

**Eighth Meeting of
the Business Facilitation Advisory Committee**

Agenda Item 3(b) : Report on the work of the Retail Task Force

Purpose

This paper reports on the work of the Retail Task Force (RTF) since the last Business Facilitation Advisory Committee (BFAC) meeting on 25 February 2008.

Work Progress of the RTF

2. The RTF met on 11 March and 5 June 2008 to consider the following issues –

- (a) Regulatory review of the beauty products/cosmetics/medicine categories;
- (b) Nutrition labelling scheme;
- (c) Concerns of the proprietary Chinese medicine trade;
- (d) Proposed Food Safety Bill; and
- (e) Introduction of a composite licence for the manufacture/sale of various types of ready-to-eat food items.

Regulatory review of the beauty products/cosmetics/medicine categories

3. The trade urges the Department of Health (DH) to impose a less stringent registration process on vitamins, minerals, other health supplements and antiseptics or to exempt them from registration as pharmaceutical products. Based on the trade's feedback, the RTF has consolidated a proposed list of beauty/health products with precise information on the types of ingredients that may be exempted from registration for the consideration of DH. The RTF has also referred the trade's specific proposals on how to streamline the registration requirements of health food products to DH for consideration.

4. Having considered the trade's proposals and DH's recommendations, the Pharmacy and Poisons Board and its Registration Committee have decided to make some relaxations on the registration requirements of beauty/health food products. The details are as follows –

- (a) With regard to beauty products, those containing any of the ingredients specified by DH at below the stated maximum concentration will no longer require registration as pharmaceutical products. In other words, nearly all beauty products containing such ingredients which are now registered as pharmaceutical products will be exempted from registration after implementation of the relaxation measures, provided that the products are not labelled for use on the broken skin, and that they do not carry any claims related to the prevention or treatment of any disease or disease symptom;
- (b) With regard to health food products, no clinical trials are to be required. However, to support the efficacy of such products, the applicants for registration should provide relevant literature reference on the efficacy for the claimed uses of the composition of the product, apart from providing relevant supporting data to prove the safety and quality of the products as required in the legislation;
- (c) As health food products (*including vitamins*) are more easily degradable than drugs, stability studies as an indication of the quality of the product concerned cannot be exempted. However, given that stability studies take time, it has been decided that applicants can lodge registration applications while the studies are still ongoing and that the results of the completed studies have to be provided for evaluation prior to registration approval of the product concerned;
- (d) If the manufacturer of health food products is not certified by the authorities of the country of origin to drug Good Manufacturing Practices (GMP) standards, food GMP certification will be acceptable; and
- (e) Recognising that some ingredients cannot be easily analysed, a list of such ingredients exempted from testing has been drawn up.

5. DH has arranged a consultation meeting with the beauty and health food products trade on 11 June 2008 on the draft guidelines for the registration of pharmaceutical products incorporating the above decisions. DH will inform the trade of the decisions of the Pharmacy and Poisons Board and its Registration Committee of the relaxation measures during the trade consultation, and report further progress to the RTF.

6. The RTF is pleased with the proposed relaxations on the registration requirements of beauty/health food products, which will benefit the trade. The RTF encourages DH to sustain its efforts to facilitate the trade and continue to step up communication with the trade. As the Pharmacy and Poisons Ordinance is considered outdated, the RTF also appeals to the Food and Health Bureau for a critical review and revamping of the Ordinance to align with the present-day requirements at an opportune time. The RTF will monitor the progress of development.

Nutrition labelling scheme

7. The Amendment Regulation for the nutrition labelling scheme was published in the Gazette on 3 April 2008 and tabled in the Legislative Council for negative vetting on 9 April 2008. The gazetted version of the Amendment Regulation has included further relaxation measures as suggested by the RTF. They include –

- (a) allow trans fat free claim;
- (b) allow % fat free claim;
- (c) remove the requirement for declaration of polyunsaturated and monounsaturated fat when a nutrition claim on fat is made; and
- (d) (for nutrients without a standard for making claims, e.g. Omega 3) allow food traders to make a quantitative declaration of the nutrient value provided that the declaration does not place any emphasis on the high/low content, presence/absence of that nutrient contained in the food.

8. The Legislative Council then formed a Subcommittee to examine the Amendment Regulation. In response to the Subcommittee's invitations, the RTF made two submissions to the Subcommittee on 29 April 2008 and

26 May 2008 respectively, appealing for further relaxation of the nutrition labelling requirements to relieve the trade's regulatory impact.

9. Having considered the various views from Members of the Subcommittee and the concerns expressed by members of the public, the Administration has put forward two amendments to the Legislative Council. These include extension of the small volume exemption scheme to food products with nutrition claims, and relaxation of the labelling of the content of trans fat. In proposing these two trade-facilitation measures to the Legislative Council, the Administration hopes to strike a delicate balance between the consumers' right to information and food choice. Separately, Hon Vincent Fang, member of the RTF, has also proposed to amend the commencement date of the Amendment Regulation from 1 July 2010 to 1 July 2011, and reduce the registration fees for new applications and renewal of exemption for small volume prepackaged food from \$345 and \$335 to \$80 and \$50 respectively.

