

**立法會**  
**Legislative Council**

LC Paper No. CB(2)1068/15-16

Ref : CB2/PL/FE

**Panel on Food Safety and Environmental Hygiene**

**Background brief prepared by the Legislative Council Secretariat**

**Proposed regulatory framework on nutrition and health claims  
on formula products and food intended for  
infants and young children under the age of 36 months**

**Purpose**

1. This paper provides background information on issues relating to the regulation of nutrition and health claims on formula products (i.e. infant formula and follow-up formula) and prepackaged food for infants and young children under the age of 36 months ("IYC foods") in Hong Kong. It also summarizes major views of members of the Panel on Food Safety and Environmental Hygiene ("the Panel") on the Administration's proposed regulatory framework on nutrition and health claims on formula products and IYC foods.

**Background**

2. According to the Administration, nutrition and health claims are representations which state, suggest or imply that a food has particular nutritional properties, or that a relationship exists between a food product and health. These claims have been widely used in various food products, including formula products and IYC foods. In the Administration's view, factually correct food labels and claims can provide consumers with useful information to arrive at informed choices. In contrast, incorrect or misleading nutrition and health claims on formula products and IYC foods may cause undue influence on the decisions of parents and caregivers on whether to breastfeed, and may in turn adversely impact their children's health. While there are currently legislation governing nutrition labelling and advertisement of food products in Hong Kong, with some of them applicable to the nutritional

composition and nutrition labelling of formula products and IYC foods<sup>1</sup>, there is presently no specific legislation regulating nutrition and health claims made on formula products and IYC foods.

3. On 22 October 2014, the Legislative Council ("LegCo") completed its scrutiny of the Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014 ("the Amendment Regulation")<sup>2</sup> which sets out requirements on nutritional composition and nutrition labelling of formula products and IYC foods. However, regulation of nutrition and health claims on these products had not been included in that legislative amendment exercise. During the discussion on the Amendment Regulation and at various committee meetings, Members expressed grave concern about the misleading and exaggerated health claims made in some formula products advertisements. The Administration was urged to expeditiously introduce legislation to regulate the marketing of formula products.

4. In order to better protect the health of infants and young children under the age of 36 months and to facilitate effective regulatory control over nutrition and health claims on formula products and IYC foods, the Administration proposed the establishment of a regulatory framework on nutrition and health claims on formula products and IYC foods. On 6 January 2015, it published a consultation document to invite public views on the Administration's proposed regulatory framework.

### **Proposed regulatory framework**

5. The Administration proposed the following five overarching principles when formulating the proposed regulatory framework -

- (a) nutrition claims (i.e. nutrient content claims and nutrient comparative claims) should be prohibited in infant formula;
- (b) reduction of disease risk claims should be prohibited in infant formula, follow-up formula and IYC foods;
- (c) nutrition claims and nutrient function claims should be permitted in IYC foods;

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<sup>1</sup> These legislation include the Public Health and Municipal Services Ordinance (Cap. 132), the Food and Drugs (Composition and Labelling) Regulation (Cap. 132W), the Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014, the Undesirable Medical Advertisements Ordinance (Cap. 231) and the Trade Descriptions Ordinance (Cap. 362).

<sup>2</sup> The Amendment Regulation has come into operation on 13 December 2015 (after a grace period of 18 months) for infant formula and on will take effect on 13 June 2016 (after a grace period of 24 months) for follow-up formula and IYC foods.

- (d) nutrients or constituents permitted to be subjects of claims should be of high importance to the health of infants and young children; and
- (e) nutrition and health claims should meet specific content conditions and health claims must be scientifically substantiated and have undergone credible evaluation process.

6. The overarching principles (a) to (c), if accepted, would set the boundary for the regulatory framework. Within this boundary, the regulatory options for the below product-claim combinations were open for discussion during the public consultation -

- (a) nutrient function claims on infant formulae;
- (b) nutrition claims and nutrient function claims on follow-up formulae; and
- (c) other function claims on formula products and IYC foods.

7. Other issues covered in the consultation document included (a) the proposed development of a mechanism for establishing and maintaining a list of approved claims and the corresponding conditions; (b) the proposed establishment of a mechanism for revising the list of approved claims; and (c) the length of the grace period.

### **Members' concerns**

8. At the Panel meeting on 14 July 2015, the Administration briefed members on the views collected during the public consultation exercise and details of the proposed regulatory framework<sup>3</sup>. The major views and concerns expressed by members are summarized in the ensuing paragraphs.

