



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

28 February 2013

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## SUBMISSIONS IN RESPONSE TO CONSULTATION OF

### HONG KONG CODE OF MARKETING AND QUALITY OF FORMULA MILK AND RELATED PRODUCTS, AND FOOD PRODUCTS FOR INFANTS & YOUNG CHILDREN, 26 OCTOBER 2012 (HK Code)

The Hong Kong Infant and Young Child Nutrition Association (**Association**) was formed in May 2011 and our mission is to support appropriate and adequate infant and young child nutrition in Hong Kong, serve as a platform for industry partners to communicate and to ensure the accuracy of information on nutrition provided in the market.

The Association fully supports breastfeeding. It also supports the World Health Organization (**WHO**) recommendation that breast milk is ideal for infants and that exclusive breastfeeding should be encouraged for the first 6 months of life.

#### **I Voluntary Nature of the Code and Implementation and Monitoring (Article 10)**

It is provided that manufacturers and distributors of designated products (**Entities**) should regard themselves as responsible for monitoring their marketing practices according to the HK Code and a complaint procedure will be in place for the Advisory Panel to issue advisory letter to inform them of the result of a complaint and remind them of the requirements of the HK Code.

Non-compliant Entities are unlikely to submit themselves to a voluntary HK Code and as such, any implementation or monitoring of the HK Code is likely to be futile and a waste of taxpayers' money. In order to offer certainty to consumers and to ensure compliance by all Entities, a proper legislation is necessary.

#### **II Regulating Marketing Practice (Articles 4 to 7), Labeling (Article 8) and Quality Standards (Article 9) in the Same Voluntary Code**

The International Code of Marketing of Breast-milk Substitutes (**WHO Code**) regulates the marketing practice of Entities and the Codex Alimentarius (**Codex**) lays down the provisions for quality and safety. They serve different purposes and are intended to be separated. Combining marketing practice, labeling and the quality standards into the same voluntary code creates fundamental problems.

The issues to be addressed in a false product labeling or poor quality product are very different from those of a misleading or an exaggerated marketing claim. If they are all put in the same voluntary code, consumers may be under the wrong impression that they should be treated the same, when in fact there is a much more pressing need for regulating the quality of formula milk products as exemplified in the recent low iodine incidents.

No country in the world currently addresses labeling, claims and product composition in a voluntary code. Such requirements are too important to be left to the discretion of Entities to voluntarily comply and are always incorporated into legislation. Existing legislation governing these areas are set out in Annex 1 of the HK Code<sup>1</sup> and include:

- i. *Food and Drugs (Composition and Labeling) Regulations* (Cap. 132W) which regulates the labeling and composition of food;
- ii. *Public Health and Municipal Services Ordinance* - False labeling and advertisement of food or drugs (Cap.132 Section 61) which prohibits label or advertisement that falsely describes a food or is calculated to mislead as to the nature, substance or quality of the food; and
- iii. *Public Health and Municipal Services Ordinance* - Offences in connection with the sale, etc. of unfit food or drugs (Cap. 132 Section 54) which prohibits the sale of food unfit for human consumption

The Administration should update and improve on these existing legislation to strengthen the regulation of formula milk and related products. The Background Brief (**Brief**) prepared by the Legislative Council Secretariat for the joint meeting of the Panel on Food Safety and Environmental Hygiene and Panel on Health Services (**Panels**) on 14 November 2012 quoted examples of various Japanese brands of infant formulae that had low iodine content which might have potential adverse health effects on infants<sup>2</sup>. Implementing a voluntary code to address these serious legislative gaps does not achieve the objective of providing safe and adequate nutrition to infants and young children. The Association therefore suggests removing provisions dealing with labeling and quality standards from the voluntary HK Code.

Legislative Proposals Relating to Formula Products and Foods Intended for Infants and Young children under the age of 36 months have been promulgated, and public consultation ended on January 21st, 2013. The Center for Food Safety (CFS) is in charge of this proposal and is currently focusing on the nutritional composition requirement and nutrition labelling requirements. The Association welcomes and fully supports the CFS working in this direction.

Further, any legislative process should be transparent and undergo thorough consultation. Any legislation to be implemented should be un-biased, non-discriminatory and also balance the legitimate interests of all key relevant stakeholders. The suggested express warning statements on product containers such as “Use of breastmilk substitutes may put infants and children at risk of diarrhoea and other illnesses”<sup>3</sup> should be imposed with caution and only if it is substantiated by sound scientific evidence, as the same risk may equally be applicable to any other food products and snacks that are taken by young children under 36 months.

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<sup>1</sup> Article 14 of Annex 1 of the HK Code

<sup>2</sup> Paragraph 2 on page 1 of LC Paper No. CB(2) 192/12-13(03)

<sup>3</sup> Article 8.2.1(d) of the HK Code



### **III The HK Code should only Target Breastmilk Substitutes of infants of 6 months or younger (Article 2)**

The nature of food for infants under 6 months and that for infants or young children older than 6 months is different.

For many infants of less than 6 month old, breast milk or infant formula is the sole source of nutrition. The Association supports the use of infant formula as a breast milk substitute only when breast milk is unavailable or insufficient. WHO agrees that infant formulas are safe and nutritionally suitable to be used as substitutes to breast milk.

Starting from 6 months onward, a variety of food products is introduced into the infant's diet gradually as part of a normal diet. Whether or not follow-up formula is available, parents are likely to include other food products such as porridge, oatmeal, minced meat and vegetables, regular milk or juice etc. for infants and young children above 6 months old.

The WHO Code encourages exclusive breastfeeding for infants during their first 6 months, after which infants should be given appropriate complementary foods and introduced to a vast array of other foods. There is no scientific evidence to show that promotion of food for children of 6 months or above has adversely affected the breastfeeding rate and its duration. On the other hand, the HK Code will have the unintended effect of allowing advertisement and promotion of junk food to parents and children under 36 months while no information regarding the more nutritious option of follow-up formula (products for older infants and young children from 6 to 36 months old) and related products can be made available. The specific needs of individual children will differ and therefore parents should be permitted to access the full range of information on nutrition options for children over 6 months old, including information from manufacturers and distributors.

The HK Code should follow internationally recognized and implemented standards as much as possible. In line with the WHO recommendation, the applicable scope of the HK Code should only apply to breast-milk substitutes for infants between newborn and 6 months old.

Further, given the wealth of reference materials available internationally, it is advisable for the terminology and definitions used in the HK Code to follow those of the internationally recognized codes such as the WHO Code and Codex. Otherwise, confusion among consumers and industry players may arise due to the different interpretation and usage of different terminology and different practice for the same product under the HK Code and other international codes and directives.

### **IV Restrictions and Ban should be Proportional (Articles 4 to 7)**

The Ex-Secretary for Food and Health, Dr York Chow, in his written reply to a question raised by the Honourable Frederick Fung during a Legislative Council meeting on 7 December 2011<sup>4</sup>, provided the following statistics:

- i. Between 2007 and 2010, the Centre for Food Safety (CFS) took a total of 960 milk powder samples (including 590 infant formula samples) for testing and all results were satisfactory.

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<sup>4</sup> Extracted from the press release on Code of Marketing of Breastmilk Substitutes applicable to Hong Kong; [www.info.gov.hk/gia/general/201112/07/P201112070343.htm](http://www.info.gov.hk/gia/general/201112/07/P201112070343.htm)



- ii. From 2009 to 2010, CFS received one complaint relating to promotional materials for infant formula and found it not to be substantiated.
- iii. In 2011, CFS has taken follow-up actions on 27 suspected cases of infant formulas with questionable claims and issued letters to only 3 of them requesting for information to support their claims. No prosecution was instituted.
- iv. For the past 3 years, the Broadcasting Authority handled a total of 10 complaints about alleged misleading infant formula advertisements but none of them was considered misleading.
- v. The ever-breastfed rate increased from 55% in 2000 to close to 80% in 2010. The percentage of ever-breastfed babies was 77% and of babies exclusively breastfed for 4 to 6 months was 14% in 2010.

The Brief<sup>5</sup> also confirmed that no prosecution had been taken in the past 2 years against infant formulae advertisement under Section 61(2) of the Public Health and Municipal Services Ordinance for falsely describing any food item although investigations were undertaken against 5 infant formulae.

Given the social and economic conditions of Hong Kong, the large proportion of working mothers and the freedom of parents to access information, and taking into account such statistics, any restriction on marketing activities should be proportionate and the Administration should not ban all information regarding formula milk and related products, particularly in relation to products for infants older than 6 months and young children, so that consumers can have sufficient information to make an informed choice. The right of parents to access information not only from the Administration but also from the private sector and the market generally is part of human rights and should not be entrenched easily. The restrictions imposed on Entities providing information of formula milk and related products to consumers should therefore be relaxed to a reasonable and proportionate degree.

In addition, intellectual property is a property that is protected by the Paris Convention<sup>6</sup>, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)<sup>7</sup> and the Basic Law of Hong Kong<sup>8</sup>. Short of contravening the law, the statistics quoted by CFS in 2011 and the Brief in 2012 do not support an overwhelming case of public interest to make it necessary to deprive<sup>9</sup> Entities of the right to use their brand name, trademarks and company names in the course of trade, consistent with their corporate policies and culture.

## **V Key concerns can be addressed effectively with alternative approaches**

The Association understands there are possible concerns regarding the marketing of formula milk that may have misleading or exaggerated claims, overwhelming campaigns that may be connected with the concern of low breastfeeding rates, leading to increasing child obesity,

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<sup>5</sup> Paragraph 10 on page 4 of the Brief

<sup>6</sup> Paris Convention for the Protection of Industrial Property

<sup>7</sup> Article 20 of TRIPS

<sup>8</sup> Article 6 and 105 of Basic Law

<sup>9</sup> Please refer to Articles 4.3, 4.4.1(d), 8.2.1(a) of the HK Code.

etc. However, we are of the view that there are other proposals that can address these concerns more effectively than implementing the draft Code. The industry has offered counter proposals, called the ‘Common Goal Proposal’, including suggestions to set up an independent panel to pre-approve advertisement for products suitable for young children aged 6 months and above, to launch a sustainable fund contributed by the formula milk industry for breastfeeding promotion in Hong Kong and to include mandatory breastfeeding statement and appropriate consumption statement on all advertising and product labels. It is believed that the above suggestions will help to ensure that advertising claims are truthful, accurate, and scientifically substantiated. Most importantly, the suggestions can help contribute to the provision of safe and adequate nutrition for infants and young children in Hong Kong.

## **VI Conclusion**

It is unfortunate that despite members of the Panels<sup>10</sup> expressed the need for the trade to be consulted during the drafting of the HK Code and for trade representatives to join the Taskforce, such suggestion was not taken on board by the Administration. The Association hopes that this submission and the detailed article-by-article comments on the HK Code in Appendix B can provide more insight to the issue of providing safe and adequate nutrition for infants and young children in Hong Kong.

We fully support breastfeeding but consider that Hong Kong currently needs an integrated approach of promotion of breastfeeding. The HK Code or proposed legislation certainly plays a part, but more important is the publicity and education of the public and the mandatory provision of breastfeeding facilities in public areas and the work place. All these factors have been highlighted in the Brief<sup>11</sup>.

For mothers who cannot breastfeed or need infant formula products as a supplement, it is both the duty of the Association and the Administration to provide them with appropriate information and advice to ensure that infants and young children receive the best nutrition.

The Association welcomes any opportunity to work with the Administration in making Hong Kong a breastfeeding-friendly city of the world.

