

Consultation Document

Legislative Proposals Relating to Formula Products and Foods Intended for Infants and Young Children under the Age of 36 Months in Hong Kong

November 2012



食物及衛生局
Food and Health Bureau



食物環境衛生署
Food and Environmental
Hygiene Department



食物安全中心
Centre for Food Safety

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Food and Health Bureau

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CHAPTER 1 INTRODUCTION

1.1 The Government is committed to protecting the health of infants and young children. Infants and young children must obtain optimal nutrition from their diet to grow and stay healthy. Nutrition is essential for growth, tissue repair and maintenance of good health. The superiority of breastfeeding in ensuring physical and psychosocial health and wellbeing of mother and child as well as the important impacts of early nutrition on long-term health are widely recognised.

1.2 Food label enables consumers to obtain specific information on individual food products, including nutrition information. Providing nutrition information on food labels is an important public health tool to promote a balanced diet. The Nutrition Labelling Scheme (the Scheme) for prepackaged food products under the Food and Drugs (Composition and Labelling) Regulations (Cap. 132W) came into force in July 2010. The Scheme covers nutrition labelling¹ and nutrition claims (which includes nutrient content claim², nutrient comparative claim³ and nutrient function claim⁴). However, the Scheme does not cover formula products and foods intended for infants and young children under the age of 36 months as the Codex Alimentarius Commission (Codex) has established different standards for these foods.

1.3 Section 54 of the Public Health and Municipal Services Ordinance (Cap. 132) stipulates that all food for sale must be fit for human consumption. This covers all food including formula products and foods intended for infants and young children under the age of 36 months. However, there are no specific provisions in Cap. 132 governing the requirements and standards of nutritional composition for formula products and foods intended for infants and young children under the age

¹ Nutrition labelling refers to the listing of the nutrient content of a food in a standardised manner. When nutrition labelling is applied, content of energy and the seven core nutrients (protein, carbohydrates, total fat, saturated fat, trans fat, sodium and sugars) or what is commonly known as “1+7”, and claimed nutrients are required to be affixed on the nutrition label.

² A nutrient content claim describes the energy value or the level of a nutrient contained in a food, e.g. “High calcium”; “Low fat”; “Sugar-free”.

³ A nutrient comparative claim compares the energy value or the nutrient levels of two or more different versions of the same food or similar food, e.g. “Reduced fat – 25% less than the regular product of the same brand”.

⁴ A nutrient function claim describes the physiological role of a nutrient in growth, development and normal functions of the body, e.g. “Calcium aids in the development of strong bones and teeth”.

of 36 months.

1.4 In the case of infant formula, where breastfeeding is not feasible, it is the only processed foodstuff which wholly fulfils the nutritional requirements of infants during the first months of life until the introduction of appropriate complementary feeding⁵. The finding of iodine deficiency in some infant formulae (paragraph 3.5 below refers) underlines the need to regulate such formulae urgently. In order to safeguard the health of infants, it is of paramount importance to ensure that infant formula has the appropriate composition and is nutritionally adequate. To assist parents to make informed food choices, it is also important to provide nutrition information on labels of foods intended for infants and young children.

1.5 To protect public health, this consultation document puts forward a package of legislative proposals relating to formula products and foods intended for infants and young children under the age of 36 months. We welcome your comments on the proposals therein.

⁵ Complementary feeding is normally introduced at 6 months of age.

CHAPTER 2 THE INTERNATIONAL SCENE

2.1 The basic requirements governing the standards of formula products and foods intended for infants and young children as agreed by the international community are stipulated in the relevant standards developed by Codex.

Codex Alimentarius Commission (Codex)

2.2 Codex was established in 1963 by the Food and Agriculture Organization of the United Nations and World Health Organization (WHO) to develop foods standards, guidelines and related texts such as codes of practice for protecting health of consumers and ensuring fair trade practices in the food trade. At present, membership of Codex comprises over 180 countries.

2.3 Codex has developed four separate standards covering specific types of formula products and foods intended for infants and young children aged 36 months or younger -

- (a) Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981);
- (b) Codex Standard for Follow-up Formula (CODEX STAN 156-1987);
- (c) Codex Standard for Canned Baby Foods (CODEX STAN 73-1981); and
- (d) Codex Standard for Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981).

In addition, labelling and claims of other foods for special dietary uses and special medical purposes, including those for infants and young children, are covered by two other standards –

- (a) General Standard for the Labelling of and Claims for

Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985); and

- (b) Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991).

Codex Classification of Formula Products and Foods

2.4 Codex defines the term “infant” as a person not more than 12 months of age. The term “young children” means persons from the age of more than 12 months up to the age of three years (36 months). Four major general food entities are included in these Codex standards relevant to infants and young children under the age of 36 months –

- (a) *Infant Formula*

Codex defines infant formula as 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*. 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.

- (b) *Follow-up Formula*

Codex Standard for Follow-up Formula defines follow-up formula as *food intended for use as a liquid part of the weaning diet for the infant from the 6th months on and for young children*.

- (c) *Processed cereal-based food*

Codex defines processed cereal-based food as food 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*. Processed cereal-based foods are prepared primarily from one or more milled cereals, which should constitute at least 25% of the final mixture on a dry weight basis. Codex further

classifies them into 4 categories, namely, (i) *cereal to be prepared with milk/nutritious liquids*, (ii) *cereal with an added high protein food*, (iii) *uncooked pasta*, and (iv) *rusk and biscuits*, with specific compositional requirements separately defined for each of them.

(d) *Baby food*

Codex Standard for Canned Baby Foods defines baby food as *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*. Baby foods in Codex glossary may be either in ready-to-eat form or in dry form requiring constitution with water only.

