

**For information
on 24 June 2011**

LegCo Panel on Food Safety and Environmental Hygiene

**Issuance of an order under section 78B of the
Public Health and Municipal Services Ordinance (Cap. 132)
to prohibit the import and supply of a tea drink and to direct
such drink supplied be recalled**

ISSUE

The Director of Food and Environmental Hygiene (DFEH) made an order (**Annex**) under section 78B of the Public Health and Municipal Services Ordinance (Cap. 132) (the Order) on 21 June 2011 to prohibit the import of ITAMACHI KING OOLONG Tea Drink into Hong Kong with effect from 12:00 noon on 22 June 2011 until further notice. The Order also prohibits the supply of ITAMACHI KING OOLONG Tea Drink within Hong Kong and directs that such drink that has been supplied in Hong Kong be recalled within a period of 30 days from 12:00 noon on 22 June 2011. The Order was published in the gazette on 22 June 2011.

JUSTIFICATIONS

2. On 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). Subsequently, further announcements by the FDA in Taiwan indicated that other drinks might also contain DEHP.

3. The Centre for Food Safety (CFS) took samples of relevant drinks manufactured in Taiwan and other places for testing. Results obtained on 21 June 2011 indicated that a sample of ITAMACHI KING OOLONG Tea Drink contained DEHP at a level of 2.9 ppm. Dietary exposure estimation revealed that the exposure to DEHP from daily consumption of this sample by average consumers (daily consumption of about 530 ml of the drink) and high consumers (daily consumption of about 1400 ml of the 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 (EFSA) for high consumers), which may pose a risk to human health. In view of the health risks and having considered the information from FDA, WHO, EFSA as well as local testing results, DFEH decided to make the Order to safeguard food safety and public health.

ORDER MADE UNDER SECTION 78B OF CAP. 132

4. Section 78B(1) of Cap. 132 provides that the Authority (i.e. DFEH) may make an order to, among others, prohibit the import and the supply of any food for the period specified in the order, as well as to direct that any food supplied be recalled and specify the manner in which, and the period within which, the recall is to be conducted. Section 78B(2) stipulates that the Authority may only make a section 78B order if the Authority has reasonable grounds at the time of making the order 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. Section 78B(6) also stipulates that a section 78B order is not a subsidiary legislation.

5. While the acute oral toxicity of DEHP is low, 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. DFEH has therefore decided it was necessary to make a section 78B order to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health brought about by the import and supply of ITAMACHI KING OOLONG Tea Drink. The Order also directs such drink supplied be recalled within 30 days.

6. A copy of the Order is at the Annex. The Order prohibits the import into and supply of ITAMACHI KING OOLONG Tea Drink within Hong Kong unless accompanied by a certificate issued by the relevant Mainland authority certifying that the levels of DEHP do not exceed 1.5 ppm. The Order also directs that such drink which has been supplied be recalled in the manner specified in Order, within a period of 30 days from the effective date of the Order.

7. The Order is directed to all persons and has taken effect at 12:00 noon on 22 June 2011. Any person who contravenes a term of the Order commits an offence and is liable on conviction to a fine at level 6 and to imprisonment for 12 months. It is not a defence for a person 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.

PUBLICITY

8. A press release was issued on 21 June 2011. A briefing for the relevant trader was arranged on the same day. A spokesman is available to answer press enquiries.

ENQUIRIES

9. Any enquiries on this brief may be addressed to Mr Kevin Yeung, Principal Assistant Secretary (Food) at 2973 8297.

Food and Health Bureau
23 June 2011

PUBLIC HEALTH AND MUNICIPAL SERVICES ORDINANCE

(Section 78C(3), Chapter 132)

Notice of Section 78B Order

Pursuant to Section 78C(3) of the Public Health and Municipal Services Ordinance (Chapter 132), it is hereby notified that a Section 78B Order (the 'Order') is issued. A copy of the Order is appended below : -

PUBLIC HEALTH AND MUNICIPAL SERVICES ORDINANCE

(Chapter 132)

(Section 78B)

Section 78B Order

Order No. : CFS/7/2011

FEHD Ref. : FEHD/CFS/78B

TO : All persons

This Order takes effect at 12:00 noon on 22 June 2011.

I now have reasonable grounds to believe that the making of this order in relation to the food specified in Annex A 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, the details of which are specified in Annex B. **I DO**, in exercise of my powers under section 78B(1) of the Public Health and Municipal Services Ordinance (Chapter 132), order that :

- a. you be prohibited from importing into Hong Kong the food specified in Annex A, that is intended for human consumption, for the period from 12:00 noon on 22 June 2011 until further notice.
- b. you be prohibited from supplying¹ within Hong Kong the food specified in Annex A, that is intended for human consumption, for the period from 12:00 noon on 22 June 2011 until further notice.
- c. the food specified in Annex A, that is intended for human consumption and has been supplied to you, be recalled in the manner specified in Annex C, within a period of 30 days from 12:00 noon on 22 June 2011.

If you feel that you are aggrieved by this order, you may, within 28 days from becoming bound by it (that is the date and time specified in paragraph 1), appeal to the Municipal Services Appeals Board.

¹ "Supplying" means (a) selling the food; (b) offering, keeping or exhibiting the food for sale; (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.

Note : A person bound by this order who contravenes a term of the order commits an offence and is liable on conviction to a fine at level 6 and to imprisonment for 12 months. It is not a defence for a person to show that the food concerned is the subject of a licence, permit or any other form of authorization issued or granted under this or any other Ordinance.

