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Legal Service Division Report on two orders made under section 78B of the Public Health and Municipal Services Ordinance (Cap. 132) (G.N. (E.) 20 and G.N. (E.) 21 of 2011) gazetted on 31 May 2011 and 2 June 2011

Background

Section 78B of the Public Health and Municipal Services Ordinance (Cap. 132) empowers the Director of Food and Environmental Hygiene (DFEH) to make an order to, among others, prohibit the import and the supply of any food for the period specified in the order and direct that any food supplied be recalled in the specified manner and within the specified period. Such an order may only be made if DFEH has reasonable grounds to believe that the making of the order is necessary to prevent or reduce a possibility of danger to public health or to mitigate any adverse consequence of a danger to public health. Under section 78C(3), if a section 78B order is addressed to a class of persons or all persons, the order must be published in the Gazette.

- 2. Section 78B(6) expressly provides that a section 78B order is not subsidiary legislation. Accordingly, such order is not required to be tabled before the Legislative Council and is not subject to amendment by the Legislative Council. According to LegCo Brief on the Public Health and Municipal Services (Amendment) Bill 2008 (Ref.: FH CR 1/3231/07), the Administration stated that section 78B of Cap. 132 was enacted to enable DFEH making orders administratively to deal with food incidents in a timely and effective manner for the protection of public health before the introduction of the Food Safety Bill.
- 3. Members may wish to note that the Food Safety Bill (enacted as the Food Safety Ordinance (FSO) (No. 5 of 2011)) was passed by the Legislative Council on 30 March 2011. The FSO repeals Part VA of Cap. 132 (sections 78A to 78L of Cap. 132 providing for additional powers in relation to food) and

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re-enacts that part in Part 4 of FSO (food safety orders). By the Food Safety Ordinance (Commencement) Notice (L.N. 60 of 2011), the Secretary for Food and Health has appointed 1 August 2011 as the day on which FSO, except Part 3 (keeping records relating to food) and Division 1 of Part 2 (requirement for registration of food importers and distributors), comes into operation. Section 61 of FSO provides for the transitional arrangement in that an order in force under section 78B of Cap. 132 immediately before the repeal of Part VA of Cap. 132 remains in force in accordance with its terms as if it were a food safety order and may be varied or revoked accordingly.

Section 78B orders gazetted on 31 May 2011 and 2 June 2011

- 4. Pursuant to section 78B of Cap. 132, DFEH issued two section 78B orders to all persons which were published respectively as General Notices in the Gazette on 31 May 2011 (G.N. (E.) 20 of 2011) (the May Order) and 2 June 2011 (G.N. (E.) 21 of 2011) (the June Order). Under these two Orders -
 - (a) all persons are prohibited from importing into Hong Kong the food specified in Annex A to the Orders, that is intended for human consumption, for the period from 12:00 noon on 31 May 2011 and 12:00 noon on 2 June 2011 respectively until further notice;
 - (b) all persons are prohibited from supplying¹ within Hong Kong the food specified in Annex A to the Orders, that is intended for human consumption, for the period from 12:00 noon on 31 May 2011 and 12:00 noon on 2 June 2011 respectively until further notice; and
 - (c) the food specified in Annex A to the Orders, that is intended for human consumption and has been supplied, is to be recalled in the manner specified in Annex C to the Orders, within a period of 30 days from 12:00 noon on 31 May 2011 and within a period of 30 days from 12:00 noon on 2 June 2011 respectively.
- 5. The effect of the May Order is to prohibit the import into and supply of, and to recall the food specified in Annex A of this Order, i.e. Speed sports drink (動力運動飲品) and Speed lemon flavor sports drink (動力運動飲品棒檬口味), unless accompanied by a certificate issued by the relevant Taiwanese authority certifying that the levels of di(2-ethylhexyl)phthalate (DEHP) do not exceed 1.5 parts per million (ppm).

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According to section 78A of Cap. 132, "supplying" means (a) selling the food; (b) offering, keeping or exhibiting the food for trade, (c) exchanging or disposing of the food for consideration; (d) transmitting, conveying or delivering the food in pursuance of (i) a sale; or (ii) an exchange or disposal for consideration; or (e) for commercial purposes, giving the food as a prize or making a gift of the food.

6. The effect of the June Order is to prohibit the import into and supply of, and to recall the food specified in Annex A of the Order, i.e. 盛香珍 Konjac Coconut Jelly (Taro flavour), unless accompanied by a certificate issued by the relevant Taiwanese authority certifying that the levels of di(2-ethylhexyl)phthalate (DEHP) do not exceed 1.5 parts per million (ppm).

