

**For discussion  
on 8 April 2014**

**Legislative Council  
Panel on Food Safety and Environmental Hygiene**

**Proposed Amendments to Schedule 1 to the  
Pesticide Residues in Food Regulation (Cap. 132CM)**

**PURPOSE**

This paper briefs Members on the Administration's proposal of amendments to Schedule 1 to the Pesticide Residues in Food Regulation (Cap. 132CM), and provides supplementary information on the proposed removal of three pesticides arising from comments received from Members during the Panel meeting on 14 January 2014.

**BACKGROUND**

2. On 26 April 2012, the Director of Food and Environmental Hygiene (DFEH), in exercise of the power under section 55(1) of the Public Health and Municipal Services Ordinance (Cap. 132), made the Pesticide Residues in Food Regulation (the Regulation) (Cap.132CM). The Legislative Council (LegCo) completed scrutiny of the Regulation in June 2012 and the Regulation will come into operation on 1 August 2014.

3. The Regulation aims to strengthen the regulation of pesticide residues in food to protect public health and promote harmonization between local and international standards. The standards for pesticide residues in food developed by the Codex Alimentarius Commission (Codex)<sup>1</sup> form the backbone of the regulatory framework. The Regulation specifies in Schedule 1 a list of maximum residue limits (MRLs)<sup>2</sup> and extraneous maximum residue limits (EMRLs)<sup>3</sup> for certain pesticide-food pairs, i.e. the

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<sup>1</sup> Codex was established by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) of the United Nations in the 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.

<sup>2</sup> MRL is the maximum concentration of specified pesticide residues legally permitted in specified food commodities.

<sup>3</sup> EMRL refers to a pesticide residue arising from environmental sources (including former agricultural uses) other than the use of a pesticide directly or indirectly on the commodity. It is the maximum concentration of specified pesticide residues legally permitted in specified food commodities.

maximum concentration of specified pesticide residues permitted in specific food commodities. The formulation of Schedule 1 to the Regulation was 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 that time, while taking into consideration comments received from stakeholders during the public consultation held between July and September 2011. These standards had been scrutinized by conducting risk assessment to ensure that they are adequate to protect public health in Hong Kong, taking into account the heavy reliance of Hong Kong on imported food.

4. Schedule 2 to the Regulation specifies a list of exempted pesticides with no MRLs/EMRLs. These are pesticides that are natural and the residues of which are identical to or indistinguishable from natural food components. Exemption of these natural pesticides is intended to facilitate their use by the trade.

5. The general principle of the Regulation is that except for exempted pesticides, import or sale of food containing pesticide residues with no specified MRLs/EMRLs in Schedule 1 is only allowed if the consumption of the food concerned is not dangerous or prejudicial to health. Based on risk assessment, the Centre for Food Safety (CFS) will decide whether the consumption of the food concerned is dangerous or prejudicial to health. Details of conducting risk assessment are provided in paragraphs 20 to 22 below.

6. As we had previously informed the LegCo Panel on Food Safety and Environmental Hygiene (the FSEH Panel) and the trade in June 2012, we would update the Schedules to the Regulation regularly, having regard to the latest international developments on application of pesticides, particularly changes to the Codex standards, and proposals received from the trade. DFEH would consider the proposals on a case-by-case basis, taking into account whether the limits concerned could pass the risk assessment scrutiny based on local food consumption pattern before deciding whether the Schedules should be amended.

## **PROPOSED AMENDMENTS TO SCHEDULE 1**

### ***Summary***

7. In summary, one pesticide will be added to Schedule 1 whilst three pesticides will be removed. As a result, the number of pesticides contained

in Schedule 1 to the Regulation will be reduced from 360 to 358. For the MRLs/EMRLs listed in Schedule 1 to the Regulation, 431 will be added, 347 will be removed, and 417 (455<sup>4</sup> in the Chinese version of the Schedule) will be revised. The number of MRLs/EMRLs will increase from 7 083 to 7 167. As for the MRLs/EMRLs laid down in Schedule 1 to the Amendment Regulation, about 40% of the residue limits are based on Codex, about 47% are from food exporting countries such as the USA, Thailand, Japan, Australia, etc. and about 13% remaining residue limits are from the Mainland. Details are provided in paragraphs 8-22 below.