Nutritional Composition Requirement for Infant Formula and Follow-up Formula

2.5 Codex has laid down detailed nutritional composition requirements for infant formula and follow-up formula in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* and the *Codex Standard for Follow-up Formula* respectively. Codex has provided specification on the essential composition of these formula products. The main requirements are related to energy and 33 nutrients for infant formula, and energy and 25 nutrients for follow-up formula. A minimum permitted level is set for all nutrients making up the essential composition defined but maximum levels are only set for some nutrients (Annex I). Apart from the main requirements on minimum and/or maximum nutrient contents, detailed requirements such as the proportion of selected nutrients or their constituents have also been stipulated in the Codex standards.

Nutritional Composition Requirement for Processed Cereal-based Foods for Infants and Young Children and Canned Baby Foods

2.6 The nutritional composition requirements for different categories of processed cereal-based foods and canned baby foods are more heterogeneous. Of note is the consistent requirement that the sodium content in these foods is not allowed to exceed, on a ready-to-eat basis,

100mg/100kcal for processed cereal-based foods and 200mg/100g for canned baby foods. The detailed requirements are shown in Annex II.

Nutrition Labelling Requirement

2.7 Codex requires formula products and foods intended for infants and young children under the age of 36 months to declare their nutrient contents on their labels. Detailed requirements of different formula products and foods have been included in the respective Codex standards. The general principle is that, if a nutritional composition requirement has been defined in the relevant standard document, the nutrient content in the food will usually be required to be listed on the label. Annex III shows a summary of the key requirements.

Nutrition Claims and Health Claims

2.8 Codex defines a nutrition claim as any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals. Codex also defines a health claim as any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Health claims, in Codex context, include nutrient function claims, other function claims⁶ and reduction of disease risk claims⁷.

2.9 Codex recommends that nutrition claims should be consistent with national nutrition policy and only nutrition claims that support national nutrition policy should be allowed. Similarly, health claims should be consistent with national health policy, including nutrition policy, and support such policies where applicable. According to Codex principle, nutrition and health claims shall not be permitted for formula

⁶ Other function claims concern specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health, e.g. “Substance A (naming the effect of substance A on improving or modifying a physiological function or biological activity associated with health). Food Y contains x grams of substance A.”

⁷ Claims relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition, e.g. “A healthful diet low in nutrient or substance A may reduce the risk of disease D. Food X is low in nutrient or substance A.”

products and foods intended for infants and young children except where specifically provided for in the relevant national legislation.

Overseas requirements

2.10 It is noted that in jurisdictions such as Singapore, United States, Australia, New Zealand, Mainland China and the European Union, infant formula is regulated in similar manner. However, nutritional composition and labelling of follow-up formula (also known as “follow-on formula” in Australia, New Zealand and European Union) and other foods intended for infants and young children under the age of 36 months have been adapted to different levels as compared with Codex requirements (Table 1). Detailed information on the regulatory approaches adopted in different jurisdictions can be found in Annex IV.

Table 1: Level of Adaptation of Codex Framework in Major Jurisdictions

Jurisdiction/Organization	Formula products	Foods for below 36 months
Codex	Age range: 0 – 36 months <ul style="list-style-type: none"> - Infant formula (0 - complementary feeding)(<12 months) - Follow-up formula (6-36 months) 	Age range: 6 – 36 months <ul style="list-style-type: none"> - Processed cereal-based foods (6 – 36 months) - Canned baby foods (weaning – 36 months)
Singapore	Age range: 0 – 12 months <ul style="list-style-type: none"> - Infant formula (0 or above) 	Age range: 6-12 months <ul style="list-style-type: none"> - Infants Foods (6 – 12 months) [only safety control specified]
United States	Age range: 0 - 12 months <ul style="list-style-type: none"> - Infant formula (0-12 months) 	Not defined (covered as general food)
Australia and New Zealand	Age range: 0 – 12 months <ul style="list-style-type: none"> - Infant formula (0 – 4 to 6 months) - Follow-on formula (6 – 12 months) 	Age range: 4 – 12 months <ul style="list-style-type: none"> - Cereal-based foods (4 – 12 months) - Non-cereal-based foods (4 – 12 months)
Mainland China	Age range: 0 - 36 months <ul style="list-style-type: none"> - Infant formula (0-6 months) - Older infants and young children formula (6-36 months) 	Age range: 6 – 36 months <ul style="list-style-type: none"> - Cereal-based complementary foods for infants and young children (6 – 36 months) - Canned complementary foods for infants and young children (6 – 36 months)
European Union	Age range: 0 – 12 months <ul style="list-style-type: none"> - Infant formula (0- complementary feeding) (<12 months) - Follow-on formula (complementary feeding- 12 months) 	Age range: 4 – 36 months <ul style="list-style-type: none"> - Processed Cereal-based foods (4 – 36 months) - Baby foods (4 – 36 months)

CHAPTER 3 SITUATION IN HONG KONG

3.1 Hong Kong is characterised by the dominance of imported food as well as a mixture of population from different parts of the world.

Current legislation

3.2 Section 54 of the Public Health and Municipal Services Ordinance (Cap. 132) stipulates that all food for sale must be fit for human consumption. This covers all food including formula products and foods intended for infants and young children under the age of 36 months. However, there are no specific provisions in Cap. 132 governing the requirements and standards for nutritional composition for formula products and foods intended for infants and young children under the age of 36 months.

3.3 As for nutrition labelling, the existing Food and Drugs (Composition and Labelling) Regulations (Cap. 132W) require prepackaged foods to provide nutrition information on their labels but do not cover formula products and foods intended for infants and young children under the age of 36 months. Although many of these products sold in Hong Kong carry nutrition labels, the information presented and the formats used are not consistent. Hence consumers may find the information provided on the nutrition labels difficult to comprehend, inconsistent and in some cases misleading.

3.4 Under Section 61 of Cap. 132, any person who sells or displays for sale any food which is presented with a label that falsely describes the food, or is calculated to mislead as to its nature, substance or quality, shall be guilty of an offence. However, in order to invoke prosecution under Section 61 of Cap. 132, there must be sufficient evidence to prove that the label is intentionally misleading or false which might be difficult in some circumstances.

