyralid
- 21. Amitraz22. Amitrole23. Anilazine24. Asulam25. Atrazine
- 26. Azinphos-methyl
- 27. Azocyclotin28. Azoxystrobin29. Benalaxyl
- 30. Benfluralin31. Benfuracarb
- 32. Bensulfuron methyl
- 33. Bentazone34. Bifenthrin35. Bioresmethrin

- 36. Bispyribac-sodium
- 37. Bisultap38. Bitertanol
- 39. Boscalid
- 40. Bromacil
- 41. Bromide Ion
- 42. Bromopropylate
- 43. Bromoxynil
- 44. Buprofezin45. Butachlor
- 46. Butafenacil
- 47. Butylate
- 48. Cacodylic acid
- 49. Cadusafos
- 50. Captan
- 51. Carbaryl
- 52. Carbendazim/Benomyl
- 53. Carbofuran
- 54. Carbon disulfide
- 55. Carbosulfan
- 56. Carboxin
- 57. Carfentrazone-ethyl
- 58. Chlorantraniliprole
- 59. Chlorbenzuron
- 60. Chlordane
- 61. Chlorfenapyr
- 62. Chlorimuron ethyl
- 63. Chlormequat
- 64. Chlorothalonil
- 65. Chlorpropham
- 66. Chlorpyrifos
- 67. Chlorpyrifos-methyl
- 68. Chlorsulfuron
- 69. Chlortoluron
- 70. Clodinafop-propargyl
- 71. Clofencet72. Clofentezine
- 73. Clomazone

74. Clopyralid 115. Dithiocarbamates 75. Clothianidin 116. Diuron 117. Dodine 76. Coumaphos 77. Cryolite 118. Edifenphos 78. Cyanide 119. Emamectin 79. Cyclanilide 120. Endosulfan 80. Cycloate 121. Endrin 81. Cyfluthrin 122. Esfenvalerate 82. Cyhalothrin 123. Ethalfluralin 83. Cyhexatin 124. Ethametsulfuron-methyl 84. Cymoxanil 125. Ethephon 126. Ethion 85. Cypermethrin 86. Cyproconazole 127. Ethoprophos 87. Cyprodinil 128. Ethoxyquin 88. Cyromazine 129. Etofenprox 89. DDT 130. Etoxazole 90. Deltamethrin 131. Famoxadone 91. Desmedipham 132. Fenamidone 92. Diazinon 133. Fenamiphos 93. Dicamba 134. Fenarimol 94. Dichlobenil 135. Fenbuconazole 95. Dichlofluanid 136. Fenbutatin oxide 96. Dichlorvos 137. Fenhexamid 138. Fenitrothion 97. Diclofop-methyl 98. Dicloran 139. Fenobucarb (BPMC) 99. Diclosulam 140. Fenoxaprop-ethyl 100. Dicofol 141. Fenpropathrin 101. Dicrotophos 142. Fenpropimorph 102. Difenoconazole 143. Fenpyroximate 144. Fenthion 103. Difenzoquat 104. Diflubenzuron 145. Fenvalerate 105. Dimethenamid-P 146. Fipronil 106. Dimethipin 147. Flonicamid 107. Dimethoate 148. Florasulam 108. Dimethomorph 149. Fluazifop-butyl 109. Dimethyl tetrachloroterephthalate 150. Fluazifop-P-butyl (DCPA) 151. Fluazinam 110. Diniconazole 152. Flucythrinate 111. Dinotefuran 153. Fludioxonil 112. Diphenylamine 154. Fluefenacet 113. Diquat 155. Flufenoxuron

