

Consultation Document

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

January 2015



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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CHAPTER 1 INTRODUCTION

1.1 Information shown on food products assists consumers to make purchasing decisions. For pre-packaged food, such information normally covers the nutrition composition and expiry or best by dates as prescribed by law. Some also include claims that the food contains certain nutritional value or is capable of achieving certain positive effect on health. Consuming food based on dubious nutrition or health claims made about them may have adverse impact on the consumer's health.

1.2 Nutrition and health claims are representations which state, suggest or imply that a food has particular nutritional properties, or that a relationship exists between a food or its constituent and health. These claims have been widely used in various food products, including formula products (i.e. infant formula and follow-up formula) and prepackaged foods for infants and young children under the age of 36 months ("IYC foods"). These claims, if properly applied, may help promote a healthy diet.

1.3 However, false, misleading and inappropriate making and application of nutrition and health claims can cause harm to human health. In view of this, there are calls to regulate the making and application of such claims on food products. The Government believes that if action is to be taken, formula products and IYC foods should be a priority area due to the unique nutrition needs and health concern of this age group.

1.4 For infants and young children, nutrition is essential for their growth, tissue repair and maintenance of good health. It is widely recognised that breastfeeding is superior in ensuring, first, physical and psychosocial health and wellbeing of mother and child as well as, secondly, early nutrition to infants and young children which has important impact on their long-term health. It is hence of paramount importance to prevent practices which would discourage

breastfeeding, and to ensure that parents are provided with accurate and appropriate information on formula products and IYC foods to facilitate informed choice.

1.5 The World Health Organization (“WHO”) recommends that infants be exclusively breastfed for the first six months of life to achieve optimal growth, development and health. Mothers should continue to breastfeed their children beyond the age of six months, until they are two years of age or older, while at the same time providing them with safe and appropriate complementary foods to meet their evolving nutritional requirements. Infants who are not breast fed need a suitable breast milk substitute, for example, infant formula. Follow-up formula and IYC foods are widely consumed as complementary foods.

1.6 In Hong Kong, certain nutrient-related claims, namely nutrient content claims¹, nutrient comparative claims² and nutrient function claims³, on general prepackaged foods are regulated by the Food and Drugs (Compositional and Labelling) Regulations (Cap. 132W). However, Cap. 132W does not cover nutrition and health claims made on formula products and IYC foods. While there is currently no specific regulation on nutrition claims and health claims on formula products and IYC foods, false labelling and advertisement of food are generally prohibited under section 61 of the Public Health and Municipal Services Ordinance (Cap. 132). Under Cap. 132, any nutrition and health claims made on formula products and IYC foods that falsely describe the products or are calculated to mislead their nature, substance or quality is an offence.

¹ Nutrient content claim refers to a nutrition claim that describes the level of a nutrient contained in a food. Please refer to Chapter 3 of this consultation document for a more detailed definition.

² Nutrient comparative claim refers to a claim that compares the nutrient levels and/or energy value of two or more foods. Please refer to Chapter 3 of this consultation document for a more detailed definition.

³ Nutrient function claim refers to a claim that describes the physiological role of the nutrient in growth, development and normal functions of the body. Please refer to Chapter 3 of this consultation document for a more detailed definition.

1.7 The Government is committed to protecting the health of infants and young children. With a view to achieving this aim, this consultation document puts forward a proposal for a regulatory framework on nutrition and health claims for formula products and IYC foods. We welcome your comments on our proposals.

CHAPTER 2 SITUATION IN HONG KONG

Local Market Situation

Food Supplies in Hong Kong

2.1 Hong Kong's food supply, including formula products and IYC foods, is characterised by the dominance of imported food. Surveys conducted by the Government revealed that formula products and IYC foods available in Hong Kong are mainly imported from places such as the European Union ("EU"), Australia, New Zealand, and the United States ("the US"), etc.

Nutrition and Health Claims on Formula Products and IYC Foods

2.2 Nutrition and health claims are commonly found in formula products, and to a lesser extent in IYC foods. A study jointly conducted by the Government and the Consumer Council in 2012 revealed that among more than 100 popular IYC food samples intended principally for infants and young children under the age of 36 months, 28% of the samples were found to bear one or more nutrition or health claims in Chinese or English. Claims made on formula products are believed to be even more common.

Current Legislation

2.3 Currently, there are legislation governing the labelling and advertisement of food products in Hong Kong, with some of them applicable to the nutrition and health claims made on formula products and IYC foods. A summary of the relevant legislation is set out in the ensuing paragraphs.

Public Health and Municipal Services Ordinance (Cap. 132)

2.4 Section 61 of the Public Health and Municipal Services Ordinance (Cap. 132) offers broad protection against misleading claims. The section stipulates that 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, the threshold for prosecution under section 61 of Cap. 132 is high as we need to prove that the label in question is intentionally misleading or false.

