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Report of the Subcommittee on Harmful Substances in Food (Amendment) Regulation 2005

Purpose

This paper reports on the deliberations of the Subcommittee on Harmful Substances in Food (Amendment) Regulation 2005.

Background

2. The Harmful Substances in Food Regulations (the Regulations) made under the Public Health and Municipal Services Ordinance (Cap. 132) govern the import and sale of food containing harmful substances. The First Schedule to the Regulations stipulates the maximum amount of harmful substances allowed in food. Any person who imports, consigns, delivers, manufactures or sells for human consumption any food containing such substances in greater concentration than that prescribed in the Regulations commits an offence. Before the gazettal of the Harmful Substances in Food (Amendment) Regulation 2005 on 26 August 2005, malachite green was not included in the First Schedule to the Regulations.

3. Malachite green is a type of industrial dye and has been used for treating infection in fish. Major agricultural economies such as the Mainland, European Union, Canada and the United States prohibit the use of the chemical in food fish. Some animal studies show that malachite green may cause liver tumour in rats but there is no such conclusive evidence in human yet.

4. In the Mainland, the Ministry of Agriculture has incorporated malachite green into the List of Veterinary Drugs and Other Chemicals Prohibited in Food Animals in accordance with the Veterinary Drugs Control Law in 2002, to ban the use of malachite green in food animals. The State General Administration of the Quality Supervision, Inspection and Quarantine also issued a directive in 2002 to explicitly prohibit the use of malachite green in aquaculture.

5. On 16 August 2005, the Guangdong Entry-Exit Inspection and Quarantine Bureau in the Mainland decided to recall eel products destined for exports as a precautionary measure to ensure that all eel products for exports do not contain malachite green. The Administration immediately collected 80 samples of eels and eel products and 62 samples of freshwater fish for sale in Hong Kong for testing, and malachite green was found to be present in 67 samples of eels and eel products and 13 samples of freshwater fish.

6. The Administration informed the LegCo Panel on Food Safety and Environmental Hygiene and the operators of fishery and food trades on 19 and 20 August 2005 respectively, of the detection of malachite green in eels and eel products, and the intention to amend the legislation to prohibit the presence of malachite green in food sold in Hong Kong. The Panel held four special meetings to discuss the issue between August and September 2005.

The Amendment Regulation

7. The Harmful Substances in Food (Amendment) Regulation 2005 (The Amendment Regulation) was gazetted on 26 August 2005. It was made under sections 55(1) and 57 of the Public Health and Municipal Services Ordinance (Cap. 132), to add malachite green into the list of substances in the First Schedule to the Regulations. The maximum concentration prescribed is 0 microgram per kilogram in “any food (including live fish, live reptiles and live poultry)”. The effect of the addition is that importing, consigning, delivering, manufacturing or selling any food (including live fish, live reptiles and live poultry) for human consumption which contains malachite green becomes an offence punishable by a fine at level 5 (\$50,000) and imprisonment for six months.

8. The Amendment Regulation commenced operation on the date it was published in the Gazette, i.e. 26 August 2005.

The Subcommittee

9. At the House Committee meeting on 7 October 2005, Members agreed to form a subcommittee to examine the Amendment Regulation. Chaired by Hon Fred LI, the Subcommittee has held two meetings to discuss with the Administration. The membership list of the Subcommittee is in **Appendix**.

Deliberations of the Subcommittee

General

10. While members of the Subcommittee generally support the prohibition of presence of malachite green in fish and other food for the protection of public health, some members have expressed concern about the justifications for making the Amendment Regulation, the implementation of the regulatory framework for live fish, the impact on the trade, and the enforcement of the Amendment Regulation.

Justifications for making the Amendment Regulation

11. Some members have queried the need for the Amendment Regulation, if food containing malachite green is already deemed to be in breach of the Public Health and Municipal Services Ordinance (Cap. 132), and the Director of Food and Environmental Hygiene (DFEH) already has the power to take samples for analysis, and seize and remove food which appears to him that any regulation made under section 55 has been contravened.