### Proposed regulatory framework on nutrition and health claims

9. Some members, including Mr WONG Kwok-hing and Dr Kenneth CHAN, supported the proposed regulatory framework on nutrition and health claims on formula products and IYC foods to regulate the marketing practices of the trade. There was, however, a view that the proposed regulatory framework

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<sup>3</sup> The gist of the comments received, a summary of the Administration's proposed regulatory framework for nutrition and health claims on formula products and IYC foods as well as the related implementation arrangements, including the proposed transitional arrangements, are set out in the Administration's paper provided for the Panel meeting (LC Paper No. CB(2)1861/14-15(03)).

did not provide sufficient protection to infants and young children. This was because according to the Codex Alimentarius Commission ("Codex"), nutrition and health claims were not permitted for formula products and IYC foods, but the Administration proposed that certain product-claim combinations be allowed in Hong Kong. There was a concern that consumers might not be able to differentiate whether the claims made in advertisements on formula products complied with the relevant requirements. Prof Joseph LEE also queried the rationale for the Administration to adopt different approaches to regulate nutrition claims and health claims on formula products and IYC foods, i.e. prohibiting nutrition claims and health claims on formula products while allowing nutrition claims, nutrient function claims and other claims on IYC foods if specific claim conditions were met. Prof LEE was of the view that the Administration should adopt the same regulatory control over claims on formula products and IYC foods to avoid causing confusion to the public.

10. The Administration advised that in coming up with the five overarching principles for the regulatory framework, it had taken into account various factors, including the Codex principles, practices of other jurisdictions and opinions of the Expert Committee on Food Safety. The regulatory options for various product-claim combinations proposed in the consultation document were open for discussion. The Administration emphasized that under the current proposal, any nutrition and health claims eventually allowed must still meet specific content conditions, and that health claims must be scientifically substantiated and had undergone credible evaluation process by the relevant authority.

11. Noting that some interest groups, health professionals and academia did not support overarching principle (c), viz nutrition claims and nutrient function claims be permitted in IYC foods, an enquiry was raised on the reasons for allowing nutrition claims, nutrient function claims and other function claims on IYC foods.

12. The Administration explained that having considered that (i) nutrition and health claims were allowed in general foods and (ii) individual IYC food products were not a main source of nutrition for infant and young children who could consume a wide variety of food during the weaning period, it was considered reasonable to allow nutrition claims and health claims to be made on IYC foods as well. The Administration stressed that nutrition and health claims on IYC foods should meet specific content conditions and the health claims must be scientifically substantiated and had undergone a credible evaluation process.

13. Some other members, nevertheless, considered the Administration's proposal to prohibit nutrition claims and health claims on formula products too stringent and unreasonable. Members belonging to the Liberal Party, including

Mr Vincent FANG, opined that the prohibition of nutrition claims and health claims on formula products would undermine parents' right to access information on formula products to make an informed choice. They opposed the introduction of the proposed regulatory framework, and questioned whether Hong Kong was the first place to impose a complete ban on claims on formula products and IYC foods.

14. The Administration clarified that nutrition claims, nutrient function claims and other function claims were allowed on IYC foods under the proposed regulatory framework. In considering the regulatory approaches to be adopted in Hong Kong, the Administration, apart from having considered the results of the public consultation exercise, had studied overseas practices and local circumstances including the current legislation, local public health policies and concerns, current market situations and consumer behaviours, etc. Although certain nutrition or health claims were allowed in some overseas jurisdictions at present, their perspectives might be different from that of Hong Kong. The situation of Hong Kong was quite unique in terms of the huge amount of promotion of formula products and marketing activities conducted by formula products suppliers. A local study conducted by the Department of Health in 2010 also found high prevalence of unbalanced diet in young children and that over-consumption of formula products was one of the unfavourable practices, which might be a result of intensive marketing drive. Having considered that nutrition and health claims on formula products were mainly useful in promotion and marketing but not providing essential information on the products, the Administration proposed to prohibit nutrition and health claims on formula products.

15. Some members, including Mr Steven HO, agreed with the Administration that there should be regulatory control on nutrition and health claims made on formula products and IYC foods. They, however, opined that the Administration should balance the views received from various stakeholders in proposing the regulatory framework. As overseas experiences showed that allowing claims to be made on formula products would provide incentives for manufacturers to invest in research and product development, there was a concern that manufacturers might not have commercial incentives to enhance the quality of their products intended for consumption by infants in Hong Kong if nutrition and health claims were prohibited on formula products.

