For discussion
on 14 July 2015

LegCo Panel on Food Safety and Environmental Hygiene

Nutrition and Health Claims for Formula Products and Foods for Infants and Young Children – Results of Public Consultation and Proposed Regulatory Framework

Purpose

The paper summarises the views collected from the public consultation exercise launched from 6 January to 17 April 2015 on the proposed regulatory framework on nutrition and health claims on formula products and foods intended for infants and young children under the age of 36 months, and seeks views from Members on the proposed regulatory approaches.

Background

2. Nutrition and health claims are representations which state, suggest or imply particular nutritional properties, or that a relationship exists between a product and health. These claims are common in foods, including formula products (i.e., infant formula and follow-up formula) and foods for infants and young children (IYC foods). 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 Government proposed to establish a regulatory framework to enhance the regulation of nutrition and health claims on formula products and IYC foods.

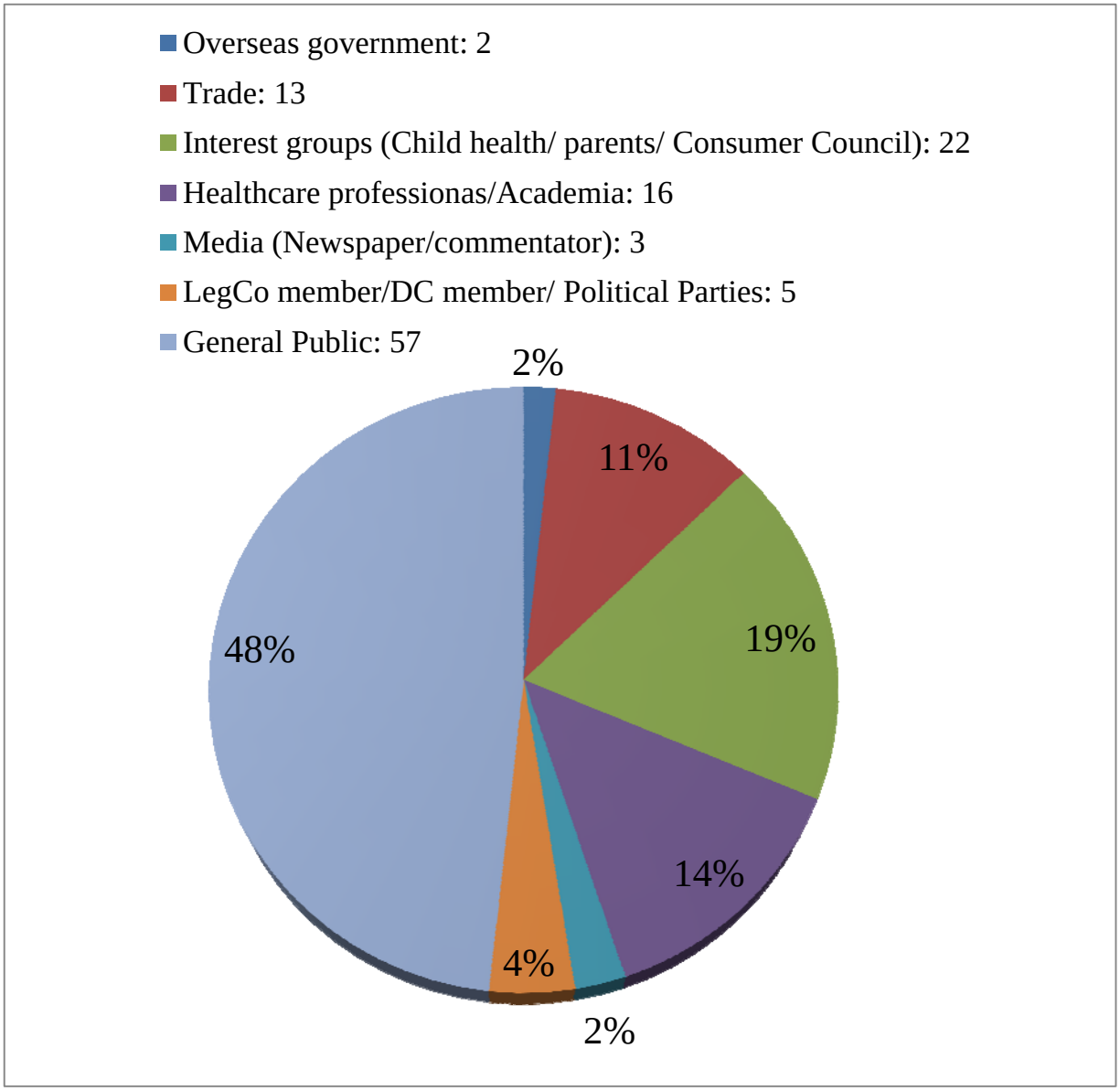
3. To seek views from members of the public, trade and other stakeholders on the broad direction and principles for regulating nutrition and health claims on formula products and IYC foods, a public consultation exercise was conducted from January to April 2015. The proposed regulatory framework was also discussed by this Panel on 10 February 2015.