Local market situation

Nutritional composition and labelling of infant formula

3.5 At present, there are more than 120 products of infant formula and follow-up formula available in Hong Kong imported from various places including the United States, Europe, Australia and Japan. A survey conducted by the Centre for Food Safety from May to September 2012 covering 63 infant formula products revealed that seven products were found to contain iodine at a level not only lower than that prescribed by Codex but also well below the intake level recommended by WHO, taking into account the feeding instructions, average infant growth parameters, as well as iodine content in the boiled tap water used for constituting the infant formula. This may affect the functioning of the thyroid gland. If the normal functions of the thyroid gland are significantly affected, there may be potential impact on the brain development of infants. The finding of iodine deficiency in some infant formulae underlines the need to regulate such formulae urgently.

Nutrition information on foods intended for infants and young children under the age of 36 months

3.6 Prepackaged foods from different countries provide an important source of nutrient and energy for infants and young children under the age of 36 months in Hong Kong. In a study reported jointly by the Centre for Food Safety and the Consumer Council in April 2012, more than 100 popular prepackaged food samples intended principally for infants and young children under the age of 36 months, and possibly falling within the Codex defined categories of processed cereal-based foods and canned baby foods, were collected for an assessment.

3.7 It was found that 68% (80/117) of the samples provided complete nutrition label in Chinese or English or both. Among them, 99% (79/80) presented the content of energy as well as the three major macronutrients namely protein, total fat and carbohydrate. Besides, among 46 samples of processed cereal-based foods surveyed, 59% (27/46) listed the content of sodium contained in the foods in accordance with the Codex requirement.

3.8 As for claims, 28% of the total samples were found to bear one or more nutrition or health claims in Chinese or English. Some of those claims are related to the function of nutrients or food components, such as vitamin E and immunity, choline and eye development, probiotic and immunity as well as probiotic and allergy that do not have adequate internationally recognized evidence for scientific substantiation.

Hong Kong Code

3.9 The Department of Health has launched a public consultation on the draft “Hong Kong Code of Marketing and Quality of Formula Milk and Related Products, and Food Products for Infants and Young Children” (Hong Kong Code) with reference to the International Code of Marketing of Breastmilk Substitutes. The Hong Kong Code aims to contribute to the provision of safe and adequate nutrition for infants and young children by protecting breastfeeding and ensuring the proper use of milk formula 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 practices. It provides guidelines to manufacturers and distributors, as well as health workers and health care facilities. Provisions on nutritional composition and labelling, including the use of nutrition and health claims, are specified in the Hong Kong Code. The Hong Kong Code is voluntary in nature and traders will be encouraged to follow the Hong Kong Code when it is implemented. Before the enactment of the legislative proposals in this document, the relevant articles of the Hong Kong Code will serve as guidelines to manufacturers and distributors of formula products and foods for infants and young children with respect to nutrition labelling and composition of these products.

CHAPTER 4 PROPOSALS

Codex-based Approach

4.1 We aim to enhance the local legislative control on the nutritional composition and labelling of formula products and foods intended for infants and young children under the age of 36 months. When formulating these legislative proposals, we have adopted the Codex principles, taking into account the international practices. This will ensure that our legislative proposals are on par with the international standards. Since most formula products and foods intended for infants and young children under the age of 36 months in the local market are imported from overseas, we believe that such approach will strike a balance between the protection of health of infants and young children and the need to maintain stable supply of formula products and foods for infants and young children.

Legislative Proposals

4.2 In light of the finding of iodine deficiency in certain infant formula products, and the urgency to protect the health of infants and young children, we propose that priority should be accorded to the introduction of legislation governing formula products and foods intended for infants and young children under the age of 36 months in the following areas -

- (a) Codex requirement on nutritional composition (i.e. energy and 33 nutrients as specified by Codex) for infant formula before complementary feeding is introduced;
- (b) nutrition labelling requirement for infant formula before complementary feeding is introduced, by listing the energy and 33 nutrients which are required to be present in infant formula as specified by Codex;
- (c) nutrition labelling requirement for follow-up formula intended for infants and young children under the age of 36 months, by listing the energy and 25 nutrients as specified by

Codex; and

- (d) nutrition labelling requirement for foods intended for infants and young children under the age of 36 months, by listing the energy and nutrients required for such foods as specified by Codex.

Nutritional Composition Requirement

4.3 Before the introduction of complementary feeding, infants will need to rely solely on breast-milk and/or infant formula for normal development and growth. To protect the health of infants, we therefore propose to stipulate in the law that the Codex requirement on energy and 33 nutrients for infant formula must be followed. In particular, the level of energy and each nutrient must fall within the range specified by Codex.

4.4. We have not proposed to impose nutritional composition requirement on follow-up formula and foods intended for infants and young children under the age of 36 months for the following reasons -

- (a) infants and young children who have begun complementary feeding are no longer solely dependent on milk formulae or the abovementioned foods for infants and young children for nutrients;
- (b) conventional child statistics has indicated satisfactory child growth and there is no data to reflect specific nutritional deficiencies;
- (c) Codex composition standard for follow-up formula was set over 20 years ago and follow-up formula has undergone significant development over the years. Codex has just started the process of reviewing this set of standard; and
- (d) balanced nutrition for growth of children should be achieved by parental and caregiver education on the appropriate food intake.

Nutrition Labelling Requirement

4.5 We propose to impose nutrition labelling requirement on all formula products and foods intended for infants and young children under the age of 36 months.

4.6 As for the nutrients to be covered, for infant formula products, we propose to require labelling of energy and 33 nutrients (“1+33”) (i.e. those nutrients on which nutritional composition requirement has been set by Codex).