156. Flufenpyr-ethyl

114. Dithianon

157. Flumethrin 199. Linuron 158. Flumetsulam 200. Malathion 159. Flumiclorac pentyl 201. Maleic hydrazide 160. Flumioxazin 202. Mandipropamid 161. Fluometuron 203. Mepiquat chloride 162. Fluopicolide 204. Mesosulfuron-methyl 205. Mesotrione 163. Fluridone 164. Fluroxypyr 206. Metalaxyl 165. Flusilazole 207. Metaldehyde 208. Metconazole 166. Fluthiacet-methyl 167. Flutolanil 209. Methamidophos 210. Methanearsonic acid 168. Fluvalinate 169. Folpet 211. Methidathion 212. Methiocarb 170. Fomesafen 171. Forchlorfenuron 213. Methomyl 172. Formetanate hydrochloride 214. Methoprene 215. Methoxyfenoxide 173. Fosetyl-Al 174. Fthalide 216. Methyl bromide 175. Glufosinate-Ammonium 217. Metolachlor 218. Metribuzin 176. Glyphosate 177. Halosulfuron-methyl 219. Metsulfuron methyl 178. Haloxyfop 220. Mevinphos 179. Heptachlor 221. Molinate 180. Hexachlorocyclohexane 222. Monocrotophos 181. Hexythiazox 223. Myclobutanil 182. Hydramethylnon 224. Naled 183. Hydrogen phosphide 225. Napropamide 184. Imazalil 226. Naptalam 185. Imazamethabenz-methyl 227. Nicosulfuron 186. Imazapyr 228. Nitrapyrin 229. N-Octyl Bicycloheptene 187. Imazethapyr Dicarboximide (Mgk-264) 188. Imidacloprid 230. Norflurazon 189. Indoxacarb 231. Novaluron 190. Iodosulfuron-Methyl-Sodium 232. Orthosulfamuron 191. Iprodione 233. Oryzalin 192. Isocarbophos 234. Oxadiazon 193. Isofenphos-methyl 235. Oxamvl 194. Isoprocarb 236. Oxydemeton-methyl 195. Isoprothiolane 237. Oxyfluorfen 196. Kresoxim-Methyl

197. Lactofen

198. Lindane

238. Oxytetracycline

239. Paclobutrazol

240. Paraquat 282. Pyrimethanil 241. Parathion 283. Pyriproxyfen 242. Parathion-methyl 284. Pyrithiobac sodium 243. Penconazole 285. Pyroxsulam 244. Pendimethalin 286. Quinalphos 245. Penoxsulam 287. Quinclorac 246. Permethrin 288. Quinoxyfen 247. Phenmedipham 289. Quintozene 248. Phenthoate 290. Quizalofop ethyl 291. Rimsulfuron 249. Phorate 250. Phosalone 292. Semiamitraz 251. Phosmet 293. Sethoxydim 294. S-Ethyl dipropylthiocarbamate 252. Phosphamidon (EPTC) 253. Phoxim 295. Simazine 254. Picloram 296. Spinosad 255. Piperonyl butoxide 297. Spirodiclofen 256. Pirimicarb 298. Spiromesifen 257. Pirimiphos-Methyl 299. Spiroxamine 258. Pretilachlor 300. Streptomycin 259. Primisulfuron-methyl 301. Sulfur dioxide 260. Prochloraz 302. Sulfuryl fluoride 261. Procymidone 303. Tebuconazole 262. Profenofos 304. Tebufenozide 263. Prohexadione calcium 305. Tecnazene 264. Prometryn 306. Teflubenzuron 265. Propachlor 307. Tefluthrin 266. Propamocarb 308. Tembotrione 267. Propanil 309. Terbufos 268. Propargite 310. Tetrachlorvinphos 269. Propazine 311. Tetraconazole 270. Propiconazole 312. Thiabendazole 271. Propoxycarbazone 313. Thiacloprid 272. Propylene oxide 314. Thiamethoxam 273. Propyzamide 315. Thidiazuron 274. Prothioconazole 316. Thifensulfuron methyl 275. Prothiofos 317. Thiocyclam 276. Pymetrozine 318. Tolclofos-Methyl 277. Pyraclostrobin 319. Tolylfluanid 278. Pyrethrins 320. Topramezone 279. Pyridaben 321. Tralkoxydim 280. Pyridalyl

281. Pyridate

322. Triadimefon

- 323. Triadimenol
- 324. Triasulfuron
- 325. Triazophos
- 326. Tribenuron methyl
- 327. Tribufos
- 328. Trichlorfon
- 329. Triclopyr
- 330. Tricyclazole
- 331. Tridemorph
- 332. Trifloxystrobin
- 333. Trifloxysulfuron
- 334. Triflumizole
- 335. Trifluralin
- 336. Triflusulfuron methyl
- 337. Triforine
- 338. Triphenyltin hydroxide (TPTH)
- 339. Triticonazole
- 340. Vamidothion
- 341. Vinclozolin
- 342. Zoxamide

Principles in interpreting MRLs/EMRLs in respect of dried, dehydrated, concentrated, processed or compounded food

When interpreting MRLs/EMRLs listed in the schedules of the proposed Regulation, the following conditions should be taken into account:

- (a) the MRLs/EMRLs shall apply to any food in a dried, dehydrated or concentrated form with adjustment determined with respect to the weight of the food after dilution or reconstitution, where appropriate;
- (b) apart from food in a dried, dehydrated or concentrated form, the MRLs/EMRLs shall apply equally to primary food commodities and processed food;
- (c) any compounded food may contain any pesticide residue if the proportion of the pesticide residue present in the compounded food does not exceed, in relation to the quantity of the relevant food used, the level permitted by the MRLs/EMRLs.

