Pesticide Residues in Food Regulation (Cap. 132CM)

26 February 2014

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Food and Environmental Hygiene Department

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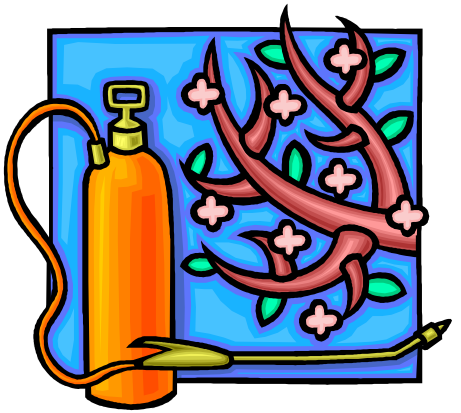
Outline

- Background
- Establishment of pesticide residue limits
- The Regulation
- Preparation for commencement of the Regulation
- Examples of Section 5 and 6 of the Regulation

Background

What are pesticides?

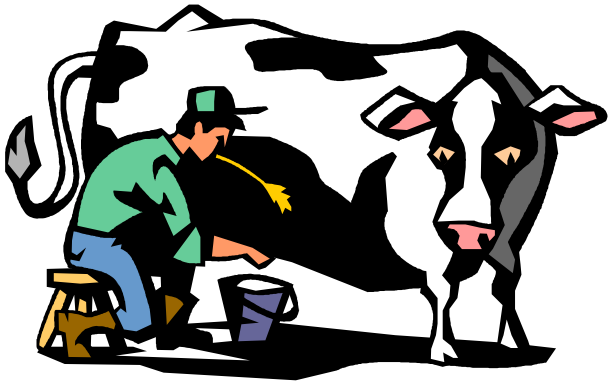


Pesticides

- Substances used to kill or control unwanted insects, plants, fungi or other pests.
  - e.g., insecticides, herbicides, fungicides, etc.
- Also includes substances intended for use as a plant growth regulator, defoliant, fruit thinning agent, or sprouting inhibitor, etc.
  - e.g., cytokinins (a group of naturally-occurring plant growth regulators that promote cell division, leaf expansion and retard leaf aging)
    - promoting fruit growth in apple and pistachio

Reasons for the presence of pesticide residues in food

- direct use of pesticides on the food crops;
- animals fed on feed that have been grown with the application of pesticides; and
- environmental contamination.



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Health effects

- Depend on the nature of individual pesticides, the amount and duration of exposure
- Dietary exposure to pesticide residues exceeding the safety reference values may lead to acute and/or chronic adverse health effects
  - Acute effects generally occur shortly (within hours or a day)
  - Chronic effects develop over a relatively longer period of time (in terms of months or years)

Safety reference values

- Acute Reference Dose (ARfD) / Acceptable Daily Intake (ADI)
- Established by the Joint Food and Agriculture Organization (FAO) and World Health Organization (WHO) Meeting on Pesticide Residues (JMPR)
- Based on available toxicological data
- Expressed on a body-weight basis
- Used to assess the risk of acute and chronic adverse effects, respectively

Establishment of pesticide residue limits

MRL (1)

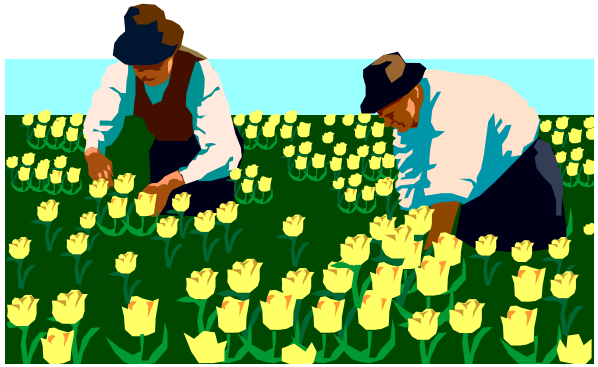
- Refers to the legally permitted maximum level of pesticide residues in food
- Objective:
  - To ensure that the use of pesticides during food production leaves residues in food as low as practically achievable, whereby minimising the potential risk to public health

MRL (2)

- Established on the basis of appropriate residue data obtained mainly from supervised field trials
  - scientific studies following Good Agricultural Practice (GAP): pesticides are applied to crops following the instruction on the pesticide label, so as to reflect the actual practice
- Toxicologically acceptable
  - i.e., do not cause acute or chronic toxicity in humans

Good Agricultural Practice (GAP)

