

**For information on
3 June 2004**

**LegCo Subcommittee on Food and Drugs (Composition and Labelling)
(Amendment) Regulation 2004**

PURPOSE

This paper updates Members on the issues raised at the first Subcommittee meeting on the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2004 (“Amendment Regulation”) on 31 May 2004.

FOOD ALLERGY AND CLINICAL RESULTS

2. Food allergies are adverse reactions to an otherwise harmless food or food component that involves an abnormal response of the body’s immune system to specific protein(s) in foods. Food allergies can be caused by a wide variety of foods. It is generally believed that only a very minute amount (in the microgram to low milligram range) of food allergen is required to cause allergic reaction in highly susceptible individuals. The allergic reaction may be immediate or delayed. Many of the allergic reactions are mild but fatal outcome may occur infrequently. The allergic reaction can occur within minutes of exposure to the allergen causing symptoms such as swelling in the mouth and throat, streaming

eyes and nose, breathing difficulties or asthmatic attack, followed by reactions in the skin or gastrointestinal tract. Individuals with allergic reactions are commonly seen at the accident and emergency departments or may be seen by their family physicians. They may be presented with a variety of symptoms and signs, including common skin manifestations (skin rash), tightness in the chest and audible wheezing. Severe cases, if untreated, these results can result in asphyxiation and circulatory collapse and be fatal.

3. It is estimated in the West that about 3-4% of children and 1-2% of adults suffer from food allergy. According to the World Health Organization (WHO), the eight most common allergy causing foods, namely cereals containing gluten, crustacean and crustacean products; eggs and egg products; fish and fish products; peanuts, soybeans and their products; milk and milk products; tree nuts and nut products; and sulphite in concentrations of 10 parts per million or more are known to cause more than 90% of all food allergies. It was reported in the US that food allergy accounts for 30,000 anaphylactic reactions and 2 000 hospitalizations and 200 deaths each year. The UK Food Standards Authority reported that 10 people die every year from food allergic reactions in the country.

THE AMENDMENT REGULATION

4. People with food allergy should be provided with sufficient information on the ingredients of the food to be consumed to avoid

consumption of those foods known to trigger an unfavourable reaction. One of the requirements of the Amendment Regulation is the declaration on the food labels the presence of the eight categories of substances as described in paragraph 3 above. As these raw materials and ingredients are added by the manufacturers, the latter would usually have information on the existence of these substances. The Amendment Regulation also requires that both the category and the exact name (or the identification number) of the additive are to be declared on the label to provide consumers with more information and to catch up on the international practice.

OVERSEAS LEGISLATION ON ALLERGENS AND ADDITIVES

5. Based on figures provided by a chained supermarket, about 36% of pre-packaged food products are supplied by Hong Kong companies. The Mainland (31%) is the largest importer of pre-packaged food products. North America, Thailand, Australia and New Zealand, and Europe each accounts for about 5% of import pre-packaged food. The summary of similar labelling requirement on allergens and additives of these regions or countries is listed below.

Summary of Legislation Requiring the Labelling of Additives and Allergens

	The Mainland	USA	Canada	Thailand	Australia/New Zealand	European Union	Japan
Labelling of Additives	Since 1994 Names or category names	Since 1977 All ingredients are to be labelled Allow the use of descriptive terms for additives.	Since 1988 All ingredients are to be declared	Since 1985 Labelling of certain food additive categories	Since 1987 Class names and additive names or INS numbers	Since 1978 Class names and additive names or E-numbers	10 categories of additives to be labelled with category names and names; 14 categories by category names only
Labelling of Allergens	No such legislative requirement	Allergens are declared as ingredients under existing legislation. A specific Food Allergen Labelling and Consumer Protection Act requiring the declaration of allergens was passed by the Senate on 9 March 2004. If the Act is passed by the House of Representatives, the Act is expected to be effective in Jan 2006.	Allergens urged to be declared as ingredients under existing legislation. Plan to amend the Food and Drugs Regulations requiring allergen labelling in 2004	No such legislative requirement	Since Dec 2002 Declaration of 12 categories of allergens (the 8 categories of allergens plus sesame seed, royal jelly, bee pollen and propolis)	25 Nov 2005 Declaration of 11 categories of allergens (the 8 allergens plus celery, mustard and sesame seed)	April 2002 Mandatory declaration of 5 categories of allergens and voluntary declaration of another 19 categories

