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## **Legislative Council Panel on Health Services**

### **Regulation of Pesticide Residues and Heavy Metals in Chinese Herbal Medicines**

#### **PURPOSE**

This paper aims to brief Members on the Administration's work in regulating Chinese herbal medicines and testing for pesticide residues and heavy metals in Chinese herbal medicines.

#### **BACKGROUND**

##### *Regulation of Chinese herbal medicines*

2. The Chinese Medicine Council of Hong Kong ("CMCHK") is an independent statutory body established in 1999 under the Chinese Medicine Ordinance (Cap. 549) ("CMO"). The Chinese Medicines Board under the CMCHK is responsible for formulating and implementing regulatory measures for Chinese medicines in accordance with the CMO. The Department of Health ("DH") is responsible for providing professional support for the CMCHK and implementing regulatory measures related to Chinese medicine.

3. A stringent regime is set up under the CMO for the regulation of Chinese herbal medicines and Chinese medicine traders. As there are a huge range of varieties of Chinese herbal medicines, under the prevailing regulatory mechanism, they are classified into different categories according to their toxicity and degree of popularity in Hong Kong. Having regard to the need of regulatory control, 605 types of Chinese herbal medicines are listed in Schedules 1 and 2 of the CMO respectively with a view to imposing the following regulatory controls –

- (i) The 31 types of Chinese herbal medicines listed in

Schedule 1 and the 574 types of Chinese herbal medicines listed in Schedule 2 can only be sold by licensed retailers or licensed wholesalers of Chinese herbal medicines in the premises specified in their licences;

- (ii) As the 31 types of Chinese herbal medicines listed in Schedule 1 are toxic, their control is more stringent. In this regard, no medicine traders shall possess or sell the Chinese herbal medicines listed in Schedule 1 unless specified in their licences;
- (iii) Chinese herbal medicines listed in Schedule 1 must be dispensed in accordance with a prescription by a registered Chinese medicine practitioner and cannot be sold by retail. In addition, licensed retailers and licensed wholesalers of Chinese herbal medicines have to keep dispensing/sales record of Chinese herbal medicines listed in Schedule 1; and
- (iv) All Chinese herbal medicines in Schedule 1 and five Chinese herbal medicines in Schedule 2 (namely Radix Clematidis, Flos Campsis, processed Radix Aconiti, processed Radix Aconiti Kusnezoffii and Radix Gentianae) are subject to import and export control.

4. Regarding the regulation of Chinese medicine traders, any person who engages in retail and wholesale business of Chinese herbal medicines must obtain a licence from the Chinese Medicine Board and comply with the relevant practicing guidelines, which include ensuring that the Chinese herbal medicines traded by them are of good quality and suitable to be used. The DH conducts inspections in the premises of licensed retailers and licensed wholesalers of Chinese herbal medicines from time to time to ensure their compliance with the requirements of the law and the practicing guidelines.

5. As at February 2016, the CMCHK has issued licences to some 4 660 retailers and 930 wholesalers of Chinese herbal medicines, and some 270 manufacturers and 1 000 wholesalers of proprietary Chinese medicines.

### ***Market Surveillance Mechanism***

6. To monitor the quality and safety of the Chinese herbal

medicines regulated under the CMO, the DH has put in place a market surveillance system under which samples of Chinese herbal medicines are collected from the market for testing on a regular basis. To safeguard public health, the DH has also established a mechanism for reporting adverse incidents related to Chinese medicines. Information is collated through various channels so as to conduct risk assessment, management and reporting. If any sub-standard Chinese herbal medicines are found, the DH may request the Chinese medicine traders concerned to recall the products and refer the case to the CMCHK for follow-up actions. Press statements will also be issued.

7. The DH has maintained close liaison with the relevant Mainland regulatory authorities. A communication mechanism has already been established for timely exchange of information about the safety and quality of Chinese medicines in both places.

#### ***Formulation of Standards for Pesticide Residues and Heavy Metal Contents in Chinese Herbal Medicines***

8. There are not many standards set specifically for pesticide residues and heavy metal contents in Chinese herbal medicines in the world. The standards currently used for testing of pesticide residues and heavy metals contents in Chinese herbal medicines sold in Hong Kong are formulated by the CMCHK with reference to other international standards, including those of the World Health Organization and those set by different countries or regions for herbs or raw materials of natural plant preparations (e.g. the Pharmacopoeia of the People's Republic of China, the United States Pharmacopoeia and the European Pharmacopoeia). These standards are related to the testing of 37 pesticide residues (including 20 organochlorine pesticides and 17 organophosphorus pesticides) and 4 heavy metal contents (including lead, arsenic, cadmium and mercury) (see **Annex I**). To monitor the quality and safety of the Chinese herbal medicines regulated by the CMO, the CMCHK selected the above-mentioned 37 pesticides residues and 4 heavy metals for testing after considering their toxicity, residual effect, popularity and prohibition or restriction in import, export and usage internationally, with a view to protecting public health. If samples of Chinese herbal medicines under regulation are found containing any of the above-mentioned 37 pesticide residues or 4 heavy metals at a level exceeding the standard set by the CMCHK, the DH will carry out follow-up actions as described in paragraph 6 above.

9. In addition, the DH established the Hong Kong Chinese Materia

Medica Standards (“HKCMMS”) Office in 2001 to co-ordinate and manage the HKCMMS research project. The project develops reference standards for commonly used Chinese herbal medicines in Hong Kong in phases. It has already completed the research work of setting reference standards for around 230 Chinese herbal medicines, with a view to providing stronger evidence-based reference standards on the safety and quality of Chinese herbal medicines which will facilitate the management of the safety and quality issues such as contamination with heavy metals and other contaminants. It also sets objective standards for safety testing of Chinese medicines in future.

