

**For information
on 14 December 2004**

Legco Panel on Food Safety and Environmental Hygiene

**Setting Up a Framework for
Mandatory Food Recall in Hong Kong**

PURPOSE

This paper seeks Members' views on the need for setting up a framework for mandatory food recall in Hong Kong.

ISSUE

2. The Government has all along relied on the co-operation of the trade to recall food products which may pose a health hazard to the public at the retail level on a voluntary basis. If the trade is reluctant to undertake the recall action, the Government is not empowered under the existing legislation to mandate the manufacturers, importers, distributors, retailers and others involved in the food distribution network to recall the concerned food products.

BACKGROUND

3. The subject of mandatory food recall was first raised by the Administration in the 2001 Policy Address. It formed part of our policy objectives to strengthen our food safety regime through enhanced food surveillance and risk assessment and communication programmes. The Administration believed that the mandatory food recall mechanism would enable prompt and effective preventive measures to be taken to protect public health.

4. In the existing food law – Part V of Public Health and Municipal Services Ordinance (Cap.132) (“PHMSO”), there are no specific provisions governing the recall of food products. The only legal provision to which the Government may resort to is Section 59 of PHMSO which empowers the authority to mark, seal, seize, remove or destroy food which is suspected to be unfit for human consumption. Action can be planned and effected swiftly for isolated food items restricted to a small locality. However, for incidents

involving food products in mass supply and are available in extensive retail outlets, this provision is too costly and inefficient for the following reasons –

- (a) food suppliers are not required to notify Government of the distribution of their products. Information on the location and volume of food products is thus not readily available;
- (b) the manpower and logistics support needed for, say, transporting and storing the impounded foods, can be enormous; and
- (c) the process can be time-consuming and may result in unaffordable delays.

Existing Mechanism on Food Recall

5. The Government has developed a set of guidelines to advise the trade on how to conduct voluntary food recalls (a copy is at [Annex A](#)). From past experience, whilst the majority of food suppliers had responded positively to the Government's appeal for food recalls, some were reluctant to comply with the advice. In the event of non-compliance, it would be very costly for the Government to invoke existing legislation to mark, seal, seize, remove or destroy foods which are suspected to be unfit for human consumption. This is because the Government will need to retrieve the problematic food from a large number of food distribution and retail outlets, not to mention that the Government may lack the full picture of the distribution network. This pitfall could best be illustrated by the following incidents:

- (a) The Belgium dioxin crisis took place in the summer of 1999 during which it was widely suspected that eggs from Belgium, France, Germany and the Netherlands were affected. Given the scale of the crisis and the severe effects of dioxin on human health, the government considered that it would be in the public's interest to withhold the sale of imported eggs until the overseas authorities could confirm their safety. However, some in the egg trade were reluctant to recall the eggs because they had yet to see the concrete evidence, such as test results, which showed that their eggs were contaminated.
- (b) In the recent cases of ciguatera fish poisoning, while we have taken immediate actions to trace the source of the problematic fish identified by the responsible importer, we do not have any immediate and mandatory means to recall the problematic fish from sale or to seize the fish from the same batch or the same supplier for disposal.

6. Under the above circumstances, it would have been more operationally effective if the government were given the statutory power to order the trade to conduct a mandatory recall. Such incidents have aroused the public's concern on food safety and they now have a higher expectation on the Government's capability to deal with food incidents. Failure to meet public expectation would not only damage the Government's credibility, but would also tarnish the reputation of Hong Kong's food industry. We therefore consider it desirable to set up a mandatory food recall mechanism to cope with cases where the Government sees an urgent need to withdraw a food product from the market as a precautionary measure when there is indication from the relevant overseas or local authorities that the safety of the food product has yet to be ascertained, and if the relevant food manufacturers, importers or distributors are unwilling to recall their products voluntarily.