6. The above summary indicates that most developed countries or regions, which are also the major suppliers of pre-packaged food products of Hong Kong have either legislated or in the process of requiring the declaration of the allergens and the full description of additives on labels. These legislations are in line with the recommendation of the Codex Alimentarius Commission (Codex), an international authority created by the Food and Agricultural Organization and WHO to set food-related standards and guidelines. In addition to providing consumers with more information on the food to be consumed, it also helps to minimize the adverse reactions of allergic individuals arising from the consumption of allergens and reduce the related medical and social costs as a whole.

LABELLING REQUIREMENT OF ALCOHOLIC DRINKS

7. Under the current legislation, alcoholic drinks with an alcoholic strength by volume more than 1.2% as determined under section 53 of the Dutiable Commodities Ordinance (Cap. 109) are exempted from all labelling requirements, i.e. its name, list of ingredients and additives, indication of “best before” or “use by” date, special condition for storage or instruction for use; count, weight or volume; and name and address of manufacturer or packer. Taking into consideration that alcohol is also regarded as food and the consumers should be provided with sufficient information on the labels, the Amendment Regulation requires that drinks with an alcoholic strength by volume of more than 1.2% but less than 10% (e.g. beer) are required to follow the labelling requirement except

declaring the list of ingredients. Wines, liqueur wines, sparkling wines, aromatized wines, fruit wines, sparkling fruit wines and other drinks with an alcoholic strength of volume of 10% or more (e.g. brandy and whiskey) are also required to follow the labelling requirement except declaring the list of ingredients and the indication of “best before” or “use by” date.

CONSULTATION EXERCISE

8. Maintaining a balance between the public health and the business interest is a critical success factor for implementing the Amendment Regulation. The Food and Environmental Hygiene Department (FEHD) conducted a public consultation exercise on the four proposed labelling amendments (declaration of the eight allergens, indication of the name or code of food additive used; flexibility on the marking of date format and strengthening the labelling requirement of alcoholic drinks) from October to December 2000. About 1 200 letters attaching detailed proposals were sent to all major stakeholders, including related trade associations, food importers and manufacturers, chained supermarkets and department stores, consulates, medical profession bodies and the Consumer Council. The detailed proposals were uploaded onto FEHD’s homepage and published in the FEHD’s publication *Food Safety Bulletin*. Press interviews were given and these were covered in local newspapers. At the end of the consultation period, a total of 29 written submissions were received, including the one from the Hong Kong Retail Management Association (HKRMA) dated 21 December 2000 and a subsequent letter from HKRMA to the then Environmental and Food Bureau (EFB) on 9

February 2001. The letters and the responses from the Administration on 27 December 2000 and 27 February 2001 are attached at Annex A to D.

9. To further discuss the concerns of the retail trade and to allow government representatives to explain the rationale behind the proposed legislation, officials of the then Commerce and Industry Bureau, the then EFB and FEHD met with representatives of the HKRMA on 10 May 2001 (notes of meeting is at Annex E). The major concerns raised by the HKRMA then were -

- (a) the proposed labelling requirement would mean extra cost to the consumers;
- (b) separate labelling would be required as some products were packed in large quantities in countries like USA and Australia;
- (c) labelling of allergenic substance would prevent food products to be imported from the Mainland and Southeast Asia countries where there was no requirement on labelling of allergenic substances;
- (d) retail trade was not in a position to know if the manufacturers had changed the ingredients;
- (e) importers would face the risk of prosecution as the technological tests might not be able to identify the additives added; and
- (f) how the amendment would be written despite their support for flexible date marking format.