4.7 For follow-up formula, we propose to require labelling of energy and 25 nutrients (“1+25”) as required by Codex.

4.8 For foods intended for infants and young children under the age of 36 months, we propose to prescribe labelling requirement following the Codex requirements as stated in Table 2 -

Table 2 Labelling requirement for foods intended for infants and young children under the age of 36 months

Food category	Expression	Energy	Protein, fat and carbohydrate	Other nutrients
Cereal-based foods				
(a) Cereal to be prepared with milk or nutritious liquid	per 100g or per 100ml as sold; <u>where appropriate</u> , also per serving as consumed	in kcal and kJ	in g	1 vitamin (B1) and 1 mineral (sodium) (vitamin A and D if added)
(b) Cereal with an added high protein food	per 100g or per 100ml as sold; <u>where appropriate</u> , also per serving as consumed	in kcal and kJ	in g	3 vitamins (A, B1 and D) and 2 minerals (sodium and calcium)
(c) Pasta	per 100g or per 100ml as sold; <u>where appropriate</u> , also per serving as consumed	in kcal and kJ	in g	1 vitamin (B1) and 1 mineral (sodium) (vitamin A and D if added)

Food category	Expression	Energy	Protein, fat and carbohydrate	Other nutrients
(d) Rusk and biscuit	per 100g or per 100ml as sold; <u>where appropriate</u> , also per serving as consumed	in kcal and kJ	in g	1 vitamin (B1) and 1 mineral (sodium) (calcium if milk is added) (vitamin A and D if added)
Canned baby foods	per 100g as sold <u>as well as per serving as consumed</u>	in kcal and/or kJ	in g	if added
Other baby foods	per 100g or per 100ml as sold; <u>where appropriate</u> , also per serving as consumed	in kcal and kJ	in g	(specific nutrients or other components which provide the characterizing essential feature of the food)

If the above food is for special medical purposes which is for the dietary management of patients and to be used only under medical supervision, requirements in Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) should be followed. For these foods, the amounts of vitamins and essential minerals should also be labelled.

Rationale

4.9 For infant formula, labelling of energy and 33 nutrients would declare the fulfilment of the nutritional composition requirement. This would ensure that infant formula for sale in Hong Kong has the appropriate composition and is nutritionally adequate, and that consumers are correctly informed about this in respect of each product through the label.

4.10 For follow-up formula and foods intended for infants and young children under the age of 36 months, the proposed labelling requirement would help parents and caretakers make informed choice. This is in line with the Nutrition Labelling Scheme.

Timeframe of Implementation

4.11 To allow sufficient time for the trade to prepare for the changes and the necessary laboratory equipment and techniques on the testing of the relevant nutrients to be in place, we propose to allow a suitable grace period before implementing the legislation on nutritional composition and nutrition labelling of these products. We will take into account the views received during the consultation before finalising the length of the grace period.

CHAPTER 5 OTHER ISSUES

Labelling of sodium content in non-cereal-based foods for infants and young children

5.1 Sodium is necessary for the proper functioning of the body. For example, sodium is required for nerve transmission and muscle contraction. However, prolonged excessive intake of sodium may increase the risk of developing high blood pressure. We therefore need to consider whether there should be any additional requirement on labelling the sodium content in non-cereal-based foods for infants and young children.

5.2 Breastmilk is low in sodium. However, sodium intake can drastically increase when complementary foods are introduced. Good complementary foods are preferably not salty.⁸ A WHO publication related to complementary feeding mentioned that the relationship between high sodium intake and hypertension had been proved experimentally in rats. The experimental data showed that sensitive rats with high sodium intake only during the first six weeks of life would still develop hypertension one year later. Although there is no data to show that high sodium intake by humans at early age would lead to the same consequences later in life, it has been suggested that the taste for salt may be established with the introduction of foods other than breastmilk, and the maintenance of this habit may in turn have a cumulative effect that results in ill health many years later.⁹

5.3 Codex does not have mandatory labelling requirement on sodium in all non-cereal-based foods for infants and young children under the age of 36 months. If we were to impose such a requirement, we would have to ensure that we would not be challenged at the World Trade Organization for setting up a trade barrier. A review of labelling practice for non-cereal-based foods for infants and young children under the age of 36 months reveals, however, that labelling of sodium content is quite common in overseas countries (United States, Australia/New Zealand and European Union countries). Table 3 shows the nutritional labelling

⁸ http://whqlibdoc.who.int/publications/2009/9789241597494_eng.pdf

⁹ [http://whqlibdoc.who.int/bulletin/1989/Vol67-Supp/bulletin_1989_67\(supp\)_4.pdf](http://whqlibdoc.who.int/bulletin/1989/Vol67-Supp/bulletin_1989_67(supp)_4.pdf)

requirement in food for infants and young children (other than cereal-based foods) in the reviewed jurisdictions. We would welcome views on this issue.

Table 3 Labelling requirement on foods for infants and young children (other than processed cereal-based food) by Codex and some jurisdictions

Jurisdiction/ Organization	Food category	Nutrition labelling requirement
Codex	<i>Canned baby food</i>	Energy + 3 macronutrients (protein, carbohydrate, fat) (+ added vitamins/minerals)
Singapore	<i>Infants' food</i>	no specific labelling requirement for <i>infants' food</i> mentioned (nutrition labelling requirement for general food if claim is made: energy, 3 macronutrients and claimed nutrients)
United States	foods intended for children < 2 years	Energy + 3 macronutrients + sodium + sugars, dietary fibre, trans fat; % daily value of protein, vitamin A, vitamin C, calcium and iron
	foods intended for children < 4 years	Energy + 3 macronutrients + sodium + sugars, dietary fibre, sat fat, trans fat, cholesterol; % daily value of protein, vitamin A, vitamin C, calcium and iron
Australia and New Zealand	<i>Foods for infants</i> (non-cereal based foods)	Energy + 3 macronutrients + sodium + sugars
Mainland China	<i>Canned complementary foods for infants and young children</i>	Energy + 3 macronutrients (+ vitamins/minerals that are characteristic of the food for special dietary purpose)
European Union	<i>Baby food</i> (other than processed cereal-based food)	Energy + 3 macronutrients + sodium + vitamin A, vitamin C, vitamin D (+ added vitamins/minerals)

Regulation on Claims

5.4 As for the claims, we propose to explore different regulatory options at a later stage in the coming year.

Rationale

5.5 Claims made about the nature, content, and functions of food in relation to their nutrition and health effects have been widely used in various forms in the food world. While some people consider claims useful for consumers, others are skeptical about any possible exaggeration or even misleading statements or representations made for the mere purpose of boosting sales. Regulators across the world are confronted with questions like how to define food claims, and how to strike a balance among competing concerns such as consumers' right to receive accurate information on the one hand, and the industry's right to promote their products on the other. How to tackle claims now when their validity or authenticity can only be verified in the medium to long term is another intriguing question.