10. The RTF is disappointed to note that both the Administration's and Hon Fang's amendments did not find sufficient support in the Legislative Council when they were put to vote at its sitting on 28 May 2008.

11. In its meeting with the RTF on 5 June 2008, the Administration has assured the RTF that it is keenly aware of the possible hurdles faced by the trade in adapting to the changes. The Administration has also undertaken to do its utmost in assisting the trade in complying with the labelling requirements before the commencement date on 1 July 2010 through various channels, including technical meetings, workshops, regular exchanges at the Trade Consultation Forum and issuance of a technical guidance note. The Administration will also launch a publicity programme to educate the public on how to read food labels.

12. The trade appears to be uncertain about the the nutrition labelling requirements and has expressed concerns about the implementation details such as the adequacy of testing capacity of local laboratories, whether it is necessary to seek manufacturer's consent in affixing nutrition labels, etc. Accordingly, the RTF has appealed to the Administration to continue working in partnership with the trade in thrashing out any implementation issues and finalise the Technical Guidance Notes for issue to the trade by the end of June 2008. To better assess the actual impact of the nutrition labelling scheme on the trade and consumer choice, the RTF has proposed that the Administration should take stock of the present situation of prepackaged food in Hong Kong and conduct a post-implementation review in due course. The

RTF has also appealed to the Administration to learn from the experience of the allergen and nutrition labelling schemes and fully consult the trade and other stakeholders concerned before enactment of the Food Safety Bill. The Administration will hold the next round of technical meeting on 18 June 2008.

13. The RTF will continue to monitor the progress of development.

Concerns of the proprietary Chinese medicine (pCm) trade

14. Regarding the progress of pCm registration, the Chinese Medicines Board has started to issue the “Notice of confirmation of transitional registration of proprietary Chinese medicine” and “Notice of confirmation of (non-transitional) registration application of proprietary Chinese medicine” since 31 March 2008. The RTF is pleased to note that the trade is generally content with the issue arrangement. The Chinese Medicines Board will continue to expedite the processing of about 4 200 applications which have not yet been issued with the Notices, and consider about 600 rejected cases which have applied for review. DH will continue to monitor the situation and step up communication with the trade.

15. Concerning the trade’s concerns about various regulatory barriers affecting the trade such as difficulties in formulating the quality standards of products and the testing methods, difficulties encountered in compliance with the Protection of Endangered Species of Animals and Plants Ordinance, etc., DH has undertaken to continue exploring possible ways to address the trade’s concerns subject to fulfilling the legal requirements under the current regulatory framework.

16. The RTF will continue to facilitate the communication between the trade and the Administration, and monitor the progress.

Proposed Food Safety Bill

17. The proposed Food Safety Bill is a new initiative pledged in the Chief Executive’s 2007 Policy Address in response to heightened public concern about food safety arising from food incidents. The Administration plans to introduce the Food Safety Bill into the Legislative Council for first and second reading in the 2008-09 legislative session.

18. The RTF generally supports the proposed Food Safety Bill. The RTF has asked the Administration to fully consult the trade and strive to

reduce compliance costs on the trade in working out the implementation details. The RTF noted that the Food and Health Bureau (FHB) had completed a three-month public consultation on the proposed Food Safety Bill on 31 March 2008. FHB has also briefed the Small and Medium Enterprises Committee of the proposal as suggested by the RTF. FHB is now examining the views received, and will report further progress to the RTF in due course.

19. The RTF will monitor the progress of the proposed Food Safety Bill.

Introduction of a composite licence for the manufacture/sale of various types of ready-to-eat food items

20. The RTF completed a review of the licensing processes and procedures for food retail business in late 2005. The RTF is pleased that the Food and Environmental Hygiene Department (FEHD) has so far made good progress in implementing the recommendations of the review (*e.g. enhancing the public consultation mechanism and streamlining some licensing procedures*). The proposed introduction of a composite licence for the manufacture/sale of various types of ready-to-eat food items is one of the review recommendations of the RTF.

21. In June 2008, FEHD briefed the RTF of the latest proposal to introduce the composite licence scheme. FEHD plans to introduce a more comprehensive composite licence system which allows an applicant the free choice of any combination of 16 food items. Since the food items covered by the proposed composite licence do not involve any complicated food handling procedures, FEHD is prepared to adopt a certification approach to further facilitate the food trade. FEHD has also reviewed the licensing requirements and conditions for food items covered by the proposed composite licence to further simplify them without compromising the integrity of the licensing regime. FEHD is working with the Financial Services and Treasury Bureau on the fee charging mechanism for the proposed composite licence, and will proceed with the preparation of the necessary legislative amendments for tabling at the Legislative Council in 2008. FEHD last consulted the trade on the proposed arrangements in October 2007 and obtained their support. The Legislative Council Panel on Food Safety and Environmental Hygiene also lent support to the latest proposal at its meeting on 8 January 2008.

22. The RTF is pleased with the Administration's efforts to introduce a more comprehensive composite licence system which provides an additional option to facilitate the trade. The RTF considers that the composite licence fee should be set at a reasonable level, and urges the Administration to expedite the legislative drafting process for early introduction of the legislative amendments into the Legislative Council.

23. The RTF will monitor the development of the proposal.

Way forward

24. Members are invited to note the work progress of the RTF.

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