12. The Administration has explained that prior to the gazettal of the Amendment Regulation, the legislation in Hong Kong did not explicitly prohibit the presence of malachite green in food. Moreover, live fish is currently excluded from the definition of “food” in the Ordinance and the relevant Regulations, and there may be disputes for DFEH to seize live fish deemed to be unfit for human consumption. To ensure food safety and protect public health, the Amendment Regulation was made to remove any ambiguity in the control of live fish as food with regard to the use of malachite green.

13. Hon Audrey EU and Hon WONG Yung-kan have asked about the international standards and practices in respect of the use of malachite green, such as the tolerance limit for presence of malachite green in food.

14. The Administration has advised that although the Codex Alimentarius Commission has not established food safety standards for malachite green in food, there is evidence that malachite green is carcinogenic in animals and is unsuitable for use in aquatic products intended for human consumption. According to the toxicological information available, consumers may risk an overdose of malachite green and suffer adverse health consequences.

15. The Administration has further advised that malachite green is either banned or not permitted to be used in aquaculture in the Mainland, the United States, Canada, the European Union, Japan and some Southeast Asian countries such as Singapore and Thailand. The setting of zero tolerance is consistent with the international practice that animal carcinogen should not be added to food or food animal.

16. Hon Vincent FANG has questioned about the risk of malachite green to human, as the Administration has advised that a person will only suffer from adverse health effects if he or she consumes more than 290 kg of freshwater fish each day over a prolonged period. The Administration has explained that it is the principle of food safety regulation that all carcinogenic substances should not be allowed to be used in food. Its advice on impact on human health was based on the level of malachite green detected in freshwater fish samples so far. If there is increased abuse of malachite green in food animals and aquaculture, the risk to human will significantly increase.

Regulatory framework for live fish and enforcement of the Amendment Regulation

17. Most members of the Subcommittee are of the view that the Administration should strengthen regulation of fish and aquatic products at source, which should be more effective than exercising control at the retail level. Hon Tommy CHEUNG considers that the regulatory control for live fish should be similar to that for live pigs and poultry, in that they should be subject to quarantine and inspection requirements before distribution to the retail markets.

18. The Administration agrees that it is important to strengthen regulation and control at source, and it has enhanced communication with the Mainland authorities in this respect. When the Administration became aware that malachite green was found in some freshwater fishes in the market in August 2005, a series of measures were taken to monitor the safety of imported freshwater fish at source. The following specific measures have also been agreed between Hong Kong and the Mainland to control supply of freshwater fish to Hong Kong –

- (a) freshwater fish supply to Hong Kong can only be provided by fish farms which are registered in the Mainland and approved by Food and Environmental Hygiene Department (FEHD);
- (b) all freshwater fish supplied by registered and approved farms must be accompanied with health certificates when entering Hong Kong to certify that they are free from malachite green or any other harmful pesticides and chemical substances;
- (c) FEHD will send staff to inspect registered and approved freshwater fish and aquaculture farms in the Mainland; and
- (d) there will be technical exchanges on freshwater fish farming and aquaculture between Hong Kong and the Mainland.

19. The Administration has also advised that as a long term policy, a food safety, inspection and quarantine centre will be set up. The Administration is also actively considering the need for amending the legislation to require all operators in the trade to register, and all aquatic products destined for Hong Kong must be accompanied with import and health certificate and landed at designated landing points. Suppliers will also be required to keep detailed sales record to facilitate source tracing.

20. The Administration has emphasised that it is necessary to strengthen control of safety of food at all levels from import to retail. The Administration has explained that regulation at source requires the support of the relevant authorities and trades of the origin. It is not possible to station FEHD staff in all registered farms in the Mainland and inspect all food for supply to Hong Kong. It is therefore necessary to continue to monitor the safety of food at the retail level.

21. Hon Vincent FANG and Hon Tommy CHEUNG have expressed grave concern that fish traders and food business operators may be prosecuted if the fish supplied by registered farms in the Mainland are still found to contain malachite green. They have asked the Administration to clarify how the Amendment Regulation will be enforced.

22. The Administration has advised that following the gazettal of the Amendment Regulation, sample testing of presence of malachite green in food has been included in the regular food surveillance programme. If presence of malachite green is found in the samples, warning letters will be issued to the traders concerned. The Administration will also examine the circumstances in each individual case, and prosecution will be taken if there is sufficient evidence of contravention of the Regulations. So far, no prosecution has been taken in cases where presence of malachite green is found in food samples.

