

Consultation Paper

**Proposed Legislative Framework for
Pesticide Residues in Food in Hong Kong**

Centre for Food Safety

Food and Environmental Hygiene Department

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CHAPTER 1 INTRODUCTION

1.1 To enhance and stabilize crop yield, protect the nutritional integrity of food, facilitate storage to assure year-round supplies, and provide attractive and appealing food products, farmers and growers have changed the way they produce crops. Among which, the use of pesticides and other chemicals has become a common agricultural practice. In general, farmers use pesticides to protect crops, e.g. fruits and vegetables, from insects, pests, weeds and fungal diseases whilst they are growing and to protect harvested crops from rats, mice, flies and other insects during storage. Pesticides are also applied to food animals for the control of diseases caused by fleas and lice, etc. In this respect, the use of pesticides is beneficial to public health because uncontrolled fungi, insects, rats, fleas and lice, etc. can contaminate crops with natural toxins and harmful microorganisms.

1.2 Despite the beneficial effects they bring forth, the use of pesticides, however, is quite controversial. This is because small amounts of pesticide residues may remain in the crops or animal food, either resulted from the direct use of pesticides on the crops as mentioned above, farm animal feeding on pesticide treated feed, or environmental contamination. Consumer exposure to pesticide residues in food, *inter alia*, is an issue that is of considerable concern to consumers, food producers, academics and government agencies. Overseas pesticide residue data demonstrates that food crop, namely fruits, vegetables and cereals, is the major dietary source of pesticide residues for the general population.

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 effects (e.g. methamidophos and triazophos, may affect the nervous system) whereas other pesticides have shown to cause chronic adverse health effects (e.g. lindane may affect the liver and kidney; and dicofol may affect foetal development) in animals.

CHAPTER 2 SITUATION IN HONG KONG

Food supplies in Hong Kong

2.1 Majority of fruits and vegetables supplied in the local market are imported from various countries/areas around the world. About 34% of fresh and semi-processed fruits, vegetables and cereals were imported from the Mainland, about 27% from Thailand and about 16% from the United States of America (USA), with other countries contributed to less than 5% of the total import in 2006.^a Local production accounted for only 4% of fresh vegetables consumed in 2006.^b

Current regulatory control on the use of pesticides

2.2 At present, the import, manufacture, formulation, distribution, sale and supply of pesticides in Hong Kong is regulated under the Pesticides Ordinance (Cap. 133), which is enforced by the Agriculture, Fisheries and Conservation Department.

2.3 As stipulated in the Pesticide Ordinance, only pesticides that have been registered in Hong Kong may be freely distributed and used. Details of registered pesticides, including the active ingredient(s), concentration limit and permitted formulations, are entered into the Pesticides Register. Individual pesticide products do not have to be registered as long as their active ingredients are registered and conformed to the specified maximum concentration of active ingredient(s) and permitted formulation detailed in the Register.

2.4 Regarding the regulation of pesticide residues in food in Hong Kong upon the application of pesticides, the Public Health and Municipal Services Ordinance (Cap. 132) stipulates that all food on sale must be wholesome, unadulterated and fit for human consumption. However, there is no specific subsidiary legislation to govern pesticide residues in food in Hong Kong.

^a Census and Statistics Department. HK Merchandise Trade Statistics December 2006 - Imports.

^b AFCD. Agriculture in HK. [cited 10 April 2007] Available from: http://www.afcd.gov.hk/english/agriculture/agr_hk/agr_hk.html

Monitoring pesticide residues in food

2.5 The Centre for Food Safety (CFS) operates a food surveillance programme and regularly takes food samples, including fruits, vegetables and cereals at import, wholesale and retail levels for testing of pesticide residues.

2.6 Currently, CFS follows the testing methods and standards recommended by the Codex Alimentarius Commission (Codex). Codex, established by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) of the United Nations in 1960s, 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. The Codex Alimentarius, or the food code, is a collection of these standards, codes of practice, guidelines and other recommendations. When there is no relevant Codex standards, CFS will conduct its own risk assessment studies to determine whether the level of pesticide residues detected in food is harmful to human health.

Regulatory and enforcement problems

2.7 The lack of relevant subsidiary legislation on pesticide residues in food in Hong Kong poses regulatory and enforcement problems. In other words, there is currently no provision which empowers CFS to take legal action against the food trade if the pesticide residue level in a particular food sample, collected during our routine food surveillance programme, is found to exceed standards recommended by Codex. Unless it could be proven that the concerned food sample is unfit for human consumption can regulatory action be taken under the provisions of the Public Health and Municipal Services Ordinance (Cap 132). Moreover, Codex do not cover all the pesticides used in our major exporting countries (e.g. Codex do not provide standards for bisultap which is a registered pesticide in the Mainland) and all food items of local interest (e.g. leafy vegetables are commonly consumed in Hong Kong, however, Codex has only established standards for a limited range of these food commodities). There is therefore a need for Hong Kong to set regulatory standards for a list of pesticides of local relevance to meet regulatory control needs.