Local Experience on Mandatory Recall of Non-food Products

7. In Hong Kong, there is legislation mandating recall of toys, childrens' products and consumer goods (except food) for the protection of public safety. Under the Toys and Childrens' Products Safety Ordinance (Cap. 424) and the Consumer Goods Safety Ordinance (Cap. 456), the Commissioner of Customs and Excise is empowered to order the recall of toys/children's products and consumer goods (except food) respectively when -

- (a) the products do not comply with a safety standard;
- (b) the products to which no safety standards or specifications apply, is or may be unsafe; or
- (c) there is a significant risk that the products will cause a serious injury.

A recall notice may be served on a person requiring the immediate withdrawal of the products from being supplied and the retrieval of those items already supplied. The person who is served with a recall notice and fails or refuses to comply with it commits an offence.

Overseas Experience in Mandatory Food Recall

8. Australia, Canada and New Zealand have regulations on mandatory food recall. The table summarizing the details of these overseas systems are at Annex B. A mandatory recall order will be used when there is reasonable ground for the relevant authority to believe that a food product poses a risk or danger to public health and that the relevant party is unable or has not taken satisfactory action to recall the concerned food product.

9. In Australia and New Zealand, the product recall level is divided into trade (wholesale and retail) and consumer level. Principal factors taken into consideration on determining the levels of recall are the significance of the estimated risks, the channels by which the goods have been distributed, and the level to which distribution has taken place. Canada uses a classification system to determine the level of food recall and whether public warning is to be issued.

10. Some countries, e.g. the United States (US), the United Kingdom and Singapore have no legislation on mandatory food recall. However, should a company refuse to comply with a request by the relevant authorities to recall its product, the Food Safety and Inspection Service of the US Department of Agriculture has the legal authority to detain and/or seize meat and poultry products which are believed to be hazardous to public health. Similarly, the Singaporean and the UK authorities can only activate food recall but not the authority to require the trade to recall the concerned food.

THE WAY FORWARD

11. As a starting point for our consideration of whether it is necessary to set up a framework for mandatory food recall, we may wish to focus preliminarily on circumstances under which Government can order a mandatory food recall, such as the occurrence of a health hazard situation which would cause serious adverse health consequences or death on the consumption or use of the food product and the number of people potentially to be affected is large.

12. Taking into account Members' views, we will further consider the details of the proposed regulatory framework for mandatory food recall in Hong Kong, e.g. the target recipient of the recall order, directives in a recall order, enforcement and penalties and the appeal mechanism, etc. and consult the trade on the details of the proposal.

ADVICE SOUGHT

13. Members are requested to comment on the proposal set out in this paper.

**Health, Welfare and Food Bureau
Food and Environmental Hygiene Department
December 2004**

Food Recall Guidelines

Introduction

- This publication is to provide a guidance for carrying out food recalls. It explains what should be done when food products have to be removed from supply or use by consumers for **public health and safety** reasons. Recall of food product is in the common interest of the industry, the government and in particular, the consumer.
- A recall is defined as an action to remove from sale, distribution and consumption, foods which may pose a safety hazard to consumers.



Legislation

There is no specific legislation governing the recall of food. Under the Public Health & Municipal Services Ordinance, food on sale for human consumption must be wholesome, unadulterated, uncontaminated, properly labelled and fit for human consumption. Violations of the provisions may lead to prosecution against the manufacturer, the importer or the distributor of the food. Specifically, under Section 59 of the Ordinance an authorised officer may examine or seize any food which he considers to be unfit for human consumption. **In actual cases, most recalls of foods are carried out voluntarily by the supplier.**

Role of the Government

- The Government's main role in a recall is to monitor the progress of the recall and assess the adequacy of a company's action. After a recall is completed, the Food and Environmental Hygiene Department will make sure that the product is destroyed or suitably improved. Where the recall is related to serious defects in the manufacturing process locally, the Food and Environmental Hygiene Department will consider if it is necessary to tighten up the licensing requirements.
- The Food and Environmental Hygiene Department will make publicity about a recall when it considers that the public need to be alerted about a health hazard or that clarification of the situation needs to be made to allay public worries.
- In cases of public health emergencies, the Food and Environmental Hygiene Department may, depending on the available evidence, alert the public before a decision on recall has been reached.