- Nationally authorised safe use of pesticides under actual conditions
  - necessary for effective and reliable pest control
  - in a manner that leaves the smallest amount of residue practicable
  - Includes:
    - the recommended application frequencies, and dosage
    - the duration between the last application of the pesticide and harvest



Level of pesticide residue > MRL

- A reflection for non-compliance to Good Agricultural Practice (GAP)
- Not automatically imply a hazard to health
- Should not be confused with safety reference values
  - expressed in terms of the Acceptable Daily Intake (ADI) of a particular pesticide residue from all sources
  - established based on available toxicological data
  - with the application of safety factor

Pesticides that have been banned or are no longer in use

- Some may persist in the environment, and therefore trace amount may be present in food
  - e.g., DDT, lindane
- Codex has established "Extraneous Maximum Residue Limits (EMRL)" for some of these pesticides
- Detection of any of these pesticide residues does not necessarily reflect their current use in agriculture

Pesticide Residues in Food Regulation (Cap. 132CM)

Objectives

- Objectives:
  - Better protect public health;
  - Facilitate effective regulation of pesticide residues in food; and
  - Promote harmonisation between local and international standards

- Pesticide Residues in Food Regulation (Cap. 132CM)
  - LegCo completed scrutiny of the Regulation in June 2012
  - Will come into operation on 1 August 2014

Section 1

- Commencement
  - This Regulation comes into operation on 1 August 2014.

Section 2 (1)

- Interpretation
  - To adopt Codex's definition of "pesticides" and other related terms
    - The main structure of the framework has taken reference from that of Codex
    - It defines terms, e.g., "pesticide" and "pesticide residue", in a way consistent with Codex
    - Promote harmonisation of local and international standards

Section 2 (2)

- Including the following -
  - Compounded food (合成食物)
  - Exempted pesticide (獲豁免除害劑)
  - Extraneous maximum residue limit (EMRL) (最高再殘餘限量)
  - Maximum residue limit (MRL) (最高殘餘限量)
  - Pesticide (除害劑)
  - Pesticide residues (除害劑殘餘)
  - Primary food commodity (原食品)
  - Residue definition (殘餘物定義)

Section 3

- Application

  This Regulation does not apply to the food which is imported solely for the purpose of export if the food –

  (a) is air transhipment cargo; or

  (b) during the period between its import and export, remains in the vessel, vehicle or aircraft in which it was imported.

Section 4 (1)

- Import and sale of food containing pesticide residues is only allowed if —
  - the food and the pesticide residues concerned are specified in Schedule 1 and the amount of the residues does not exceed the limit specified in the Schedule;
  - the pesticide residues concerned are residues of an exempted pesticide set out in Schedule 2; or
  - the consumption of the food is not dangerous or prejudicial to health
    - for pesticide residues with no specified MRLs/EMRLs in Schedule 1 , and
    - not an exempted pesticide

Section 4 (2)

- Special types of foods
  - Section 5
    - Food in a dried, dehydrated or concentrated food
    - Food in other processed forms
  - Section 6
    - Compounded food

- Penalty
  - Maximum penalty of a fine at level 5 (HK$50,000) and imprisonment for 6 months

Section 5

- Principles for determining MRL/EMRL for certain food (other than compounded food)
  - Food in a dried, dehydrated or concentrated form
    - MRL/EMRL is to be adjusted proportionately by reference to the ratio between the weight of the food before and after dilution or reconstitution
  - Food in other processed forms, e.g., rice flour
    - MRL/EMRL of the primary food commodity from which the food is derived is applicable to the food

Section 6

- Principles for determining MRL/EMRL for compounded food
  - Pro-rata MRL/EMRL
    - % of MRL/EMRL for the residue definition of the pesticide in respect of an ingredient that equals the % of the ingredient in the compounded food.

Section 7

- Factors for determining safety of food with pesticide residues include –
  - toxicological profile and safety reference values of the pesticide concerned;
  - characteristics of the pesticide and level of the pesticide residues in the food concerned;
  - consumption pattern of the food, and long-term and short-term dietary exposure data;
  - any statutory requirement related to the food;
  - information provided by an importer/supplier of the food;
  - information, reports or testing results provided by a public analyst;
  - information (including reports, decision documents) provided by an international food or health authority or food or health authority outside Hong Kong, etc.

Section 8

- Provides that a prosecution of an offence under the Regulation may be brought in the name of DFEH.