***(a) Update of MRLs/EMRLs in Schedule 1***

8. The proposed amendments to Schedule 1 incorporate the latest changes to MRLs/EMRLs adopted by Codex in 2012 and 2013, while taking into account proposals put forth by relevant stakeholders<sup>5</sup> since the enactment of the Regulation in June 2012. All of the proposed amendments have undergone risk assessment to protect public health.

***(b) Update of pesticides in Schedule 1 proposed by stakeholders***

9. We have received a technical proposal from a stakeholder<sup>6</sup> to add one pesticide, i.e. thiodicarb, to Schedule 1. After conducting analysis, we recommend adding thiodicarb to Schedule 1 as a separate pesticide to make our regulation of pesticides more refined. As thiodicarb has already been included in the residue definition of another pesticide, i.e. methomyl, the residue definition of methomyl is revised accordingly to reflect the separate application of thiodicarb and methomyl.

10. We have also received a proposal from the same stakeholder<sup>7</sup> on the removal of three pesticides, i.e. fosetyl aluminium, thidiazuron and triphenyltin hydroxide, from Schedule 1 on the grounds that Codex has not established any MRLs or residue definitions for the three pesticides and there is no international consensus on the regulation of these three pesticides in terms of both residue limits and residue definitions. We accept the

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<sup>4</sup> To further refine the “description of food” and the Chinese translation of the definition of one of the residues, the number of items in the Chinese version of the Schedule to be revised has been increased from 449 (as stated in the FSEH Panel paper discussed on 14 January 2014) to 455.

<sup>5</sup> Relevant stakeholders include the General Administration of Quality Supervision, Inspection and Quarantine of the People’s Republic of China (AQSIQ), Consulate-General (CG) of Canada, CG of Japan, CG of the USA, Bayer CropScience, DuPont Crop Protection and Northwest Horticulture Council of the USA.

<sup>6</sup> AQSIQ

<sup>7</sup> AQSIQ

proposal and therefore recommend the removal of these three pesticides from Schedule 1. If the residues of these three pesticides are detected in food in the future, CFS would conduct risk assessment to determine whether the consumption of the food concerned is dangerous or prejudicial to health in accordance with the Regulation.

***(c) Update of residue definitions in Schedule 1***

11. In addition, the residue definitions of six pesticides in Schedule 1 will be updated, based on the latest recommendations from Codex and other regulatory authorities, and the availability of reference materials for laboratory analysis. These six pesticides are 2-methyl-4-chlorophenoxyacetic acid (MCPA), clothianidin, imidacloprid, methomyl, pyrethrins and quinterozone. Furthermore, we have noticed that the Chinese translation of the residue definition of spirotetramat in milks requires further refinement and the change has also been included in the present exercise.

***(d) Update of item number (Column 1 of Schedule 1) and description of food (Column 4 of Schedule 1) due to new Codex's food classification***

12. In formulating the list of MRLs in the Regulation, we have adopted the Codex's food classification system. Having conducted a review, Codex has adopted a new classification on fruits since 2012. Accordingly, we need to reflect the new classification by amending Column 1 of Schedule 1. In addition, since the name of a food subgroup "Shaddocks or Pomelos" has been renamed "Pummelo and Grapefruits", the corresponding food description in Column 4 of Schedule 1 has to be updated.

13. We have also reviewed the need to retain the MRLs on flaxseed in Schedule 1 to the Regulation. Codex, the Mainland and other overseas jurisdictions have generally regulated flaxseed as food, and established the relevant MRLs/EMRLs. However, the situation is different in Hong Kong. Section 2 of Cap. 132 states that food does not include Chinese herbal medicine as defined under the Chinese Medicine Ordinance (Cap. 549). Flaxseed, in the name of "Semen Lini" (Ripe seed of *Linum usitatissimum* L.), is listed in Schedule 2 to Cap. 549. As such, we propose to repeal 19 MRLs on flaxseed for a clear delineation of the purview of the Regulation and Cap. 549.

***(e) Refinement of Chinese translation of food commodities***

14. We have identified a number of food commodities/food groups whose Chinese translation needs to be refined. The changes are also

included in the present exercise.