Food and Drugs (Composition and Labelling) Regulations (Cap. 132W)

2.5 The Food and Drugs (Composition and Labelling) Regulations (Cap. 132W) provides for the Nutrition Labelling Scheme (“NL Scheme”) for prepackaged food products. The NL Scheme regulates nutrient content claim, nutrient comparative claim and nutrient function claim made on prepackaged foods targeted for people aged 36 months or above (“general prepackaged foods”). However, nutrition and health claims made on formula products and IYC foods are outside the scope of the NL Scheme.

Food and Drugs (Composition and Labelling) (Amendment) (No.2) Regulation 2014

2.6 The Food and Drugs (Composition and Labelling) (Amendment) (No.2) Regulation 2014 was published in the Gazette on 13 June 2014⁴ with a view to better regulating the nutritional composition of infant formula, as well as nutrition labelling of formula products and IYC foods. However, regulation of nutrition and health claims on these products has not been included in this recent legislative

⁴ On 22 October 2014, the Legislative Council has completed its vetting of the Food and Drugs (Composition and Labelling) (Amendment) (No.2) Regulation 2014, which will come into force on 13 December 2015 (after a grace period of 18 months) for infant formula and on 13 June 2016 (after a grace period of 24 months) for follow-up formula and IYC foods.

amendment in view of the complexity and controversies of the matter, and the more urgent need for first regulating the nutritional composition and nutrition labelling of these products.

Undesirable Medical Advertisements Ordinance (Cap. 231)

2.7 The Undesirable Medical Advertisements Ordinance (Cap. 231) under the purview of the Department of Health prohibits any person from publishing or causing to be published any advertisements likely to lead to the use of, inter alia, any medicine⁵ for the purpose of treating human beings for, or preventing them from contracting specified diseases or conditions. It also regulates the advertising of specified claims for orally consumed products (“OCP”)⁶ (some examples of claims so prohibited are shown in **Annex I**). However, OCP does not include products which are customarily consumed only as food or drink. Hence, nutrition and health claims on formula products and IYC foods are generally not covered by Cap. 231 as these products do not fall within the definition of medicine or that of OCP under Cap. 231. That said, whether a formula product and IYC food is or is not considered a medicine or OCP has to be decided on a case-by-case basis, taking into consideration the facts and circumstances of the case (e.g. product nature and way of presentation, etc.).

Trade Descriptions Ordinance (Cap. 362)

2.8 The Trade Descriptions Ordinance (Cap. 362) under the purview of the Customs and Excise Department prohibits, inter alia, false trade descriptions, false, misleading or incomplete information, false marks and misstatements in respect of

⁵ Under section 2 of Cap. 231, “medicine” includes any kind of medicament or other curative or preventive substance, and whether a proprietary medicine, a patent medicine, a Chinese herbal medicine, a proprietary Chinese medicine, or purported natural remedy.

⁶ Under section 2 of Cap. 231, “orally consumed products” include oral medicines and other oral products which are in the form of pill, capsule, tablet, granule, powder, semi-solid, or in liquid. They do not, however, include products which are customarily consumed only as food or drink (that is to say, to provide energy, nourishment or hydration), or to satisfy a desire for taste, texture or flavour.

goods provided in the course of trade⁷. Depending on how the nutrition and health claims on formula products and IYC foods are made, such claims can be governed by Cap. 362. That said, similar to Cap. 132, the threshold for prosecution under Cap. 362 is high, requiring, among other things, expert evidence, including those to be tendered by the Centre for Food Safety, to prove that the trade description is false to a material degree.

2.9 To sum up, there is currently no legislation capable of effectively regulating the nutrition and health claims made on formula products and IYC foods for the following reasons —

- (a) some legislation that govern general food labelling and advertisement are simply not applicable to the nutrition and health claims made on formula products and IYC foods (e.g. Cap. 132W and the Food and Drugs (Composition and Labelling) (Amendment) (No.2) Regulation 2014);
- (b) for legislation that is applicable to the nutrition and health claims on formula products and IYC foods, they lack specific provisions on the claims made on these products. A great deal of efforts and research have to be undertaken by the Centre for Food Safety to establish the truthfulness of a nutrition and health claim before a case for prosecution can be established (e.g. section 61 of Cap. 132 and Cap. 362); and
- (c) the threshold for prosecution under such legislation is high, requiring the prosecution to prove with sufficient evidence that the label in question is intentionally misleading or false (in the case of section 61 of Cap. 132) or that the trade description concerned is false to a material degree (in the case of Cap. 362).

⁷ Section 7 of Cap. 362 stipulates that, any person who (a) in the course of any trade or business, applies a false trade description to any goods, or supplies or offers to supply any goods to which a false trade description is applied; or (b) has in his possession for sale or for any purpose of trade or manufacture any goods to which a false trade description is applied, commits an offence.