5.6 Statutory requirements on nutrition and health claims with varying emphasis have been introduced in Singapore, Australia, and New Zealand, as well as in EU countries and the United States. Some have set up formal mechanisms to review individual food claims, while others have defined positive lists of claims for different food categories or nutrients. To achieve that, overseas experiences suggest that the food authority will have to establish a pre-evaluated list of permitted claims, and develop a mechanism to evaluate requests for including new claims onto the list. In so doing, we need to address the technical complexity involved in screening requests for new claims by applying evidence-based scientific evaluation. This requires time for more in-depth research, in particular, with reference to overseas experience.

5.7 At present, there is still lack of international consensus on the regulation of claims. Overseas experiences suggest that regulation of claims require a careful balance between the protection of public health, the right-to-know of the public, and the food choice, and that it may take considerable time and effort before a consensus among various stakeholders can be reached.

5.8 In view of the complexity and controversy on issues related to regulation of claims, this will entail a much longer lead time before we could finalise the proposals. To avoid delay in the more urgent task of

regulating the nutritional composition of infant formulae and nutrition labelling of formula products and foods intended for infants and young children under the age of 36 months, we propose to tackle the issue of regulating claims at a later stage in the coming year.

5.9 That said, we have already started to examine various regulatory options for claims. We have organised a symposium and a consultation meeting with experts from overseas and the Mainland in October 2012 to seek their views on regulation of claims. We will take into account the international practices as well as the current situation in Hong Kong in mapping out the way forward. In the meantime, as the Hong Kong Code will include provisions on claims, traders will be encouraged to comply with the Hong Kong Code upon its implementation when they make claims on formula products and foods intended for infants and young children under the age of 36 months.

CHAPTER 6 VIEWS SOUGHT

6.1 Salient features of the legislative proposals, as set out in Chapter 4, are summarised as follows -

- (a) Codex requirement on nutritional composition (i.e. energy and 33 nutrients as specified by Codex) for infant formula before complementary feeding is introduced¹⁰;
- (b) nutrition labelling requirement for infant formula before complementary feeding is introduced, by listing the energy and 33 nutrients which are required to be present in infant formula as specified by Codex;
- (c) nutrition labelling requirement for follow-up formula intended for infants and young children under the age of 36 months by listing the energy and 25 nutrients as specified by Codex;
- (d) nutrition labelling requirement for foods intended for infants and young children under the age of 36 months by listing the energy and nutrients required for such foods as specified by Codex; and
- (e) commencement of the proposed legislation after a suitable grace period.

6.2 The Government invites you to let us have your views on the legislative proposals. Please send your comments by letter, facsimile or e-mail to the Centre for Food Safety before 21 January 2013:

Centre for Food Safety
(Attn: Consultation on formula products and foods for infants and young children)
Food and Environmental Hygiene Department
43/F, Queensway Government Offices,
66 Queensway, Hong Kong

¹⁰ Complementary feeding is normally introduced at 6 months of age.

Facsimile: (852) 2893 3547

E-mail address: formulafoods_consultation@fehd.gov.hk

Enquiry tel. no.: (852) 2867 5699

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

6.4 It is voluntary for any member of the public to supply his / her personal data upon providing views on the consultation document. Any personal data provided with a submission will only be used for purpose of this consultation exercise.

6.5 The submissions and personal data collected may be transferred to the relevant Government bureaux, departments or agencies for purposes directly related to this consultation exercise. The relevant parties receiving the data are bound by such purposes in their subsequent use of such data.

6.6 The names and views of individuals and organisations which put forth submissions in response to the consultation document (senders) may be published for public viewing after conclusion of the consultation exercise. The Centre for Food Safety may, either in discussion with others or in any subsequent report, whether privately or publicly, attribute comments submitted in response to the consultation document. We will respect the wish of senders to remain anonymous and / or keep the views confidential in relation to all or part of a submission; but **if no such wish is indicated, it will be assumed that the sender can be named and his/her views be published for public information.**

6.7 Any sender providing personal data to the Centre for Food Safety in the submission will have the right of access and correction with respect to such personal data. Any request for data access or correction of personal data should be made in writing to the contact specified in paragraph 6.2 above.

Annex I

Codex Requirement on Nutritional Composition in Infant Formula and Follow-up Formula *(NS = not specified) (RE = retinol equivalent)*

Composition/Nutrient	Unit	Infant Formula	Follow-up Formula	Remarks
Energy	kcal/100ml	60.0 - 70.0	60.0 - 85.0	
Protein	g/100kcal	1.8 - 3.0	3.0 - 5.5	
Total fat	g/100kcal	4.4 - 6.0	3.0 - 6.0	
Linoleic acid	mg/100kcal	300.0 - NS	300 - NS	For infant formula, ratio of linoleic acid to α -linolenic acid between 5:1 to 15:1 GUL for infant formula: 1400
α-Linolenic acid	mg/100kcal	50.0 - NS	-	
Total carbohydrates	g/100kcal	9.0 - 14.0	-	For follow up formula, available carbohydrate to provide the remaining energy requirement
Vitamins				
Vitamin A	iu/100kcal	200.0 - 600.0 (or 60.0-180.0ug RE/100kcal)	250.0 - 750.0 (or 75.0 - 225.0ug RE/100kcal)	
Vitamin D	ug/100kcal	(Vit D3: 1.0 - 2.5)	1.0 - 3.0 (or 40-120 iu/100kcal)	
Vitamin E	mg alpha-TE/100kcal	0.5 - NS	0.7 - NS(iu/100kcal)	GUL for infant formula: 5
Vitamin K	ug/100kcal	4.0 - NS	(Vit K1: 4.0 - NS)	GUL for infant formula: 27
Thiamin	ug/100kcal	60.0 - NS	40.0 - NS	GUL for infant formula: 300
Riboflavin	ug/100kcal	80.0 - NS	60.0 - NS	GUL for infant formula: 500
Niacin	ug/100kcal	300.0 - NS	(Nicotinamide: 250.0 - NS)	GUL for infant formula: 1500
Vitamin B6	ug/100kcal	35.0 - NS	45.0 - NS	GUL for infant formula: 175