10. After briefing the Legislative Council (LegCo) Panel on Food Safety and Environmental Hygiene on 22 January 2001 on the proposed amendments at which Members did not raise objection, the Administration commenced the drafting process of the Amendment Regulation. On different occasions, Administration had reiterated to the public that the drafting of the Amendment Regulation was in progress and would be submitted to LegCo for consideration as soon as possible (the summary of events is at Annex F). However, the drafting process had been delayed as the Administration was also engaged in other major tasks, including the regulatory impact assessment on labelling of genetically modified food, the feasibility study of nutrition labelling. There were also other bills and subsidiary legislations being prepared at the same time, e.g. the Public Health (Animals and Birds) Regulation, the Marine Fish Culture Ordinance and the ground works for Fisheries Protection Ordinance. Some unprecedented major events, e.g. the outbreaks of avian influenza and the Severe Acute Respiratory Syndrome, also happened during these years of which the Administration had to allocate much resource to attend to.

TIMETABLE

11. The Amendment Regulation is expected to come into operation on 9 July 2004. A grace period of 18 months will be allowed for the trade after the commencement of the Amendment Regulation on the labelling of additives and allergens, the flexible date marking format and the labelling of alcoholic drinks. The relaxation of additives in condensed milk or

evaporated milk and butter will be implemented immediately.

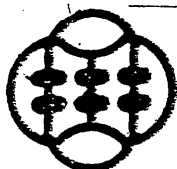
CONCLUSION

12. Our objective is to enhance food safety for the protection of public health and to facilitate consumer in making healthy choices. The Amendment Regulation follows the recommendation of Codex and is in line with the international trend of requiring more information to be declared on the labels of the pre-packaged food products, in particular the presence of allergens.

Health, Welfare and Food Bureau

Food and Environmental Hygiene Department

June 2004



HONG KONG RETAIL MANAGEMENT ASSOCIATION
香港零售管理協會

21 December 2000

Mr W T Wong
Food and Environmental Hygiene Department
45/F Queensway Government Offices
66 Queensway
Hong Kong

By fax: 2521 4784 & mail

Dear Mr Wong,

CONSULTATION PAPER ON PROPOSED AMENDMENT TO FOOD AND
DRUGS (COMPOSITION AND LABELLING) REGULATIONS
PUBLIC HEALTH AND MUNICIPAL SERVICES ORDINANCE, CAP.132

Thank you for your letter dated 16 October 2000 inviting our Association to comment on the captioned subject.

Please find below our comments as follows:

1. General

Mandatory labelling of products should only be required where there are good consumer safety or consumer choice reasons to do so. Furthermore, mandatory labelling requirements carry a compliance cost, which ultimately the consumer has to partly bear. Accordingly, additional labelling requirements therefore have to be fully justified based on the above factors.

We therefore feel that the proposed legislation is impractical and costly.

2. Hong Kong

Hong Kong imports almost all of its food from many different parts of the world. While reference should be taken from Codex on food labelling standards, it is most important that Hong Kong's labelling laws are consistent with its major trading partners. If Hong Kong has stricter labelling laws than its trading partners, this would lead to:

- (a) restricted choice of products available in Hong Kong (overseas manufacturers would not be willing to export products to Hong Kong because the additional costs would outweigh potential benefits in such a competitive market); and

(b) increase in the price of products (resulting from the compliance costs).

3. Labelling of Allergenic Substances

Although Codex has recommended that 8 allergen categories should be declared, we are unaware of which Hong Kong's main trading partners have to date imposed this specific requirement. In EU, for example, there are presently no specific mandatory labelling requirements for these allergens. Again, any requirements should not be more onerous than those which are set by our trading partners. To impose it in Hong Kong would place an enormous cost on retailers in terms of checking ingredients. It is therefore impracticable and would be very costly to control and label.

