

**Wholesale and Retail Task Force
Business Facilitation Advisory Committee**

***Proposed Regulatory Framework on Nutrition and Health Claims
on Infant Formula, Follow-up Formula, and Prepackaged Foods for
Infants and Young Children under the Age of 36 Months in Hong Kong***

Purpose

This paper aims to introduce the proposed regulatory framework on nutrition and health claims on formula products (i.e. infant formula and follow-up formula) and prepackaged foods for infants and young children under the age of 36 months (“IYC foods”), and seeks members’ views on the proposals.

Background

2. Nutrition and health claims¹ are representations which state, suggest or imply a food has particular nutritional properties, or that a relationship exists between a food or its constituent and health. These

¹ Nutrition claims include —

- (a) *nutrient content claims*, which describe the level of a nutrient contained in a food (e.g. “contains choline (144mg / 100g)"); and
- (b) *nutrient comparative claims*, which compare the nutrient levels and/or energy value of two or more foods (e.g. “increased DHA level by 3 times (compared to its original formula)").

On the other hand, health claims include —

- (a) *nutrient function claims*, which describe the physiological role of the nutrient in growth, development and normal functions of the body (e.g. “phospholipids (PhD) are essential for the function of brain cells");
- (b) *other function claims*, which concern specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body (e.g. “probiotics (益生菌) helps to maintain a healthy digestive system"); and
- (c) *reduction of disease risk claims*, which relate the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition (e.g. “fortified with an appropriate level of iron to reduce the risk of anaemia (貧血)").

Please refer to the Chapter 3 of the Annex (i.e. the consultation document) for details on the classification and definition of these claims.

claims have been widely used in various food products, including formula products and IYC foods. 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.

3. The Government is committed to protecting the health of infants and young children. Infants and young children must obtain optimal nutrition from their diet to grow and stay healthy. The superiority of breastfeeding in ensuring physical and psychosocial health and well-being of mother and child, as well as the important impacts of early nutrition on long-term health of the child are widely recognised. It is hence of paramount importance to prevent practices which would discourage breastfeeding, and to ensure that parents are provided with accurate and appropriate information on formula products and IYC foods to facilitate informed choice.

4. The Food and Drugs (Composition and Labelling) (Amendment) (No.2) Regulation 2014 ("the Amendment Regulation") gazetted in June 2014 sets out requirements on nutritional composition and nutrition labelling of formula products and IYC foods. The Legislative Council has completed on 22 October 2014 the scrutiny of the Amendment Regulation, which will come into force on 13 December 2015 (after a grace period of 18 months) for infant formula and on 13 June 2016 (after a grace period of 24 months) for follow-up formula and IYC foods. However, regulation of nutrition and health claims on these products has not been included in this recent legislative amendment in view of the complexity and controversies of the issues involved, and the more urgent task of first regulating the nutritional composition and nutrition labelling of these products.

Proposed Regulatory Framework

5. The Government proposes to establish a regulatory framework to enhance the regulation of nutrition and health claims on formula products and IYC foods in Hong Kong. The purposes of the proposed regulatory

framework are —

- (a) to better protect the health of infants and young children under the age of 36 months; and
- (b) to facilitate effective regulatory control over nutrition and health claims on formula products and IYC foods.

6. According to the Codex Alimentarius Commission (“Codex”)², nutrition and health claims shall not be permitted for formula products and IYC foods, except where specifically provided for in relevant Codex standards or national legislation. The Government understands that there are different views on this controversial subject. For instance, pro-breastfeeding groups advocate more stringent regulation of the nutrition and health claims on formula products and IYC foods, as they are of the view that such claims might discourage breastfeeding and mislead parents and caregivers into believing that such food products are superior to breastfeeding. The trade, however, considers that nutrition and health claims provide useful information to consumers and serve as an incentive for the trade to invest in product development.

7. In considering the regulatory framework, the Government has taken into account, in addition to the views mentioned above, the current legislation in Hong Kong, the Codex principles and practices of other jurisdictions, opinions of the Expert Committee on Food Safety, as well as a host of other factors including public health concern, implication on food choice, impact on the food trade, availability of resources and implementation issues, etc.