Composition/Nutrient	Unit	Infant Formula	Follow-up Formula	Remarks
Vitamin B12	ug/100kcal	0.1 - NS	0.15 - NS	GUL for infant formula: 1.5
Pantothenic acid	ug/100kcal	400.0 - NS	300.0 - NS	GUL for infant formula: 2000
Folic acid	ug/100kcal	10.0 - NS	4.0 - NS	GUL for infant formula: 50
Vitamin C	mg/100kcal	10.0 - NS	8.0 - NS	GUL for infant formula: 70
Biotin	ug/100kcal	1.5 - NS	1.5 - NS	GUL for infant formula: 10
Minerals				
Iron	mg/100kcal	0.45 - NS	1.0 - 2.0	
Calcium	mg/100kcal	50 - NS	90.0 - NS	Calcium to phosphorus ratio between 1:1 to 2:1 GUL for infant formula: 140
Phosphorus	mg/100kcal	25 - NS	60.0 - NS	GUL for infant formula: 100
Magnesium	mg/100kcal	5 - NS	6.0 - NS	GUL for infant formula: 15
Sodium	mg/100kcal	20 - 60	20.0 - 85.0	
Chloride	mg/100kcal	50 - 160	55.0 - NS	
Potassium	mg/100kcal	60 - 180	80.0 - NS	
Manganese	ug/100kcal	1 - NS	-	GUL for infant formula: 100
Iodine	ug/100kcal	10 - NS	5.0 - NS	GUL for infant formula: 60
Selenium	ug/100kcal	1 - NS	-	GUL for infant formula: 9
Copper	ug/100kcal	35 - NS	-	GUL for infant formula: 120
Zinc	mg/100kcal	0.5 - NS	0.5 - NS	GUL for infant formula: 1.5
Other micronutrients				
Choline	mg/100kcal	7 - NS	-	GUL for infant formula: 50
Myo-Inositol	mg/100kcal	4 - NS	-	GUL for infant formula: 40

Composition/Nutrient	Unit	Infant Formula	Follow-up Formula	Remarks
L-Carnitine	mg/100kcal	1.2 - NS	-	

GUL: Guidance upper levels are for nutrients without sufficient information for a scientific-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GUL is to provide guidance to manufacturers and they should not be interpreted as goal values. Nutrient contents in infant formula should usually not exceed the GUL unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formula or due to technological reasons.

* For formulas for special medical purposes intended for infants, requirements are also provided in CODEX STAN 72-1981. The energy content and nutrient composition shall be based on the requirement for general infant formula as listed in the above table, except for the composition 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.

Annex II

Codex Requirement on Nutritional Composition in Processed Cereal-based Foods and Canned Baby Foods for Infants and Young Children *(RE = retinol equivalent)*

Category	Processed Cereal-based Foods for Infants and Young Children				Canned Baby Foods
Definition	<p>prepared primarily from one or more <u>milled cereals</u>, which should constitute at least 25% of the final mixture on a dry weight basis;</p> <p>[milled cereal products: such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat; may contain legumes (pulses), starchy roots (such as arrow root, yam or cassava) or starchy stems or oil seeds in smaller proportions.]</p>				<p>prepared from any suitable nutritive material that is used, recognized or commonly sold as an article or ingredient of food</p>
Sub-category	cereals for consumption with milk or other appropriate nutritious liquids	cereals with added high protein food prepared for consumption with water or other appropriate protein-free liquid	pasta	rusks and biscuits	-
Energy	≥0.8kcal/g	≥0.8kcal/g	≥0.8kcal/g	≥0.8kcal/g	Not specified
Protein	Not specified	5.5g/100kcal or below (the added protein ≥2g/100kcal)	Not specified	5.5g/100kcal or below (for biscuit made with addition of a high protein food, the added protein ≥1.5 g/100kcal)	Not specified

	cereals for consumption with milk or other appropriate nutritious liquids	cereals with added high protein food prepared for consumption with water or other appropriate protein-free liquid	pasta	rusks and biscuits	Canned Baby Foods
Lipids	3.3g/100kcal or below	4.5g/100kcal or below (if lipid >3.3 g/100kcal, then linoleic acid 0.3-1.2 and lauric acid and myristic acid each ≤15% of lipid content)	Not specified	3.3g/100kcal or below	Not specified
Carbohydrates	Not more than 7.5g/100kcal from added sucrose, fructose, glucose, glucose syrup, honey; added fructose not more than 3.75g/100kcal	Not more than 5g/100kcal from added sucrose, fructose, glucose, glucose syrup, honey; added fructose not more than 2.5g/100kcal	Not specified	not more than 7.5g/100kcal if sucrose, fructose, glucose, glucose syrup, honey added; added fructose not more than 3.75g/100kcal	Not specified
Vitamin A	60-180ug RE/100 kcal (if added)	60-180ug RE/100 kcal	60-180ug RE/100 kcal (if added)	60-180ug RE/100 kcal (if added)	Not specified
Vitamin D	1-3ug/100kcal (if added)	1-3ug/100kcal	1-3ug/100kcal (if added)	1-3ug/100kcal (if added)	Not specified
Thiamin	Not less than 50ug/100kcal	Not less than 50ug/100kcal	Not less than 50ug/100kcal	Not less than 50ug/100kcal	Not specified
Calcium	Not specified	not less than 80mg/100kcal	Not specified	not less than 50mg/100 kcal if manufactured with the additional of milk and presented as such	Not specified
Sodium	not exceed 100mg/100kcal (on ready-to-eat basis)	not exceed 100mg/100kcal (on ready-to-eat basis)	not exceed 100mg/100kcal (on ready-to-eat basis)	not exceed 100mg/100kcal (on ready-to-eat basis)	not exceed 200mg/100g (on ready-to-eat basis)