3.1 The Codex Alimentarius Commission (“Codex”) was established in 1963 by the Food and Agriculture Organization of the United Nations and WHO to develop food standards, guidelines and related texts such as codes of practice for protecting the health of consumers and ensuring fair trade practices in the food trade.⁸ Notwithstanding the principles set by Codex, national authorities of different jurisdictions have established different requirements in light of their national situation as well as nutrition and health policies when it comes to the regulation of nutrition and health claims on formula products and IYC foods. The regulatory framework for nutrition and health claims in different jurisdictions can, therefore, vary substantially. To ensure consistency in terminology used and avoid errors in interpretations, where possible, the Codex definitions will be used throughout this chapter.

Standards, Guidelines and Definitions Established by Codex

Relevant Codex Standards and Guidelines

3.2 Currently, Codex has established four standards covering formula products and IYC foods —

- (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 Processed Cereal-based Foods for Infants and Young Children (CODEX STAN 074-1981); and
- (d) Codex Standard for Canned Baby Foods (CODEX STAN 73-1981).

⁸ At present, the membership of Codex comprises over 180 countries.

- 3.3 For nutrition and health claims, relevant Codex guidelines include —
- (a) General Guidelines on Claims (CAC/GL 1-1979); and
 - (b) Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997).

Terms Defined in Codex

3.4 According to the Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1977) (“the Guidelines”), “nutrition claim” means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals. Under the Guidelines, nutrition claims include —

- (a) Nutrient content claim: a nutrition claim that describes the level of a nutrient contained in a food (e.g. “source of calcium”, “high in fibre and low in fat”) ; and
- (b) Nutrient comparative claim: a claim that compares the nutrient levels and/or energy value of two or more foods (e.g. “reduced”, “less than”, “fewer”, “increased”, “more than”).

3.5 Table 1 below shows a few examples of nutrition claims that can be found on food products in the local and/or overseas markets.

Table 1 : Examples of nutrition claims available in the local/overseas markets

Claim	Example*
Nutrient content claim	<ul style="list-style-type: none"> • Good source of calcium • Excellent source of vitamins • Contains choline (144mg / 100g) • With DHA • Sucrose free

Claim	Example*
Nutrient comparative claim	<ul style="list-style-type: none"> • Enriched with vitamin D • More vitamins, minerals and fibre • Added vitamin B1 • Extra iron • Increased DHA level by 3 times (compared to its original formula) • Higher level of phospholipids

* The examples are shown to illustrate the classification of claims which may appear on various types of food, including but not limited to those on formula products and IYC foods. There is no implication on the acceptance or prohibition of the respective claims in Hong Kong or overseas.

3.6 On the other hand, “health claim” is defined under the Guidelines 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 include —

- (a) *Nutrient function claim*: a claim that describes the physiological role of the nutrient in growth, development and normal functions of the body. For instance, “phospholipids (PhD) are essential for the function of brain cells”;
- (b) *Other function claim*: a claim that concerns 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. For instance, “probiotics (益生菌) helps to maintain a healthy digestive system”; and
- (c) *Reduction of disease risk claim*: a claim that relates 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. Risk reduction means significantly altering a major risk factor(s) for a disease or

health-related condition. Diseases have multiple risk factors and altering one of these factors may or may not have a beneficial effect. The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims. For instance, “fortified with an appropriate level of iron to reduce the risk of anaemia (貧血)”.

3.7 Table 2 below shows some examples of health claims that could be found on food products in the local and/or overseas markets.

Table 2 : Examples of health claims available in the local/overseas markets

Claim	Example*
Nutrient function claim	<ul style="list-style-type: none"> • DHA supports eye and brain development • With calcium for growing bones • Iron builds strength and energy • Zinc, iodine and iron have been shown to support mental functions • Phospholipids (PhD) are essential for the function of brain cells
Other function claim	<ul style="list-style-type: none"> • Probiotics (益生菌) helps to maintain a healthy digestive system • Probiotics helps in digestion • Advanced carbohydrate blend provides balanced energy • Galacto-oligosaccharides (GOS) helps promote softer stools and reduce constipation
Reduction of disease risk claim	<ul style="list-style-type: none"> • A healthy diet with adequate calcium and vitamin D, with regular exercise, helps to achieve strong bones and may reduce the risk of osteoporosis; (food name) is a good source of / high in / enriched in / fortified with calcium • A healthy diet rich in fibre-containing foods such as whole grains, fruits and vegetables may reduce

Claim	Example*
	<p>the risk of some types of cancers; (food name) is low in fat and high in dietary fibre</p> <ul style="list-style-type: none"> • Fortified with an appropriate level of iron to reduce the risk of anaemia (貧血) • Contains ganglioside (GA) which helps reduce the risk of enterovirus infection

* The examples are shown to illustrate the classification of claims which may appear on various types of food, including but not limited to those on formula products and foods for infants and young children. There is no implication on the acceptance or prohibition of the claims in Hong Kong or overseas.

Nutrition and Health Claims for Formula Products and IYC foods

3.8 As stipulated in the Guidelines, 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 should support such policies where applicable. Concerning formula products and IYC foods, the Guidelines clearly state that 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.