4. Food Additives

The consultative paper states that the proposal to declare the category and exact name of the additives on the food labels is "to provide consumers with more information". Although we believe that there is a benefit to the consumer in knowing the functional class of food additives (colour, preservative, etc), we believe the compliance costs outweighs any benefit for the consumer if it is mandatory to include details of food additives used in products.

E numbers are a requirement in Europe and Australia but not in the USA and other countries such as PRC and South Asia in general. To impose a requirement where every pack from these countries be labelled with a list of ingredients would be a nightmare. This would limit consumer choice and add a cost burden.

5. More Flexible Date Marking Format

Already, goods that are imported from overseas require re-labelling to comply with Hong Kong's bilingual labelling requirements for the "best before" or "use by" dates. Accordingly, using the example used in the Consultation Paper, even if the products imported from the United States followed the same marking sequence as in Hong Kong, those products must be re-labelled anyway to comply with the bilingual requirements. Hence this provision will not prevent the need to re-label imported products.

Furthermore, consumers in Hong Kong are aware of the day, month, and year sequence required by existing regulations and any change would only serve to confuse customers.

Again, we believe that the compliance costs outweigh any perceived benefit to the consumers.

6. **Date Coding – Add bi-lingual characters/bigger labels required**

The use of Chinese characters as well as roman numerals on sell-by-dates will impose a bit of problem for overseas labelers and ink jet machines which are not programmed for Chinese characters. This means hand-labels for every single imported product at a massive cost.


7. **Responsibility**

The question of responsibility when a product infringes the legislation should be looked into - whether a retailer should also be held responsible in addition to the manufacturer.

I hope the above comments will be useful in assisting the Government's review on the subject.

In the meantime, should you have any queries, please do not hesitate to contact the undersigned at 2866 8311.

Yours sincerely,



Anita Bagaman (Miss)
Executive Director

食物環境衛生署

FOOD AND ENVIRONMENTAL HYGIENE DEPARTMENT

食物及公共衛生部

Food and Public Health Branch

香港金鐘道六十六號，金鐘道政府合署四十三樓

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本署檔號 Our Ref. :

來函檔號 Your Ref. :

27 December 2000

To: Hong Kong Retail Management Association
Unit B, 22/F, United Centre,
95 Queensway,
Hong Kong
(Attn: Miss Anita Bagaman, Executive Director)

Dear Sir

**Proposed Amendments to
the Food and Drugs (Composition and Labelling) Regulations**

Thank you for your letter of 21 December 2000 providing resourceful information regarding the captioned subject. We note its content and we will duly consider your valuable comments upon reviewing of the legislation in this respect.

For further enquiry, you are welcome to contact the undersigned on 2867 5581.

Yours faithfully



(CHEUNG Sui-chun)

for Director of Food and Environmental Hygiene

**HONG KONG RETAIL MANAGEMENT ASSOCIATION****香港零售管理協會**

9 February 2001

Mrs Lily Yam
Secretary for Environment and Food
Environment and Food Bureau
9-10/F Citibank Tower
3 Garden Road
Central
Hong Kong

Dear Mrs Yam

**PROPOSED AMENDMENTS TO THE FOOD AND DRUGS (COMPOSITION
AND LABELLING) REGULATIONS
PUBLIC HEALTH AND MUNICIPAL SERVICES ORDINANCE, CAP.132**

I am writing on behalf of the Hong Kong Retail Management Association to draw your attention to the captioned proposed amendments which has gained much concern amongst our industry. The proposals bring about much impact to operators within our trade. We have earlier responded to the consultation paper of the proposed amendments and a copy of our letter is attached hereto for your reference.

We sincerely hope that you could grant us your attention to the subject which warrants vital importance to its progress. Your attention and input will be much highly appreciated.

In anticipation of your favourable reply, I thank you.

Yours sincerely,

Yu Pang Chun
Chairman

c.c. Mrs Rita Lau, Director of Food and Environmental Hygiene, FEHD.
Mrs Selina Chow, JP, Legislative Councillor, Wholesale & Retail.