CHAPTER 3 THE INTERNATIONAL SCENE

3.1 In developing a legislative framework on pesticide residues in food, the recommendations by Codex and the practice of other international regulatory authorities, including Australia, European Community, Japan, the Mainland, New Zealand, Singapore and the USA, have been studied. The ensuing paragraphs in this chapter details the international practice in the following areas:

- (a) definitions of “pesticide” and related terms;
- (b) approaches in regulating pesticide residues in food;
- (c) approaches in determining the maximum residue limits (MRLs);
- (d) approaches in regulating pesticide residues that are not specified;
and
- (e) approaches in classification of food.

Definition of “pesticide” and related terms

3.2 The Codex Alimentarius has laid down the definitions of pesticide and pesticide residues, which demarcates the scope of regulatory control of pesticide residues in food:

“Pesticide” means any substance intended for preventing, destroying, attracting, repelling, or controlling any pest including unwanted species of plants or animals during the production, storage, transport, distribution and processing of food, agricultural commodities, or animal feeds or which may be administered to animals for the control of ectoparasites. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant, fruit thinning agent, or sprouting inhibit and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport. The term normally excludes fertilizers, plant and animal nutrients, food additives and animal drugs.

“Pesticide residue” means any specified substance in food, agricultural commodities, or animal feed resulting from the use of pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products, and

impurities considered to be of toxicological significance.

3.3 The Codex Alimentarius has also laid down the definitions of pesticide residue limits as follows:

“Maximum residue limit” (MRL) is the maximum concentration of a pesticide residue (expressed as mg/kg) to be legally permitted in or on food commodities and animal feeds.

“Extraneous maximum residue limit” (EMRL) refers to the maximum permitted limit of residues of compounds, which were used as pesticide but not any more registered as pesticide, arising from environmental contamination (including former agricultural use of pesticides) or uses of compound other than agricultural uses.

3.4 It is noted that some authorities (e.g. the Mainland) have taken reference from the above Codex definitions when developing the definitions of pesticide and pesticide residues and hence the scope of their regulations. Some authorities might take into account their own local situation and define terms in different ways (e.g. pesticide residues and veterinary drug residues are defined and regulated together as agricultural chemical residues in Australia). However, most regulatory authorities have similar definitions of MRL and EMRL as those of Codex.

Approaches in regulating pesticide residues in food

3.5 Regulating pesticide residues in food in the international arena can be broadly classified into the “positive list” approach and “non-positive list” approach.

3.6 Under a “positive list” approach, MRLs of pesticides that are allowed to be found in food are specified in the legislation whereas any other pesticide residues without specified MRLs are not allowed. This approach has been adopted in a number of overseas jurisdictions such as Australia, European Community, Japan, New Zealand, Singapore and the USA.

3.7 Under a “non-positive list” approach, MRLs of a list of pesticides are also laid down in the legislation. However, the presence of pesticide

residues in food without specified MRLs may not necessarily contravene the legislation. This approach has been adopted in the Mainland.

Approaches in determining MRLs

3.8 Under Codex, the Codex Committee on Pesticide Residues (CCPR) is charged to develop MRLs for pesticides. CCPR refers and prioritises pesticides to the Joint Food and Agriculture Organization (FAO) / World Health Organization (WHO) Meeting on Pesticide Residues^c (JMPR) for assessing their toxicities and estimating MRLs. Recommendation from JMPR will then be forwarded to CCPR for further consideration and the final sets of MRLs will be adopted by Codex as the international reference standards.

3.9 Generally speaking, MRLs are established on the basis of appropriate data obtained mainly from supervised field trials according to Good Agricultural Practice^d (GAP). A residual level exceeding the MRL is a reflection for non-compliance to GAP.

3.10 A distinction needs to be made here between MRLs and safety reference values, i.e., acceptable daily intake (ADI) for chronic toxicity or acute reference dose (acute RfD) for acute toxicity. Even though the primary purpose of setting MRLs in food is to protect the health of consumers and the levels are intended to be toxicologically acceptable (i.e. do not cause acute or chronic toxicities in humans), it should not be confused with safety reference values. It follows that exposure to pesticide residue in excess of MRL does not automatically imply a hazard to health provided the dietary exposure to that particular pesticide falls within the safety reference value. The acceptability of MRLs is thus judged on the basis of a comparison of the safety reference values with dietary exposure estimates, as determined on the basis of suitable dietary exposure studies. On the other hand, establishment of EMRLs is mainly based on residue data obtained from national food control or monitoring activities.