3.9 The Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981) reiterates the prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation. On the other hand, Codex Standard for Processed Cereal-based Foods for Infants and Young Children (CODEX STAN 074-1981) states that nutrition claims may be permitted under national legislation for the foods that are the subject of the standard provided that they have been demonstrated in rigorous studies with adequate scientific standards.

Regulation in Other Jurisdictions

3.10 The scope and product categorisation of formula products and IYC foods as well as the definition of nutrition and health claim on formula products and IYC foods adopted by different authorities vary, as detailed in Annexes II and III. Regulatory control over nutrition and health claims on formula products and IYC foods among different authorities is also different, as shown in Annex IV. Table 3 shows an overview of the regulation in different jurisdictions on nutrition and health claims.

Table 3 : Overview of regulation in different jurisdictions on nutrition and health claims

	Nutrition claim		Health claim		
	Nutrient content claim	Nutrient comparative claim	Nutrient function claim	Other function claim	Reduction of disease risk claim
Infant formula *	<p>Not allowed in most jurisdictions, except, e.g. —</p> <ul style="list-style-type: none"> Mainland China currently allows such claims, but will prohibit those on essential composition from July 2015 onwards EU, Australia and New Zealand allow “lactose free” claim US accepts the statement “infant formula with iron” 		<p>Not allowed in many jurisdictions, except, e.g. —</p> <ul style="list-style-type: none"> Singapore allows selected claims (e.g. “nucleotides support body’s natural defences”) 	<p>Not allowed in most jurisdictions, except, e.g. —</p> <ul style="list-style-type: none"> EU may allow certain of these claims to be made subject to evaluation and approval, but no such claim is currently allowed Singapore allows claims related to probiotics and digestive system, but such is generally not allowed in other jurisdictions 	<p>Not allowed in most jurisdictions, except, e.g. —</p> <ul style="list-style-type: none"> EU currently allows claims related to reduction of risk to allergy to milk protein

	Nutrition claim		Health claim		
	Nutrient content claim	Nutrient comparative claim	Nutrient function claim	Other function claim	Reduction of disease risk claim
Follow-up formula*	Allowed in a number of jurisdictions (e.g. Mainland China, EU, Australia and New Zealand)		Allowed in a number of jurisdictions (e.g. Mainland China and EU)	Not allowed in most jurisdictions, except, e.g. — <ul style="list-style-type: none"> • EU may allow certain of these claims to be made subject to evaluation and approval • Singapore allows claims related to probiotics and digestive system, but such is generally not allowed in other jurisdictions 	Not allowed in most jurisdictions, except, e.g. — <ul style="list-style-type: none"> • EU may allow certain of these claims to be made subject to evaluation and approval, but those currently allowed are generally not relevant to persons under 36 months
IYC foods*	Allowed in a number of jurisdictions (e.g. Mainland China, EU, Australia and New Zealand)		Allowed in a number of jurisdictions (e.g. Mainland China, EU, Australia and New Zealand)	Not allowed in most jurisdictions, except, e.g. — <ul style="list-style-type: none"> • EU may allow certain of these claims to be made subject to evaluation and approval • Australia and New Zealand do not prohibit such claims • Singapore allows claims related to probiotics and digestive system, but such is generally not allowed in other jurisdictions 	Not allowed in most jurisdictions, except, e.g. — <ul style="list-style-type: none"> • EU may allow certain of these claims to be made subject to evaluation and approval, but those currently allowed are generally not relevant to persons under 36 months

* The scope and categorisation of these products refer to those as defined in the relevant overseas regulations. Requirements as stipulated in relevant specific regulations were summarised where available. It should be noted that in the US, there is no specific regulation on follow-up formula and IYC foods, whereas in Singapore, there is no specific regulation on follow-up formula.

3.11 In general, nutrition claims are not allowed to be made on infant formula, even though some jurisdictions (e.g. EU, the US, Australia and New Zealand) permit the use of limited nutrition claims (e.g. “lactose free”) in these products. Comparatively, more jurisdictions (e.g. EU, the US, Australia, New Zealand and Mainland China) allow nutrition claims to be made on follow-up formula and/or IYC foods.

3.12 For health claims, it is observed that a number of jurisdictions, including Singapore, Mainland China and EU, do not prohibit the use of nutrient function claims on formula products and/or IYC foods. On the other hand, most jurisdictions do not allow other function claims to be made on these foods. For example, claims related to probiotics and digestive system are accepted in Singapore, but similar claims have not been accepted in some other places such as the EU. For reduction of disease risk claims, although places such as EU have not prohibited their use on IYC foods, it is noted that the reduction of disease risk claims currently approved in these places are usually related to chronic diseases and are not relevant to infants and young children.