10. The Government is now actively establishing the Government Chinese Medicines Testing Institute (“GCMTI”) under the management of the DH. The GCMTI aims to devise internationally recognised reference standards for Chinese herbal medicines and decoction pieces through scientific research, assist the Chinese medicine industry in ensuring the quality and safety of Chinese herbal medicines and improve the quality and overall testing standard of Chinese herbal medicines in Hong Kong. At present, the Government is actively identifying a site for setting up the GCMTI. Prior to the establishment of the permanent GCMTI, a temporary institute will be set up in the Hong Kong Science Park which is expected to commence operation in phases starting from March this year.

## **TESTING OF CHINESE HERBAL MEDICINES**

11. At present, the DH adopts a two-pronged approach for the testing of Chinese herbal medicines. Besides drawing samples of Chinese herbal medicines every month from market for testing, targeted testing is conducted for Chinese herbal medicine samples obtained from other channels, including adverse drug reaction reporting system, public complaints and referrals from other government departments. The regular testing items include pesticide residues, heavy metal contents and morphological identification. The testing of pesticide residues and heavy metal contents in Chinese herbal medicines is carried out by the Government Laboratory in accordance with the international standard ISO / IEC 170251<sup>1</sup>.

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<sup>1</sup> The “General requirements for the competence of testing and calibration laboratories” jointly formulated by the International Organization for Standardization (“ISO”) and the International Electrotechnical Commission (“IEC”) include both management system requirements and technical requirements.

12. In general, the test consists of two stages. The first stage involves tests on the Chinese herbal medicine samples to check whether they contain the aforementioned 37 pesticides and 4 heavy metals and their residue levels/contents. If pesticide residues or heavy metals exist at a level exceeding the standards, the second stage test, which simulates the condition during human consumption, will be conducted to see if pesticide residues or heavy metals exist in the decoctions of the Chinese herbal medicines concerned. The procedures and scope of the test are recognised by the Chinese Medicines Board of the CMCHK. Besides, the international expert group of the Scientific Committee set up under the HKCMMS also considers testing for pesticide residues and heavy metals in the decoctions of Chinese herbal medicines a closer simulation of the condition during actual consumption/exposure. Therefore, it is more appropriate to adopt the results of the second-stage testing for human risk assessment.

### *Strengthen the Testing of Chinese Herbal Medicines*

13. As regulatory authorities around the world are increasingly concerned about the impact of pesticide residues and heavy metals on human body, the Chinese Medicines Board of the CMCHK will review the standards of pesticide residues and heavy metal contents in Chinese herbal medicines from time to time. It will also review the strategy of testing Chinese herbal medicines and continue to improve the market surveillance mechanism to safeguard the public health.

14. The DH will continue to maintain close liaison with the Mainland authorities for exchange of information on quality and safety of Chinese herbal medicines according to the established mechanism.

### **ADVICE SOUGHT**

15. Members are invited to note the content of this paper.

## Annex I

### Standards for Pesticide Residues and Heavy Metal Contents in Chinese Herbal Medicines

#### (1) The maximum residue limits for organochlorine pesticides

	<b>Chinese name</b>	<b>English name</b>	<b>Test range (A total of 20 items)</b>	<b>Maximum residue limit</b> (milligrammes per kilogramme)
1.	艾氏劑及狄氏劑	Aldrin & Dieldrin	Sum of Aldrin & Dieldrin	0.05
2.	氯丹	Chlordane	Sum of isomer cis-, trans-, and oxychlordane	0.05
3.	滴滴涕	DDT	Sum of p,p'-DDT, o,p'-DDT, p,p'-DDE and p,p'-TDE	1.0
4.	異狄氏劑	Endrin	endrin	0.05
5.	七氯	Heptachlor	Sum of heptachlor and heptachlor epoxide	0.05
6.	六氯苯	Hexachlorobenzene	hexachlorobenzene	0.1
7.	六六六	Hexachlorocyclohexane	Sum of isomers $\alpha$ -, $\beta$ - and $\delta$ -	0.3
8.	林丹	Lindane	lindane	0.6
9.	五氯硝基苯	Quintozene	Sum of quintozene, pentachloroaniline and methyl pentachlorophenyl sulphide	1.0

**(2) The maximum residue limits for organophosphorus pesticides**

	<b>Chinese name</b>	<b>English name</b>	<b>Maximum residue limit</b>
1	滴滴畏	Dichlorvos	Shall not be detected
2	甲胺磷	Methamidophos	
3	滴百蟲	Trichlorphon	
4	氧樂果	Omethoate	
5	二嗪磷	Diazinon	
6	樂果	Dimethoate	
7	馬拉硫磷	Malathion	
8	水胺硫磷	Isocarbophos	
9	三唑磷	Triazophos	
10	對硫磷	Parathion	
11	甲基對硫磷	Parathion-methyl	
12	久效磷	Monocrotophos	
13	磷胺	Phosphamidon	
14	毒死蜱	Chlorpyriphos	
15	乙酰甲胺磷	Acephate	
16	乙硫磷	Ethion	
17	殺撲磷	Methodathion	

**(3) The limits of heavy metals and toxic elements**

<b>Chinese name</b>	<b>English name</b>	<b>Maximum permitted level (total intake)</b>
砷	Arsenic	1,500 microgram/day
鎘	Cadmium	3,500 microgram/dose
鉛	Lead	179 microgram/day
汞	Mercury	36 microgram/day