4. In order to explain the legislative proposals to the public and stakeholders in detail, we arranged two public consultation forums. The legislative proposals were also introduced in CFS' Consumer Liaison Group meeting and Trade Consultation Forum, as well as various meetings and briefings to stakeholders. The Advisory Council on Food and Environmental Hygiene (ACFEH) was also consulted.

Views Collected from the Public Consultation

5. During the consultation period, we have received 131 written submissions, including 104 submissions in response to the consultation exercise (via email/letter/fax), 26 submissions to the Legislative Council (LegCo) Panel on Food Safety and Environmental Hygiene, and 1 online petition with more than 700 supporters. Discounting 13 repeated submissions, we have received effectively 118 submissions. Nearly half of the submissions (48%) were from members of the public. The remaining were from interest groups (19%), healthcare professionals and academia (14%), food trade and associations (11%), political parties, LegCo member, and district council members (4%), overseas governments (2%), and the media (2%) (Figure 1). The views and comments received by the Government are summarised below.

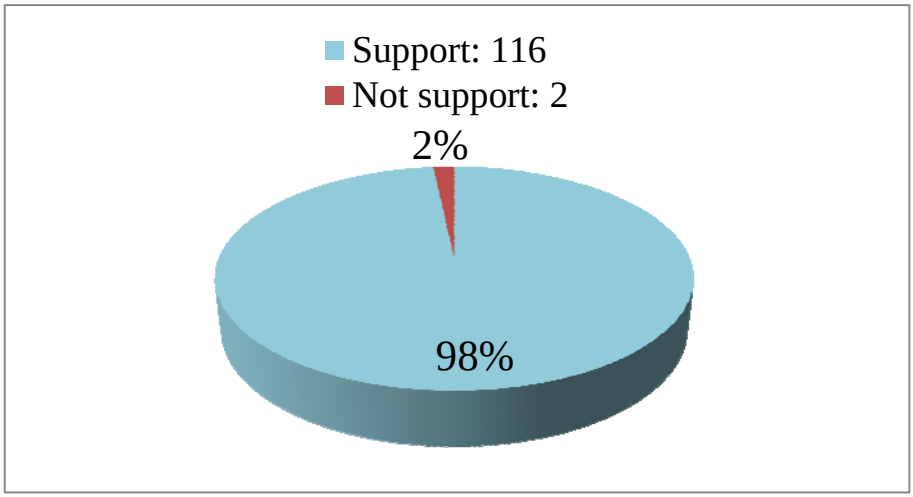
Figure 1. Breakdown of comments received by subgroup



General Comments

6. Vast majority of traders and members of the public supported the establishment of a regulatory framework for nutrition and health claims on formula products and IYC foods. Nonetheless, 2 respondents from the media have concerned about the influence of the regulatory framework to the freedom of information (Figure 2).