## **PROPOSED REMOVAL OF THREE PESTICIDES**

15. At the FSEH Panel meeting on 14 January 2014, some Members requested further information on the proposed removal of the three pesticides.

16. Annex I sets out the application of the three pesticides concerned. When the Administration formulated Schedule 1 to the Regulation in June 2012, Codex had not established any MRLs and residue definitions for these three pesticides, and the major supplying source of fruits and vegetables to Hong Kong (i.e. the Mainland) also had not established any relevant standard at that time. We therefore made reference to the standards of a major food exporting country available at the time (i.e. the USA) for the three pesticides concerned. Subsequently, the Ministry of Health and the Ministry of Agriculture of the People's Republic of China promulgated the new national standard for MRLs for pesticides in food (Maximum Residue Limits for Pesticides in Food (GB2763-2012)) in November 2012, including the temporary MRLs for the three pesticides concerned.

17. As far as the residue definitions for the three pesticides are concerned, the standards established in the Mainland and the USA are different. The differences in residue definitions will cause difficulties in laboratory analysis. A probable situation is that if we fully adopt the Mainland standards, the residue levels of food imported from the USA may exceed the concerned limits. Likewise, residue levels of food imported from the Mainland may also exceed the concerned limits if we keep the existing standards adopted from the USA.

18. There is as yet no international consensus on the regulation of these three pesticides in terms of residue limits and residue definitions. The residue definitions adopted in Schedule 1 to the Regulation, which make reference to the US standards, are in fact different from those adopted by the regulatory authorities in the European Union, Australia, Japan, the Mainland, etc. (see Annex II for details). Neither has Codex established any relevant standards.

19. These three pesticides are not highly toxic. Taking into account the results of risk assessment based on the local food consumption pattern, CFS considers that removal of these three pesticides from Schedule 1 will not pose food safety risks to the general public. The relevant risk

assessment can be found in Annex III. That said, we will closely monitor the latest international developments of these three pesticides and will table further amendments to the Regulation as necessary.

### ***Risk assessment***

20. Although we recommend the removal of these three pesticides from Schedule 1 to the Regulation, it will not compromise the protection to the public health as offered under the Regulation. If the residues of these three pesticides are detected in food in the future, CFS will conduct risk assessment in accordance with the Regulation to determine whether the consumption of the food concerned is dangerous or prejudicial to health.

21. Risk assessment conducted by CFS is a science-based practice which is well-recognized internationally. The assessment methodology involves comparison between the data determined by the detected level of pesticide residues in a food sample in combination with the relevant consumption pattern of the food (i.e. the result of risk assessment) and the safety reference values<sup>8</sup> (e.g. acceptable daily intakes (ADI) for long-term exposure assessment, or acute reference dose (ARfD) for short-term exposure assessment).

22. Section 7 of the Regulation lays down the factors to be considered during risk assessment, including:

- (a) the toxicological profile and safety reference values of the pesticide concerned;
- (b) the characteristics of the pesticide and the level of the pesticide residues in the food concerned;
- (c) the consumption pattern of the food, and the long-term and short-term dietary exposure data of the general public and vulnerable groups to the pesticide residues, etc.

## **LEGISLATIVE TIMETABLE**

23. We plan to table the above amendments to the Regulation in LegCo within this legislative session. The amendments to the Regulation will

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<sup>8</sup> The Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Meeting on Pesticide Residues (JMPR) is responsible for evaluating the toxicological and related data of pesticides and estimating the safety reference values, including ADI and ARfD for humans. Apart from JMPR, regulatory agencies worldwide also conduct toxicological evaluation and establish safety reference values during pesticide registration.

come into operation on 1 August 2014 after completion of negative vetting by LegCo.

## **PREPARATION FOR COMMENCEMENT OF THE REGULATION**

24. Over the past year, 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. CFS has also prepared guidelines on the interpretation of MRLs/EMRLs in the Regulation as well as use of the Codex's food classification to identify the appropriate pesticide residue limits to assist the trade in complying with the requirements of the Regulation.