Annex III

Codex Requirement on Nutrition Labelling in Formula Products and Foods for Infants and Young Children, and Prepackaged Food for Special Dietary Uses

	Expression	Energy	Protein, Fat, Carbohydrates	Vitamins & Minerals
Infant formula#	per 100g or per 100mL as sold <u>as well as</u> per 100mL as consumed [in addition, may also include per 100 kcal/kJ]	in kcal <u>and/or</u> kJ	in g	13 vitamins, 12 minerals and choline (optional ingredient if added)
Follow-up formula	per 100g as sold <u>as well as</u> per serving as consumed [in addition, may also include per 100 kcal/kJ]	in kcal <u>and/or</u> kJ	in g	13 vitamins and 9 minerals (optional ingredient if added)
Cereal-based foods				
(a) Cereal to be prepared with milk or nutritious liquid	per 100g or per 100ml as sold; <u>where appropriate</u> , also per serving as consumed	in kcal <u>and</u> kJ	in g	1 vitamin (B1) and 1 mineral (sodium) (vitamin A and D if added)
(b) Cereal with an added high protein food	per 100g or per 100ml as sold; <u>where appropriate</u> , also per serving as consumed	in kcal <u>and</u> kJ	in g	3 vitamins (A, B1 and D) and 2 minerals (sodium and calcium)
(c) Pasta	per 100g or per 100ml as sold; <u>where appropriate</u> , also per serving as consumed	in kcal <u>and</u> kJ	in g	1 vitamin (B1) and 1 mineral (sodium) (vitamin A and D if added)

	Expression	Energy	Protein, Fat, Carbohydrates	Vitamins & Minerals
(d) Rusk and biscuit	per 100g or per 100ml as sold; <u>where appropriate</u> , also per serving as consumed	in kcal and kJ	in g	1 vitamin (B1) and 1 mineral (sodium) (calcium if milk is added) (vitamin A and D if added)
Canned baby foods	per 100g as sold <u>as well as</u> per serving as consumed	in kcal and/or kJ	in g	If added
Prepackaged food for special dietary uses	Per 100g or 100ml as sold; where appropriate, also per serving as consumed	in kcal and kJ	in g	(specific nutrients or other components which provide the characterizing essential feature of the food)

Codex only requires labelling of the content of 29 of the 33 nutrients considered to be essential in infant formula. However, we propose in our legislative proposal to require listing of the nutrient content of all 33 nutrients as a means to declare the fulfilment of the nutritional composition requirement

* If the above product is a food for special medical purposes which is for the dietary management of patients and to be used only under medical supervision, requirements in Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) should be followed. For these foods, the amounts of vitamins and essential minerals should also be labelled.

Regulatory Control in Major Jurisdictions

Singapore

1. In the Singaporean context, *Infants' Food* and *Infant Formula*, under the category of *Special Purpose Foods*, are the only two concerned legal entities defined in the Food Regulations under Sale of Food Act (Chapter 283, Section 56(1)). Nutritional composition requirements are defined for Infant Formula but not Infants' Food (Regulation 252 to 254). While "infant" is defined under Regulation 2 as "a person not more than 12 months of age," there is no specific terminology defined for foods for young children between 12 to 36 months of age as in the Codex context. Separately, the term "infant formula" refers to "any food described or sold as an alternative to human milk for the feeding of infants" without defining whether there is complementary feeding.

2. Detailed nutritional composition requirements, including those on energy, protein, fat (including linoleic acid and other fatty acids), 13 vitamins and 12 minerals, are defined for infant formula. For each nutrient, the specific quantity defined in the Singaporean legal context differs from that of the current Codex standard to varied degrees. There is no specific nutritional composition requirement prescribed for infants' food.

3. The labelling requirement in the Food Regulations is provided as a set of general requirements under Part III Regulation 5. No specific exemption on the labelling requirement is granted for infants' food or infant formula¹. Additional labelling requirement for infant formula especially on the feeding instructions is also specified.

4. Nutrition claims (e.g. nutrient content and nutrient comparative claims) and health claims (e.g. nutrient function and other function claims) are generally permitted for use for infant food in Singapore. However, use of disease risk reduction claims is guided by national health policy and

¹ In Singapore, exemption on general labelling requirement is granted for foods weighed, counted or measured in the presence of the purchaser, loosely packed in the retailer's premises, and partially for intoxicating liquor (Regulation 6, Food Regulations, Sale of Food Act).

has not been allowed for infant food. In Singapore, nutrition and health claims have long been permitted for use in infant foods based on a list of approved claims. New claims for use in foods, including infant foods, will be evaluated by the Advisory Committee on Evaluation of Health Claims. The Committee, chaired by the Agri-Food and Veterinary Authority, comprises representatives from public health agencies, higher learning institutes, industry and consumer associations.

United States

5. Food safety control is governed under Title 21 of Code of Federal Regulations on Food and Drugs in which the term “*infant formula*” is defined as “*a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.*” In other words, US has not made distinction on whether the products are taken as the sole human milk substitute or during the weaning period and provides only a set of nutritional composition requirement for this type of products. This seems to be a simpler approach as compared with Codex in the implementation but apparently does not address the specific nutritional requirements of infant solely fed on the formula products.

6. The US requirement on the composition of the infant formula for those aged 0 to 12 months is provided in the Code of Federal Regulations Part 107. The requirements on energy density and carbohydrate content are not specified. When the nutrients need to be present in formula for infants below and above 6 months of age, the lower limit is specified.