23. As regards the enforcement of existing provisions in the Regulations, the Administration has advised that in 2004, some 4 100 samples were tested for compliance with the Regulations, and two prosecutions had been taken in two cases with unsatisfactory test results. In the first six months of 2005, some 1 600 food samples were tested for harmful substances and no prosecution had been taken so far.

24. The legal adviser to the Subcommittee has advised that the enforcement powers are in the existing provisions of the Ordinance. According to section 58 of the Ordinance, DFEH has the power to call for information as to composition of substances used in the preparation of food. Under section 59(1)(b) of the Ordinance, DFEH can authorise any public officer to seize and remove any food if it appears to him that any regulation made under section 55 has been contravened. Under section 62, any public officer authorised by DFEH may take samples for analysis.

25. Some members have requested the Administration to pay special attention to “smuggling” activities in that fish obtained from sources other than the registered and approved farms may be mixed with those from authorised sources during consignment or at the wholesale level. The Administration has responded that FEHD and Customs and Excise Department will continue to take action to combat these “smuggling” activities.

Strict liability and defence provisions

26. Hon Tommy CHEUNG has expressed dissatisfaction that the Administration has put the onus of proof on the live fish traders and operators of food business, in that they are required to prove that they have exercised all due diligence to ensure the safety of fish sold by them. Hon Tommy CHEUNG considers it unfair to prosecute the trader or food business operator if the fish or food products found to have malachite green are actually supplied by authorised and approved sources. He also considers the penalty of a fine of \$50,000 and six-month imprisonment too harsh on retailers, because they do not actually apply malachite green to the fish and are ignorant of the presence of malachite green in the food they sell.

27. The Administration has stressed that persons involved in all levels of the supply chain have the responsibility to ensure the safety of food they sell for human consumption. The offence and penalty in respect of selling food containing harmful substances are already stipulated in the existing provisions in the Ordinance and the Regulations. The Subcommittee also notes that all persons involved in the import, consignment, delivery, manufacture and sale of any food containing the prohibited or restricted substances specified in the Schedules to the Regulations are subject to the offence and penalty provisions.

28. As regards the defence for contravening the Regulations, the Administration and the legal adviser to the Subcommittee have advised that there are defence provisions in the Ordinance. Under section 70 of the Ordinance, a person against whom proceedings are brought under the Principal Regulations is entitled to have any person to whose act or default he alleges that the contravention of the provisions in question was due brought before the court. If, after the contravention has been proved, the original defendant proves that the contravention was due to the act or default of that other person, that other person may be convicted of the offence, and, if the original defendant further proves that he has used all due diligence to secure that the provisions in question were complied with, he shall be acquitted of the offence. Moreover, under section 70 of the Ordinance, where DFEH is satisfied that the contravention was made due to an act or default of some other person and that the defendant can establish a defence, the proceedings may be taken against that other person instead. There is another defence provision in section 71 of the Ordinance which provides that it shall be a defence for the defendant to prove, among other things, that the article or substance was sold under the

descriptions as given in a written warranty. The defence is also available to a servant or agent of the person who purchased the article or substance under a warranty.

29. The Administration has advised that for the purpose of the defence, the trader or operator concerned can keep records of supply invoices and the health certificates issued by the relevant authorities. However, it will be for the court to decide whether such documents are sufficient evidence that the defendant has used all due diligence to secure compliance with the provisions in the Regulation.

Advice and guidelines to the trade

30. Hon Tommy CHEUNG and Hon Vincent FANG have expressed concern that the Administration has not clearly advised the trades to assist them to comply with the Amendment Regulation, for example, what are the “due diligence” measures to be adopted for defence by the trade. They urge the Administration to clearly inform the trades how they can obtain supplies from authorised and approved sources, and what types of documents they should keep for record and defence purposes.

31. The Administration has advised that they will continue to meet with the trades to advise them on ways to comply with the Regulations. However, it may not be possible to provide conclusive and exhaustive guidelines to suit all scenarios, and it will be for the court to decide whether the measures adopted by the person concerned are sufficient defence for contravening the Regulations.