^c JMPR is the abbreviated title for the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. The FAO Panel of Experts is responsible for reviewing residue and analytical aspects of the pesticides considered, estimating the maximum residue levels according to supervised trials and GAP. The WHO Core Assessment Group is responsible for reviewing toxicological data on the pesticides, estimating safety reference (i.e. acceptable daily intake) and levels of dietary intakes of pesticide residues. As necessary, acute reference doses for pesticides are estimated along with appropriate estimates of short-term dietary intake.

^d GAP in the use of pesticides includes the authorized safe use of pesticides under actual conditions necessary for effective and reliable pest control and in a manner which leaves a residue which is the smallest amount practicable.

Schematic diagrams illustrating how MRLs are established and the relationship between MRLs and safety reference values are at Annex I.

3.11 As of July 2007, Codex has discussed and recommended the MRLs /EMRLs for some 220 pesticides. These maximum limits are updated or revoked periodically and new ones are established from time to time.

3.12 Member countries of Codex may not necessarily adopt the complete set of Codex standards. They may permit the use of different pesticides in different food commodities according to their own climatic and environmental conditions as well as dietary habits. MRLs of these pesticides in different food commodities are then established based on the residue data obtained from individual countries' own supervised field trials or provided by the industry.

Approaches in regulating pesticide residues that are not specified

3.13 For overseas jurisdictions that adopt a "positive list" approach in regulating pesticide residues in food, there are generally three ways in controlling pesticide residues for which specified MRLs are not available.

3.14 The first one is that the detection of any such pesticide residue is considered illegal, i.e., "zero tolerance". This approach has been adopted by Australia, Singapore and the USA. The second one is that the detection of any such pesticide residue is only considered unacceptable when the residual level exceeds a "default value". The European Community and Japan have adopted a default value of 0.01 mg/kg whereas the New Zealand food authority has adopted a default value of 0.1 mg/kg. Lastly, some regulatory authorities (e.g., Australia, European Community, Japan, New Zealand and the USA) further established a list of substances for which MRLs are not necessary for situations (i) where residues do not occur in food, or (ii) where the residues are identical to or indistinguishable from natural food components, or (iii) are otherwise of no toxicological significance. These substances can then be used without contravening relevant legislation.

Approaches in classification of food

3.15 Codex has developed a Codex Classification of Food and Feed which is intended primarily to ensure the use of uniform nomenclature. It also helps to classify foods into groups and/or sub-groups for the purpose of establishing group MRLs for food commodities with similar characteristics and residue potential. A number of overseas jurisdictions such as Australia, European Community, Mainland, Japan and the USA have also developed similar food classifications according to their local situation.

3.16 The following table depicts a brief summary of major approaches in the regulation on pesticide residues in food in various countries:

Table: Summary of major approaches in overseas regulation of pesticide residues in food

Codex / Countries	Approach in Regulating Pesticide Residues in Food	Approach in Regulating Pesticide Residues without MRLs	Listed of “Exempted” Substances
Codex	Not applicable	Not applicable	Not available
Australia	“Positive list”	Zero tolerance	Yes
European Community	“Positive list”	Default value of 0.01 mg/kg	Yes
Japan	“Positive list”	Default value of 0.01 mg/kg	Yes
Mainland China	“Non-positive list”	Not applicable	Not available
New Zealand	“Positive list”	Default value of 0.1 mg/kg	Yes
Singapore	“Positive list”	Zero tolerance	Not available
USA	“Positive list”	Zero tolerance	Yes

CHAPTER 4 THE LEGISLATIVE PROPOSAL

Objectives of developing the legislative framework

4.1 In considering the proposed legislative framework for pesticide residues in food in Hong Kong, it is aimed to achieve the following objectives:

- a. better protect public health;
- b. facilitate effective regulatory control;
- c. promote fair trade practices; and
- d. promote harmonization between local and international standards.

4.2 After taken into account the international practice and the need to achieve the above objectives, the detailed legislative proposal for regulating pesticide residues in food is set out in the following paragraphs.

To adopt the definition of “pesticides” and other related terms from Codex

4.3 As in Codex and other overseas regulatory authorities, it is necessary to define key terms such as “pesticide”, “pesticide residue”, “MRL” and “EMRL” in the new subsidiary legislation in order to demarcate the scope of control.

4.4 In defining the terms in the new subsidiary legislation, it is proposed to take reference mainly from the Codex definitions which emphasised the use of pesticide during the production, storage, transport, distribution and processing of food. By following the Codex definitions, our trading partners will have a better understanding of the scope of our regulatory requirement. This will also facilitate the selection of appropriate MRLs and EMRLs for relevant pesticides to our new legislation.