Schedule 1 (1)

- Sets out the maximum limits of certain pesticide residues that are allowed in certain food and the interpretation provisions for that Schedule
  - consists of 360 pesticides and MRLs/EMRLs for over 7 000 pesticide-food pairs
    - Part 1: MRLs
    - Part 2: EMRLs

Schedule 1 (2)

- Based primarily on the available standards recommended by Codex in 2011
  - supplemented by standards of the Mainland and other major food exporting countries to Hong Kong available at the time
  - taking into consideration comments received from stakeholders during the public consultation held in July to September 2011.
- These standards had been scrutinized by conducting risk assessment.

Column 1	Column 2	Column 3	Column 4	Column 5
Item	Pesticide	Residue definition	Description of food	Maximum residue limit (MRL) (mg/kg)
138.7	Fenpyroximate	Fenpyroximate	Cattle milk (F)	0.005
138.8	Fenpyroximate	Fenpyroximate	Cattle meat (Fat)	0.02
138.9	Fenpyroximate	Fenpyroximate	Cattle kidney	0.01
138.10	Fenpyroximate	Fenpyroximate	Cattle liver	0.01
138.11	Fenpyroximate	Fenpyroximate	Tree nuts	0.05
138.12	Fenpyroximate	Fenpyroximate	Melons, except watermelon	0.05
138.13	Fenpyroximate	Fenpyroximate	Cucumber	0.03
138.14	Fenpyroximate	Fenpyroximate	Fruiting vegetables, other than Cucurbits	0.2
139.1	Fenthion	Sum of fenthion, its oxygen analogue and their sulphoxides and sulphones, expressed as	Rice, husked	0.05

Interpretation of MRLs/EMRLs for Foods of Animal Origin (1)

- Part 3 of Schedule 1 - Certain meat or poultry meat

Column 1	Column 2	Column 3	Column 4	Column 5
Item	Pesticide	Residue definition	Description of food	Maximum residue limit (MRL) (mg/kg)
63.39	Chlorpyrifos	Chlorpyrifos	Cattle meat (Fat)	1
63.40	Chlorpyrifos	Chlorpyrifos	Goat meat	0.05
63.41	Chlorpyrifos	Chlorpyrifos	Horse meat	0.25

Interpretation of MRLs/EMRLs for Foods of Animal Origin (2)

- Part 3 of Schedule 1 - Certain meat or poultry meat
  - Where "(Fat)" forms part of the description of a food (i.e., meat from mammals other than marine mammals or poultry meat) as set out in Column 4 of either Part 1 or Part 2 of the Schedule 1 to the Regulation, the corresponding MRL/EMRL in Column 5 applies only to the fat of the food (i.e., expressed on a fat basis)

Interpretation of MRLs/EMRLs for Foods of Animal Origin (3)

- Part 3 of Schedule 1 - Certain milk products

Column 1	Column 2	Column 3	Column 4	Column 5
Item	Pesticide	Residue definition	Description of food	Maximum residue limit (MRL) (mg/kg)
136.12	Fenpropathrin	Fenpropathrin	Pig fat	1
136.13	Fenpropathrin	Fenpropathrin	Sheep fat	1
136.14	Fenpropathrin	Fenpropathrin	Cattle milk (F)	0.1
136.15	Fenpropathrin	Fenpropathrin	Cattle meat (Fat)	0.5

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Interpretation of MRLs/EMRLs for Foods of Animal Origin (4)

- Part 3 of Schedule 1 - Certain milk products
  - the pesticide residue is fat soluble and the corresponding MRLs for milk products shall be applied as explained below:
    a) For a "milk product" with a fat content less than 2%, the MRL applicable is half that specified for "milk". For example, the MRL of fenpropathrin in skimmed milk (<2% fat) will be "0.1mg/kg (MRL for milk specified in Column 5) divided by 2", i.e., 0.05mg/kg
    b) For a "milk product" with a fat content of 2% or more, the MRL applicable is 25 times that specified for milk, expressed on a fat basis. For example, the MRL of fenpropathrin in butter (a milk product >2% fat) will be "25*0.1mg/kg, expressed on a fat basis", i.e., 2.5mg fenpropathrin residues per kg fat content of butter

Schedule 2

- Sets out the exempted pesticides (78)
  - Criteria –
    - whether the use of the pesticide will result in residues occurring in food;
    - whether the residues of the pesticide are identical to or indistinguishable from natural food components; and
    - whether the residues of the pesticide have any toxicological significance or will be dangerous or prejudicial to human health.
  - Made reference to the lists adopted by major food exporting countries to Hong Kong in drawing up our own

Schedule 2

[s. 2]