3.13 Apart from the above, it is noted that a number of overseas jurisdictions (e.g. EU, the US, Australia, New Zealand and Singapore) have established a list of pre-approved nutrition and health claims. Traders supplying to these jurisdictions can make such pre-approved claims on their products when relevant claim conditions are fulfilled.

3.14 On top of the prescribed lists, application for making new claims is usually possible, although the evaluation mechanisms including application procedures and requirements vary among different jurisdictions. In these jurisdictions, specific guidelines are usually drawn up to assist traders in preparing the application as well as collecting scientific evidence. Advisory committees are established in many jurisdictions, such as EU, Singapore, Australia and New Zealand, to provide expert advice on the scientific substantiation of the applications,

while final decision will be made by the relevant authorities. In other jurisdictions such as Mainland China, case-by-case evaluation approach for some claims on specific food is adopted.

3.15 Detailed information on the regulatory approaches and mechanisms for evaluating nutrition and health claims adopted in different jurisdictions are set out at **Annexes V and VI** respectively.

CHAPTER 4 PROPOSED REGULATORY FRAMEWORK

4.1 The Government proposes to establish a regulatory framework to enhance the regulation of nutrition and health claims on formula products and IYC foods. The purposes of proposed regulatory framework are —

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

4.2 In striving to achieve the above objectives, the Government is mindful of the need to maintain a stable supply of food for infants and young children under the age of 36 months in Hong Kong.

Overview of the Regulatory Framework

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

4.4 In considering the regulatory framework, the Government has taken into account, in addition to the views mentioned above, the current legislation (as depicted in Chapter 2 above), the Codex principles and practices of other

jurisdictions (as detailed in Chapter 3 above), as well as a host of other factors including public health concern, implication on food choice, impact on the food trade, availability of resources and implementation issues, etc.

4.5 The Government has come up with five overarching principles which govern the scope of the regulatory framework. The principles are meant to protect public health by stating the category of formula products and IYC food for which claims may be made and in what manner. They will be elaborated in paragraphs 4.7 to 4.16 below. If accepted, the first three principles will define the boundary of the framework within which pros and cons of different regulatory options can be discussed, whereas principles 4 and 5 will prescribe certain conditions that will bind any claims that are eventually allowed under the regulatory framework.

4.6 We consulted the Expert Committee on Food Safety⁹ in September 2014 concerning the structure for the regulatory framework. The Expert Committee was generally agreeable to the establishment of overarching principles to govern the scope of the framework but no definitive conclusion was reached with regards to the regulatory options elaborated in paragraphs 4.17 to 4.28 below. The views of the Expert Committee on various issues have been taken on board and reflected in this consultation document as appropriate.

⁹ To strengthen the consultative framework on food safety issues, an Expert Committee on Food Safety has been set up under the Centre for Food Safety. The Expert Committee is responsible for advising the Director of Food and Environmental Hygiene in the formulation of food safety measures, review of food safety standards in light of international practices, trends and developments, as well as risk communication strategies. The Expert Committee consists of academics, professionals, food experts, members of the trade and consumer group, and other experts.

Overarching Principles to be Adopted

Principle 1 — Nutrition claims (i.e. nutrient content claims and nutrient comparative claims) should be prohibited in infant formula

4.7 The Government strongly supports breastfeeding. However, breastfeeding may not be feasible for all mothers and babies. For mothers who do not choose to breastfeed for various reasons, breast milk substitute (i.e. infant formula) becomes the only nutrition source for their babies during their first months of life. To better protect formula-fed infants, the Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014 (the Regulation) was introduced to require all infant formula¹⁰ for sale in Hong Kong to comply with the requirements on nutritional composition and labelling for infant formula in accordance with Codex as stipulated in the Regulation. When the Regulation becomes effective, all infant formula available in the Hong Kong market should be able to fulfil the essential nutritional needs of infants.

4.8 Considering the need to further protect the health of infants and to promote breastfeeding, we suggest prohibiting nutrition claims on infant formula for the following reasons —

- (a) parents and care-givers are not deprived of essential information to make informed choices as they can always refer to the nutrition labelling which provides factual information on the amount of essential nutrients in infant formula;

¹⁰ Under the Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014, the definition of “infant formula” covers products that are intended for consumption as a substitute for human breast milk that is specially manufactured to satisfy, by itself, the nutritional requirements of persons of any age up to and including 12 months, until the introduction of appropriate complementary feeding, as well as products which are marked or labelled as “infant formula” or “嬰兒配方產品”, or with any other words of similar meaning. Reference has been made to the definition of “infant formula” maintained by Codex when devising this definition.

- (b) allowing nutrition claims in infant formula highlighting certain nutrient contents of formula products may discourage breastfeeding as these claims may mislead parents and care-givers into thinking that infant formula products consist of nutrients/constituents which are absent or deficient in breast milk, and therefore infant formula products are superior to breast milk; and
- (c) in fact, nutrition claim on infant formula is generally not allowed in most jurisdictions, including major formula product exporting countries supplying to Hong Kong (i.e. EU, the US, Australia and New Zealand) and Mainland China.