To adopt a “positive list” approach

4.5 In order to better protect public health, it is proposed to adopt a “positive list” approach in the subsidiary legislation. Compared with the “non-positive list” approach, the “positive list” approach offers a more comprehensive control by stating clearly the MRLs of pesticides that are allowed to be found in food and also facilitate effective enforcement measures.

4.6 As new pesticides and new applications on crops keep emerging, a mechanism will be instituted to regularly update the “positive list”.

To adopt MRLs developed by Codex as the backbone

4.7 Since Hong Kong depends almost entirely on imported food, it is of little practical use to conduct our own supervised field trials for establishing our own MRLs, or to assess pesticide residue data provided by the industry.

4.8 A two-step approach is therefore proposed to determine MRLs and EMRLs for Hong Kong. As a first step, it is proposed to adopt the MRLs and EMRLs recommended by Codex as the backbone with supplementation from standards of the Mainland and other major exporting countries, notably Thailand and the USA. This approach is considered pragmatic taking into account the heavy reliance of Hong Kong on imported food. As a second step, risk assessment studies will be conducted using internationally accepted methods to assess whether the proposed MRLs and EMRLs are adequate to protect public health in the local setting. It is estimated that MRLs of some 430 pesticides need to be adopted.

4.9 The proposed list of pesticides for which MRLs will be established in our new subsidiary legislation is at Annex II. Examples of MRLs/EMRLs being adopted by Codex is at Annex III.

To develop a “default value” for MRLs not specified in the subsidiary legislation and a list of “exempted substances”

4.10 To tie in with the “positive list” approach, it is necessary to deal with pesticide residues for which no MRLs or EMRLs have been specified in the subsidiary legislation. According to international practice, either a “default value”, residue level below which is considered acceptable or a “zero tolerance” is set for such chemicals. It is proposed to set a “default value” for those chemicals in which no MRLs and EMRLs have been set under the “positive list” based on the following reasons:

- it is difficult to build and maintain a comprehensive list of MRLs, taking into account the frequent amendment to MRLs in Codex and other major exporting countries;

- the limit of detection of laboratory testings may vary in different food commodities, and with different laboratories and the advancement of technology. The establishment of a “default value”, taking into account the available analytical methods, will facilitate the trade in monitoring pesticide residues in their products and the laboratories in conducting corresponding analyses; and
- the “default value” approach has been adopted in a number of overseas jurisdictions such as the European Community, Japan and New Zealand.

4.11 Nevertheless, the exact value for this “default value” needs further exploration.

4.12 On the other hand, in order 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 develop a list of “exempted substances”. The principles of developing such a list should be: (i) the substances used fall under the definition of pesticides; (ii) MRLs are considered not necessary by other regulatory authorities; and (iii) the substances will not pose any public health risk. It should however be noted that such a list of “exempted substances” is not available from Codex. It is proposed to make reference to the list adopted by our major exporting countries. The list of “exempted substances” adopted in the USA is at Annex IV.

To adopt Codex’s classification of food

4.13 A classification of food is considered necessary for uniform nomenclature among international trade and for the purpose of establishing MRLs/group MRLs for food commodities of similar characteristics and residue potential. As it is proposed to adopt Codex MRLs as the backbone of the local set of MRLs for pesticide residues in food, to ensure compatibility, it is also proposed to make reference to Codex when developing such classification system under the new legislative framework.

4.14 Index and examples of Codex classification of food is extracted at Annex V.

To implement the new subsidiary legislation with a grace period

4.15 To allow sufficient time for laboratories (both private and government) to develop testing methods for pesticides as listed in the new subsidiary legislation and the trade in complying with the new regulatory requirement, it is proposed to grant a two-year grace period for this new piece of subsidiary legislation.

CHAPTER 5 VIEWS SOUGHT

5.1 The Administration proposes to introduce a new subsidiary legislation to govern pesticide residues in food. The proposed legislative framework, as set out in Chapter 4, is summarised as follows:

- to adopt the definition of “pesticides” and other related terms from Codex;
- to adopt a “positive list” approach;
- to adopt MRLs developed by Codex as the backbone;
- to develop a “default value” for MRLs not specified in the subsidiary legislation and a list of “exempted substances”;
- to adopt Codex’s classification of food; and
- to implement the new subsidiary legislation with a grace period.

5.2 The Administration invites you to let us have your views on the proposed legislative framework. Please send your comments by letter, facsimile or e-mail to the Centre for Food Safety before []:

Centre for Food Safety
(Attn.: Risk Assessment Section)
Food and Environmental Hygiene Department
43/F, Queensway Government Offices,
66 Queensway,
Hong Kong
Facsimile : 2893 3547
E-mail address : []

5.3 The Administration will take full account of the views received before finalising the new subsidiary legislation on regulating pesticide residues in food under the Public Health and Municipal Services Ordinance (Cap. 132).

5.4 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.