Hong Kong Infant and Young Child Nutrition Association  
28 February 2013

Founding members in alphabetical order:  
Abbott Laboratories Limited  
Danone Baby Nutrition (HK) Limited  
FrieslandCampina (Hong Kong) Limited  
Mead Johnson Nutrition (Hong Kong) Limited  
Nestlé Hong Kong Limited  
Wyeth (Hong Kong) Holding Company Limited

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<sup>10</sup> Paragraph 8 on page 3 of the Brief

<sup>11</sup> Paragraphs 11 and 12 on page 4 of the Brief

**Detailed Analysis on the draft *Hong Kong Code of Marketing and Quality of Formula Milk and Related Products, and Food Products for Infants & Young Children* (“HK Code”)  
(28 February 2013)**

**Key**

<b>Term</b>	<b>Meaning</b>
WHO	World Health Organization
WHO Code	International Code of Marketing of Breast-milk Substitutes, published by the WHO in 1981
Model Law	Model Law, published by IBFAN
Codex	Codex Alimentarius
EC	EC Directives
US FDA	US Food and Drug Administration
CFS	Centre for Food Safety
BMS	Breast-milk substitutes

**Article 1 – Title of the Code**

**General comments:**

The HK Code is a hybrid document that attempts to package multiple different objectives within a single package, which makes it difficult to achieve its goals.

**Issues:**

1. The WHO recommends exclusive breastfeeding for up to 6 months, while some developed countries such as Singapore and New Zealand regulate marketing of infant formula for infants up to 6 months. However, the HK Code covers products for infants and young children up to 36 months. The HK Code’s ban on non-BMS products such as follow-up formula neither promotes nor protects breast-milk feeding.
2. Provisions for labeling, nutritional claims and composition criteria are critical elements for regulation of formula and food for infants and young children. These should not be addressed on a voluntary basis under a code primarily dealing with the marketing of the products because of the lack of enforceability of the HK Code. Instead, regulation on labeling and the quality of products should be addressed separately in legislation.

Since the inception of the CODEX Alimentarius Commission and the World Trade Organization (WTO), matters of food labeling are considered within the purview of the CODEX Commission. The WHO Code defers to the CODEX Alimentarius Commission for labeling standards.

**Suggestions:**

1. Separate the labeling and quality requirements from the HK Code. These two elements should become legislation; a mandatory requirement rather than a voluntary request.
2. Regulate marketing for infant formula (products applicable to 0-6 months old infants) only, and not products for older infants or young children beyond 6 months old.

Draft HK Code	International/Local References	Issues	Suggestions
<p>1. Title of the Code</p> <p>This Code is named as the Hong Kong Code of Marketing and Quality of Formula Milk and Related Products, and Food Products for Infants &amp; Young Children.</p>	<p>WHO Code</p> <p>UK, Singapore and New Zealand's codes on marketing human milk substitutes</p> <p>Codex STAN 72 -1981: Infant formula standard</p> <p>Codex STAN 1-1985: Labeling for all pre-packaged foods</p>	<p>The draft HK Code introduces a new term "formula milk" that is not defined by any other regulatory authority or scientific expert body. This term is misleading and confused, because neither infant formula nor follow up formula need be a dairy product - some formula may contain small amounts of milk or no milk at all. There is no need to introduce this term as both infant formula and follow-up formula are well defined by globally recognized and referenced regulatory authorities (e.g., Codex Alimentarius, European Union)</p>	<p>Replace "Formula Milk": with "breast-milk substitute", and adopt the WHO Code's definition with a slight amendment to include the age range:</p> <p>"means any food being marketed or otherwise presented as a partial or total replacement for breast milk, whether or not suitable for that purpose, for infants from 0 up to 6 months old."</p>

### **Article 2 – Aim and Scope:**

We reiterate our comments at Article 1 above.

Draft HK Code	International/Local References	Issues	Suggestions
<p>2.1 The Aim</p> <p>The aim of this Code is to contribute to the provision of safe and adequate nutrition for infants and young children, by—</p> <p>(a) protecting breastfeeding; and</p> <p>(b) ensuring the proper use of formula milk, formula milk related products, and food products for infants and young children up to the age of 36 months, on the basis of adequate and unbiased information and through appropriate marketing.</p>	<p>WHO Code:</p> <p><i>"Article 1 Aim of the code The aim of this Code is to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breast-feeding, and by ensuring the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution. "</i></p>	<p>Terminology should reflect that of internationally recognized codes.</p>	<p>Replace "formula milk" with "breast-milk substitute" (please refer to Article 1 suggestions for definition)</p>

Draft HK Code	International/Local References	Issues	Suggestions
<p>2.2 Scope</p> <p>The scope of this Code covers the marketing practices of designated products as defined in Article 3. This Code also applies to their quality and availability, and to information on the use of designated products</p>	<p>WHO Code:</p> <p><i>“Article 2 Scope of the code The Code applies to the marketing, and practices related thereto, of the following products: breast-milk substitutes, including infant formula; other milk products, foods and beverages, including bottle fed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast milk; feeding bottles and teats. It also applies to their quality and availability, and to information concerning their use.”</i></p>	<p>Please refer to the comments regarding the scope of the HK Code at Article 1 above. Advertisement is not the reason for low breastfeeding rate.</p>	<p>Change the definition of “Designated products” in Article 3</p> <p>Please refer to the suggestions regarding the scope of the HK Code at Article 1 above.</p>

### **Article 3 - Definitions:**

#### **General comments:**

The HK Code introduces many terms that are not used in codes published by recognized international authorities.

#### **Suggestions:**

We submit that terminology in the HK Code should closely reflect that of existing, internationally recognized codes such as the WHO Code.

Draft HK Code	International/Local References	Issues	Suggestions
<p>Breast feeding and formula milk feeding means breastfeeding and feeding by formula milk of infants and young children, including nutrition of breast milk and formula milk</p>	<p>Reference not found</p> <p>Codex Standard for Infant Formula – Section A: Revised Standard for Infant Formula (Codex STAN 72-1987), Section 2.1 defines infant formula as:</p> <p><i>“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.”</i></p> <p>WHO Code, article 3 defines “Breast-milk substitute” as:</p> <p><i>“any food being marketed or otherwise presented as a partial or total replacement for breast milk, whether or not suitable for that purpose“</i></p>	<p>The terminology of formula milk or formula milk feeding is not used by regulatory or scientific authorities. This definition hence creates confusion as to exactly what it means.</p> <p>The HK Code follows the Model Law approach, which does not include a reference to “breast-milk substitute” which is a term consistently used by other international regulatory authorities (e.g., Codex Alimentarius, EC, US FDA) as well as by international health organizations, such as WHO.</p>	<p>Replace “formula milk” with “breast-milk substitute” (please also refer to Article 1 suggestions for definition):</p> <p>Adopting the WHO Code definition of breast-milk substitute with a slight amendment to include the age range,</p> <p>“Breast-milk substitute means any food being marketed or otherwise presented as a partial or total replacement for breast milk, whether or not suitable for that purpose, for infants from 0 up to 6 months old.”</p>
Draft HK Code	International/Local References	Issues	Suggestions
<p>Complementary food means any food except milk or milk-like product suitable or represented as suitable as an addition to breastmilk or formula milk for infants of or above the age of 6 months and young children of or below the age of 24 months</p>	<p>Draft Codex Guidelines on Formulated Complementary Foods for Older Infants and Young Children [2] (at step 5 of the procedure) provides:</p> <p><i>“Complementary feeding period means the period when older infants and young children transition from exclusive feeding of breast-milk and/or breast-milk substitutes to eating the family diet”</i></p> <p>Also: <i>“The provisions of these Guidelines apply to Formulated Complementary Foods</i></p>	<p>Milk or milk product are complementary foods. Follow-up formula is designed based on milk, with the addition of vitamins and minerals. Therefore, excluding milk or milk-like products from complementary food is not reasonable.</p> <p>The definition of “complementary food” in the draft Codex Guidelines does not exclude milk or milk-like products from being defined as “complementary food”.</p>	<p>Delete “except milk or milk-like product” from the definition. The definition should read:</p> <p><i>“means any food suitable or represented as suitable as an addition to breast-milk or infant formula for infants of or above the age of 6 months and young children of or below the</i></p>

Draft HK Code	International/Local References	Issues	Suggestions
	<p><i>for Older Infants and Young Children as defined in Section 3.1 below and include but are not limited to porridges containing cereals, ready-to-use products and food-based home fortificants. Micronutrient supplements, processed cereal based foods”</i></p> <p>(Codex STAN 1981-74) [3]. Canned baby foods (Codex STAN 1981-73) [4] are not covered by these Guidelines.”</p> <p>Section 3.1 defines complementary foods as:</p> <p><i>”foods that are suitable for use during the complementary feeding period. These foods are specifically formulated with appropriate nutritional quality to provide additional energy and nutrients to complement the family foods derived from the local diet by providing those nutrients which are either lacking or are present in insufficient quantities”</i></p>		<p><i>age of 24 months”</i></p> <p>Replace “formula milk” with “breast-milk substitute” (please refer to Article 1 suggestions for definition)</p>

Draft HK Code	International/Local References	Issues	Suggestions
<p>Designated product</p> <p>Means (a) formula milk;</p> <p>(b) formula milk related products;</p> <p>(c) food products for infants and young children; and</p> <p>(d) any other product declared as a designated product by the Department of Health for the purposes of this Code.</p>	<p>No reference found</p>	<p>This is a very important term in the HK Code. It defines its scope. The definition should therefore be drafted with reference to the internationally recognized WHO Code.</p> <p>The term “designated product” originates from the Model Law, which defines “designated product” broadly to cover infant formula, follow-up formula, feeding bottles, teats, pacifiers and any other product marketed or represented as suitable for feeding infants.</p> <p>Such a broad definition in the Model Law draws more products into the ambit of the law than necessary for this exercise.</p>	<p>Modify the scope of “designated product” according to the WHO Code, which only cover breast-milk substitutes, as follows:</p> <p>“designated product means –</p> <p>(a) breast-milk substitutes; and</p> <p>(b) breast-milk substitutes related products.”</p> <p>Where:</p> <p>“breast-milk substitute related products means –</p> <p>breast-milk substitutes, including infant formula; other milk products, foods and beverages, including bottle fed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast milk; feeding bottles and teats.”</p>

Draft HK Code	International/Local References	Issues	Suggestions
<p>Distributor</p> <p>means a person, corporation or other entity engaged in the sale, whether wholesale or retail, of any designated product.</p>	<p>WHO Code, Article 3:</p> <p><i>“Distributor: means a person, corporation or any other entity in the public or private sector engaged in the business (whether directly or indirectly) of marketing at the wholesale or retail level a product within the scope of this Code“</i></p>		<p>The definition of “designated products” should be revised to align with the WHO Code as above.</p>
<p>Follow-up formula</p> <p>(a) a milk or milk-like product of animal or plant origin formulated industrially and marketed or otherwise represented as a food suitable for use as a liquid part of the weaning diet for infants from the 6th month on and for young children</p>	<p>Codex Standard for Follow-Up Formula (Codex STAN 156-1987) [7], Section 2.1 defines follow-up formula as follows:</p> <p><i>“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”</i></p> <p>EC Directive 2006/141/EC [8] on infant formula and follow-on formula is a relevant reference. Article 2 (d) defines follow-on formula as follows:</p> <p><i>“follow-on formula’ 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”</i></p> <p>Article 13 (b) provides the following labeling requirements for follow-on formula that also provide guidance to the definition <i>“in the case of follow-on formula, a statement to the effect that the product is suitable only for particular nutritional use by infants over the age of six months, that it should form only part of a diversified diet, that it is not to be used as a substitute for breast milk during the first six months of life and that the</i></p>	<p>The draft HK Code definition is not aligned with international regulatory authorities as far as (a) is concerned.</p> <p>The term “milk or milk-like product” originates from the Model Law, which is not used by any international regulatory authority, and hence may give rise to confusion and different interpretations.</p>	<p>Adopt definition of Follow-up Formula from Codex STAN 156-1987) as follows:</p> <p><i>“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”</i></p>