Role of the Company

- Companies supplying products to Hong Kong carry the prime responsibility of implementing the recall, and for ensuring compliance with the recall procedure at its various stages including follow-up checks to ensure that recalls are successful and that subsequent batches of the food products are safe for human consumption. A recall should be undertaken in consultation with the Food and Environmental Hygiene Department and preferably with prior agreement on the recall strategy. During the recall process, company personnel should keep all relevant parties informed of the latest developments.
- If the recall involves products exported overseas, the company concerned should notify, as soon as practicable, overseas recipients of recalled stocks.

Initiation of a Recall

- A recall may be initiated as a result of reports/complaints referred to the company from a variety of sources. The reports may be referred by manufacturers, wholesalers, retailers, medical practitioners, government agencies and consumers. A recall of goods manufactured overseas may also be initiated by reports appearing in overseas bulletins and similar publications of health authorities, or from information received directly from such authorities.
- To minimize the risk that may arise, recalls are usually carried out in the shortest time practicable. Companies are encouraged to develop its own recall procedure so that it can respond promptly to any emerging situation. The procedure should be able to achieve the purposes of stopping distribution and sale of an affected item, notifying the public and the Food and Environmental Hygiene Department of the problem, and effectively and efficiently retrieve from the market any product which is potentially unsafe.

Notification to the Food and Environmental Hygiene Department

Safety-related recalls referred to in this document involve the risk of death, illness or injury to the public. In view of the increasing aspiration of the consumer and to avoid possible confusion in the event of a food recall, the company should notify the Food and Environmental Hygiene Department immediately after the recall exercise has been initiated. While the information on the recall together with any opinions on the risk to public health and safety and the action proposed by the company should be forwarded to the Food and Environmental Hygiene Department in writing within two days of initiating the recall using the 'Food Recall Notification Form' as provided at Appendix A, such information should be provided to the Department by telephone (tel. no. 2867 5566) or by fax (fax no. 2521 4784) immediately after the recall has been initiated. Any enquiries about recall procedures or actual cases of recall should be directed to the Senior Superintendent (Food Surveillance and Certification) of the Food and Environmental Hygiene Department at the above tel. no.

Informing the Consumer

Depending on the extent of the recall, the company concerned should inform the consumer of the recall at the earliest possible moment. Information dissemination may take the form of a press release, letter to the concerned parties or paid advertisement in the media. Sufficient telephone hotline service should be made available to deal with enquiries.

Assessment of the Recall

- Depending on the imminent risk that may be involved, there are two classes of recall:
 - (a) Class one recall-emergency situation**
This arises when there is a reasonable probability that the use or consumption of the product would cause adverse health consequences or death.
 - (b) Class two recall-concern situation**
The product may have serious defects which represent a potential health risk.
- This classification is to be determined by the Food and Environmental Hygiene Department in consultation with the company concerned. To expedite the classification, the company should provide all information on the 'Food Recall Notification Form'. Other relevant details may include:
 - (a) availability for investigation of suspect sample or other samples;
 - (b) assessment of risk; and
 - (c) proposed recall classification.
- Since some of the above information may be of a commercially sensitive or private nature, the Department will, upon request by the company concerned, maintain confidentiality on selected information as and when necessary.
- The party initiating the recall should, in consultation with the Food and Environmental Hygiene Department, work out the extent of the recall. In determining the recall level, the principal factors to be considered are the significance of the risk, the channels by which the goods have been distributed and the level to which distribution has taken place.

Product Recovery

Products may be recovered by return to supermarkets, return via distribution chains or direct return from consumers. The product is to be recovered to a central site, or in the case of widely distributed product, to major recovery sites. The recovered product must be stored in an area which is separated from any other food product. Accurate records are to be kept of the amount of recovered product and the batch codes of the product recovered. After recovery, products may be corrected or reprocessed before release to the market if it is fit for human consumption. Otherwise the product is to be destroyed.