Exempted Pesticide

Column 1 Item	Column 2 Description of pesticide
1.	1,4-Diaminobutane
2.	Acetophenone
3.	Alder bark
4.	*Alternaria destruens* strain 059
5.	Ammonium acetate
6.	Ammonium bicarbonate / potassium bicarbonate / sodium bicarbonate
7.	Amorphous silicon dioxide
8.	*Ampelomyces quisqualis* isolate M10 and strain AQ10
9.	*Bacillus cereus* strain BP01
10.	*Bacillus pumilus* strain QST2808
11.	*Bacillus subtilis* strains GBO3, MBI600 and QST713
12.	*Bacillus thuringiensis*
13.	*Beauveria bassiana* strain GHA
14.	Boric acid / borates (borax (sodium borate decahydrate), disodium octaborate tetrahydrate, boric oxide (boric anhydride), sodium borate and sodium metaborate)
15.	Bromochlorodimethylhydantoin (BCDMH)
16.	Calcium carbonate / sodium carbonate
17.	Capsaicin

Statutory defences (1)

- 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.
- Applicable to the offences under the Regulation.
  - e.g., a vendor charged under the 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.

Statutory defences (2)

- 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 all due diligence to secure that the provisions in question were complied with, he may plead this as a defence.
  - Applicable to offences under the Regulation.

Update of the lists of MRLs/EMRLs and exempted pesticides (1)

- DFEH will update Schedules 1 and 2 to the Regulation as necessary.
- Traders are welcomed to make proposals, with sufficient supporting information to DFEH for consideration:
  - to revise existing MRLs/EMRLs
  - to propose new MRLs/EMRLs and exempted pesticides for inclusion in Schedules 1 and 2
    - will be suitably incorporated in the next updating exercise
    - free of charge

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Update of the lists of MRLs/EMRLs and exempted pesticides (2)

- Factors for consideration –
  - latest international developments;
  - consistency with the existing list;
  - availability of relevant supporting information and reference materials for testing; and
  - whether the limits concerned could pass the risk assessment scrutiny.

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

- 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 Regulation.
- Registration of a pesticides intended for use on local food crops –
  - If no MRL(s) related to the pesticide concerned could be found in Schedule 1 to the Regulation and it is not an exempted pesticide in Schedule 2 to the Regulation, the application under Cap. 133 would not be accepted by DAFC.
  - The applicant may make a proposal to DFEH for including the relevant MRL(s) in Schedule 1 or including the pesticide in Schedule 2 to the Regulation in the next updating exercise, and wait for the same to become effective before he could submit the application to DAFC under Section 5 of Cap. 133.

Preparation for Commencement of the Regulation

Update of Schedule 1

- Incorporate the latest changes to MRLs adopted by Codex in 2012 and 2013, while taking into account proposals put forth by relevant stakeholders since the enactment of the Regulation in June 2012

- Amendments to the Regulation will be tabled at LegCo in 2014

Briefing Sessions

- CFS has conducted a series of briefings for the trade and other interested stakeholders to prepare for the commencement of the Regulation on 1 August 2014.

Preparation of Guidelines

- CFS has prepared guidelines to assist the trade in complying with the requirements of the Regulation –
  1. User Guidelines
  2. Guidelines on Food Classification for the Regulation
  3. Guide to the Proposal for Addition or Revision of MRLs and EMRLs, and Addition of Exempted Pesticides under the Regulation (Cap. 132CM)

Online Searchable Database

- To facilitate the trade and relevant stakeholders to find appropriate MRL/EMRL for the pesticide-food pair concerned
- Will be launched after LegCo has completed scrutiny of the amendments to the Regulation

Examples of Section 5 and 6 of the Regulation

Section 5

- Principles for determining MRL/EMRL for certain food (other than compounded food)
  - Food in a dried, dehydrated or concentrated form
    - MRL/EMRL is to be adjusted proportionately by reference to the ratio between the weight of the food before and after dilution or reconstitution

Example 1 – Carbendazim in Dehydrated Carrot

1. Search the MRL of carbendazim in carrot specified in Schedule 1

⇒ 0.2mg/kg (item 49.62)

2. Look up the water content of fresh carrot and dehydrated carrot from reliable database(s) or determine the water content by conducting laboratory analysis

⇒ water content of fresh carrot = 89%

⇒ water content of dehydrated carrot = 10%

$$\frac{100\% - \text{“Water content in dehydrated carrot” (\%)}}{100\% - \text{“Water content in fresh carrot” (\%)}} \times \text{MRL (or EMRL)}$$

= ((100 – 10) / (100 – 89)) × 0.2

= 8.2 × 0.2

= 1.6mg/kg

The adjusted MRL for carbendazim in the dehydrated carrot is calculated to be 1.6mg/kg

