Hong Kong
Infant and Young Child
Nutrition Association
香港嬰幼兒營養聯會

To: Legislative Council Panel on Food Safety and Environmental Hygiene

Initial Views on the Public Consultation on "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"

The Hong Kong Infant and Young Child Nutrition Association ("The Association") is formed by the major players in the industry, who are long-established manufacturers and suppliers of infant and young child formula and food products. To meet the nutrition needs of infants and young children, our members invest heavily in research and development all along to develop and provide products that satisfy the nutrition needs of the local infants and young children.

The Association's initial views on the related public consultation are as follows:

1) We welcome the Government's initiative to launch a consultation on the regulatory framework on nutrition and health claims on formula products and prepackaged foods for infants and young children.

Basic principles

2) We believe that the regulatory framework on nutrition and health claims should follow the basic principles of being clear, highly transparent, consistent and fair. Hence, we support regulating through legislation instead of voluntary compliance.

Regulation standards, basis and approach

3) On regulation standards and basis, we concur with the Government's opinion that international practices should be followed. This will allow parents to take reference to facts and the latest information on nutrition science and research around the world while choosing nutrition products for infants and young children. Besides, as an international city, Hong Kong should refer to international experiences in public policy formulation. In fact, the products supplied by our members are all manufactured and imported from overseas, including Europe, the United States, Australia, New Zealand, and Singapore. The nutrition and health claims provided in these products are scientifically substantiated and in compliance with the regulations in those jurisdictions. Therefore, there is a need for Hong Kong to take reference to the regulatory systems in those jurisdictions.

4) We would like to stress that international practices put a strong emphasis on scientific substantiation and evidence-based foundation and they follow a clear and open regulatory system and procedures to deal with (include making approvals or imposing restrictions) various nutrition and health claims of different products, instead of imposing a blanket ban on all claims. Relevant examples include (please refer to the appendix for details):

   - Europe: The European Union allows infant and young child formula products to make specific nutrition and health claims which have to be approved by expert panels through very stringent review procedures based on scientifically substantiated and evidence-based information.

   - The United States: The United States allow infant and young child formula products to make different nutrient content claims and health claims. These claims are under various forms of regulations that some do not need approval while some need to meet specific conditions or requirements.

   - Mainland China: Mainland China allows formula products to have nutrient content and function claims for optional ingredients. These claims need to meet specific conditions and in alignment with authorized language in description.

Regulation mechanism and direction

5) According to the above-mentioned international practices, The Association is convinced that the Government should take reference to international regulation practices to set up designated expert panels to formulate approval mechanism and relevant conditions, as well as to conduct regular review for the latest nutrition and health claims. This can ensure that Hong Kong parents can have access to the latest product research and nutrition information.

6) Upon the readiness of the above-mentioned mechanism, regulation according to an "inclusive approach" can be adopted, allowing relevant products to make specific claims based on sound facts and scientifically substantiated nutrition information, but not to impose a blanket ban on all claims, which will restrict parents and healthcare professionals from receiving key product information and making informed choices. For Hong Kong and parents, this will be a significant step backward, which is not in line with neither parents' interests nor international practices. In the long run, it will also

obstruct scientific research and product improvement, thus affecting the supply of quality infant and young child nutrition products to Hong Kong. An inclusive regulatory framework is more advantageous. It allows circulation of nutrition information under an appropriate fact-based regulatory framework employing strict assessment criteria. It can safeguard parents' right to information, and allow them to make most suitable choices in selecting nutrition products for their children.

7) The consultation document suggests that nutrition and health claims on infant and young child formula products and IYC foods should only be allowed to feature nutrients/constituents for which Dietary Reference Intakes (DRIs) or Nutrient Reference Values (NRVs) have been established. We would like to point out that there is currently no widely adopted NRV list internationally or any specially established list for Hong Kong targeting infants and young children under 36 months. As a result, we suggest that nutrition claims with reasonable scientific substantiation should be allowed before the Government's establishment of the relevant NRV list.

Exemption

8) We concur that foods for special medical purposes should be exempted from the claims regulation.