Dated this 21st June 2011

(Constance HY CHAN)

Director of Food and Environmental Hygiene (Acting)

FOOD SPECIFIED IN THE ORDER

Brand Name & Food Name	Manufacturer's Name	Place of Origin	Count/ Weight/ Volume	Batch No.	Photo (for reference)
ITAMACHI KING OOLONG Tea Drink (板町烏龍の王-茶飲料), unless accompanied by a certificate issued by the relevant Mainland authority certifying that the levels of di(2-ethylhexyl)phthalate (DEHP) do not exceed 1.5 parts per million (ppm)	Fuzhou Jinhe Ecolcil Science And Technology Co., Ltd. (福州金和生物科技有限公司)	Mainland China	All count/ weight/ volume	All batches	

**REASON FOR MAKING THE ORDER AND
PRINCIPAL FACTORS THAT LED TO MAKING OF THE ORDER**

Summary of incident:

On 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). Subsequently, further announcements by the FDA indicated that other drinks might also contain DEHP.

The Hong Kong Centre for Food Safety (CFS) took samples of relevant drinks manufactured in Taiwan and other places for testing. Results obtained on 21 June 2011 indicated that a sample of tea drink listed at Annex A contained DEHP at a level of 2.9 ppm. Dietary exposure estimation revealed that the exposure to DEHP from daily consumption of this sample by average consumers (daily consumption of about 530 ml of the drink) and high consumers (daily consumption of about 1400 ml of the 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 (EFSA) for high consumers), which may pose a risk to human health.

Source of information:

- The Food and Drug Administration in Taiwan
- World Health Organization
- European Food Safety Authority
- Local testing result

Health effects:

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 (IARC) concluded DEHP is possibly carcinogenic to humans.

MANNER IN WHICH A RECALL SHOULD BE CONDUCTED

(A) Importer

1. Set up telephone enquiry service to handle enquiries related to the recall incident as soon as possible.
2. Immediately notify all known distributor(s), retailer(s) and consumers of the recall and its arrangement.
3. Conduct a stock take of the in-house storage facilities and isolate any remaining stock that relates to the recalled food.
4. Inform the Food and Environmental Hygiene Department of the list of 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.
5. Display posters of not less than A4 size (21cm x 30cm) at a conspicuous location on the importer's premises and on the premises of distributor to whom the food has been supplied. The posters shall have:
 - (a) the heading "Food/Product's Name - Recall Announcement";
 - (b) the description and brand of the food ;
 - (c) picture(s) of the food;
 - (d) details of the recall arrangement (such as period of recall, place of recall or return of the food);
 - (e) the full name, address and telephone number of the recalling trader(s); and
 - (f) the telephone enquiry service and (if any) Internet website for the recall.

If an Internet website is operated, upload the poster, or the relevant information specified in (a) to (f) above, to the website for public announcement.
6. If the food concerned is returned by distributor(s), retailer(s) or consumers, the recalling trader(s) shall retract the food.
7. Provide the Food and Environmental Hygiene Department progress reports on a bi-weekly basis with the following details:
 - (a) date and quantity of the food recalled;
 - (b) name, address and telephone number of the companies, organizations or persons from which the food have been returned;

- (c) name, address and telephone number of the companies, organizations or persons from which the food has not been returned;
 - (d) quantity of the food concerned stored in warehouse before commencement of the recall;
 - (e) corrective action taken to improve effectiveness of the recall and the estimated time frame for the completion of the recall; and
 - (f) location(s) of keeping the recalled food.
8. Submit final report to FEHD within one month from the date of completion of recall and the report should contain the following information:
- (a) the names of the organizations or persons from whom the food was returned;
 - (b) the amount of the food returned;
 - (c) a reconciliation between the delivered and recovered quantities of the food;
 - (d) the effectiveness of the recall and what corrective actions have been taken with respect to the recall;
 - (e) the decision on the disposal method of the returned food; and
 - (f) the means of preventing recurrence of the defect.

(B) Distributor

1. Set up a telephone enquiry service to handle enquiries related to the recall incident as soon as possible.
2. Immediately notify all known retailer(s) and consumers of the recall and its arrangement.
3. Display posters of not less than A4 size (21cm x 30cm) at a conspicuous location on the distributors' premises. The posters shall have:
 - (a) the heading "Food/Product's Name - Recall Announcement";
 - (b) the description and brand of the food ;
 - (c) picture(s) of the food;
 - (d) details of the recall arrangement (such as period of recall, place of recall or return of the food);
 - (e) the full name, address and telephone number of the recalling trader(s); and
 - (f) the telephone enquiry service and (if any) Internet website for the recall.

If an Internet website is operated, upload the poster, or the relevant information specified in (a) to (f) above, to the Internet website for public announcement.

4. Conduct a stock take of the in-house storage facilities and isolate any remaining stock that relates to the food concerned.

5. If the food concerned is returned by retailer(s) or consumers, the recalling trader(s) shall retract the food.
6. To keep records of recalled food, which should contain:
 - (a) a description of the food returned such as brand and product name, size, identifying codes;
 - (b) the date and quantity of food returned; and
 - (c) what has been done with the food, for example, returned to the supplier(s).

(C) Retailer

1. Remove the food concerned from the shelves immediately and store it in a place not accessible by the customers while pending return to the supplier concerned. Also, 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.
2. If the food is returned by consumers, store the food in a place not accessible by customers while pending return to the supplier concerned.