Follow-up Action

- **Post-recall reporting**

The party initiating the recall should provide the Department with an interim report as soon as a recall is completed, in any case not later than one month after the announcement of a recall. A final report should be ready within two months of the recall. The reports should contain essential information such as:

- (a) the circumstances leading to the recall;
- (b) the action taken by the company including details of any publicity;
- (c) the extent of distribution of the relevant batch in Hong Kong and overseas;
- (d) the result of the recall (quantity of stock returned, corrected, outstanding, etc.);
- (e) the proposed method of disposal or otherwise of recalled stock with record of destruction; and
- (f) the action proposed to be implemented in future to prevent a recurrence of the problem.

The report helps to establish the effectiveness of the recall. Unless satisfactory reports are received, the Department may consider taking further action, e.g. stepped-up inspection, against the company concerned.

- **Effectiveness of Recall Action**

To be effective, recall notification must reach as far as the product has been distributed. The effectiveness of the recall is assessed upon the amount of product returned as a percentage of the amount of product which left the manufacturer while taking into account the retail turnover of that product.

Conclusion

Worldwide, cooperation between the company and the regulatory authority has proven over the years to be the quickest and most reliable method to remove potentially dangerous products from the market. These guidelines outline the procedures which would enhance efficiency and transparency in the recall of food products. The implementation of such guidelines will hopefully minimize the loss inflicted on the company and the community at large.

A [flow chart](#) summarizing the procedures to be followed in a food recall is at Appendix B.





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Safe Food & Public Health

FOOD RECALL NOTIFICATION

To: Director of Food and Environmental Hygiene
 (Attn: Assistant Director (Food Surveillance and Control))
 43/F, Queensway Government Offices, 66 Queensway, Hong Kong.
 (Facsimile: 2521 4784)

General

Originating Company:	
Contact Officer: (Post)	Telephone:
	Fax:
Date of report/complaint to Company	Date of notification to Food and Environmental Hygiene Department

Description of Food

Food Type:	
Brand Name:	Product/Pack Size:
Date Marking:	Batch/Number code:
Quantity/No. of Product Affected:	

Nature of Hazard

Name & Tel. No. of person and post reporting the problem:	Date of reporting:
Has any testing been undertaken:	Nature of problem:
Results:	

Extent of Distribution of the Product

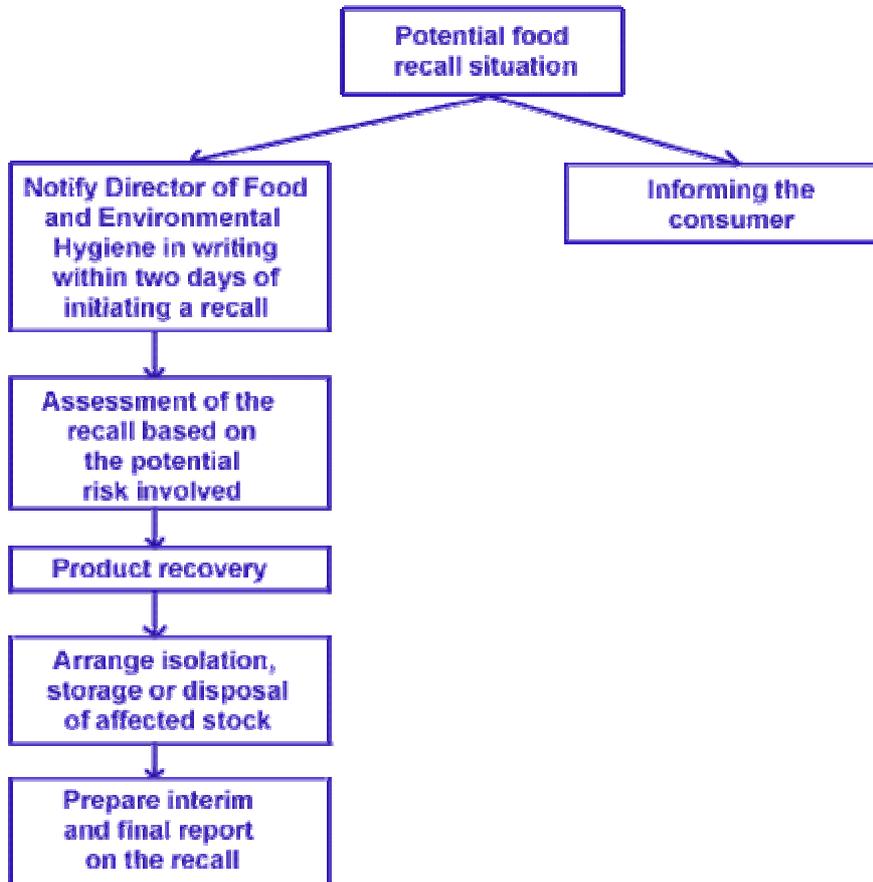
Hong Kong:	Overseas:
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Action Proposed and Actions Taken