Draft HK Code	International/Local References	Issues	Suggestions
	<p><i>decision to begin complementary feeding, including any exception to six months of age, should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, based on the individual infant's specific growth and development needs"</i></p>		
<p>Food products for infants and young children</p> <p>Means (a) any food, except formula milk, intended primarily for use during the normal infant's weaning period and for the progressive adaptation of infants and young children to ordinary food, which may be either in ready-to-eat form or in dry form requiring reconstitution with water, milk or other suitable liquids, and includes complementary food;</p>	<p>Codex standard definition for canned baby foods (Codex Stan 73-1981) is as follows:</p> <p><i>"Baby foods are foods intended primarily for use during the normal infant's weaning period and also for the progressive adaptation of infants and children to ordinary food. "</i></p> <p>Codex standard definition for processed cereal-based foods for infants and young children (Codex Stan. 1981) is as follows:</p> <p><i>"This standard covers processed cereal-based foods intended for feeding infants as a complementary food generally from the age of 6 months onwards, taking into account infants' individual nutritional requirements, and for feeding young children as part of a progressively diversified diet, in accordance with the Global Strategy for Infant and Young Child Feeding and World Health Assembly Resolution WHA 54.2 (2001)."</i></p>		<p>Replace "formula milk" with "breast-milk substitute" (please refer to Article 1 suggestions for definition)</p> <p>Delete any food product not related to breast-milk substitutes</p>
<p>Formula milk</p> <p>Means infant formula and follow-up formula</p>	<p>No reference found</p>	<p>The draft HK Code introduces a new term "formula milk" that is not defined by any other regulatory authority nor scientific expert body. This term is misleading and very confused because infant formula or</p>	<p>Replace "formula milk" with "breast-milk substitute" (please refer to Article 1 suggestions for definition)</p>

Draft HK Code	International/Local References	Issues	Suggestions
		follow up formula is not dairy product, some formula may contain small amount of milk or no milk at all. There is no need to introduce this term as both infant formula and follow-up formula are well defined by globally recognized and referenced regulatory authorities (e.g., Codex Alimentarius, European Union)	
<p>Formula milk related products</p> <p>Means feeding bottles, teats, and pacifiers for infants and young children.</p>	Reference not found	Please refer to our comments in the preceding definition above	<p>Replace “formula milk related products” with “breast-milk substitute related products” (please also refer to Article 3, “designated products” above) as follows:</p> <p>“breast-milk substitute related products means – breast-milk substitutes, including infant formula; other milk products, foods and beverages, including bottle fed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast milk; feeding bottles and teats.”</p>
<p>Infant formula, means</p> <p>(a) a milk or milk-like product of animal or plant origin formulated industrially to</p>	Codex Standard for Infant Formula – Section A: Revised Standard for Infant Formula (Codex STAN 72-1987), Section 2.1 defines	The draft HK Code defines “infant formula” as “a milk or milk-like product”, which is misleading and very confusing. Some infant	Replace “formula milk” with “breast-milk substitute” (please refer

Draft HK Code	International/Local References	Issues	Suggestions
<p>satisfy by itself the nutritional requirements of infants during the first months of life up to the introduction of feeding by appropriate complementary food; and</p>	<p>infant formula as:</p> <p><i>“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.”</i></p> <p>EC Directive on infant formula and follow-on formula (2006/141/EC):</p> <p><i>“infant formula’ 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.</i></p> <p>WHO Code includes a similar definition for infant formula as Codex and EC directive:</p> <p><i>“a breast-milk substitute formulated industrially in accordance with applicable Codex Alimentarius standards, to satisfy the normal nutritional requirements of infants up to between four and six months of age, and adapted to their physiological characteristics, infant formula may also be prepared at home, in which case it is described as “home-prepared”</i></p>	<p>formula may contain small amount of milk or no milk at all.</p> <p>The term “milk or milk-like product” is from the Model Law. This term is not used by international regulatory authorities, hence it may give rise to confusion and different interpretations.</p>	<p>to Article 1 suggestions for definition)</p>
<p>Ingredient</p> <p>Means any substance, including any additive and any constituent of a compound ingredient, which is used in the manufacture or preparation of a food and which is still present in the finished product, even if in an altered form.</p>	<p>The definition for “ingredient” in the Regulation 2 of the Food and Drugs (Composition and Labeling) Regulations, Cap. 132W [9] is as follows:</p> <p><i>“Means any substance, including any additive and any constituent of a compound ingredient, which is used in the manufacture or preparation of a food and which is still</i></p>	<p>The definition for “ingredient” included in the draft HK Code is identical to the one included in Regulation 2 of the Food and Drugs (Composition and Labeling) Regulations, Cap. 132W [9].</p> <p>However, it is very different from how other international regulatory authorities (e.g., Codex, EC) deal with the term “ingredient”.</p>	<p>As per our suggestions above, labeling should be regulated by legislation instead of this voluntary code.</p> <p>If labeling must be included in the HK Code, then the Codex definition</p>

Draft HK Code	International/Local References	Issues	Suggestions
	<p><i>present in the finished product, even if in an altered form.</i> “</p> <p>General standard for the labeling of prepackaged foods (Codex Stan 1985) uses the following:</p> <p><i>“Ingredient” means any substance, including a food additive, used in the manufacture or preparation of a food and present in the final product although possibly in a modified form.</i>“</p> <p>The “ingredient” in Codex Standard for Infant Formula – Section A: Revised Standard for Infant Formula (Codex STAN 72-1987) is defined in Section 3 as follows.</p> <p><i>“Essential composition and Quality Factors”</i> of infant formula. Under Section 3.1 reference is being giving the criteria that should be applied when manufacturing infant formula, which includes reference to the rationale for “ingredients” used <i>“Infant formula is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be suitable for infant feeding. The nutritional safety and adequacy of infant formula shall be scientifically demonstrated to support growth and development of infants. All ingredients and food additives shall be gluten-free.</i> “</p> <p>Section 9 defines <i>“Labeling”</i> for infant formula and provides guidance on how to list ingredients on labels as follows:</p> <p><i>“9.1.1. A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added</i></p>	<p>The HK definition includes “any constituent of a compound ingredient”, which could put the whole food industry at risk of non-compliance.</p>	<p>on “ingredient” should be adopted.</p>

Draft HK Code	International/Local References	Issues	Suggestions
	<p><i>vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.</i></p> <p><i>9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate class names for these ingredients and additives may be included on the label. “</i></p>		
<p>Label</p> <p>Means any tag, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed, attached or otherwise appearing on a container of a designated product.</p>	<p>Codex Standard for the Labeling of Prepackaged Foods (CODEX STAN 1-1985), Article 2:</p> <p><i>“Label” means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container of food. “</i></p> <p>WHO Code, Article 3:</p> <p><i>“Label means any tag, brand, marks, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container (see above) of any products within the scope of this Code.”</i></p>	<p>The definition is similar to the one included in the WHO Code and Codex.</p>	<p>The definition of “designated products” should be revised to align with the WHO Code as above.</p>
<p>Labeling</p> <p>in relation to a <u>designated product</u> other than formula milk related products, includes any word, particular, trade mark, brand name, pictorial matter or symbol relating to the designated product and</p>	<p>Codex Standard for the Labeling of Prepackaged Foods (CODEX STAN 1-1985), Article 2:</p> <p><i>“labeling includes any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near</i></p>	<p>The definition for “labeling” should be in line with the Codex Standard for the Labeling of Prepackaged Foods, and definitions by other international regulatory authorities (e.g., EU, US)</p>	<p>Adopt the CODEX labeling requirements.</p> <p>The limitation on the use of trademarks and company names should also be removed or a</p>

Draft HK Code	International/Local References	Issues	Suggestions
<p>appearing on the packaging of the designated product or on any document, notice, label, ring or collar accompanying the designated product.</p>	<p><i>the food, including that for the purpose of promoting its sale or disposal</i></p> <p>Under Regulation 2 of the Food and Drugs (Composition and Labeling) Regulations, Cap. 132W [9], labeling means</p> <p><i>“in relation to a food, includes any words, particulars, trademark, brand name, pictorial matter or symbol relating to the food and appearing on the packaging of the food or on any document, notice, label, ring or collar accompanying the food”.</i></p> <p>However, Schedule 3 of the Regulation allows the use of the brands and trademarks: <i>“If any brand name, including any fancy name, or any trade mark would be likely to mislead a purchaser in any respect as to the nature of the food, such name or mark shall be immediately followed by the word “Brand” (牌子) or the letters “TM”(商標), as appropriate, printed in legible letters or characters of not less than 3 mm in height.”</i></p> <p>Article 20 of the Agreement on Trade-related Aspects of Intellectual Property Rights further provides that <i>“The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings...”</i></p>		<p>similar approach as that provided in the Food and Drugs (Composition and Labeling) Regulations should be adopted as there is no evidence that trademarks or brands per se impact on the breast feeding rates.</p>

Draft HK Code	International/Local References	Issues	Suggestions
<p>Marketing</p> <p>Means product promotion, distribution, selling and advertising, product public relations and information services and “market” will be construed accordingly.</p>	<p>The definition for “marketing” included in the HK Code includes similar wording to the one included in the WHO International Code for the Marketing of Breast-Milk Substitutes (1981):</p> <p><i>“product promotion, distribution, selling, advertising, product public relations, and information services”.</i></p> <p>There is no definition for marketing that is included in international regulatory provisions established by Codex Alimentarius or other international regulatory authorities (e.g., EU, US).</p>	<p>A definition needs to be crystal clear. The last part of the definition “and market will be construed accordingly” included in the HK Code may cause confusion.</p>	<p>Delete the last part “and market will be construed accordingly”, and adopt definition of “Marketing” in WHO code.</p>

Draft HK Code	International/Local References	Issues	Suggestions
<p>Pack shot</p> <p>Means any representation of a <u>designated</u> product either by photograph or graphic illustration.</p>	<p>No reference found</p>		<p>The definition of “designated products” should be revised to align with the WHO Code as above.</p>
<p>Promote</p> <p>Means to employ any method of directly or indirectly encouraging a person to purchase or use a <u>designated product</u>.</p>	<p>No reference found</p>	<p>This is a very broad definition; there is in fact no need to define this, as Article 5.4 describes promotional practice in any case.</p>	<p>Delete the definition</p>
<p>Quality standard</p> <p>Means the requirements of a <u>designated product</u> other than formula <u>milk</u> related products on essential composition and quality factors (including but not limited to energy content, nutrient content, ingredients, consistency/particular size, and purity requirements), food additives, contaminants and hygiene.</p>	<p>None of the international regulatory provisions dealing with nutrition products for infants and young children introduces a definition for “quality standard”.</p> <p>Alternatively they define the different key compositional criteria individually, namely “Essential composition”, “Food additives” of these products and include safety criteria for these products.</p> <p>Codex Standard for Infant Formula – Section A: Revised Standard for Infant Formula (Codex STAN 72-1987) is a relevant reference [5].</p> <p>Section 3 defines “<i>Essential composition and Quality Factors</i>” of infant formula.</p> <p>Section 4 defines “<i>Food additives</i>” of infant formula.</p> <p>Section 5 defines “<i>Contaminants</i>” of infant formula.</p> <p>Section 6 defines “<i>Hygiene</i>” of infant formula.</p>	<p>The term “Quality standard” is not used by any international regulatory authorities and may give rise to confusion.</p>	<p>As explained above, quality standards should be regulated by legislation and not by a voluntary code.</p> <p>If quality standard provisions must be included, however, we suggest the following:</p> <p>Delete the definition of “Quality standard” and include instead the compositional criteria for the infant nutritional products along the same line as Codex Alimentarius and other reference regulatory authorities (e.g., EU, USA).</p> <p>The definition of “designated products” should be revised to align</p>