Preliminary List of Exempted Substances to be Included in the Proposed Regulation (Note: The list is being updated and subject to change)

Chemical pesticides

Inorganics

- 1. Ammonium, potassium and sodium salts of bicarbonate
- 2. Calcium and sodium salts of carbonate
- 3. Calcium oxide
- 4. Ferric phosphate (Iron (III) phosphate)
- 5. Lime sulphur (calcium polysulphide)
- 6. Potassium dihydrogen phosphate
- 7. Potassium tri-iodide
- 8. Sodium aluminum silicate
- 9. Sodium hypochlorite
- 10. Sulphur

Organics

- 11. 1,4-Diaminobutane
- 12. 6-Benzyladenine
- 13. Acetophenone
- 14. Ammonium acetate
- 15. Fatty acid C7-C20
- 16. Fatty alcohols/aliphatic alcohols
- 17. Gamma aminobutyric acid
- 18. Indole-3-butryic acid
- 19. Iron-EDTA complex
- 20. Lactic acid
- 21. Lysophosphatidylethanolamine
- 22. Methyl anthranilate
- 23. Methyl nonyl ketone
- 24. Mineral oil
- 25. Monocarbamide dihydrogen sulphate (urea sulphate)
- 26. Peracetic acid

- 27. Poly-N-acetyl-D-glucosamine
- 28. Protein hydrolysate
- 29. Rhamnolipid biosurfactant
- 30. Sodium and potassium salts of o-nitrophenolate and p-nitrophenolate
- 31. Sorbitol octanoate
- 32. Sucrose octanoate esters
- 33. Trimethylamine hydrochloride
- 34. Yeast extract hydrolysate from Saccharomyces cerevisiae

Pheromones

- 35. (E)-8-Dodecenyl acetate
- 36. (E,E) 8,10-Dodecadien-1-ol
- 37. (Z)-8-Dodecenol
- 38. (Z)-8-Dodecenyl acetate
- 39. E-11-tetradecen-1-yl-acetate
- 40. 3,7,11-Trimethyl-1,6,10-dodecatriene-1-ol (Farnesol) and 3,7,11-trimethyl-2,6,10-dodecatriene-3-ol (Nerolidol)

Plant materials / derivatives

- 41. Alder bark
- 42. Capsaicin
- 43. Cinnamaldehyde
- 44. Clove oil
- 45. Cytokinins
- 46. Extract from tea tree
- 47. Extract of Chenopodium ambrosioides near ambrosioides
- 48. Garlic extract
- 49. Geraniol
- 50. Lecithins, soya
- 51. Neem oil
- 52. Extract from *Opuntia lindheimeri*, *Quercus falcata*, *Rhus aromatica* and *Rhizophoria mangle*
- 53. Extract from *Quillaja saponaria* (saponins)
- 54. Rotenone
- 55. Seaweed extracts
- 56. Tall oil

Non-chemical Pesticide

Bacteria

- 57. Bacillus cereus strain BPO1
- 58. Bacillus pumilus strain QST 2808
- 59. Bacillus subtilis strains GB03, MBI 600 and QST 713
- 60. Bacillus thuringiensis
- 61. Pseudomonas chlororaphis strains 63-28 and MA342
- 62. Streptomyces lydicus strain WYEC 108

Fungi

- 63. Alternaria destruens strain 059
- 64. Ampelomyces quisqualis isolate M10 and strain AQ10
- 65. Beauveria bassiana strain GHA
- 66. Coniothyrium minitans strain CON/M/91-08
- 67. Gliocladium catenulatum strain J1446
- 68. *Muscodor albus* strain QST 20799 and the volatiles produced on rehydration
- 69. Paecilomyces fumosoroseus Apopka strain 97
- 70. Paecilomyces lilacinus strain 251
- 71. Pseudozyma flocculosa strain PF-A22 UL
- 72. Pythium oligandrum strain DV 74
- 73. Trichoderma asperellum strain ICC 012
- 74. Trichoderma gamsii strain ICC 080
- 75. Trichoderma harzianum Rifai strains T-22 and T-39

Protozoans

76. Nosema locustae

Viruses

- 77. Inclusion bodies of the multi-nuclear polyhedrosis virus of *Anagrapha falcifera*
- 78. Indian meal moth granulosis virus
- 79. Occlusion bodies of the granulosis virus of Cydia pomonella
- 80. Spodoptera exigua nuclear polyhedrosis virus

Summary of initial response to address the stakeholders' concerns

We have conducted a total of 14 briefings and consultation sessions for the stakeholders since January 2011. Participants include trade associations, food manufacturers, food importers, food distributors, retailers, Consulate Generals, local farmers, private laboratories, pesticide suppliers and food safety experts. Below is a summary of our initial response to address their concerns.