Other Relevant Information

(Please attach extra sheets if space is insufficient)

Food Recall Procedures



Mandatory Food Recall Systems in Australia, New Zealand and Canada

	Australia	New Zealand	Canada
The relevant legislation	At the Commonwealth level, the mandatory recall power is provided for under the Trade Practices Act 1974. At the States/Territories level, the local governments have mandatory recall powers under the food legislation and/or consumer protection legislation.	New Zealand Food Act	Canadian Food Inspection Agency Act
Who to make the mandatory recall order	The power to make a mandatory recall order rests with the Minister for Financial Services and Regulation under the Trade Practices Act. At the States/Territories level, the authorities to order a mandatory recall are largely the health authorities.	Minister of Health	Minister of Agriculture and Agri-Food
Under what circumstances would a recall order be made	Specific wording in individual pieces of legislation of the States/Territories differ. For example, in New South Wales, a recall order may be made if there are <i>reasonable grounds</i> to believe that the order is necessary to prevent or mitigate <i>a serious danger to public health</i> . In Victoria, a recall order may be made if of the opinion that a particular food or class of food may <i>pose a risk to the health</i> of any member of the public who may consume or come into contact with that food and <i>it is in the public interest to do so immediately</i> .	If the food is <i>unsound or unfit for human consumption or is damaged or deteriorated or perished, or that is contaminated with any poisonous, deleterious, or injurious substance</i> .	On <i>reasonable grounds</i> that a food product <i>poses a risk to public health</i> .

	Australia	New Zealand	Canada
Role of the Authority	<p>Australia New Zealand Food Authority (ANZFA) is responsible for coordinating and supervising the commonwealth, state/territory and local governments in carrying out the following roles for food recalls :</p> <p>(a) Initiation</p> <ul style="list-style-type: none"> ◆ Risk assessment ◆ Gathering product information <p>(b) Communication</p> <ul style="list-style-type: none"> ◆ Transmitting the product information to the appropriate health authority ◆ Issuing media statement where recalls involve consumers and the risk warrants it <p>(c) Monitoring/auditing</p> <ul style="list-style-type: none"> ◆ Receiving interim and final reports from the sponsor (i.e. supplier/importer/manufacture) ◆ Conducting effectiveness checks and audits ◆ Providing scientific, technical and operational advice where necessary <p>(d) Product disposal/collection</p> <ul style="list-style-type: none"> ◆ Determining the method of collection and disposal <p>(e) Evaluation/review</p> <ul style="list-style-type: none"> ◆ Evaluating and reviewing the food recalls 	<p>Ministry of Health carries out :</p> <ul style="list-style-type: none"> ◆ Initiation ◆ Providing support and technical advice ◆ Disseminating information ◆ Ensuring consumers are adequately informed ◆ Auditing/reviewing procedure ◆ Ensuring supervised disposal of recalled goods ◆ Emergency response 	<p>The roles of Canadian Food Inspection Agency (CFIA), the national food safety authority, include :</p> <ul style="list-style-type: none"> ◆ Investigating whether there is any violation of legislation enforced by CFIA ◆ Deciding risk management strategy ◆ Servicing the order, preparing media lines, informing local governments ◆ Assisting the recalling firm to release a public warning ◆ Conducting effectiveness checks ◆ Monitoring the corrective actions ◆ Conducting evaluation
Role of the food trader/manufacture concerned	<p>Having an up-to-date recall plan is a legal requirement for all sponsors. They have the prime responsibility for implementing the recall and for ensuring compliance with the recall procedure.</p>	<p>It is a legal requirement for the importer, manufacturer or seller, on receipt of the recall order, to advise the Minister the details of</p>	<p>It is the prime responsibility of the recalling firm to develop and implement a recall strategy that ensures rapid and efficient control</p>