環境食物局
 食物部



Environment and Food Bureau
 Government Secretariat

Tel : 2136 3336

Fax : 2136 3328

Ref : EFB 5/1/8

27 February 2001

Mr Yu Pang-chun
 Chairman
 Hong Kong Retail Management Association
 Unit B 22/F United Centre
 95 Queensway
 Hong Kong

Dear Mr Yu

**Proposed Amendments to the Food and Drugs
 (Composition and Labelling) Regulations
 Public Health and Municipal Services Ordinance, Cap 132**

Thank you for your letter dated 9 February 2001 to Mrs Yam on the above.

I note that your Association has written to the Food and Environmental Hygiene Department (FEHD) who will no doubt consider your comments carefully before finalizing legislative amendments to the Food and Drugs (Composition and Labelling) Regulations, Public Health and Municipal Services Ordinance, Cap 132.

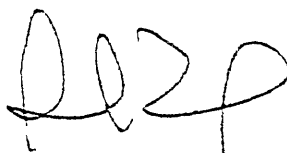
You may also wish to note that FEHD has received a total of 29 sets of written comments, including that of your Association, on the proposed amendments. Most of the views expressed are in support of the proposals. We have also notified the World Trade Organization (WTO) and through its notification system consulted the international community on our proposals and have not received any objections from members of the WTO within the notification period.

香港中環花園道三號英國實業銀行大廈十樓

10TH FLOOR CITIBANK TOWER 3 GARDEN ROAD CENTRAL HONG KONG

Thank you for your attention.

Yours sincerely



(Paul Tang)

for Secretary for the Environment and Food

cc - Hon Mrs Selina Chow, JP

→ - Mrs Rita Lau, Director, FEHD

(25301368)



香港特別行政區政府工商業
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本署檔號 Our Ref.: CIB/BSPU/3/1/2 Pt.6

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6 June 2001

Miss Anita Bagaman
 Executive Director
 Hong Kong Retail Management Association
 Unit B, 22/F, United Centre
 95 Queensway
 Hong Kong

By Fax : 2866 8380

[Total Pages : 4]

Dear *Anita*,

**Proposed Amendments to
 Food and Drugs (Composition and Labelling) Regulations**

Further to our meeting of 10 May, I attach the notes of meeting for your reference.

We hope that you and your members have found the discussion session useful. Please let me know if we could be of further assistance.

Yours sincerely,

(Mrs Brenda Yip)

Business and Services Promotion Unit
 for Secretary for Commerce and Industry

Encl.

c.c.

Director of Food and Environmental Hygiene
 (Attn.: Dr P Y Leung, Fax : 2536 9731)
 Secretary for Environment and Food
 (Attn.: Mr David Leung, Fax : 2136 3281)

**Notes of Meeting with
Hong Kong Retail Management Association on
Proposed Amendment to Food and
Drugs (*Composition and Labeling*) Regulations held on 10 May 2001**

Present:

Mr Kenneth Mak	CIB	
Mrs Brenda Yip	BSPU/CIB	
Mr David Leung	EFB	
Dr PY Leung	FEHD	
Miss Linda Law	FEHD	
Ms Caroline Luk	CRS (HK) Co. Ltd.	
Mr Steve Fitten	Dairy Farm - Wellcome	
Mr David Bound	Dairy Farm - Wellcome	
Mr Keith Bartlett	Parknshop	
Mr Peter Johnston	Parknshop	
Mrs Medea Chiu	BSPU, CIB	<i>(notes-taker)</i>

Purpose of the Meeting

Mr Mak explained the purpose of the meeting was to:

- bring the retail industry and the government department/bureau together to exchange views; and
- provide a forum for allow government representatives to explain the thinking behind the proposed legislation.