Draft HK Code	International/Local References	Issues	Suggestions
			<p>with the WHO Code as above.</p> <p>Replace the term “Formula Milk” with breast-milk substitute (please refer to Article 1 suggestions for definition).</p>

References:

- [1] Codex General Guidelines on Claims (CAC/GL 1-1979 (Rev. 1-1991))
- [2] REP 12/NFSDU Appendix IV.
- [3] Codex Standard for Processed Cereal-Based Foods for Infants and Young Children (Codex STAN 74-1981)
- [4] Codex Standard for Canned Baby Foods (Codex STAN 73-1981)
- [5] C. Agostoni et al. (2008) Complementary Feeding: A Commentary by the ESPGHAN Committee on Nutrition. JPGN, 46:99–110
- [6] WHO (1981) International Code of Marketing of Breast-Milk Substitutes
- [7] Codex Standard for Follow-Up Formula (Codex STAN 156-1987)
- [8] EC Directive 2006/141/EC on infant formula and follow-on formula
- [9] Food and Drug (Composition and Labeling) Regulations, (Cap. 132W)

#### **Article 4 - Information and Education (to the general public, pregnant women and mothers)**

##### **General comments:**

The HK Code proposes to severely restrict the information that manufacturers and distributors can impart to consumers on the rationale that:

- (i) misleading or incorrect informational materials on breastfeeding and formula milk feeding and nutrition can be harmful to children’s health;
- (ii) manufacturers and distributors’ objectives are to increase sale or improve corporate image. The contents of such materials therefore very often tilt towards formula milk feeding and aim to lead parents to use their products; and
- (iii) evidence showed that breastfeeding cessation increased significantly in the first 2 weeks in mothers who were given formula company-produced materials about infant feeding at the first antenatal visit, compared to those given breast-feeding promotion materials without formula advertising.

However, even assuming that these rationale can be supported by scientific evidence, it is noted that:

- (i) The WHO Code does not have similar restrictions;
- (ii) Article 4.4 of the HK Code allows the provision of such information and education by parties other than manufacturers and distributors;
- (iii) There is no concrete evidence showing that manufacturers and distributors do provide misleading or incorrect informational on breastfeeding and formula feeding; and

Therefore, the ban is unnecessary and disproportionate.

##### **Suggestions:**

Manufacturers and distributors should be allowed to provide information to consumers about their products as long as they are not false or misleading – restrictions should not be unnecessary nor disproportionate.

<b>Draft HK Code</b>	<b>International/Local References</b>	<b>Issues</b>	<b>Suggestions</b>
<p>4.1 No information and education on breastfeeding and formula milk feeding by manufacturers and distributors.</p> <p>4.1.1 A manufacturer or distributor should not himself or herself, or by any other person on his or her behalf –</p> <p>(a) perform, carry out or sponsor educational functions or activities relating to breastfeeding and formula milk feeding which are intended to reach the general public, pregnant women or mothers of</p>	No reference found	Please refer to our general comments above.	Delete this article 4.1

Draft HK Code	International/Local References	Issues	Suggestions
<p>children aged 36 months or below; or</p> <p>(b) produce informational or educational materials referring to breastfeeding and formula milk feeding and distribute such materials to the general public, pregnant women or mothers of children aged 36 months or below or sponsor such production and distribution.</p>			
<p>4.2</p> <p>Product information provided by manufacturers and distributors</p> <p>4.2.1 A manufacturer or distributor of formula milk and formula milk related product may provide information on specific brands of formula milk and formula milk related product to any person on its websites, at the premises of retailers or at health care facilities provided that such information –</p> <p>(a) is restricted to technical and textual information appearing on the label of the product and may only contain information relating to breastfeeding and formula milk feeding in Article 4.4.1(e);</p> <p>(b) is devoid of photographs, pictures or any graphic representation other than for illustrating methods of preparation, except for a pack shot of a size not more than one-tenth of the total space occupied by the information;</p> <p>(c) is devoid of any health claim or</p>	<p>No reference found</p>	<p>Infant formula and follow up formula should be subject to different regulation as they are different products, and play different role from nutrition science perspective.</p> <p>The restrictions on follow up formula are not proportionate and should be deleted, as parents should have the right to make informed choice based on adequate information.</p>	<p>Replace “formula milk” with breast-milk substitute (please refer to Article 1 suggestions for definition).</p> <p>Note: There is a conflict between the English and Chinese versions regarding Article 4.2.1 (a).</p> <p>The English version is acceptable, whereas the Chinese translation is confusing.</p>

Draft HK Code	International/Local References	Issues	Suggestions
<p>nutrition claim regarding the product or its ingredient or constituent, except those health claim or nutrition claim or representations allowed in Articles 8.5.1 to 8.5.3;</p> <p>(d) satisfies the requirements in Article 4.4.1(a) to (c); and</p> <p>(e) is provided only upon request.</p> <p>4.2.2 The information referred to in Article 4.2.1 may include the name, address and telephone hotline of the manufacturer or distributor.</p>			
<p>4.3 Information and education on other matters provided by manufacturers and distributors.</p> <p>4.3.1 A manufacturer or distributor may produce, donate or distribute informational or educational materials, or sponsor or perform educational activities on matters related to infants and young children other than breastfeeding and formula milk feeding, provided that –</p> <p>(a) the brand name, logo or trade mark of any <u>formula milk</u> and formula milk related product is not displayed on the materials or in the activities; and</p> <p>(b) such materials or activities are not associated with promotional practices not permitted under Article 5.</p>	<p>WHO Code:</p> <p><i>“4.3 Donations of informational or educational equipment or materials by manufacturers or distributors should be made only at the request and with the written approval of the appropriate government authority or within guidelines given by governments for this purpose. Such equipment or materials may bear the donating company’s name or logo, but should not refer to a proprietary product that is within the scope of this Code, and should be distributed only through the health care system.”</i></p>	<p>As mentioned above, the prohibition on manufacturers and distributors’ involvement in breastfeeding and formula feeding educational activities is unnecessary and disproportionate.</p>	<p>Delete “other than breastfeeding and formula milk feeding”</p> <p>Replace “Formula Milk” with breast-milk substitute (please refer to Article 1 suggestions for definition).</p>

Draft HK Code	International/Local References	Issues	Suggestions
<p>4.4 Information and education on infant and young child feeding and nutrition <u>other than manufacturers and distributors.</u></p> <p>4.4.1 Informational and educational materials produced or distributed by parties other than manufacturers and distributors, whether written, audio or visual, which refer to infant and young child feeding and nutrition and are intended to reach the general public, pregnant women and/or mothers of children aged 36 months or below should –</p> <p>(a) contain only correct and current information and should not use any pictures or texts that encourage feeding by <u>formula milk</u> or discourage breastfeeding;</p> <p>(b) be written in Chinese and/or English (with or without other language(s));</p> <p>(c) not give an impression or create a belief that a designated product is equivalent to, comparable with or superior to breastmilk or breastfeeding;</p> <p>(d) not contain the brand name, logo or trade mark of formula milk and formula milk related product nor of the names of</p>	<p>WHO Code:</p> <p><i>“4.2 Informational and educational materials, whether written, audio, or visual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, should include clear information on all the following points:</i></p> <p><i>(a) the benefits and superiority of breast-feeding;</i></p> <p><i>(b) maternal nutrition, and the preparation for and maintenance of breast-feeding;</i></p> <p><i>(c) the negative effect on breast-feeding of introducing partial bottle-feeding;</i></p> <p><i>(d) the difficulty of reversing the decision not to breast-feed; and</i></p> <p><i>(e) where needed, the proper use of infant formula, whether manufactured industrially or home-prepared. When such materials contain information about the use of infant formula, they should include the social and financial implications of its use; the health hazards of inappropriate foods or feeding methods; and, in particular, the health hazards of unnecessary or improper use of infant formula and other breast-milk substitutes. Such materials should not use any pictures or text which may idealize the use of breast-milk substitutes.”</i></p>	<p>The restrictions on exposure of the names of manufacturers and distributors are unreasonable; exposure of manufacturers’ and distributors’ names does not conflict with the promotion of breastfeeding.</p> <p>The key point here is the content of information and education.</p> <p>Restrictions on infant formula name and product brand should be sufficient to service the intended purpose; the exposure of manufacturers’ and distributors’ names will not undermine the accuracy or authenticity of the information and education provided.</p> <p>On the other hand, allowing manufacturers’ and distributors’ involvement in the education exercise will give incentive to them to improve corporate image, which should not be prohibited.</p> <p>One of the aims of the WHO code is to promote breast-feeding and the safe use of breast-milk substitutes. Manufacturers and distributors should be allowed to provide educational information on breast feeding. Educational materials without product brand names but with company names or logos should be allowed.</p>	<p>In keeping with our position that manufacturers and distributors should not be restricted from providing educational information, the following is proposed:</p> <p>Delete “other than manufacturers and distributors” and the last sentence of (d) “nor of the names of any manufacturer or distributor of formula milk and formula milk related product”,</p> <p>The definition of “designated products” should be revised to align with the WHO Code as above.</p> <p>Replace “Formula Milk” with breast-milk substitute (please refer to Article 1 suggestions for definition).</p>

Draft HK Code	International/Local References	Issues	Suggestions
<p>any manufacturer or distributor of formula milk and formula milk related product;</p> <p>(e) clearly and conspicuously explain the following matters, which are considered appropriate to the age of the infants and young children and the stage of feeding in discussion and the type of informational and educational materials made –</p> <p>(i) where the materials are about breastfeeding –</p> <p>(A) the benefits and superiority of breastfeeding;</p> <p>(B) the value of exclusive breastfeeding for six months followed by sustained breastfeeding for two years or beyond;</p> <p>(C) how to initiate and maintain exclusive and sustained breastfeeding;</p> <p>(D) why it is difficult to reverse a decision not to breastfeed;</p> <p>(E) the importance of introducing complementary food from the age of six months;</p> <p>(F) how and why any introduction of bottle feeding or early</p>			

Draft HK Code	International/Local References	Issues	Suggestions
<p>introduction of complementary food negatively affects breastfeeding;</p> <p>(ii) where the materials are on complementary feeding –</p> <p>(A) the benefits and superiority of breastfeeding;</p> <p>(B) the importance of introducing complementary food from the age of six months;</p> <p>(C) how and why any introduction of bottle feeding or early introduction of complementary food negatively affects breastfeeding;</p> <p>(D) that complementary food can easily be prepared at home using ordinary ingredients; and</p> <p>(iii) where the materials are on feeding by formula milk or the use of a feeding bottle –</p> <p>(A) the benefits and superiority of breastfeeding;</p> <p>(B) the value of exclusive breastfeeding for six months followed by sustained breastfeeding for two years or beyond;</p> <p>(C) how to initiate and maintain exclusive and sustained breastfeeding;</p> <p>(D) why it is difficult to reverse a decision not to breastfeed;</p>			

Draft HK Code	International/Local References	Issues	Suggestions
<p>(E) instructions for the proper preparation and use of feeding bottle and teat, including cleaning and sterilisation of feeding utensils;</p> <p>(F) the health risks of feeding by formula milk, feeding by using a feeding bottle and teat and improper preparation of feeding bottle and teat;</p> <p>(G) explanations that powdered formula milk is not a sterile product and that to minimize the risks of serious illness, formula should be prepared one feed at a time using boiled water cooled to no less than 70°C* and that the reconstituted formula milk should be consumed within 2 hours after preparation and any unused milk must be discarded;</p> <p>(H) the approximate financial cost of feeding an infant with feeding bottle and teat in the recommended quantities,</p> <p>except that all of the matters in paragraph (iii) (A) to (H) should be covered if the materials are about feeding of infants below 6 months of age.</p>			

## **Article 5 - Promotion to the Public**

### **General comments:**

The HK Code fails to distinguish infant formula from follow up formula, which are different from nutrition science perspective, and imposes the same marketing restriction on these two products. Furthermore, it treats follow up formula and food products for infant and young children, which are both complementary products, differently.