	Australia	New Zealand	Canada
	<p>Their main roles are :</p> <p>(a) Convening recall committee</p> <ul style="list-style-type: none"> ◆ Comprising senior management of the principal areas involved in a recall <p>(b) Hazard/risk assessment</p> <ul style="list-style-type: none"> ◆ Obtaining all relevant information about the product and the problem ◆ Determining the seriousness of the hazard <p>(c) Determining the level of the recall</p> <ul style="list-style-type: none"> ◆ Trade recall ◆ Consumer recall <p>(d) Notification</p> <ul style="list-style-type: none"> ◆ Statutory authorities ◆ Distribution network and trade consumers ◆ Public – for a consumer recall <p>(e) Recovery</p> <ul style="list-style-type: none"> ◆ Stopping distribution and sale ◆ Storing recovered product safely ◆ Proper recording system ◆ Isolating and disposal <p>(f) Recall reporting</p> <ul style="list-style-type: none"> ◆ Assessing the effectiveness ◆ Investigating reason for the recall ◆ Taking action to prevent recurrence 	<p>the manner in which he proposes to comply with the order and when the recall has been completed. A Product Recall Co-ordinating Committee should be formed with the following roles :</p> <ul style="list-style-type: none"> ◆ Assessment of the overall problem ◆ Notification of the relevant authorities ◆ Evaluation of the hazard ◆ Decision on the strategy ◆ Recommendations as to whether or not to close production plants ◆ Provision of sole contact with the media ◆ Contact with suppliers and customers ◆ Assessment of effectiveness and when production may recommence 	<p>of the affected product. Its roles in various stages are :</p> <ul style="list-style-type: none"> ◆ Assisting in the determination of the root cause and defining the affected product ◆ Implementation of the recall and verification of the effectiveness of the risk management strategy employed ◆ Releasing a public warning with the assistance of CFIA ◆ Ensuring effective action in removing the product from the marketplace ◆ Ensuring recalled product does not reenter the market and appropriate correction or disposition taken ◆ Evaluation of the recall
What directives can be included in the recall order	The nature and scope of order vary in different states/territories. In general, a recall order may direct the recall of any food or require the destruction or disposal of the food	A recall order may direct the recall of any food or require the destruction or denaturing of food.	A recall order may direct the product be recalled or sent to a designated place.

	Australia	New Zealand	Canada
	concerned. In some states/territories, an order or a prohibition notice may prohibit the cultivation, taking, harvesting or obtaining of any food; require a manufacturer, importer or seller of food to publish appropriate advertisements, or specify methods of analysis of food		
Enforcement	For consumer recalls, enforcement officers would conduct inspection and effectiveness checks at retail levels to ensure compliance. Products will be seized if necessary.	For consumer recalls, enforcement officers would conduct inspection and effectiveness checks at retail levels to ensure compliance. Products will be seized if necessary.	For consumer recalls, enforcement officers would conduct inspection and effectiveness checks at retail levels to ensure compliance. Products will be seized if necessary.
Maximum penalty¹ for non-compliance of the order	The penalty levels vary in different states/territories, but can be as high as \$40,000 or imprisonment for 1 year for a natural person and \$200,000 for a body corporate	\$300,000 or 12 months' imprisonment. Additional fine of \$3,000 per day for continuing offence.	\$250,000 and/or imprisonment for 6 months.

¹ The prescribed fines are converted to HK dollars in approximate amounts.

	Australia	New Zealand	Canada
How to ensure that the public is well informed	For consumer level recalls, advertisements paid for by the order recipients are to be placed in the daily print media.	<ul style="list-style-type: none"> ◆ Recall notice, paid by the order recipient, in the press. ◆ Media release with Director-General of Health's statement in most urgent cases. 	<ul style="list-style-type: none"> ◆ Recalling firm issues news release ◆ In unacceptable situations, CFIA releases the recall news