7. There is no specific definition for foods for infants, or food groups equivalent to Codex defined processed cereal-based food products and canned baby foods, in the US regulatory framework.

8. In US, except for “*a statement that describes the percentage of a vitamin or mineral in the food in relation to a Reference Daily Intake*” that is allowed for foods intended specifically for use by infants and children less than 2 years of age and a claim in relation to iron content in infant formula as specified in the federal regulation, nutrient content claims are

generally not allowed. Health claims are not permitted on foods for children under 2 years of age unless otherwise approved by the authority, with the request of the trade through a petition mechanism, and specifically provided for use on these foods.

Australia and New Zealand

9. Australia New Zealand Food Standards Code defines, in Standard 2.9.1, “**infant formula product**” as a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants. This is further sub-categorized into a) *infant formula*, meaning an infant formula product represented as a breast-milk substitute for infants and which satisfies the nutritional requirements of infants aged up to four to six months; and b) *follow-on formula*, an infant formula product represented as either a breast-milk substitute or replacement for infant formula and which constitutes the principal liquid source of nourishment in a progressively diversified diet for infants aged from six months. Nutritional composition requirements have been developed for infant formula and follow-on formula with different degree of variations from Codex requirements.

10. Separately, in Standards 2.9.2, the term *Food for Infants* is used for referring to a food that is intended or represented for use as a source of nourishment for infants, but does not include infant formula products, formulated meal replacements, formulated supplementary foods and unprocessed fruit and vegetables. In addition, in the Australian context, Food for Infant is further subdivided into two sub-categories: *cereal-based foods* and *non-cereal-based foods*, each with additional requirements. Cereal-based food for infants is defined as that “contains more than 70% cereal, on a moisture free basis, and is promoted as suitable for infants over the age of 6 months.” This is drastically different from that defined by Codex.

11. Nutritional composition requirements on the content of iron, sodium, and vitamin C are defined for each of the cereal-based and non-cereal-based foods. To minimize the risk of choking, the requirement on consistency is also defined. For sodium content,

maximum permitted quantity has been defined for rusks and biscuits (a subtype of cereal-based foods for infants) to be at 350mg/100g and 300mg/100g respectively, and that for other cereal-based foods and fruit-based foods at a maximum of 100mg/100g.

12. Australia and New Zealand allow foods for young children up to 12 months of age to bear nutrient content claims on selected vitamins and minerals when specified conditions are fulfilled.

Mainland

13. In the regulatory context, the Mainland Ministry of Health has defined the categories of *infant formula* (嬰兒配方食品) and *older infants and young children formula* (較大嬰兒和幼兒配方食品) in two sets of national standards (GB10765-2010, GB10767-2010) published in March 2010. The former refers to those that are able to meet the nutritional requirements of normal 0 to 6 months infants. The specific nutritional requirements for infant formula are largely similar to Codex with modifications in the specified levels for selected nutrients.

14. Two other national standards cover the two categories of *cereal-based complementary foods for infants and young children* (嬰幼兒穀類輔助食品), and *canned complementary foods for infants and young children* (嬰幼兒罐裝輔助食品) (GB10769-2010, and GB10770-2010) for control purpose. Classification of the former is very similar and with greater details as compared with those defined in the Codex framework while the latter is specifically referred to 食品原料經處理、灌裝、密封、殺菌或無菌灌裝後達到商業無菌，可在常溫下保存的適於6月齡以上嬰幼兒食用的食品 [literally translated as: "*Infant and Young Children Foods for infants of 6 months old and above made through raw materials pre-treatment, filling, sealing, sterilization or aseptic filling to achieve commercial sterilization and can be stored at a normal temperature.*"]. As compared with the Codex requirement defined in the Codex Standards for Canned Baby Foods, additional requirements on ingredients, texture, consistency, and content of protein, fats and sodium are prescribed. The sodium content limit is the same as that prescribed in the Codex standard at not more than 200mg/100g.

15. Formula products and foods for infants and young children in the Mainland China need to fulfil the labelling requirements as stated in the General Standard for the labelling of prepackaged foods for special dietary uses (預包裝特殊食用食品標籤通則) (GB13432-2004). The same standard also lists nutrient content claims that are allowed, as well as the specified conditions for making nutrient comparative claims and nutrient function claims. Claims regarding the prevention, alleviation, treatment or cure of a disease are prohibited.

European Union

16. In the EU regulatory context, the Commission Directive 2006/141/EC of 22 December 2006 defines *infant formulae* as “*the only processed foodstuff which wholly satisfies the nutritional requirements of infants during the first months of life until the introduction of appropriate complementary feeding*”, and *follow-on formulae* as “*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.*”

17. As for foods, the Commission Directive 2006/125/EC of 5 December 2006 has incorporated requirement on *processed cereal-based foods* similar to the Codex equivalent, including *simple cereals* which are or have to be reconstituted with milk or other appropriate nutritious liquids; *cereals with an added high protein food* which are or have to be reconstituted with water or other protein-free liquid; *pastas* which are to be used after cooking in boiling water or other appropriate liquids; and *rusks and biscuits* which are to be used either directly or, after pulverization, with the addition of water, milk or other suitable liquids. In the same Directive, the term “*baby foods*” are used for foods other than processed cereal-based foods. In addition, the Directive also defines “*baby foods*” as all the other foods for young children. Detailed nutritional composition requirements have been stipulated in these Directives.

18. As for claims, for infant formula (for 0 months to weaning, <12 months), nutrition and health claims are generally not permitted, with the exception of a few specific claims related to lactose, added ingredients

(such as DHA) or allergy condition. For follow-up formula (for <12 months) and other foods for infant and young children, similar to other general foods, they are eligible for making nutrition claims when relevant conditions were met. On the other hand, only those health claims which have been included in the lists of authorized claims are allowed. Authorization procedures have been established to develop the list of permitted health claims.