As mentioned above regarding the scope of the HK Code, we submit that the HK Code should only govern matters to do with breast-milk substitutes, and reiterate that manufacturers and distributors should not be unreasonably restricted from imparting information to consumers.

Please also see our comments relating to Article 4 above.

<b>Draft HK Code</b>	<b>International/Local References</b>	<b>Issues</b>	<b>Suggestions</b>
5.1 A manufacturer or distributor should not himself or herself, or by any other person initiated by or on his or her behalf, carry out any promotional activities involving formula milk and formula milk related products.	No reference found	<p>This article will differentiate follow up formula from infant formula.</p> <p>Follow up formula and other foods for infant and young children are both complementary foods and in this sense, are not different.</p> <p>There should therefore not be any difference in regulation of these two products.</p> <p>If communication on follow-up formula was to be seriously limited and these products could no longer bear advertising, consumers would receive unbalanced information about their product options, thereby restricting their right to choose.</p>	<p>Replace “formula milk” with breast-milk substitute (please refer to Article 1 suggestions for definition), and “formula milk related products” with “breast-milk related products”.</p>
<p>5.2 A manufacturer or distributor may promote food products for infants and young children, provided that the promotional practice –</p> <p>(a) does not take place in a health care facility;</p>		<p>The WHO only bans promotion of breast-milk substitutes.</p> <p>All other infant nutrition products, including follow-up formula are complementary to breastfeeding. The HK Code should therefore not treat follow-up formula and food products for infants and young children</p>	<p>Replace “food products for infants and young children” with “products other than breast milk substitute”.</p> <p>Delete Article 5.2(c)</p>

Draft HK Code	International/Local References	Issues	Suggestions
<p>(b) satisfies the requirements under Articles 4.2.1 (c), 4.4.1(a) and (c) and 4.4.1 (e) (ii); and</p> <p>(c) does not promote formula milk or formula milk related products.</p>		<p>differently in terms of restriction on promotion. Otherwise, consumers would receive unbalanced information about their product options, thereby restricting their right to choose.</p>	
<p>5.3</p> <p>A manufacturer or distributor should not himself or herself, or by any other person on his or her behalf–</p> <p>(a) seek directly or indirectly personal details of infants, young children, pregnant women or mothers of children aged 36 months or below; or</p> <p>(b) invite participation of infants, young children, pregnant women and mothers of children aged 36 months or below in activities including baby shows, mother craft activities for the purpose of promoting its products and its brand(s).</p>	<p>WHO Code:</p> <p><i>“5.5 Marketing personnel, in their business capacity, should not seek direct or indirect contact of any kind with pregnant women or with mothers of infants and young children.”</i></p>	<p>Collecting personal details with consent should not lead to mothers being discouraged from breastfeeding or being misinformed about breastfeeding or formula milk feeding.</p> <p>The HK Code intends to prevent manufacturers and distributors from sending information to mothers and pregnant women. However, a blanket prohibition on collecting personal details is too broad in scope and unnecessary for satisfying the objectives of the HK Code.</p> <p>There is no such prohibition with respect to the promotion of any other consumer product, or indeed pharmaceuticals or medical devices that are subject to greater regulatory control under Hong Kong law.</p> <p>Invitations to infants, young children and women to participate in activities will not discourage breastfeeding. Manufacturers and distributors use such activities to improve corporate image and should not be banned. This restriction is disproportionate.</p>	<p>Suggest replacing the article with the following:</p> <p>“Marketing Personnel, in their business capacity, should not seek direct or indirect contact with pregnant women or with parents of Infants and young children for the promotion of breast-milk substitutes. This does not prevent appropriately qualified personnel from responding to complaints or unsolicited requests for information. For these requests, parents should be referred to a Health Practitioner whenever health advice is required.”</p>
<p>5.4</p> <p>Promotional practices include but are not limited to –</p> <p>(a) advertising;</p>	<p>WHO Code:</p> <p><i>“5.1 There should be no advertising or other form of promotion to the general public of products within the scope of this Code.”</i></p>	<p>As above.</p> <p>Manufacturers and distributors should have a role in promoting breastfeeding which is in the spirit of the WHO Code.</p>	<p>In keeping with our position that manufacturers and distributors should not be restricted from providing</p>

Draft HK Code	International/Local References	Issues	Suggestions
<p>(b) using sales inducement devices such as special displays, discount coupons, premiums, rebates, special sales, loss-leaders, tie-in sales, prizes or gifts;</p> <p>(c) giving one or more samples of formula milk or formula milk related products to any person;</p> <p>(d) production and distribution of informational or educational materials on breastfeeding and formula milk feeding or sponsoring such production and distribution, except as allowed under Articles 4.2.1, 4.2.2, and 4.4.1; and</p> <p>(e) performance or carrying out of educational functions or activities relating to breastfeeding and formula milk feeding or sponsoring such functions or activities.</p>	<p><i>“5.2 Manufacturers and distributors should not provide, directly or indirectly, to pregnant women, mothers or members of their families, samples of products within the scope of this Code.”</i></p> <p><i>“5.3 In conformity with paragraphs 1 and 2 of this Article, there should be no point of sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales, for products within the scope of this Code. This provision should not restrict the establishment of pricing policies and practices intended to provide products at lower prices on a long-term basis.”</i></p> <p><i>“5.4 Manufacturers and distributors should not distribute to pregnant women or mothers or infants and young children any gifts of articles or utensils which may promote the use of breast-milk substitutes or bottle-feeding.”</i></p>		<p>educational information, the following is proposed:</p> <p>Delete Article 5.4(e).</p> <p>Replace “formula milk or formula milk related products” with “infant formula or infant formula related products”</p>
<p>5.5</p> <p>Promotional practices do not include the following –</p> <p>(a) any establishment of pricing policies and practices intending to provide designated products at lower prices on a long-term basis;</p> <p>(b) provision of designated products or information or materials about designated products to health worker</p>	<p>No reference found</p>		<p>The definition of “designated products” should be revised to align with the WHO Code as above.</p>

Draft HK Code	International/Local References	Issues	Suggestions
<p>under Article 7.2; and</p> <p>(c) provision of funding or sponsorship to health worker or</p> <p>associations of health workers under Articles 7.3.2. and 7.3.3.</p>			

#### **Article 6- Promotion in Health Care Facility**

Draft HK Code	International/Local References	Issues	Suggestions
<p>6.1 A manufacturer or distributor should not himself or herself, or by any other person on his or her behalf –</p> <p>(a) donate or provide at a price lower than the prescribed wholesale price, where one exists, or, in its absence, 80 percent of the retail price, any quantity of a designated product to a health worker or a health care facility;</p> <p>(b) donate to or distribute within a health care facility any equipment, service or material such as pen, calendar, poster, note pad, growth chart, toy which refers to or may promote the use of a designated product; or</p> <p>(c) promote designated product through health workers or health care facility or distribute designated product through health workers or health care facility to any person.</p>	<p>WHO Code:</p> <p><i>“6.3 Facilities of health care systems should not be used for the display of products within the scope of this Code, for placards or posters concerning such products, or for the distribution of material provided by a manufacturer or distributor other than that specific it Article 4.3.”</i></p>	<p>As ‘health care facilities’ include practices engaged directly / indirectly in providing health care, 6.1(b) affects the freedom of private practices’ decision making and autonomy.</p> <p>6.1(c) may prohibit health care facilities from delivering samples to mothers.</p>	<p>Companies already agree the principle of not providing low price products to health care professionals. However, it’s difficult to implement “80 percent of the retail price” .</p> <p>Suggest following the WHO Code provision.</p>

**Article 7 - Information and Promotion to Health Worker**

Draft HK Code	International/Local References	Issues	Suggestions
<p>7.1 Responsibilities of health worker</p> <p>7.1.1 Health worker should encourage and protect breastfeeding and those who are concerned in particular with maternal and infant nutrition</p> <p>should make themselves familiar with their responsibilities under this Code, including the matters specified in Article 4.4.1 (e).</p> <p>7.1.2 Health worker engaged in maternal and child health may demonstrate the use of infant formula to parents when it is considered necessary and, where demonstration is considered necessary, should give a clear explanation of the risks of the use of infant formula as well as the information specified in Article 4.4.1 (e)(iii) during the demonstration.</p>	<p>WHO Code:</p> <p><i>“7.1 Health workers should encourage and protect breast-feeding; and those who are concerned in particular with maternal and infant nutrition should make themselves familiar with their responsibilities under this Code, including the information specified in Article 4.2.”</i></p>		<p>The definition of “designated products” should be revised to align with the WHO Code as above.</p>
<p>7.2 Product and product information for health worker</p> <p>7.2.1 Manufacturers or distributors may provide designated product to health worker or health care facility only for the purpose of professional evaluation or research at the institutional level.</p>	<p>WHO Code:</p> <p><i>“7.4 Samples of infant formula or other products within the scope of this Code, or of equipment or utensils for their preparation or use, should not be provided to health workers except when necessary for the purpose of professional evaluation or research at the institutional level. Health workers should not give samples of infant formula to pregnant women, mothers of infants and young children, or members of their families.”</i></p>		<p>The definition of “designated products” should be revised to align with the WHO Code as above.</p>

Draft HK Code	International/Local References	Issues	Suggestions
<p>7.2.2 Notwithstanding Article 4, manufacturers or distributors may give any materials about designated product to health worker if such materials –</p> <p>(a) are restricted to scientific and factual matters regarding the technical aspects and methods of use of the product; or</p> <p>(b) provide references to published peer-reviewed studies to support any representation or claim that states or suggests that a relationship exists between the product or constituent thereof and health, growth or development of infants and young children.</p>	<p>WHO Code:</p> <p><i>“7.2 Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code should be restricted to scientific and factual matters, and such information should not imply or create a belief that bottle-feeding is equivalent or superior to breast-feeding. It should also include the information specified in Article 4.2”</i></p>		<p>The definition of “designated products” should be revised to align with the WHO Code as above.</p>

## **Article 8: Labeling:**

### **General comments:**

#### International/Local References

Codex Alimentarius defines a specific section in each standard regarding labeling and claims. General standards have been established providing guidelines on claims as well as on the criteria for scientific substantiation. Similarly the European Union and US Code of Federal Regulations lay down similar provisions on nutrition and health claim.

#### **Issues:**

Provisions for labeling and claims are to provide criteria to appropriately communicate to the consumers on and off pack information on the nutritional value of the products as well as to assure their safe use. Additionally these provisions are to provide most relevant nutrition and health information about the benefits of the products.

The “one size fits all” approach is misleading the consumers and is inappropriate. Only infant formula are breast-milk substitutes, whereas all other infant nutritional products are complementary to breastfeeding.

### Suggestions:

Labeling and claim standards should be separated from the voluntary HK Code and laid down in a food regulation or food law as mandatory requirements.

If the labeling provisions must be kept in the HK Code, we strongly recommend that the HK Code should not adopt a “one size fits all” approach for the wording to be put on the label, as not all infant nutritional products require similar wording, and such products should not be juxtaposed to breast-milk.