16. The Administration proposed to develop a mechanism for establishing and revising a list of approved claims to provide guidance for the trade to make nutrition and health claims on the relevant products legally. Some members enquired about the details of the proposed mechanism and whether claims that had been accepted by a recognized authority in their country of origin would be considered for adoption in Hong Kong.

17. According to the Administration, it would make reference to overseas practices to establish certain conditions for nutrition claims, under which some nutrient content claims and nutrient comparative claims would be permitted. As regards health claims, the Centre for Food Safety ("CFS") would establish a list of approved claims by way of application from the trade. For claims that had been accepted in other jurisdictions, as long as the applicant was able to produce adequate documentary proof that the claim in question had already been accepted by a recognized authority in their country of origin or another country, and that relevant claim conditions had been set by the relevant authority, the claim would be considered for adoption in Hong Kong through a "fast-track" assessment mechanism. Once a claim had been included in the list of approved claims, the applicant and other traders could make the claim on the relevant product as well as other products in the same product category, so long as the specified conditions had been fulfilled. As regards claims that had never been approved by a recognized authority, traders would need to submit relevant documents on the scientific substantiation of the claims for assessment by CFS and a longer approval process might be required in such cases. In developing the mechanism for approving claims, the Administration would make reference to the practices of overseas jurisdictions and the Mainland where there were recognized authorities to approve claims under established mechanisms.

#### Regulating the advertising of formula products and IYC foods

18. Concern was raised about the use of graphics and images in the advertisements to associate the formula products with the healthy growth and achievement of children if claims were prohibited on formula products and IYC foods. Some members, including Mr WONG Kwok-hing, considered that sensational way of advertising formula products and IYC foods, as well as the frequent use of claims often overstated the advantages of formula products over the benefit of breastfeeding. There was a concern that the advertisements were misleading to parents and caretakers, causing undue influence on mothers in their decision on whether to breastfeed. These members enquired how the Administration would ensure the accuracy of information in the advertisements of formula products.

19. The Administration assured members that the Amendment Regulation would better regulate the nutritional composition of infant formula and nutrition labelling of formula products and IYC foods. The relevant articles of the Hong Kong Code of Marketing and Quality of Formula Milk and Related Products, and Food Products for Infants and Young Children ("the Hong Kong Code") drafted by the Department of Health would also serve as guidelines with respect to the marketing practices of formula products, including advertisements on these products. The Administration would promulgate the revised Hong Kong Code in due course upon completion of the legislative exercises on nutritional

composition, nutrition labelling and claims relating to formula products and IYC foods.

20. There was concern that the introduction of a series of legislative proposals on formula products and IYC foods would put an undue burden on the trade in complying with the new requirements. The Administration explained that while there were legislation governing the labelling and advertisement of food products, there was currently no legislation capable of specifically regulating the nutrition and health claims made on formula products and IYC foods. The proposed regulatory framework was conducive to enhancing the health protection for infants and young children.

#### Grace period

21. Some members, including Mr WONG Kwok-hing, expressed concern that the grace periods of 18 months and two years proposed for the trade to prepare for the respective implementation of the new compliance requirements for formula products and IYC foods were too long. An enquiry was raised as to whether the Administration would shorten the grace periods in order to minimize the negative impact of the advertisements of formula products and IYC foods on consumers' choices.

22. According to the Administration, CFS had consulted the trade and make reference to past experiences in proposing the two grace periods for the trade to prepare for the new compliance requirements for formula products and IYC foods. As time was needed to process the claim applications for IYC foods, the grace period for IYC foods was longer. In the Administration's view, the proposed length of the two grace periods was reasonable, having regard to the time required for handling the existing products by the trade and other relevant considerations.

#### **Relevant papers**

23. A list of the relevant papers on the LegCo website is in the **Appendix**.

## Relevant papers on

**Proposed regulatory framework on nutrition and health claims  
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<b>Committee</b>	<b>Date of meeting</b>	<b>Paper</b>
Subcommittee on Food and Drugs (Composition and Labelling) (Amendment) (No.2) Regulation 2014	2.7.2014 (Item II)	<a href="#">Agenda</a> <a href="#">Minutes</a>
	22.7.2014 (Items I and II)	<a href="#">Agenda</a> <a href="#">Minutes</a>
Panel on Food Safety and Environmental Hygiene	10.2.2015 (Item IV)	<a href="#">Agenda</a> <a href="#">Minutes</a>
Panel on Food Safety and Environmental Hygiene	14.7.2015 (Item III)	<a href="#">Agenda</a> <a href="#">Minutes</a>

Council Business Division 2  
Legislative Council Secretariat  
8 March 2016