32. While the Subcommittee agrees that it will be difficult to issue comprehensive guidelines on all scenarios for the trades, the Subcommittee considers that the Administration should advise the fish trade and food business operators on the measures or precautions they should take in obtaining supply of fish and aquatic products, and the documentation required for compliance with the Regulations. Hon Alan LEONG and Hon Audrey EU consider that the enforcement authorities have the responsibility to advise the public on how to comply with the law.

Proposed amendment to exempt retailers from the Amendment Regulation

33. Hon Tommy CHEUNG is strongly of the view that retailers, including food business operators who sell live fish, should not be held liable for the presence of malachite green in the live fish they sell. He considers that retailers have no motive to apply malachite green to the fish they bought from authorised sources, and they are innocent if malachite green is found in such fish. He therefore proposes an amendment to exempt retailers from the Amendment Regulation. The legal effect of the proposed amendment is that regulation 3 (Prohibition of import and sale of food containing certain

substances in excessive concentrations) and regulation 5 (Offence and penalties) of the principal Regulations will not apply to live fish sold by retail containing malachite green.

34. The Subcommittee has discussed Hon Tommy CHEUNG's proposed amendment at a meeting with the Administration. The Administration considers that while the proposed amendment is technically in order, by virtue of the amendment power provided under section 34(2) of the Interpretation and General Clauses Ordinance (Cap. 1), it is contradictory to and defeats the purpose of introducing the Amendment Regulation in a number of contexts. The Administration has explained that by excluding retailers from legal liability under the principal Regulations, the amendment will render the law ineffective in protecting health by crippling enforcement actions at the most relevant level. The Administration has advised that the purpose of the Ordinance and its Regulations is to protect public health by requiring all vendors, including importers, wholesalers and retailers, to be responsible in ensuring that the food supplied for sale is fit for human consumption and complies with the legal requirements. During investigation, source tracing of problematic food products needs to be done at all levels of the supply chain. If a particular group of vendors within the supply chain is exempted from the law, it will be difficult to trace the source of the problematic products and the Government will have no tools to enforce the law to ensure food safety.

35. The Administration has further advised that the amendment will have the effect that the sale by retailer to the public of live fish with malachite green will not be sanctioned under the public health legislation. The authority will then have no power to seize any live fish containing malachite green at the retail outlets. The proposed amendment, if adopted, will send a wrong message to the trade that retailers have no legal liability even if they do not exercise due diligence in sourcing fish. It will also be confusing to the public as to whether the prohibition of malachite green is still in force. Consequently, consumers' confidence in consuming live fish will be eroded and this will have negative impact on the entire live fish trade.

36. The Administration has stressed that it is the joint responsibility of the Government, traders and consumers to protect the food safety regime. The Administration sees no reason for exempting live fish retailers, from which ordinary people buy their fish, from the food safety requirement in the Amendment Regulation.

37. In the light of the Administrations' comments, most members agree that given the present legislative framework for ensuring food safety, it will not be appropriate to adopt the proposed amendment which will seriously undermine the effectiveness of the present regulatory system. These members agree that retailers, being an important part of the supply chain, should not be exempted from the Amendment Regulation to facilitate source tracing of problematic foods for the protection of public health. Nevertheless, these members

consider that the Administration should expedite its review of the existing regulatory framework to strengthen regulation at source, and to provide clear advice and guidelines to the trades for compliance with the Regulations.

Recommendation of the Subcommittee

38. Most members of the Subcommittee support the Amendment Regulation. The Subcommittee will not move amendments to the Amendment Regulation. Hon Tommy CHEUNG has indicated that he will further consider whether to move amendment in the light of members' comments.

Advice sought

39. Members are invited to note the deliberations of the Subcommittee.

Council Business Division 2
Legislative Council Secretariat
16 November 2005

**Subcommittee on
Harmful Substances in Food (Amendment) Regulation 2005**

Membership list

Chairman	Hon Fred LI Wah-ming, JP
Members	Hon CHAN Yuen-han, JP Hon WONG Yung-kan, JP Hon Tommy CHEUNG Yu-yan, JP Hon Audrey EU Yuet-mee, SC, JP Hon Vincent FANG Kang, JP Hon Alan LEONG Kah-kit, SC (Total : 7 members)
Clerk	Mrs Constance LI
Legal adviser	Mr Stephen LAM
Date	25 October 2005