Therefore it would be more appropriate to introduce appropriate labeling sections for each of the specific infant and child nutritional products under consideration in the HK Code. The wording to be used for these provisions should follow that of the WHO Code.

Draft HK Code	International/Local References	Issues	Suggestions
<p>8.1 Label of designated product</p> <p>8.1.1 The label affixed to a designated product should not give an impression or create a belief that the product is equivalent to, comparable with or superior to breast-milk or breastfeeding.</p>	<p>WHO Code:</p> <p><i>“Article 9.1 Labels should be designed to provide the necessary information about the appropriate use of the product, and so as not to discourage breast-feeding”</i></p> <p>Codex standards lay down label requirements for each specific infant nutrition product:</p> <p>For infant formula the Codex Standard for Infant Formula – Section A: Revised Standard for Infant Formula (Codex STAN 72-1987), Section 9.6 Additional Labeling Requirements:</p> <p><i>“9.6.1 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:</i></p> <p><i>a) the words “important notice” or their equivalent;</i></p> <p><i>b) the statement “Breast milk is the best food for your baby” or a similar statement as to the superiority of breastfeeding or breast milk;</i></p> <p><i>c) a statement that the product should only be used on advice of a independent health worker as to the need for its use and the proper method of use.</i></p> <p><i>9.6.2 The label shall have no pictures of infants and women nor any other picture or text which</i></p>	<p>The labeling requirements in WHO Code relate to breast-milk substitutes only.</p> <p>The requirements laid down by international regulatory authorities differ depending on the infant nutrition product.</p> <p>Only infant formula are breast-milk substitutes, whereas all other infant nutrition products are complementary to breastfeeding and therefore should be treated differently.</p>	<p>Article 8.1.1 should apply to breast-milk substitutes only.</p> <p>For infant formula, suggest adopting the labeling requirements defined in Section “9.6 Additional Labeling Requirements” of the Codex Standard for Infant Formula – Section A: Revised Standard for Infant Formula (Codex STAN 72-1987).</p> <p>For Formula for Special Medical Purposes intended for Infants, suggest adopting the labeling requirements defined in Section “9.6 Additional Labeling Requirements” of the Codex Standard for Infant Formula – Section B: Formula for Special Medical Purposes intended for Infants (Codex STAN 72-1987).</p> <p>For follow-up formula, suggest adopting the labeling requirements defined in Section “9.6 Additional Labeling Requirements” of the</p>

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	<p><i>idealizes the use of infant formula.</i></p> <p><i>9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.</i></p> <p><i>9.6.4 Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.</i></p> <p><i>9.6.5 The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula, and formula for special medical purposes."</i></p> <p>Similar wording is also used by other international regulatory authorities (e.g., EU, US)</p> <p>Label for "Formula for special medical purpose intended for infants", Codex Standard for Infant Formula – Section B: Formula for Special Medical Purposes intended for Infants (Codex STAN 72-1981), Section 9.6 Additional Labeling Requirements:</p> <p><i>"9.6.1 Formula for Special Medical Purposes Intended for Infants shall be labelled with the additional information as specified in Sections 4.4.1, 4.4.3, 4.4.4, 4.5.1 and 4.5.5 of CODEX STAN 180-1991 Standard for Labeling of and Claims for Foods for Special Medical Purposes.</i></p> <p><i>9.6.2 A prominent statement indicating that the product is intended as the sole source of nutrition shall appear on the label.</i></p> <p><i>9.6.3 In addition, the information specified in Sections 4.5.2, 4.5.3 and 4.5.6 of CODEX STAN 180-1991 shall be included on the label or be</i></p>		<p>Codex Standard for Follow-Up Formula (Codex STAN 156-1987).</p>

Draft HK Code	International/Local References	Issues	Suggestions
	<p><i>provided separately from the package.</i></p> <p><i>9.6.4 Labels and information provided separately from the package should not discourage breastfeeding, unless breastfeeding is contraindicated on medical grounds for the disease(s), disorder(s) or medical condition(s) for which the product is intended.</i></p> <p><i>9.6.5 See Section A 9.6.5"</i></p> <p>Similar wording is also used by other reference international regulatory authorities (e.g., EU, US)</p> <p>For follow-up formula, the Codex Standard for Follow-Up Formula (Codex STAN 156-1987) provides under Section 9.6 Additional Labeling Requirements:</p> <p><i>"The products covered by this standard are not breast-milk substitutes and shall not be presented as such".</i></p> <p>In relation to labeling requirements for follow-on formula (6-12 months of age), EC Directive 2006/141/EC on infant formula and follow-on formula provides in Article 13.1 (b):</p> <p><i>"in the case of follow-on formula, a statement to the effect that the product is suitable only for particular nutritional use by infants over the age of six months, that it should form only part of a diversified diet, that it is not to be used as a substitute for breast milk during the first six months of life and that the decision to begin complementary feeding, including any exception to six months of age, should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, based on the individual infant's specific growth and development needs."</i></p>		

Draft HK Code	International/Local References	Issues	Suggestions
	<p>Additionally, Article 14.7 states that</p> <p><i>“Infant formula and follow-on formula shall be labeled in such a way that it enables consumers to make a clear distinction between such products so as to avoid any risk of confusion between infant formula and follow-on formula.”</i></p>		
<p>8.2 Labeling requirements for formula milk</p>	<p>Codex Alimentarius consistently defines labeling requirements in all standards under the following Sections, which then further specify the requirements for the specific product:</p> <p>9.1 The Name of the Food</p> <p>9.2 List of Ingredients</p> <p>9.3 Declaration of Nutritive Value</p> <p>9.4 Date Marking and Storage Instructions</p> <p>9.5 Information for Use</p> <p>9.6 Additional Labeling Requirements</p>	<p>The wording for labeling requirements included in the draft HK Code is different from how other international regulatory authorities (e.g., Codex Alimentarius, EC, US FDA) deal with labeling requirements</p> <p>The labeling requirements laid down in international regulatory authorities differ depending on the infant nutrition product.</p> <p>As such it is not appropriate to go for one size fits all approach such as proposed in the draft HK Code.</p>	<p>Follow the logical approach laid down by the Codex Alimentarius for labeling requirements, and create provisions to deal with breast-milk substitutes and other infant nutrition products separately.</p> <p>Replace “formula milk” with breast-milk substitutes (please refer to Article 1 suggestions for definition).</p>
<p>8.2.1 In addition to the relevant legal requirements on labeling stipulated in Regulations 4 and 4A of and Schedules 2 to 4 to the Food and Drugs (Composition and Labeling) Regulations, Cap. 132W, the container of formula milk or the label affixed thereto should satisfy the following requirements:</p>	<p>Codex Standard for Infant Formula – Section A: Revised Standard for Infant Formula (Codex STAN 72-1981):</p> <p><i>“The requirements of the Codex General Standard for the Labeling of Prepackaged Foods (CODEX STAN 1-1985), the Codex Guidelines on Nutrition Labeling (CAC/GL 2-1985) and the Guidelines for Use of Nutrition and Health Claims apply to <u>infant formula and formula for special medical purposes for infants</u>”</i></p>		<p>In the case of infant formula, change the wording in Section 8.2.1 to:</p> <p><i>“In addition to ..., the container of <u>breast-milk substitutes</u> or the label affixed thereto should satisfy the following requirements”</i></p> <p>In the case of follow-up formula, the wording changed to”</p>

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			<p><i>"In addition to ..., the container of follow-up formula or the label affixed thereto should satisfy the following requirements".</i></p>
<p>(a) does not show any photograph, drawing or graphic representation other than for illustrating methods of preparation but may show one occurrence of either a company logo or a trade mark of the product;</p>	<p>WHO Code, Article 9.2: <i>"Neither the container nor the label should have pictures of infants, nor should they have other pictures or text which may idealize the use of infant formula. They may, however, have graphics for easy identification of the product as a breast-milk substitute and for illustrating methods of preparation. The terms "humanized", "materialized" or similar terms should not be used."</i></p> <p>Codex Standard for Infant Formula (Codex STAN 72-1981) provides: <i>9.6.2 The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of infant formula.</i> <i>9.6.3 The terms "humanized", "maternalized" or other similar terms shall not be used.</i></p>	<p>WHO Code only restricts the showing of pictures of infants and other pictures that may idealize the use of infant formula.</p> <p>The Codex standard for infant formula has similar wording to the WHO Code. However, the HK Code expands the restriction to "any photograph, drawing or graphic representation other than for illustrating methods of preparation", by following the Model Law.</p> <p>The last part of the provision ("may show one occurrence of either a company logo or a trade mark of the product") does not serve the purpose of protecting breastfeeding and public health. This wording may lead to products from different companies having similar appearances.</p> <p>The function of a trademark or logo is to distinguish one trader from another. A trade mark <i>"means any sign which is capable of distinguishing the goods or services of one trader from those of others"</i>.</p> <p>If a company logo/trademark can only appear once in each label, the consumer may not be able to tell</p>	<p>Change <i>"does not show any photograph, drawing or graphic representation other than for illustrating methods of preparation"</i> to: <i>"does not show picture of infants and other pictures or text which may idealize the use of infant formula"</i>.</p> <p>The above restriction should not apply to follow-up formula.</p> <p>Delete the last part "but may show one occurrence of either a company logo or a trade mark of the product".</p>

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		<p>one manufacturer from the other. This stipulation would then do more harm than benefit to consumers.</p> <p>The restriction on the manner of use of the trademarks is also contrary to international conventions such as the Paris Convention and TRIPS which protect an owner's right to use its trademarks.</p> <p>There is no internationally recognized provision that prohibits a company from using its company logo or trademark on product label more than once as is required under the HK Code.</p>	
<p>(b) does not contain any representation that states or suggests any health claim or nutrition claim, except those health claims and representations provided in Articles 8.5.2 to 8.5.3; and</p>	<p>Codex guidelines for use of nutrition and health claims (CAC/GL 23-1997):</p> <p><i>"1.4 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"</i></p> <p>EC directive on infant formula and follow-on formula (2006/141/EC):</p> <p><i>"6. The labeling of infant formula may bear nutrition and health claims only in the cases listed in Annex IV and in accordance with the conditions set out therein.</i></p> <p><i>(Six nutrition claims and one health claim are authorized for infant formula)"</i></p>	<p>The HK Code prohibits nutrition claims in infant formula and follow-up formula.</p> <p>Although the Codex guidelines prohibit the use of nutrition and health claims for foods for infants and young children, some countries, e.g. EU, Singapore have established mechanism of claim evaluation and authorization. Those nutrition and health claims that have been authorized by international regulatory authorities should not be prohibited.</p>	<p>Permit nutrition claim for infant formula and follow-up formula if the claim meets requirements in articles 8.5.1 (b),(c) and (d) by adopting the following instead:</p> <p>"(b) does not contain any representation that states or suggests any health claim or nutrition claim, except those nutrition claims, health claims and representations provided in accordance with Articles 8.5.1, 8.5.2 to 8.5.3"</p>
<p>(c) indicates in a clear, conspicuous</p>	<p>Not in WHO Code, nor required by other</p>	<p>This is not in alignment with</p>	<p>Delete Article 8.2.1(c)(ix)</p>