Overarching Principles to be Adopted

8. The Government has come up with the following five overarching principles which govern the scope of the regulatory framework —

- (a) Principle 1 – Nutrition claims (i.e. nutrient content claims and

² Codex was established in 1963 by the Food and Agriculture Organization of the United Nations and World Health Organization to develop food standards, guidelines and related texts such as codes of practice for protecting the health of consumers and ensuring fair trade practices in the food trade.

nutrient comparative claims) should be prohibited in infant formula

- (b) Principle 2 – Reduction of disease risk claims should be prohibited in formula products and IYC foods
- (c) Principle 3 – Nutrition claims (i.e. nutrient content claims and nutrient comparative claims) and nutrient function claims should be permitted in IYC foods
- (d) Principle 4 – Nutrients or constituents permitted to be subjects of claims should be of high importance to the health of infants and young children
- (e) Principle 5 – Nutrition and health claims should meet specific content conditions and health claims must be scientifically substantiated and have undergone credible evaluation process

Various Approaches of Regulating Nutrition Claims and Health Claims

9. Overarching principles 1 to 3, if accepted, would allow certain claims on certain formula products / IYC foods while prohibiting others. Together they would set the boundary for the regulatory framework. Within this boundary are some product-claim combinations, the regulatory options for which are open for discussion, namely –

- (a) Nutrient function claim on infant formula;
- (b) Nutrition claim (i.e. nutrient content claim and nutrient comparative claim) and nutrient function claim on follow-up formula; and
- (c) Other function claim on formula products and IYC foods

10. Among the above product-claim combinations, we would like to seek public views on whether an inclusive approach (whereby all of the above claims would be allowed) or a restrictive approach (whereby all of the above claims would be prohibited) is preferred, or whether we should take the middle ground in allowing some claims but prohibiting others. The table below summarises the different scenarios under the inclusive and

restrictive approaches —

Category of claim	Type of claim	Inclusive approach	Restrictive approach		
Infant formula					
Nutrition claim	Nutrient content claim, e.g. “contains choline (144mg / 100g)”	Not allowed (<i>Principle 1</i>)			
	Nutrient comparative claim, e.g. “increased DHA level by 3 times (compared to its original formula)”				
Health claim	Nutrient function claim, e.g. “phospholipids (PhD) are essential for the function of brain cells”	Allowed	Not allowed		
	Other function claim, e.g. “probiotics (益生菌) helps to maintain a healthy digestive system”	Allowed	Not allowed		
	Reduction of disease risk claim, e.g. “fortified with an appropriate level of iron to reduce the risk of anaemia (貧血)”	Not allowed (<i>Principle 2</i>)			
Follow-up formula					
Nutrition claim	Nutrient content claim	Allowed	Not allowed		
	Nutrient comparative claim	Allowed	Not allowed		
Health claim	Nutrient function claim	Allowed	Not allowed		
	Other function claim	Allowed	Not allowed		
	Reduction of disease risk claim	Not allowed (<i>Principle 2</i>)			
IYC foods					
Nutrition claim	Nutrient content claim	Allowed (<i>Principle 3</i>)			
	Nutrient comparative claim				
Health claim	Nutrient function claim			Allowed (<i>Principle 3</i>)	
	Other function claim	Allowed	Not allowed		
	Reduction of disease risk claim	Not allowed (<i>Principle 2</i>)			

11. Details of the proposed regulatory framework, including the justifications for the overarching principles, as well as arguments for and against specific product-claim combinations, are set out in the public consultation document at **Annex**.

Way Forward

12. A public consultation was launched on 6 January 2015, and will last for more than three months until 17 April 2015, with a view to collecting comments from the public on our proposal, in particular the following —

- (a) the establishment of five overarching principles to delineate the boundary of the regulatory framework and to prescribe conditions that will bind any claims eventually allowed;
- (b) the regulatory options for the product-claim combinations that are within the bounds of the relevant overarching principles;
- (c) the development of a mechanism for establishing and maintaining a list of approved claims and the corresponding conditions;
- (d) the establishment of a mechanism for revising the list of approved claims; and
- (e) the length of the grace period.

13. The Government will take into account the views received before finalising the details of the legislative proposals.

Advice Sought

14. Members are invited to offer comments on the proposed regulatory framework relating to nutrition and health claims on formula products and IYC food.

Food and Health Bureau
Food and Environmental Hygiene Department
Centre for Food Safety
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