Figure 2. Views on establishment of regulatory framework



Overarching Principles

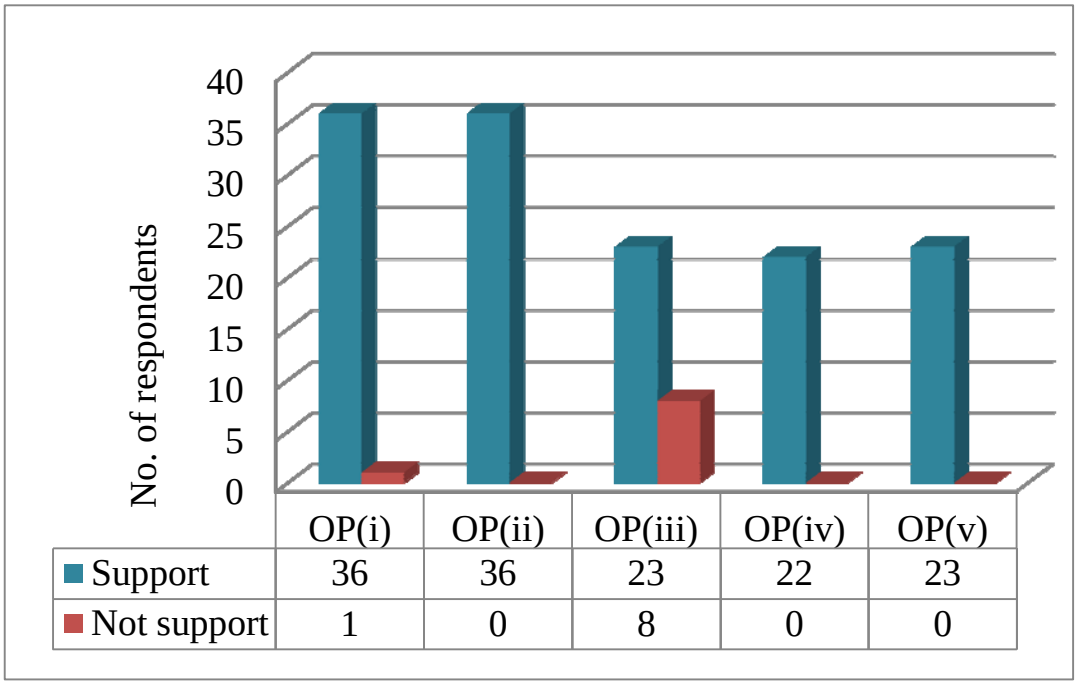
7. The Government proposed the following five overarching principles when formulating the proposed regulatory framework:

(i) Nutrition claims (i.e. nutrient content claims* and nutrient comparative claims*) should be prohibited in infant formula;
(ii) Reduction of disease risk claims* should be prohibited in infant formula, follow-up formula and IYC foods;
(iii) Nutrition claims and nutrient function claims* should be permitted in IYC foods;
(iv) Nutrients or constituents permitted to be subjects of claims should be of high importance to the health of infants and young children; and
(v) Nutrition and health claims should meet specific content conditions and health claims must be scientifically substantiated and have undergone credible evaluation process.

* Please refer to Annex for definitions and examples of nutrition and health claims.

8. The five overarching principles are generally supported by the stakeholders and the public (Figure 3). However, some interest groups, health professionals and academia did not support overarching principle (iii) and considered that nutrition claims and nutrient function claims should not be permitted for IYC foods.

Figure 3. Views on the five overarching principles (OP)



	OP(i)	OP(ii)	OP(iii)	OP(iv)	OP(v)
Support	36	36	23	22	23
Not support	1	0	8	0	0

9. They opined that IYC foods should not be regarded as common food commodities and therefore should not be regulated in a similar way as general food. They have great concern on the current local practice of promoting and advertising activities and opined that parents are susceptible to the inflated claims often appearing in advertisements, which are inherently misleading to consumers. In addition, some members of the academia expressed that the argument of "allowing claims on IYC foods to protect consumers' choice" is not valid, because there are studies showing that choice overload actually reduces engagement, decision quality and satisfaction. As such, there are views that nutrition information on IYC foods suffice to keep parents and caretakers informed of the composition and characteristics of the IYC foods, while nutrition claims and nutrient function claims should be prohibited. Such a practice is also in line with the World Health Organization (WHO) guidelines and Codex Alimentarius Commission's (Codex) recommendation. More than 100 local child healthcare professionals have reached a consensus to urge the Government to prohibit nutrition claims and nutrient function claims on IYC foods.

Product-Claim Combinations

10. Overarching principles (i) to (iii), if accepted, would set the boundary for the regulatory framework. Within this boundary, the regulatory options for the below product-claim combinations are open for discussion —

(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.

11. The comments received during the consultation exercise regarding various product-claim combinations are summarised in table 1 and table 2 below.

Table 1. Breakdown of Comments by Written Response on Product-claim Combinations

		No. of Response##	**Support a more inclusive approach**	**Support a more restrictive approach**
(a) Nutrient function claim on infant formula		42	12 *	30 ^#
(b) Nutrition claim and nutrient function claim on follow-up formula	Nutrient content claim	41	17 *	24 ^#
	Nutrient comparative claim	41	15 *	26 ^#
	Nutrient function claim	40	16 *	24 ^#
(c) Other function claim on formula products and IYC foods	Infant formula	41	12 *	29 ^#
	Follow-up formula	41	15 *	26 ^#
	IYC foods	37	15 *	22 ^#

Remarks:
* 23 respondents using the same template is only counted as 1 response.