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<p>and legible manner the following particulars –</p> <p>....</p> <p>(ix) where the product is an infant formula, a declaration that the product is made in accordance with the Standard for Infant Formula and Formula for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981);</p>	<p>international regulatory authorities</p>	<p>international standards and it is not necessarily useful information to mention the infant formula is in accordance with a Codex standard.</p> <p>This statement would become completely irrelevant if HK authorities have a mandatory regulatory standard for infant formula which all infant formula have to comply with.</p>	
<p>(x) where the product is a follow-up formula, a declaration that the nutritional composition standard(s) adopted are those of the Codex or other recognised international / national authorities;</p>	<p>Not in WHO Code, nor required by other international regulatory authorities</p>	<p>This is not in alignment with international standards and it is not necessarily useful information to mention the infant formula is in accordance with a Codex standard.</p> <p>This statement would become completely irrelevant if HK authorities have a mandatory regulatory standard for infant formula which all infant formula had to comply with</p>	<p>Delete Article 8.2.1(c)(x)</p>
<p>(d) Contains the word “IMPORTANT NOTICE” in capital letters and indicates thereunder the statement “Breastfeeding is the normal means of feeding infants and young children. Breastmilk is the natural food for their healthy growth and development. Use of breastmilk substitutes may put infants and children at risk of diarrhoea and other illnesses” of not less than 2 mm in height;</p>	<p>WHO Code Article 9.2 requires labels of infant formula to include the following points:</p> <p><i>“a) the words "Important Notice" or their equivalent;</i></p> <p><i>(b) a statement of the superiority of breastfeeding;</i></p> <p><i>(c) a statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of use;</i></p> <p><i>(d) Instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation.”</i></p>	<p>The statement for “Important Notice” included in the draft HK Code originates from the Model Law, which is not in alignment with the provisions of the WHO Code or other international regulatory authorities (e.g., Codex Alimentarius).</p> <p>The wording includes several imprecise or even incorrect statements:</p> <p>(i) Breastfeeding is NOT the normal</p>	<p>Suggest to replace the important notice as follows:</p> <p>“Inappropriate storage and use of breast-milk substitute may put your baby’s health at risk”,</p> <p>or the notice should adopt the wording as used in the WHO code Article 9.2.</p> <p>Also take reference from Codex Standard: CAC/RCP 66-2008_Code of Hygienic Practice for Powdered Formula</p>

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	<p>Codex Standard for Infant Formula – Section A: Revised Standard for Infant Formula (Codex STAN 72-1981):</p> <p><i>“9.6.1 Each container label shall have a clear, conspicuous and easily readable message which includes the following points:</i></p> <p><i>a) the words "important notice" or their equivalent;</i></p> <p><i>b) the statement "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk;</i></p> <p><i>c) a statement that the product should only be used on advice of a independent health worker as to the need for its use and the proper method of use”</i></p> <p>Article 5 of CFS's guidelines on preparation of legible food label:</p> <p>“(i) Suitable font size</p> <p><i>In general, a font size of at least 1.2 mm x-height* for English letter and Chinese characters in comparable size is recommended (see example 1). However, the recommended font size may not be always practically feasible. Examples of these situations are some products with limited package size (e.g. package of total surface area less than 400 cm<sup>2</sup>) some products required to present information in addition to local laws such as those required by international standards and guidelines, infant formula and related food products that needed to provide detailed nutrition information and instruction for consumer use, imported food products that have packaging with limited spacing for affixing label with larger font size, or when the information is presented in more than one language. Moreover, a minimum font</i></p>	<p>means of feeding for young children (1-3 years).</p> <p>Although mothers may decide to continue breastfeeding after 6 months of age, it is definitely not considered the normal means of feeding older infants and even less so for young children. Hence making this a requirement does not necessarily benefit the mothers nor the older infants or young children and such a statement is also misleading.</p> <p>(ii) Stating that breast-milk is the natural food for their (infants and young children) healthy growth and development is again misleading as it is well recognized that complementary feeding is critical to ensure adequate nutritional support for older infants and young children.</p> <p>(iii) Stating that breast-milk substitutes may put infants and children at risk of diarrhea and other illnesses is too broad-brushed.</p> <p>If the guidelines for reconstitution are appropriately followed there is no risk.</p> <p>Further, the studies done in Brazil (Feachem), Ghana, India and Peru (Bahl and others) to demonstrate that the risk of diarrhea in the non-breastfeeding babies was much higher than that in the breastfeeding babies are not</p>	<p>for Infants and Young Children (Section 9.3), “When considering the wording of such information, consideration should also be given to any potential risk of caregivers being inadvertently encouraged to use inappropriate alternatives to powdered infant formula (e.g., milk powder)”.</p> <p>There is no consistency in the font size recommendation in the HK Code and the CFS guidelines. Suggest follow CFS’ guidelines.</p>

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	<p><i>size of at least 0.8 mm x-height for English letters and 1.8 mm total height for Chinese characters should be provided (see example 2). “</i></p>	<p>conclusive as “non-breastfeeding” does not necessarily mean feeding such babies with formula milk. Cow’s milk was the most common substitute for breast milk in Brazil and buffalo milk is used in India.</p> <p>Given the state of health care in Hong Kong and the wide use of infant formula prepared with boiled water, the risk of diarrhea in Hong Kong is much lower than many other countries.</p> <p>Moreover the term breast-milk substitute is not defined in the current HK Code.</p>	
<p>(e) contains the word “Warning” and indicates thereunder the following statement –</p> <p>(i) in the case of infant formula: “Before deciding to supplement or replace breastfeeding with this product, seek the advice of a health professional as to the necessity of its use. It is important for your baby’s health that you follow all preparation instructions carefully. <u>If you use a feeding bottle, your baby may refuse to feed from the breast.</u>” of not less than 1.5 mm in height;</p>	<p>Wording of “warning statement” included in the HK Code is taken from the Model Law</p>	<p>There should be more flexibility in the wording of the warning</p>	<p>Add the clause “or with similar wording” to allow the industry to have some flexibility in rephrasing the statement as needed.</p> <p>Delete “If you use a feeding bottle, your baby may refuse to feed from the breast”</p> <p>There is no consistency in the font size recommendation in the HK Code and CFS guidelines.</p> <p>Make the font size requirement the same as that stated in the CFS guidelines. (see above)</p>

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<p>(ii) in the case of follow-up formula: “Before deciding to supplement or replace breastfeeding with this product, seek the advice of a health professional as to the necessity of its use. It is important for your baby’s health that you follow all preparation instructions carefully.” of not less than 1.5 mm in height;</p>	<p>Wording of “warning statement” included in the HK code is taken from the Model Law</p>	<p>Follow-up formula is not a breast-milk substitute and as such can only complement breastfeeding, and not replace it.</p>	<p>The font size requirement should follow CFS guidelines. (see above)</p>
<p>(f) contains the following statements under the instructions for preparation of <u>formula milk</u> in powdered form, of not less than 1.5 mm in height –</p> <p>(i) “Powdered formula milk is not a sterile product and may become contaminated during preparation”;</p>	<p>WHO guidelines on safe preparation, storage and handling of powdered formula:</p> <p><i>“Powdered infant formula is not a sterile product and may be contaminated with pathogens that can cause serious illness”</i></p>		<p>Replace “formula milk” with breast-milk substitutes (please refer to Article 1 suggestions for definition).</p> <p>Make the font size requirement the same as that stated in the CFS guidelines. (see above)</p>

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<p>(ii) "It is necessary for formula milk to be prepared one feed at a time using boiled water allowed to cool to no less than 70°C; and</p>	<p>WHO's "Guidelines for the safe preparation, storage and handling of powdered infant formula" states that "It is best to make PIF fresh for each feed and to consume immediately, as reconstituted PIF provides ideal conditions for the growth of harmful bacteria. WHO therefore recommended mixing powdered infant formula at 70°C + temperature.</p>	<p>The use of 70°C water temperature for the preparation of powder formula may cause scalding of the baby and preparer.</p> <p>For practical reasons, feeds may need to be prepared in advance. In the health care or institutional settings, feeds may have to be prepared in batches and stored until required. The statement "It is necessary for formula milk to be prepared one feed at a time" in the HK Code does not reflect the practical issue considered by WHO.</p>	<p>Replace "formula milk" with breast-milk substitutes (please refer to Article 1 suggestions for definition).</p> <p>i) WHO's "Guidelines for the safe preparation, storage and handling of powdered infant formula" states that "It is best to make PIF fresh for each feed and to consume immediately, as reconstituted PIF provides ideal conditions for the growth of harmful bacteria. For practical reasons, feeds may need to be prepared in advance. In care or institutional settings, feeds may have to be prepared in batches and stored until required." The statement "It is necessary for formula milk to be prepared one feed at a time" in the draft code does not reflect the practical issue considered by WHO.</p> <p>ii) 70 degree water for follow-on formula doesn't seem necessary. WHO's "Guidelines for the safe preparation, storage and handling of powdered infant formula" states that "Powdered infant formula should be prepared with water that is no cooler than 70oC in order to kill microorganisms</p>

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			including <i>Cronobacter sakazakii</i> "
(j) specifies the source of protein contained in the <u>formula milk</u> ; and	<p>Not in WHO Code.</p> <p>Codex standard for Infant formula has similar wording:  <i>"9.1.3 The sources of protein in the product shall be clearly shown on the label."</i></p> <p>Codex standard for Follow-up formula has similar wording:  <i>"9.1.3 All sources of protein shall be clearly shown on the label in close proximity to the name of the food in descending order of proportion by weight"</i></p>		Replace "formula milk" with breast-milk substitutes (please refer to Article 1 suggestions for definition).

Draft HK Code	International/Local References	Issues	Suggestions
<p>(k) contains the information that infants should receive complementary food in addition to the formula milk from an age, as advised by an independent health worker, that is appropriate for their specific growth and development needs, and in any case from the age of over six months.</p>	<p>Not in WHO Code</p> <p>Codex standard for Infant formula has similar wording:</p> <p><i>“9.6.4 Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months. “</i></p> <p>Codex standard for Follow-up formula has similar wording:</p> <p><i>“9.5.3 Information that infants and children fed Follow-up Formula shall receive other foods in addition to the food shall appear on the label“</i></p>		<p>Replace “formula milk” with breast-milk substitutes (please refer to Article 1 suggestions for definition).</p>
<p>8.4 Labelling requirements for formula milk related products</p> <p>8.4.1 In addition to the relevant legal requirements stipulated in Toys and Children’s Products Safety Ordinance (Cap 424) and the Consumer Goods Safety Ordinance (Cap. 456), the container or package of a formula milk related products or the label affixed thereto should –</p> <p>(b) where the product is a feeding bottle or a teat, indicate in a clear, conspicuous and easily readable manner the following particulars –</p> <p>(i) the word “IMPORTANT NOTICE” in capital letters and indicated thereunder the statement</p>	<p>No reference found</p>	<p>Please refer to our comments above in relation to Article 8.2.1(d) regarding the statements required in the “IMPORTANT NOTICE” provision.</p>	<p>Suggest to replace the important notice as follows:</p> <p>“Inappropriate storage and use of breast-milk substitute may put your baby’s health at risk”,</p> <p>or the notice should adopt the wording as used in the WHO code Article 9.2.</p> <p>Also take reference from Codex Standard: CAC/RCP 66-2008_Code of Hygienic Practice for Powdered Formula for Infants and Young Children (Section 9.3), “When considering the wording of such information, consideration should also be given to any</p>