Proposed Amendments

2. Dr Leung explained that the proposed amendments had four proposals:

- Requiring food labels to declare the presence of eight types of substances which are known to cause allergy in some individuals;
- Requiring food labels to declare the specific name or code of any food additive used;
- Making the labelling of date marking clearer and more flexible; and
- Requiring the labelling of certain alcoholic drinks.

Comments from the Trade

3. Trade representatives commented that the proposed legislation was impractical and costly to implement. Their concerns were as follows:

Labelling Requirement

- Proposed labelling requirement would mean extra cost to consumers. The average cost of a label being \$0.50, the annual cost to consumers could amount to \$150 million. This would be an undue burden on low-income consumers.
- Some products were packed in large quantities in countries like USA, Australia. Hong Kong was not a big market to warrant a separate labelling job.
- Some products were too small for bilingual labelling.

Labelling of Allergenic substances

- Food in Hong Kong was mainly imported from China and some Southeast Asia countries like Malaysia. These countries did not have such labelling requirement. The proposed labelling of allergenic substances would prevent them supply food products to Hong Kong, thus this restricting the choice of products of Hong Kong consumers.
- Ingredients were considered trade secret by some suppliers, food manufacturers might change the ingredients from time to time and the retail trade was not in a position to know.
- Importer would face the risk of prosecution as the present technological tests might not find out the very details of products ingredients.

Date marking Format

- Flexibility was welcome but the trade was concerned about how the legislation would be written.

FEHD's response

4. Dr Leung agreed that whilst the labelling might lead to additional cost to be borne by the trade, there was medical cost if not done so. The proposed legislative amendments were intended to ensure food safety and to provide consumers with as much information as possible about the food they consumed.

5. Dr Leung also made reference to overseas experience. Hong Kong was following the practices of its trading partners. The Compliance Policy Guide issued by US Food and Drug Administration specifically required labelling of allergenic substances. EU would have the same directive by December 2001. Australia and New Zealand had already had legislation in place and implementation would take place in late 2002. Mainland China was well aware of Hong Kong's stance in this regard.

6. Dr Leung said that the Government was aware of the trade's concern. To facilitate the transition, a grace period of 18 to 24 months to be followed by a warning period of considerable length would be considered.

Other issues

7. The trade representatives said that it was very difficult to obtain a licence to import dairy products. The following issues were raised -

- documentation requirement on factory origin; some factories were not keen to provide the required documentation; and
- the 2-week quarantine period taking up costly storage space.

8. Dr Leung explained that dairy products were perishable food. Documentation was important for tracing the origin. Noting the trade's concern, FEHD would examine the feasibility of a sampling strategy.

Follow-up action

9. FEHD would -

- arrange a meeting between the trade and Government Laboratory to discuss the methodology used to test ingredients and work out testing guidelines;
- review the prosecution procedure;
- brief frontline staff on enforcement action; and
- meet the trade as and when required.

Annex F

Date	Event	Remarks
5 Dec 2001	Motion Debate on “Reviewing the Labelling System for Prepackaged Foods”	Secretary for Environment and Food mentioned that the drafting of the composition and labelling amendment regulation was in progress and expected to submit them to LegCo in 2002
28 Mar 2002	LegCo FSEH Panel meeting	In response to Dr Lo Wing Lok’s suggestions for the improvement of the food surveillance programme, Deputy Director(F&PH) responded that the proposed amendments relating to food labelling would include declaration of the presence of allergens; the type of food additives used; flexible marking of date format; and strengthening the labelling of alcoholic drinks.
20 Mar 2003	LegCo FSEH Panel meeting	Deputy Secretary (FEH) said that the amendment regulation would be introduced into LegCo for negative vetting in 2003.
29 Apr 2003	LegCo FSEH Panel meeting	Deputy Secretary (FEH) mentioned that the Administration was planning to introduce the legislation amendment.
26 Jun 2003	Motion Debate on “Establishing a Labelling System for Genetically Modified Food”	Secretary for Health, Welfare and Food mentioned in the reply that the Administration had proposed to introduce the regulation on nutrition labelling and the labelling of allergenic substances.