^ 4 respondents using the same template only is counted as 1 response.
#717 supporters of an online petition for the restrictive approach is only counted as 1 response.
The total numbers do not round up as not every written response offers comments specifically on individual product-claim combinations.

Table 2. Breakdown of Comments by Respondents on Product-claim Combinations

		No. of Respondents	**Support a more inclusive approach**	**Support a more restrictive approach**
(a) Nutrient function claim on infant formula		783	34	749
(b) Nutrition claim and nutrient function claim on follow-up formula	Nutrient content claim	782	39	743
	Nutrient comparative claim	782	37	745
	Nutrient function claim	781	38	743
(c) Other function claim on formula products and IYC foods	Infant formula	782	34	748
	Follow-up formula	782	37	745
	IYC foods	778	37	741

12. As seen from table 1 and table 2 above, a larger portion of the respondents, including those from professional bodies, academia, interest groups, individual healthcare workers, as well as the general public (including more than 700 supporters of the online petition), urged the Government to adopt a more restrictive approach, i.e. to prohibit claims to be made on the concerned products. Nonetheless, respondents from the trade and the media generally support a more inclusive approach, i.e. to allow claims to be made on the concerned products.

Other Comments

13. Some stakeholders also provided comments regarding the claims approval mechanism. They generally supported the development of a mechanism for establishing and maintaining a list of approved claims and the corresponding conditions, as well as revising the list of approved claims. There are suggestions on recruiting a panel of experts to evaluate and approve claims. However, some stakeholders were concerned that the Government would likely encounter problems in the evaluation of health claims. They opined that the task of health claims evaluation was very complicated and there might be difficulties in recruiting suitable experts to work on this aspect.

14. Concerning the grace period, it is noted that some stakeholders, mainly from interest groups and healthcare professionals, urged for a short grace period. However, the trade considered that they would require a longer grace period, for example, at least 24 months after the establishment of the list of approved claims, to get prepared for compliance of the new regulation. An overseas government suggested that a grace period of 3-5 years should be suitable to allow manufacturers to comply with the labelling changes and cater for stock in trade.

Proposed Regulatory Framework

15. By and large, most respondents supported a more restrictive approach to prohibit claims on formula products and IYC foods. In considering the regulatory approaches to be adopted in Hong Kong, the Government, apart from having considered the results of the public consultation, has carefully studied the local circumstances, including the current legislation, local public health policies and concerns, current market situation and consumer behaviours, implications on food choice, impact on the food trade, as well as availability of resources and implementation issues, etc. In addition, to ensure that our proposed regulatory framework is on a par with the international standards, reference was made to the relevant Codex principles, WHO recommendations, and practices of overseas jurisdictions. We are mindful that the proposed regulatory framework shall be in line with the local breastfeeding policy. Generally speaking, a more restrictive approach would be adopted in light of overwhelming public support to breastfeeding promotion. The following proposed regulatory approaches have been discussed in the meetings of the Expert Committee on Food Safety and the ACFEH in June 2015 respectively, and received their support.

Infant Formulae

16. It is proposed that for infant formulae, nutrition and health claims will not be allowed. Such an approach is strongly supported by stakeholders from various sectors (including health professionals, interest groups, members of the general public, as well as individual traders) who urged for stricter control on infant formulae in order to better protect the health of infants and support breastfeeding. In particular, there are views that claims on infant formulae often inflates the advantages of infant formulae over the superiority of breastfeeding, which not only undermines breastfeeding but is also misleading to parents and caretakers who opt to feed their children with infant formulae.

17. The passage of the Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014 (the Amendment Regulation) introduced new requirements on infant formula for sale in Hong Kong with respect to nutritional composition and labelling for infant formula in accordance with Codex as stipulated in the Regulation. When the Regulation comes into effective in December 2015, all infant formulae available in the Hong Kong market should be able to fulfil the essential nutritional needs of infants.

18. Parents and caretakers who need information on the composition of infant formulae may refer to the nutrition label and ingredient list, which will be mandatorily required to be legibly labelled on the package of infant formulae. Other factual information such as “no added sugar”, “natural”, “organic”, “made with vegetable oil” would not be treated as nutrition and health claims. This information will still be allowed as long as they are factual, not misleading, and fulfill the relevant legal requirements, if any. In addition, parents and caretakers are advised to consult healthcare professionals for information on infant feeding. As such, prohibiting nutrition and health claims on infant formulae would not deprive parents/caretakers of essential product information that may adversely affect the health of infants.