4.9 However, we propose that claims which provide essential health information for parents and care-givers, including information which is critical for infants and young children with certain medical conditions, should be allowed. For instance, claims like “lactose free” should be permitted as the products concerned address the medical condition of infants with lactose digestive problems (such as lactose intolerance) and the making of such a claim is providing essential health information. As such, claims providing essential health information would form an exception to the first principle. Other jurisdictions which prohibit nutrition claims in infant formula products (e.g. EU, Australia and New Zealand) have likewise provided for such exception.

Principle 2 — Reduction of disease risk claims should be prohibited in formula products and IYC foods

4.10 Formula products and IYC foods are generally intended to provide energy and nutrients to meet the nutritional needs for growth and normal physiological functions of their target customers. They are food for growth and for meeting nutritional needs, rather than designed to reduce risks of a particular disease. No known formula products and IYC foods are created primarily to prevent a disease. As such, formula products and IYC foods should not be

marketed in the same manner as “health food” with reduction of disease risk claims. We therefore suggest that reduction of disease risk claims should not be allowed in formula products and IYC foods. This is in line with the practice of many overseas jurisdictions, including the US, Australia, New Zealand and Singapore, where reduction of disease risk claims specifically targeting infants and young children under the age of 36 months have not yet been allowed.

Principle 3 — Nutrition claims (i.e. nutrient content claims and nutrient comparative claims) and nutrient function claims should be permitted in IYC foods

4.11 Under the NL Scheme, nutrition claims (i.e. nutrient content claims and nutrient comparative claims) and nutrient function claims are allowed to be made on general prepackaged foods provided that they comply with the requirements set out in Cap. 132W.

4.12 For IYC foods, their consumption may not be considered essential as their target customers are young children above the age of six months but under the age of 36 months who are slowly progressing to a regular adult diet. Indeed, IYC foods contain similar ingredients as general prepackaged foods. We therefore suggest that, with reference to the NL Scheme for general prepackaged foods, IYC foods should similarly be allowed to make nutrition claims and nutrient function claims. Many jurisdictions (e.g. EU, the US, Australia, New Zealand and Mainland China) also allow these claims on IYC foods.

Principle 4 — Nutrients or constituents permitted to be the subjects of claims should be of high importance to the health of infants and young children

4.13 There have been views that many of the nutrition and health claims on formula products and IYC foods are not of relevance and importance to the healthy growing up of infants and young children. The Government are urged to tighten the control over these claims, particularly those using exaggerated wordings and representations.

4.14 To this end, we propose that nutrition and health claims on formula products and IYC foods should only be allowed to feature nutrients/constituents for which Dietary Reference Intakes (DRIs)¹¹ or Nutrient Reference Values (NRVs)¹² have been established for the respective or appropriate age subgroup. In other words, if no appropriate DRI or NRV has been established for a nutrient, no claims should be made in respect of that nutrient. This proposition is in line with available science that has been evaluated thoroughly and applied widely by Codex and other food/health authorities. In addition, in accordance with Codex principles, the claims made should be consistent with the nutrition and health policies in Hong Kong. We also propose that the content information of the claimed nutrients/constituents must be listed on the packaging and, where appropriate, on the nutrition label.

Principle 5 — Nutrition and health claims should meet specific content conditions and health claims should be scientifically substantiated and have undergone credible evaluation process

4.15 Nutrition and health claims featuring a nutrient/constituent should be allowed only if the relevant product has been proven to contain a certain amount of the subject nutrient/constituent, which is set by the relevant authority. In addition, such content information should also be listed on the nutrition label.

4.16 Specifically for health claims, in order to ensure they are factual, not misleading and useful to consumers, health claims must have undergone a credible evaluation process, during which relevant authority evaluates whether the claimed

¹¹ DRIs are reference values that are quantitative estimates of the daily nutrient intakes required by an individual. DRIs are used for planning and assessing diets for healthy eating habits. DRIs vary with different gender and age groups.

¹² NRVs are derived for nutrition labelling purposes by making reference to the recommended intake levels of various nutrients, such as DRIs. NRVs are intended to assist consumers in evaluating the contribution of a food to their daily nutrient intake and can be used as a standard for comparing the nutrient contents among different foods, serving as a scale to help consumers make food choices by comparing different foods.

health effect for the concerned nutrient/constituent is scientifically substantiated, and that the content of the nutrient/constituent in the product shall fulfil the requirement set by the authority. Underpinning scientific substantiation is the mechanism to approve and establish corresponding conditions for the claims mentioned in paragraph 4.29 to 4.35 below.

Various Approaches of Regulating Nutrition Claims and Health Claims

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

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

4.18 Among the above product-claim combinations, we would like to seek public views on whether an inclusive approach (whereby all of the above claims would be allowed) or a restrictive approach (whereby all of the above claims would be prohibited) is preferred, or whether we should take the middle ground in allowing some claims but prohibiting others. To facilitate understanding and discussion, Table 4 below summarises the different scenarios under the inclusive and restrictive approaches.