Example 2 – Propargite in Concentrated (Ten times (10X)) Orange Juice

1. Search the MRL of propargite in orange juice specified in Schedule 1
   ⇒ 0.3mg/kg (item 277.14)

2. Obtain the concentration factor from the food manufacturer/supplier
   ⇒ 10X (this example)

3. Compute the adjusted MRL of propargite in concentrated (10X) orange juice:
   ⇒ 0.3mg/kg × 10 = 3mg/kg

The adjusted MRL for propargite in the concentrated (10X) orange juice is calculated to be 3mg/kg

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Section 5

- Principles for determining MRL/EMRL for certain food (other than compounded food)
  - Food in other processed forms, e.g., rice flour
    - MRL/EMRL of the primary food commodity from which the food is derived is applicable to the food

Example 3 – Deltamethrin in Orange Juice

- Orange juice is derived from "orange, sweet". When MRL for orange juice is not available, MRL for "orange, sweet" will be applicable to orange juice
- MRL for deltamethrin in "orange, sweet, sour" specified in Schedule 1, i.e., 0.05mg/kg (item 86.15), is applicable to its orange juice

Example 4 – Peanut oil, edible

- Edible peanut oil is refined from crude peanut oil, which is derived from peanut.
- When MRL for "peanut oil, edible" is not available, MRL for its raw ingredient, "peanut oil, crude" will be applicable to edible peanut oil.
  - MRL for propargite in "peanut oil, crude" specified in Schedule 1, i.e., 0.3mg/kg (item 277.26), is applicable to the edible peanut oil product.
- When MRLs for both "peanut oil, edible" and "peanut oil, crude" are not available, MRL for its primary food commodity, peanut, will be applicable to edible peanut oil.
  - MRL for deltamethrin in peanut specified in Schedule 1, i.e., 0.01mg/kg (item 86.54), is applicable to its peanut oil product.

Section 6

- Principles for determining MRL/EMRL for compounded food
  - Pro-rata MRL/EMRL
    - % of MRL/EMRL for the residue definition of the pesticide in respect of an ingredient that equals the % of the ingredient in the compounded food.

Example 5 – Abamectin in Strawberry Milk Shake

1. Look up the recipe of the concerned food product –
   - Assuming that a 200g sample of strawberry milk shake contains 20g of strawberry (i.e., 10% of the strawberry milk shake by weight) and 180g of milk (i.e., 90% of the strawberry milk shake by weight)

2. Search the MRL of abamectin for each ingredient specified in Schedule 1, i.e.,
   - MRL of abamectin in strawberry = 0.02mg/kg (item 7.4)
   - MRL of abamectin in cattle milk = 0.005mg/kg (item 7.16)

3. Compute the adjusted MRL of abamectin in the strawberry milk shake
   = (MRL for abamectin of strawberry) × [% of strawberry in strawberry milk shake (by weight)] + (MRL of abamectin in milk) × [% of milk in strawberry milk shake (by weight)]
   = 0.02mg/kg x 10% + 0.005mg/kg × 90%
   = 0.007mg/kg

The maximum permitted residue level of abamectin in the strawberry milk shake sample is calculated to be 0.007mg/kg

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Example 6 – Pirimicarb in Mixed Salad

1. Look up the recipe of the concerned food product –
   - Assuming that a 100g sample of mixed salad contains 30g of tomato (i.e. 30% of the mixed salad by weight), 50g of lettuce (i.e., 50% of the mix salad by weight) and 20g of sweet corn kernels (i.e., 20% of the mixed salad by weight)

2. Search the MRL of pirimicarb for each ingredient specified in Schedule 1, i.e..,
   - MRL of pirimicarb in tomato (i.e., fruiting vegetables, other than cucurbits) = 0.5mg/kg (item 265.29)
   - MRL of pirimicarb in "Lettuce, Head" = 5mg/kg (item 265.27)
   - MRL of pirmicarb in "Sweet corn (kernels)" = 0.05mg/kg (item 265.30)

3. Compute the adjusted MRL of pirimicarb in mixed salad
   = (MRL of pirimicarb in tomato) × [% of tomato in mixed salad (by weight)] + (MRL of pirimicarb in lettuce) × [% of lettuce in mixed salad (by weight)] + (MRL of pirmicarb in sweet corn kernel) × [% of sweet corn kernels in mixed salad (by weight)]
   = 0.5mg/kg × 30% + 5mg/kg × 50% + 0.05mg/kg × 20%
   = 2.7mg/kg

The maximum permitted residue level of pirimicarb in the mixed salad sample is calculated to be 2.7mg/kg

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