19. The proposal is in line with the international practice. Nutrition and health claims are generally not allowed to be made on infant formulae internationally. We note that a limited number of claims such as “lactose free” are accepted in some overseas jurisdictions. We will consider allowing some of these claims as they provide essential health information addressing medical conditions of infants and young children.

Follow-up Formulae

20. The results of the public consultation supported the adoption of a similar approach for infant formulae and follow-up formulae, i.e. nutrition and health claims will not be allowed in follow-up formulae as well. This approach is also supported by a spectrum of stakeholders, including healthcare professionals, interest groups, and general public. The approach would also work hand in hand with the Government's policy of promoting breastfeeding and healthy infant and young child feeding. In today's market, there is no clear distinction between infant formulae and follow-up formulae in terms of packaging, branding and labelling. Nutrition and health claims on follow-up formulae would most likely lead parents and caretakers to believe that infant formulae products from the same brand are superior to breastfeeding, and hence would have a major impact on parents' desire to breastfeed.

21. Although certain nutrition or health claims are allowed in some overseas jurisdictions at present, their perspectives may be different from that of Hong Kong. The situation of Hong Kong is quite unique in terms of the huge amount of promotion of formula products and marketing activities conducted by formula products suppliers, which are rarely found in many other places. This kind of promotion has an immense impact on consumer behaviours. A local study conducted by the Department of Health in 2010 found high prevalence of unbalanced diet in young children and over-consumption of formula products was one of the unfavourable practices, which might be a result of intensive marketing drive. Not surprisingly, many parents believe that follow-up formulae have added nutrients that benefit the health and development of their children that are not found in other foods. Some professionals consider that evidence is lacking to support the claims of those products that they provide additional benefits to the health of older infants and young children. In light of the results of public consultation, local breastfeeding and dietary situation, and nutrition and health policies of Hong Kong, we propose to prohibit nutrition and health claims for follow-up formulae.

22. Prohibiting nutrition and health claims on formula products is in line with the Codex principles and WHO recommendations. For follow-up formula, WHO considers that its use is not necessary, and it is unsuitable when used as a breast-milk replacement from six months of age onwards. Local professionals and interested groups share the same comment. WHO also opines that follow-up formulae are marketed in a way that may cause confusion and have a negative impact on breastfeeding. Nutrition and health claims on follow-up formulae are mainly useful in promotion and marketing of follow-up formulae, but the products themselves are considered unnecessary for infants and young children by WHO.

IYC Foods

23. As for IYC foods, there are divergent views regarding the regulatory approach to be adopted. Having regard to the nature of IYC foods and with a view to balancing the interest and concern of different stakeholders, it is proposed to allow nutrition claims (nutrient content claims and nutrient comparative claims), nutrient function claims and other function claims. During the weaning period, infant and young children can consume a wide variety of food. Although there are views that IYC food should not be considered as common food commodities, individual IYC food products are not a main source of nutrition for weaning infants and young children, who can consume general foods instead of IYC food. As nutrition claims and health claims are already allowed in general foods, it is considered reasonable to allow nutrition claims and health claims to be made on IYC foods as well, provided that specific claim conditions are fulfilled.

24. Nutrition and health claims on IYC foods are generally allowed overseas when specific conditions are met. For example, nutrition claims and nutrient function claims are allowed in jurisdictions such as the EU, Australia, New Zealand and Mainland China. A limited number of other function claims have been accepted in places such as Singapore.

25. Nonetheless, to ensure the nutrition and health claims on IYC foods are appropriate and not misleading, the Government will make prudent efforts in establishing the proposed claims approval mechanism. Only those nutrition and health claims made on nutrients or constituents which are of high importance to the health of infants and young children will be accepted. In addition, nutrition and health claims should meet specific content conditions and health claims must be scientifically substantiated and have undergone a credible evaluation process.

Medicinal Claims

26. During the consultation exercise, concerns were raised regarding the use of medicinal claims on formula products and foods for infants and young children. At present, some products bearing medicinal claims are not regulated as medicine, proprietary Chinese medicine, or controlled under the Undesirable Medical Advertisements Ordinance (UMAO). As formula products and IYC foods are generally not intended for curing or preventing disease, to prevent possible loophole in the regulatory control, it is proposed to take the opportunity to specify the prohibition of medicinal claims on formula products and IYC foods in the proposed regulatory framework.