Table 4 : Inclusive and restrictive approaches of regulating nutrition and health claims on formula products and IYC foods

Category of claim	Type of claim	Inclusive approach	Restrictive approach
Infant formula			
Nutrition claim	Nutrient content claim ^(a)	Not allowed (<i>Principle 1</i>)	
	Nutrient comparative claim ^(b)		
Health claim	Nutrient function claim ^(c)	Allowed ^(f)	Not allowed ^(f)
	Other function claim ^(d)	Allowed ^(h)	Not allowed ^(h)
	Reduction of disease risk claim ^(e)	Not allowed (<i>Principle 2</i>)	
Follow-up formula			
Nutrition claim	Nutrient content claim	Allowed ^(g)	Not allowed ^(g)
	Nutrient comparative claim	Allowed ^(g)	Not allowed ^(g)
Health claim	Nutrient function claim	Allowed ^(g)	Not allowed ^(g)
	Other function claim	Allowed ^(h)	Not allowed ^(h)
	Reduction of disease risk claim	Not allowed (<i>Principle 2</i>)	
IYC foods			
Nutrition claim	Nutrient content claim	Allowed (<i>Principle 3</i>)	
	Nutrient comparative claim		
Health claim	Nutrient function claim	Allowed ^(h)	
	Other function claim		
	Reduction of disease risk claim	Not allowed (<i>Principle 2</i>)	

(a) E.g. “contains choline (144mg / 100g)”.

(b) E.g. “increased DHA level by 3 times (compared to its original formula)”.

(c) E.g. “phospholipids (PhD) are essential for the function of brain cells”.

(d) E.g. “probiotics (益生菌) helps to maintain a healthy digestive system”.

(e) E.g. “fortified with an appropriate level of iron to reduce the risk of anaemia (貧血)”.

(f) Arguments for and against such claims are set out in paragraphs 4.20 to 4.21 below.

(g) Arguments for and against such claims are set out in paragraphs 4.22 to 4.25 below.

(h) Arguments for and against such claims are set out in paragraphs 4.26 to 4.28 below.

4.19 Public views are particularly sought on whether each of these product-claim combinations should be allowed or prohibited. To facilitate discussion, paragraphs 4.20 to 4.28 set out the arguments for and against specific product-claim combinations.

(a) Nutrient function claim on infant formula

4.20 Nutrient function claims provide information on the physiological role of a nutrient/constituent in growth, development and normal functions of the body. Through nutrient function claims, the trade can communicate with consumers on the nutritional properties of their products in addition to the information provided through nutrition label and ingredient list, thus enabling parents and care-givers to make better-informed purchasing decisions based on such additional information.

4.21 On the other hand, some groups (e.g. pro-breastfeeding groups) consider that infant formula with nutrient content claims tend to highlight the infant formula to be offering unique advantages over breast milk. This may mislead parents and care-givers to believe that certain infant formula is superior to breast milk, which may in turn cause undue influence to mothers on their decision on whether or not to breastfeed. Besides, given that composition requirements stipulated in the Food and Drugs (Composition and Labelling) (Amendment) (No.2) Regulation 2014 have already governed the contents of the most important nutrients for infants' growth and development, an infant formula bearing a nutrient function claim does not necessarily mean that the product carries more health benefits than those which do not make such claims. Parents and care-givers may be unduly influenced to be biased towards infant formula with nutrient function claims. We note that nutrient function claims are not allowed on infant formula in many jurisdictions such as EU, the US, Australia and New Zealand.

(b) Nutrition claim (i.e. nutrient content claim and nutrient comparative claim) and nutrient function claim on follow-up formula

4.22 Selected groups opine that follow-up formula is not breast milk replacement, and hence nutrition claims and nutrient function claims should be allowed as they will not affect mothers' decision on breastfeeding. In addition, unlike infant formula with mandatory nutritional composition requirements, there is no such requirement for follow-up formula. Composition of follow-up formula can therefore vary. Under this circumstance, nutrition claims can provide useful descriptive information to consumers on the nutrient content of follow-up formula, whereas nutrient function claims can provide useful information on the physiological role of the nutrients in growth, development and normal functions of the body. Such benefits are particularly pertinent to follow-up formula which may contain unique nutrients compared with other similar products in the market. Such information is considered important to assist parents and care-givers in making informed purchasing decisions.

4.23 As for the trade, in the absence of mandatory nutritional composition requirements for follow-up formula, being allowed to make nutrition claims and nutrient function claims on such products help them distinguish their products from others. This is considered an incentive for traders to invest in research and product development.