Timetable and grace period

9) We propose that the Government should provide a clear timetable on the legislative process and claims approval mechanism and procedures.

10) We believe the Government will receive massive claims approval submission when the legislation takes effect and the corresponding approval mechanism and procedures are confirmed. In order to ensure and allow sufficient time for the industry to follow the new legislation, we suggest the Government to provide a clear timeline and procedures for the first batch of claims approval, in addition with a grace period of not less than 24 months for the industry to conduct implementation according to the approval result, such as arranging redesigning packaging, manufacturing, shipping, replacing products, etc,. It also takes into account that the industry's need to conduct comprehensive relabeling of products following the recent nutrition labeling legislation. If the transition period is too short, it will create implementation difficulties for the industry, which may affect the

supply and cause inconvenience to the public. If the Government is going to adopt a negative vetting procedure, a sufficient grace period is especially important.

The Association will further study the details of the consultation document and provide more in-depth positions and suggestions. We hope the community will participate in the consultation by considering consumers' interest and help facilitate the discussion and policy formulation by sharing the industry's latest information and professional advice.

The Hong Kong Infant and Young Child Nutrition Association
10 February 2015

The Hong Kong Infant and Young Child Nutrition Association *(in alphabetical order of the company names)*

- *Abbott Laboratories Limited*
- *Danone Nutricia Early Life Nutrition (Hong Kong) Limited*
- *FrieslandCampina (Hong Kong) Limited*
- *Mead Johnson Nutrition (Hong Kong) Limited*
- *Nestle Hong Kong Limited*
- *Wyeth (Hong Kong) Holding Company Limited*

Hong Kong
Infant and Young Child
Nutrition Association
香港嬰幼兒營養聯會

To: Legislative Council Panel on Food Safety and Environmental Hygiene

Initial Views on the Public Consultation on "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"

APPENDIX: International Practices on Handling Nutrition and Health Claims

<table>
<tr><th></th><th>Type</th><th>Age (month)</th><th>Nutrient content claim</th><th>Nutrient comparative claim</th><th>Nutrient function claim</th><th>Other function claim</th><th>Reduction of disease risk claim</th><th>Remarks</th></tr>
<tr><td rowspan="2">Codex</td><td>Infant Formula</td><td>0-w (first months of life)</td><td colspan="5" rowspan="2">Codex Alimentarius "Guidelines for use of nutrition and health claims (CAC/GL 23-1997)"

<u>Types of claim and definitions:</u>
• Nutrition claims: include nutrient content claim and nutrient comparative claim

• Health claims: include nutrient function claims, other function claims and reduction of disease risk claims.

"Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation."</td><td rowspan="2">• Definition of "infant formula" and "follow-up formula" in Codex

• "Infant formula" means a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding.

• "Follow-up formula" means a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children.</td></tr>
<tr><td>Follow-up Formula</td><td>6-36</td></tr>
</table>

	Type	Age (month)	Nutrient content claim	Nutrient comparative claim	Nutrient function claim	Other function claim	Reduction of disease risk claim	Remarks

EU	Infant Formula	0 – w (first months of life)	O	X	O	O	O	• Definition of "infant formulae" and "follow-on formulae"
								  • "Infant formulae" means foodstuffs intended for particular nutritional use by infants during the first months of life and satisfying by themselves the nutritional requirements of such infants until the introduction of appropriate complementary feeding
								  • "Follow-on formulae" means foodstuffs intended for particular nutritional use by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants
								
								• Annex IV of Commission Directive 2006/141/EC on infant formulae and follow-on formulae lists authorised nutrition (content) claims for infant formulae in Annex IV, indicating that this type of claim is expressly permitted by the Commission. (not only optional ingredients – e.g., lactose)
								
								• Annex IV of Commission Directive 2006/141/EC also lists authorized health claim (disease risk reduction claim) for infant formula.
								