Pesticide residues outside the list of MRLs/EMRLs

- 2. Some were concerned whether they would contravene the proposed Regulation once pesticide residues outside the list of MRLs/EMRLs were detected.
- 3. We have explained that since our lists of MRLs/EMRLs are primarily based on the standards in Codex, supplemented by those in our major food supplying countries (the Mainland, the USA and Thailand), most of the pesticide-food pairs applicable to Hong Kong should have been covered. Under normal circumstances, the chance of detecting pesticide residues not included in the proposed Regulation is relatively small.
- 4. In addition, the proposed Regulation would state clearly that except for exempted substances, where pesticide residues are found outside the list, it will be prohibited unless DFEH is satisfied that the level of residue will not be dangerous or prejudicial to health. In coming to his decision, DFEH will conduct risk assessment.
- Segulation. At present, section 71 of Cap. 132 stipulates conditions under which warranty may be pleaded by the defendant as defence in any proceedings for an offence under the relevant part of the Ordinance. This is also applicable to the offences under the proposed Regulation. For example, a vendor charged under the proposed Regulation may produce evidence such as invoices to demonstrate that the food concerned is in the original state as obtained from the supplier without any further treatment and the supplier's earlier confirmation of safe food supply. In addition,

section 70 of Cap.132 provides that if the defendant could prove that the contravention was due to the act or default of some other person, and that he has exercised due diligence to secure that the provisions in question were complied with, he may plead this as a defence. Again, this is applicable to offences under the proposed Regulation.

Cost Increase

- 6. The food trade was concerned about the cost incurred in carrying out laboratory tests in order to comply with the proposed Regulation. We have advised food traders that they should deal with reputable food suppliers who can provide documentary proof on compliance with the proposed Regulation. Food traders should keep the relevant transaction documents for record.
- 7. Although around 300 pesticides are included in the list, the number of residue limits applicable to individual food would be much smaller. It is because normally only a few pesticides would be applied to individual food crops. As a result, we do not anticipate an undue increase in cost incurred by food traders.

Testing capability of private laboratories

- 8. Some members of the trade were worried about the testing capability of local private laboratories.
- 9. We have pointed out that there are currently a few private laboratories offering the services. Two of them have been accredited under the Hong Kong Laboratory Accreditation Scheme to provide testing service for pesticide residues in food. Since 2008, the Government Laboratory (GL) has outsourced the tests for pesticide residues in food to private laboratories. As such, private laboratories have gained considerable experience in conducting tests for pesticide residues in food.
- 10. Operators of private laboratories consider that the proposed two-year grace period would allow sufficient time for them to acquire the necessary facilities to enhance their testing capability. In the meantime, the GL will continue to provide technical assistance to private laboratories.

- 11. As most vegetables are imported from the Mainland, GL will also contact laboratories in the Mainland, in particular those in Shenzhen and Guangzhou, to explore the possibility for them to provide testing services for food traders in Hong Kong.
- 12. With the above measures, we are confident that private laboratories would have sufficient capability to meet the demand for testing pesticide residues in food arising from the proposed Regulation.

Maintaining stable food supply

- 13. Since Hong Kong relies heavily on imported food, some members of the trade were concerned whether the proposed Regulation would affect the stability in food supply by reducing food choices.
- 14. In formulating the proposed Regulation, the Administration is mindful of the need to maintain stable food supply. Since we have adopted MRLs from the Codex, supplemented by standards in the Mainland and other major food supplying countries (the USA and Thailand), we believe that the adoption of the pesticide residue standards in Hong Kong would unlikely reduce the supply of food items to Hong Kong due to inability of food items to meet our proposed standards. If there is sufficient scientific evidence that a standard is too stringent, we would adjust as appropriate without compromising the protection of food safety.
- 15. To address the concern of the trade, we have also proposed to set up a mechanism where a person may apply to DFEH for adding a new MRL or revising an existing MRL, or adding an exempted substance. DFEH may approve the application if he is satisfied, among other things, that the level of residue is not dangerous or prejudicial to health. In coming to his decision, DFEH will conduct risk assessment. DFEH would revise the lists of MRLs and exempted substances regularly and incorporate all MRLs/exempted substances approved during the period.