Reasons for making the Orders

- 7. Annex B to the May Order sets out the reasons for making this Order and the principal factors that led to making of this Order. 23 May 2011, the Food and Drug Administration (FDA) in Taiwan announced that a plasticiser di(2-ethylhexyl)phthalate (DEHP) had been detected in 16 samples of drinks at levels up to 34.1 parts per million (ppm). According to the list of drinks published by FDA on 23 May 2011, the Hong Kong Centre for Food Safety (CFS) took samples of relevant drinks for testing. obtained on 30 May 2011 indicated that 6 samples of the drinks listed at Annex A to the May Order contained DEHP at levels ranged from 11 to 43 ppm. Dietary exposure estimation revealed that the exposure of DEHP from the consumption of the above samples by average consumers (daily consumption of about half bottle of 600ml sports drink) and high consumers (daily consumption of about one bottle of 600ml sports drink) would exceed the safety reference value, i.e. the tolerable daily intake (TDI) of 0.025 mg/kg of body weight under the World Health Organization (WHO) Guidelines for drinking-water quality (also exceeded the TDI of 0.05 mg/kg of body weight established by the European Food Safety Authority regarding high consumers), which may pose a risk to human health.
- 8. Annex B to the June Order sets out the reasons for making this Order and the principal factors that led to making of this Order. the announcement of the FDA on 23 May 2011, further results announced by the FDA indicated that DEHP had also been detected in other food products, including konjac coconut jelly. The CFS took samples of relevant food products for testing. A result obtained on 31 May 2011 indicated that one sample of konjac coconut jelly listed at Annex A to the June Order contained DEHP at a level of 18 ppm. Dietary exposure estimation revealed that the exposure of DEHP from the consumption of this sample by a 5 year-old average consumer (daily consumption of a cup of jelly of about 25 gram) or a 5 year-old high consumer (daily consumption of 2 cups of jelly, about 25 gram each) would exceed the safety reference value, i.e. the TDI of 0.025 mg/kg of body weight under WHO Guidelines for drinking-water quality (also exceeded the TDI of 0.05 mg/kg of body weight established by the European Food Safety Authority regarding a 5 year-old high consumer), which may pose a risk to human health.

9. According to the health effects set out in Annex B to these Orders, the acute oral toxicity of DEHP is low. As for chronic toxicity, DEHP was found to affect the liver and kidney as well as the reproduction and development of experimental animals. The International Agency for Research on Cancer concluded DEHP is possibly carcinogenic to humans.

Manner in which a recall should be conducted

- 10. Annex C to the two Orders set out the manner in which a recall should be conducted. The following requirements are imposed on importers under Annex C -
 - (a) the setting up of telephone enquiry service to handle enquiries related to the recall incident as soon as possible;
 - (b) immediately notifying all known distributors, retailers and consumers of the recall and its arrangement;
 - (c) conducting a stock take of the in-house storage facilities and isolating any remaining stock relating to the recalled food;
 - (d) informing the Food and Environmental Hygiene Department (FEHD) of the parties involved (e.g. distributor(s) retailer(s), organization(s) or person(s) to whom the food has been supplied) within one week from the commencement of the Order:
 - (e) displaying posters of not less than A4 size containing specified recall information at a conspicuous location on the importers' premises and on the premises of distributors to whom the food has been supplied (and on their Internet websites, if so operated);
 - (f) if the food concerned is returned by distributors, retailers or consumers, the recalling trader shall retract the food;
 - (g) providing FEHD progress reports on a bi-weekly basis on certain specified information about the recall; and
 - (h) submitting a final report to FEHD within one month from the date of completion of recall containing certain specified information (e.g. the effectiveness of the recall, the decision on the disposal method of the returned food and the means of preventing recurrence of the defect).

- 11. The following requirements are imposed on distributors under Annex C to the Orders -
 - (a) setting up a telephone enquiry service to handle enquiries related to the recall incident as soon as possible;
 - (b) immediately notifying all known retailers and consumers of the recall and its arrangement;
 - (c) displaying posters not less than A4 size containing specified recall information at a conspicuous location on the distributors' premises (and on their Internet websites, if so operated);
 - (d) conducting a stock take of the in-house storage facilities and isolating any remaining stock that relates to the food concerned;
 - (e) if the food is returned by retailers or consumers, the recalling traders shall retract the unsafe food; and
 - (f) keeping records of recalled food containing a description of the food returned such as brand and product name, size, identifying codes, the date and quantity of food returned and what has been done with the food (e.g. returned to the supplier(s)).
- 12. The following requirements are imposed on retailers under Annex C to the Orders -
 - (a) removing the food concerned from the shelves immediately and storing it in a place not accessible by the customers while pending return to the supplier concerned. The food should be separately stored and not available for use in any production processes in case it is an ingredient for producing food product inside the premises; and
 - (b) if the food is returned by consumers, store the food in a place not accessible by customers while pending return to the supplier concerned.

Enforcement and appeal

13. Under section 78D of Cap. 132, a person bound by the Orders who contravenes a term of the Orders commits an offence and is liable to a fine at level 6 and to imprisonment for 12 months. Section 78D(2) provides that it is

not a defence for the person charged with the offence to show that the food concerned is the subject of a licence, permit or any other form of authorization issued or granted under Cap. 132 or any other Ordinance.

- Under section 78G of Cap. 132, a person bound by the Orders who is aggrieved by the Orders may, within 28 days from becoming bound by the Orders, appeal to the Municipal Services Appeals Board against the Orders. Under section 78H, a person bound by the Orders may apply for an amount of compensation that is just and equitable in all the circumstances of the case, for losses arising as a direct result of compliance with the Orders. These losses include total or partial loss of the food that is the subject of the Orders and costs or expenditure actually and directly incurred.
- 15. The May Order took effect at 12:00 noon on 31 May 2011. The June Order took effect at 12:00 noon on 2 June 2011.
- Members may refer to the LegCo Brief (ref: FHB CR 11/1886/05 Pt. 3) issued by the Food and Health Bureau dated 31 May 2011 for background information about the May Order. According to the Administration, a LegCo Brief on the June Order will be issued.
- 17. The Administration will brief the Panel on Food Safety and Environmental Hygiene on measures to follow up on the plasticiser contamination incident in Taiwan at the Panel meeting to be held on 14 June 2011.

Conclusion

18. The Legal Service Division is scrutinizing the legal and drafting aspects of the Orders. Although the Orders are not subsidiary legislation, in view of the policy implications, Members may wish to consider whether to set up a subcommittee to examine the Orders.

Prepared by

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