								• Commission Regulation No 440/2011 demonstrates that specific nutrition and health (function) claims are permitted for follow-on formulae, as evidenced by an express approval for a DHA function claim. Example: "Docosahexanenoic acid (DHA) intake contributes to the normal visual development of infants up to 12 months of age."

	Follow-on Formula	W – 12 (suitable only for infants over the age of 6 months)	O	O	O	O	O	

	Type	Age (month)	Nutrient content claim	Nutrient comparative claim	Nutrient function claim	Other function claim	Reduction of disease risk claim	Remarks
USA	Infant Formula	0-12	O	X	O	O	O	• In USA, only infant formula is defined in regulations which govern 0-12 months. • Specific nutrient content claims (*i.e.*, content claims communicating the % Daily Value for essential nutrients) are allowed for products intended for <2 years of age, including infant and follow-on formulas (21 CFR 101.13(b)(3)). • Foods intended for <2 years of age can utilize any infant formula claims provided for in 21 CFR 107 (e.g., "with iron"), "unsweetened" and "unsalted" taste claims, and "sugar free" and "no added sugar" claims for dietary supplements for this population.[1] • Function claims (structure / function) are permitted on all foods in the U.S., including infant formula and follow-up formulas (follow-up formulas are classified as infant formulas when targeted to infants (0-12 months) and as conventional foods if targeted to young children (1-3 years), for both essential nutrients and optional ingredients. The legal basis for structure / function claims is predicated in the definition of a drug according to the Food, Drug, and Cosmetic Act, which has been in effect since 1938. The Act (Sec 201(g)(C) defines a drug as "articles (other than food) intended to affect the structure or any function of the body of man ….." Thus, the statute recognizes that foods affect the structure / function of
	Follow-up Formula		O	X	O	O	O	

[1] http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064916.htm

								the body, and claims are made on this basis. FDA has further elaborated on the allowance of such claims on food products in industry letters and other public documentation.[2,3] • All foods are permitted to utilize health claims (disease risk reduction claims) if U.S. FDA has reviewed and either codified a regulation authorizing such claim without qualification or if U.S. FDA has reviewed and issued a letter of enforcement discretion for the claim, with specific qualifications required. One such claim is currently permitted on infant formula. It is a qualified health claim (disease risk reduction claim) based on an FDA letter of enforcement discretion.[4]

[2] http://www.fda.gov/food/guidanceregulation/ucm053425.htm

[3] http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm111447.htm

[4] http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm256731.htm

	Type	Age (month)	Nutrient content claim	Nutrient comparative claim	Nutrient function claim	Other function claim	Reduction of disease risk claim	Remarks
Mainland China	Infant Formula	0-6	O	X	X	O	X	• Content and function claims for optional ingredients on infant formulas are allowed.[5, 6] • To make a content or function claim in accordance with GB13432-2013[6], the formula must first provide the minimum level of such nutrient (if established by a relevant Chinese product standard) [5,6,7], and then must utilize authorized language[8]. For example, DHA, taurine, dietary fiber are allowed to have content and function claims for infant formulas and follow-on formulas[9]. In the case where no minimum level of the nutrient exists in the relevant product standard, or no such claim exists on the China positive list, one can then refer to claims already approved in other jurisdictions; provided that all criteria are met by the authorizing authority.[6, 9]
	Follow-up Formula	6-36	O	O* * Not allowed from July 2015	O	O	X	

[5] GB 10765-2010 http://www.shfda.gov.cn/spaqbz/GB%2010765-2010%20 婴儿配方食品.pdf

[6] GB 13432-2013 http://www.nhfpc.gov.cn/ewebeditor/uploadfile/2014/05/20140505140531583.pdf

[7] GB 10767-2010 http://www.shfda.gov.cn/spaqbz/GB%2010767-2010%20 较大婴儿和幼儿配方食品.pdf

[8] GB 28050-2011 http://www.shfda.gov.cn/spaqbz/GB28050-2011%20 预包装食品营养标签通则.pdf

[9] GB 13432-2013 Q&A http://www.nhfpc.gov.cn/sps/s3594/201409/dc38ac8f1c154bb5aaa616e3a8da1061.shtml