Formulae for Special Medical Purposes

27. Formulae for special medical purposes (FSMP), normally used under medical supervision, are meant for infants and young children with special nutrient requirements. FSMP is currently exempted from nutritional composition and nutrition labelling requirements in Hong Kong under the Amendment Regulation. As information such as product features, nutrient profiles, indications and special health purposes are helpful and essential reference to healthcare professionals and parents, we propose that FSMP for infants and young children should be exempted from the regulation on nutrition and health claims, provided that specific labelling requirements are fulfilled.

Transitional Arrangements

28. Most formula products and IYC foods are imported. Taking into account the production, shipping and marketing patterns, the lead-time between placement of order and delivery in Hong Kong is around 15 – 18 months. If the proposed changes are implemented immediately upon enactment of the legislation, all stock at hand at the retailing end, in warehouses at the wholesaling end, during shipping and being produced would all have to be written off. This would be neither fair to the trade nor bode well for Hong Kong's reputation as an international trading hub that upholds legal and trade certainty. We therefore consider it important to put in place a reasonable grace period, say 18 months, before any regulatory control comes into force regarding infant and follow-up formula. For IYC foods, as time is needed to process the claim applications. It is proposed to allow a minimum of two years for traders to adequately prepare themselves for the new compliance requirements.

29. During the consultation process, a question was raised on whether a similar transitional arrangement is warranted for advertisements; and if so, how long the grace period should be. Of note is that the lead time for production of advertisement is shorter than 18 months. Nevertheless, the advertisement would often carry the images of the products in question. We would further consult the stakeholders before finalising our position on this in the law drafting process.

Gist of the Proposed Regulatory Framework

30 Having considered the comments received in the consultation exercise, and taking into account the local situation and overseas practices, we propose to establish a regulatory framework to govern nutrition and health claims on formula products and IYC foods under the age of 36 months, as summarised in

the table below.

Table 3. Summary of proposed regulatory framework of nutrition and health claims for formula products and IYC foods

Category of claim	Type of claim	Infant formula	Follow-up formula	IYC food
Nutrition claim	Nutrient content claim	Not allowed	Not allowed	Allowed
	Nutrient comparative claim	Not allowed	Not allowed	Allowed
Health claim	Nutrient function claim	Not allowed	Not allowed	Allowed
	Other function claim	Not allowed	Not allowed	Allowed
	Reduction of disease risk claim	Not allowed	Not allowed	Not allowed
Medicinal claim		Not allowed	Not allowed	Not allowed

31. In order to enhance regulatory control of nutrition claims and health claims on formula products and IYC foods and subject to legal advice, we propose to amend the Food and Drugs (Composition and Labelling) Regulations (Cap. 132W) to stipulate the relevant requirements, including the following:

(a) to define claims and other key terms in the regulatory framework;
(b) to prohibit nutrition claims and health claims on infant formulae and follow-up formulae;
(c) to allow nutrition claims, nutrient function claims and other function claims on IYC foods;
(d) to prohibit reduction of disease risk claims and medicinal claims on formula products and IYC foods;
(e) to establish a mechanism of approving claims and the corresponding claim conditions;
(f) to establish a mechanism for adding new claims or revising approved claims; and
(g) to implement the proposed regulatory measures after a grace period.

Advice Sought

32. Members are invited to note the comments received in the consultation exercise and advise on the proposed regulatory framework in paragraph 30, and the related implementation arrangements, including and the proposed transitional arrangements in paragraphs 28 and 29 above.

Food and Health Bureau
Food and Environmental Hygiene Department
Centre for Food Safety
July 2015

Annex

Terms and Definitions

1. **Nutrition and health claims**
   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 or its constituent and health.

2. **Nutrition claims**
   Nutrition claims include —
   (a) nutrient content claims, which describe the level of a nutrient contained in a food (e.g. “excellent source of vitamins”); and
   (b) nutrient comparative claims, which compare the nutrient levels and/or energy value of two or more foods (e.g. “increased DHA level”).

3. **Health claims**
   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 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”.

4. **Nutrient**
   As defined in the Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014, “nutrient” -
   (a) means any substance present in food which-
      (i) belongs to, or is a component of, one of the following categories—
         (A) protein;
         (B) carbohydrates;
         (C) fat;
         (D) dietary fibre;
         (E) vitamins;
         (F) minerals; and

(ii) satisfies any of the following conditions-

(A) the substance provides energy;

(B) the substance is needed for growth, development and normal function of the body;

(C) a deficit of the substance will cause characteristic bio-chemical or physiological changes to occur; and

(b) in relation to any infant formula, includes myo-inositol, L-carnitine and taurine.