## **ADVICE SOUGHT**

25. Members are invited to comment on the proposed amendments above.

**Food and Health Bureau  
Food and Environmental Hygiene Department  
April 2014**

**Application of the three pesticides**

<b>Pesticide</b>	<b>Application</b>
Fosetyl aluminium	<ul style="list-style-type: none"><li>• Can be used as a fungicide in food crops such as various types of fruits and vegetables, tree nuts, etc.</li><li>• Registered for use in Hong Kong.</li></ul>
Thidiazuron	<ul style="list-style-type: none"><li>• Mainly used as a defoliant in cotton seed, may also be used to regulate the growth of crops such as cucumber, grapes and melons.</li><li>• As cotton seed and its by-products can be used as animal feed, MRLs for foods of animal origin have been established in the USA.</li><li>• Registered for use in Hong Kong.</li></ul>
Triphenyltin hydroxide	<ul style="list-style-type: none"><li>• Can be used as a fungicide in pecan, potato and sugar beet.</li><li>• As the leaves of sugar beet can be used as animal feed, MRLs for foods of animal origin have been established in the USA.</li><li>• Not registered for use in Hong Kong.</li></ul>



**An overview of the residue definitions in international jurisdictions  
for the three pesticides proposed to be deleted**

	<b>Triphenyltin hydroxide (TPTH)</b>	<b>Fosetyl aluminium</b>	<b>Thidiazuron</b>
Hong Kong (Same as USA)	Sum of TPTH, its monophenyltin (MPTH) and diphenyltin (DPTH) hydroxide and oxide metabolites, expressed as TPTH	Fosetyl aluminium	Sum of thidiazuron and its aniline containing metabolites
The Mainland (Temporary MRL)	Triphenyltin	Sum of ethylphosphonic acid, phosphoric acid and its salts, expressed as ethylphosphonic acid	Thidiazuron
Australia	Fentin hydroxide, excluding inorganic tin and mono- and diphenyltin	Fosetyl	Thidiazuron
European Union	Fentin, expressed as triphenyltin cation	Sum of fosetyl and phosphorous acid and their salts, expressed as fosetyl	Relevant standards have not been established
Japan	Residues of triphenyltin hydroxide, triphenyltin acetate, and triphenyltin chloride, which are individually calculated as fentin	Sum of residues of fosetyl and phosphorous acid, calculated as fosetyl	Thidiazuron

### Annex III

#### Risk assessment results based on local consumption pattern conducted by CFS<sup>9</sup>

<b>Pesticide</b>	<b>Results of risk assessment</b>
Fosetyl aluminium	<u>Leafy vegetables (including lettuce, choisum (Chinese flowering cabbage), etc)</u>  Assuming that the level of fosetyl aluminium in leafy vegetables is at its MRL (i.e. 100mg/kg) <sup>10</sup> , a person of a 60kg body-weight (bw) who consumes 1.8kg of leafy vegetables per day for a long period will have the dietary exposure of fosetyl aluminium reaching a level that may constitute food safety risk.
Thidiazuron	<u>Cucumber</u>  Assuming that the level of thidiazuron in cucumber is at its MRL (i.e. 0.05mg/kg) <sup>11</sup> , a person of 60kg bw who consumes 48kg of cucumber per day for a long period will have the dietary exposure of thidiazuron reaching a level that may constitute food safety risk.
Triphenyltin hydroxide (TPTH)	<u>Potato</u>  Assuming that the level of TPTH in potato is at its MRL (i.e. 0.05mg/kg) <sup>12</sup> , a person of 60kg bw who consumes 360g of potato <sup>13</sup> per day for a long period will have the dietary exposure of TPTH reaching a level which may constitute food safety risk.

<sup>9</sup> We have chosen food commodities with relatively higher dietary intakes among the Hong Kong population to illustrate the risk due to exposure to these three pesticides.

<sup>10</sup> Based on the ADI of 3mg/kg bw/day and the MRL in the USA for estimation.

<sup>11</sup> Based on the ADI of 0.04mg/kg bw/day and the MRL in the Mainland for estimation.

<sup>12</sup> Based on the ADI of 0.0003mg/kg bw/day and the MRL in the USA for estimation.

<sup>13</sup> According to the local food consumption pattern, the dietary intakes of potato for average and high consumers of Hong Kong population are 6.46g and 45g respectively.