Draft HK Code	International/Local References	Issues	Suggestions
<p>“Breastfeeding is the normal means of feeding infants and young children. Breastmilk is the natural food for their healthy growth and development. Use of breastmilk substitutes may put infants and children at risk of diarrhoea and other illnesses” of not less than 2 mm in height;</p> <p>(ii) the statement “Warning: It is important for your baby’s health that you follow cleaning and sterilization instructions very carefully. If you use a feeding bottle, your baby may no longer want to feed from the breast” of not less than 2 mm in height;</p> <p>(iii) instructions for cleaning and sterilization in words and graphics;</p> <p>(iv) a warning that infants should not be left to self-feed at all and children should not be left to self-feed for long periods of time because extended contact with sweetened liquids, including formula milk, may cause severe tooth decay; and</p> <p>(v) the name and address of the manufacturer or distributor</p>			<p>potential risk of caregivers being inadvertently encouraged to use inappropriate alternatives to powdered infant formula (e.g., milk powder)”.</p> <p>Replace “formula milk” with breast-milk substitutes (please refer to Article 1 suggestions for definition).</p>
<p>8.5 Representations allowed to appear on the container or label</p> <p>8.5.1 Nutrition claim should not appear on a designated product, except that a nutrition claim meeting the following conditions may be present on the container or labeling</p>	<p>Codex guidelines for use of nutrition and health claims ( CAC/GL 23-1997):</p> <p><i>“1.4 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”</i></p>	<p>The HK Code prohibits nutrition claims for infant formula and follow-up formula but not for food products for infants and young children.</p> <p>Although the Codex guidelines prohibit the use of nutrition and health claims for foods for infants</p>	<p>Change Article 8.5.1 as follows:</p> <p>“8.5.1 Nutrition claim should not appear on a designated product, except that a nutrition claim meeting the following conditions may be present on the container or labeling of</p>

Draft HK Code	International/Local References	Issues	Suggestions
<p>of food products for infants and young children, unless prohibited by existing law –</p> <p>(a) the claim is related to sodium, sugars, vitamins and minerals;</p> <p>(b) the claim is permitted by a recognised international / national authority;</p> <p>(c) the relevant claim condition(s) set by the concerned recognised international/ national authority is complied with; and</p> <p>(d) the absolute amount of the nutrient claimed either on labels or in advertisement of the designated product must be declared on the container or label.</p>	<p>EC directive on infant formula and follow-on formula (2006/141/EC):</p> <p><i>“6. The labeling of infant formula may bear nutrition and health claims only in the cases listed in Annex IV and in accordance with the conditions set out therein. “</i></p> <p>(Six nutrition claims and one health claim are authorized for infant formula)</p>	<p>and young children, some countries, e.g. EU, Singapore have established mechanisms of claim evaluation and authorization. Those nutrition and health claims authorized by international regulatory authorities should not be prohibited.</p>	<p>infant formula, follow-up formula and food products for infants and young children, unless prohibited by existing law –</p> <p>(a) In the case of food products for infants and young children the claim is related to sodium, sugars, vitamins and minerals;</p> <p>(b) the claim is permitted by a recognised international / national authority;</p> <p>(c) the relevant claim condition(s) set by the concerned recognised international/ national authority is complied with; and</p> <p>(d) the absolute amount of the nutrient claimed either on labels or in advertisement of the designated product must be declared on the container or label.”</p>
<p>8.5.2 Health claim should not appear on a designated product, except that a health claim meeting the following conditions may be present on the container or labeling of follow-up formula and food products for infants and young children, unless prohibited by existing law –</p> <p>a) the claim is permitted by recognised international / national authority;</p>	<p>Codex guidelines for use of nutrition and health claims (CAC/GL 23-1997):</p> <p><i>“1.4 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“</i></p> <p>EC directive on infant formula and follow-on formula (2006/141/EC):</p> <p><i>“6. The labeling of infant formula may bear nutrition and health claims only in the cases listed</i></p>	<p>Please refer to our comments to the preceding article above.</p>	<p>Change Article 8.5.2 as follows:</p> <p>“8.5.2 Health claim should not appear on a designated product, except that a health claim meeting the following conditions may be present on the container or labeling of infant formula, follow-up formula and food products for infants and young children, unless prohibited by existing</p>

Draft HK Code	International/Local References	Issues	Suggestions
<p>(b) the claim must be based on current relevant scientific substantiation and the level of proof must be sufficient to substantiate the type of the effect claimed and the relationship with health as recognised by generally accepted scientific review of the data;</p> <p>(c) the relevant claim condition(s) and the exact claim statement set by the concerned recognised international / national authority is complied with; and</p> <p>(d) the absolute amount of the nutrient claimed either on the labels or in the advertisement of the designated product must be declared on the container or label.</p>	<p><i>in Annex IV and in accordance with the conditions set out therein.</i> “</p> <p>(Six nutrition claims and one health claim are authorized for infant formula)</p>		<p>law –</p> <p>a) the claim is permitted by recognised international / national authority;</p> <p>(b) the claim must be based on current relevant scientific substantiation and the level of proof must be sufficient to substantiate the type of the effect claimed and the relationship with health as recognised by generally accepted scientific review of the data;</p> <p>(c) the relevant claim condition(s) and the exact claim statement set by the concerned recognised international / national authority is complied with; and</p> <p>(d) the absolute amount of the nutrient claimed either on the labels or in the advertisement of the designated product must be declared on the container or label.”</p>
<p>8.5.3 The following representations are allowed on the container or label of <u>formula milk</u> or food products for infants and young children –</p> <p>Table of allowed “Representation and Examples”</p>	<p>Under the CFS guidelines on nutrition labeling and nutrition claims, the following would not be considered a nutrition claim –</p> <ol style="list-style-type: none"> <li>i. Mentioning of any nutrient content in a list of ingredients;</li> <li>ii. Any quantitative or qualitative declaration of any nutrient content as specified in the labeling</li> </ol>		<p>Replace “formula milk” with breast-milk substitutes (please refer to Article 1 suggestions for definition).</p>

Draft HK Code	International/Local References	Issues	Suggestions
	<p>requirements under section 2(4E)(a) of Schedule 3 of the Food and Drugs (Composition and Labeling) Regulations [Note: As such, “Does not contain gluten”, “Lactose free” and similar presentations are not considered as nutrition claim.]</p> <p>iii. Any quantitative or qualitative declaration of energy value or any nutrient content as required by the law;</p> <p>iv. Any quantitative declaration of energy value or any nutrient content contained in a prepackaged food, provided that the declaration is expressed in (a) actual amount (e.g. “650 mg omega-3 per serving”)</p>		

### **Article 9: Quality Standards:**

#### **General comments:**

#### International/Local References

Product quality standards define nutritional composition and food safety criteria. The Codex Alimentarius stipulates the following sections relating to quality and safety:

- Scope
- Definitions and description
- Essential composition and quality factors
- Food additives
- Contaminants
- Hygiene
- Methods of analysis and sampling

The European Union, US Code of Federal Regulations and Mainland China lay down similar provisions for quality and safety.

### Issues:

The nutritional and safety standards of formula and foods for infants and young children are extremely important and utmost attention should be given. Attempting to regulate through the voluntary HK code instead of mandatory legislation is therefore inappropriate.

### Suggestions:

Product quality standards that define nutritional composition and food safety criteria should be mandatory and set out in a regulation or law.

If the nutritional composition and food safety criteria are to be kept in the HK Code, then for Article 9.1.1, the following sentence should be added at the end - "or any other relevant quality standard(s) on nutritional composition and food additive established by recognized international authorities or national authorities, provided that following such standard(s) will not pose public health risk to the local population" in line with Article 9.2.1 of the HK Code.

Draft HK Code	International/Local References	Issues	Suggestions
<p>9.1 Quality standards of infant formula</p> <p>9.1.1 A manufacturer or distributor should not offer for sale or sell infant formula unless the products are formulated industrially in accordance with: –</p> <p>(a) Standard for Infant Formula and Formula for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981);</p> <p>(b) General Standard for Food Additives (CODEX STAN 192-1995); and</p> <p>(c) Code of Hygienic Practice for Powdered Formula for Infants and Young Children (CAC/RCP 66-2008).</p>	<p>WHO Code, Article 10 Quality:</p> <p><i>"10.1 The quality of products is an essential element for the protection of the health of infants and therefore should be of a high recognized standard.</i></p> <p><i>10.2 Food products within the scope of this Code should, when sold or otherwise distributed, meet applicable standards recommended by the Codex Alimentarius Commission and also the Codex Code of Hygienic Practice for Foods for Infants and Children. "</i></p> <p>Standard for Infant Formula and Formula for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981), Section B:</p> <p><i>"3.1.3, except for the compositional provisions which must be modified to meet the special nutritional requirements arising from the disease(s), disorder(s) or medical condition(s) for whose dietary management the product is specifically formulated, labelled and presented. "</i></p>	<p>The wording in the HK Code relating to the criteria which infant formula should comply with should fully reflect the international regulatory authorities (e.g., --Codex Alimentarius, EC, US FDA).</p> <p>The nutritional and safety standards of formula and foods for infants and young children are extremely important and should be paid the utmost attention. It is too risky for infants and young children in Hong Kong if the standards are set in a voluntary code.</p> <p>The term "Quality standards" is not used by other regulatory authorities. It would be more appropriate to elaborate in further details the requirements for composition and safety for each of the specific infant and child nutrition products under consideration in the HK Code.</p>	<p>Adopt Article 10 of the WHO Code instead.</p> <p>In addition to the Codex standards, other internationally recognized standards, e.g. EU, US, A/N should be also included.</p>

Draft HK Code	International/Local References	Issues	Suggestions
	<p>Please also refer to the Commission Directive 1999/21/EC on dietary foods for special medical purposes, and US FDA regulation on " Exempt formula" as defined in Code of Federal Regulations Title 21</p>	<p>For formula for special medical purposes intended for infants, the Codex Standards (referred to by the HK Code) do not define how nutrients can be modified and which additional food additive can be used. This will put lots of existing HK specialty products at risk of non-compliance if regulations developed by EU, US and other international recognized regulatory authorities are not referred to.</p>	
<p>9.2 Quality standards of follow-up formula and food products for infants and young children</p> <p>9.2.1 A manufacturer or distributor should not offer for sale or sell follow-up formula and food products for infants and young children unless the products are formulated industrially in accordance with: –</p> <p>(a) the relevant quality standard(s) established by Codex below:</p> <p>(i) Standard for Follow-up formula (CODEX STAN 156-1987);</p> <p>(ii) Standard for Canned Baby Foods (CODEX STAN 73-1981);</p> <p>(iii) Standard for Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981);</p> <p>(iv) General Standard for Food Additives (CODEX STAN 192-1995);</p>	<p>Relevant Codex quality standards are as follows:</p> <p>(i) Standard for Follow-up formula (CODEX STAN 156-1987);</p> <p>(ii) Standard for Canned Baby Foods (CODEX STAN 73-1981);</p> <p>(iii) Standard for Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981);</p> <p>(iv) General Standard for Food Additives (CODEX STAN 192-1995);</p> <p>(v) Code of Hygienic Practice for Powdered Formula for Infants and Young Children (CAC/RCP 66-2008);</p> <p>(vi) Guidelines for Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 08-1991)</p>	<p>The Codex standards referred to in this article are not enough to cover all aspects of quality standard for infant formula.</p>	<p>Please see our suggestions for the preceding article</p>

Draft HK Code	International/Local References	Issues	Suggestions
<p>(v) Code of Hygienic Practice for Powdered Formula for Infants and Young Children (CAC/RCP 66-2008);</p> <p>(vi) Guidelines for Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 08-1991); or</p> <p>(b) any other relevant quality standard(s) on nutritional composition established by recognised international authorities or national authorities, provided that following such standard(s) will not pose public health risk to the local population.</p>			

**Article 10: Implementation and Monitoring:**

**General comments:**

Given that the HK Code is to be voluntarily adopted and self-enforced by manufacturers and distributors in Hong Kong, we reiterate our position that the provisions on labeling and quality standards should be handled separately in mandatory legislation instead of this HK Code.

We further implore the government to take into account the voice of the industry when considering revisions to the HK Code.