4.24 However, some groups hold opposite views and argue against the allowing of nutrition claims and nutrient function claims on follow-up formula. One of the reasons is that as the presentation of follow-up formula (e.g. branding, packing, etc.) often resembles that of its sister infant formula products, nutrition claims and nutrient function claims on follow-up formula may mislead parents and care-givers by creating an impression that such claims are also valid for infant formula products from the same brand, and hence influence parents' choice for breastfeeding. Besides, although there is no mandatory nutritional composition requirement on follow-up formula, most manufacturers of these formula products

in fact closely follow the standards on composition requirements established by Codex. As such, follow-up formula carrying a nutrition claim or nutrient function claim does not necessarily provide additional health benefits as compared to other formula products without such claims.

4.25 Furthermore, WHO issued a statement in July 2013 concerning the use and marketing of follow-up formula.¹³ WHO recommends that infants be exclusively breastfed for the first six months of life to achieve optimal growth, development and health, and that mothers should continue to breastfeed their child until they are two years of age or older, while providing them with safe and appropriate complementary foods from six months of age. WHO also quotes in the statement that "...as well as being unnecessary, follow-up formula is unsuitable when used as a breast-milk replacement from six months of age onwards." Since nutrition claims and nutrient function claims may induce parents and care-givers to introduce follow-up formula in the diet of a young child, there are views that such claims should not be allowed lest they undermine sustained breastfeeding up to two years of age or beyond.

(c) Other function claims on formula products and IYC foods

4.26 Under the current legislative regime in Hong Kong, there is no requirement of listing out the content of non-nutrient constituents in formula products and IYC foods. Other function claims provide a direct and convenient way for manufacturers to provide parents and care-givers with information about the functional role, together with the content information, of a constituent in formula products and IYC foods, which will in turn enable them to make informed choices and select formula products with constituents that can better meet the needs of their children. Furthermore, claims relating to such constituents are often findings of new research and outcomes of product innovation. Allowing other function claims therefore provides incentives for manufactures to invest in research

¹³ "Information concerning the use and marketing of follow-up formula", WHO, 17 July 2013.

and product development.

4.27 On the other hand, the Food and Drugs (Composition and Labelling) (Amendment) (No.2) Regulation 2014 already requires infant formula to contain essential ingredients in prescribed ranges of quantity, whereas most follow-up formula available in the market are already following the respective Codex or national requirements on composition. Allowing other function claims may divert attention of parents and care-givers from important essential nutrients to non-essential constituents. Also, infants shall gradually progress to an adult diet (i.e. consuming regular food) starting at around six months of age. Other function claims on IYC foods may give an impression to parents and care-givers that such IYC foods are better than regular food, which may interfere with the child's progression from an infant/young children diet to an adult diet.

4.28 At present, there is no international consensus as to whether other function claims should be allowed. For example, while claims describing the function of probiotics on digestive health are accepted in Singapore, it is generally not accepted in most other jurisdictions including EU. In any case, there are only a limited number of other function claims on formula products and IYC foods allowed in other jurisdictions.

Mechanism to Approve Claims and Establish Corresponding Conditions

4.29 As explained in paragraph 4.17 above, the acceptance of the first three overarching principles in paragraphs 4.7 to 4.12 would mean that certain claims on certain formula products / IYC foods would be allowed or prohibited, irrespective of whether the regulatory framework is eventually developed based on the inclusive or restrictive approach described in paragraph 4.18.

4.30 Against this background, there may be merits in establishing a list of approved claims as with the practice in some overseas jurisdictions (paragraphs 3.13 to 3.14 refer) with a view to providing clear guidance for the trade to make

nutrition and health claims on the relevant products legally. If so, a mechanism to develop the list as well as to detail the conditions under which each approved claim can be made would be needed. The mechanism should preferably be simple, with short processing time and low demand on manpower, professional support and other supporting resources. Making reference to well-researched assessments already conducted by overseas jurisdictions may be a viable way forward.

Establishing a List of Approved Claims

4.31 Under the proposed mechanism, a list of approved claims would be established by the Centre for Food Safety by way of application by the trade. Traders interested in making claims on their products which are not on the list (be they existing claims on products which are already in the market prior to the coming into force of the proposed regulatory framework, or new claims) would need to submit applications to the relevant authority for consideration.

4.32 For nutrition and health claims that have been accepted in other jurisdictions, as long as the applicant is able to produce adequate documentary proof that the claim in question has already been accepted by a recognised authority in their country of origin or another country, and that relevant claim conditions (such as definition/characterisation of the claimed substance, the required amount of the claimed substance in the formula products / IYC foods, and the target population of the claim, etc.) have been set by the relevant authority, the claim will be considered for adoption in Hong Kong through a “fast-track” assessment mechanism. Applications relating to claims that have been rejected by a recognised authority in their country of origin or another country will not be entertained. As regards claims that have never been approved by a recognised authority, traders would need to submit relevant documents on the scientific substantiation of the claims for detailed assessment by the Centre for Food Safety. Application fee calculated on a cost recovery basis will likely apply.

4.33 For claims that are eventually rejected by the Centre for Food Safety for inclusion in the list, we will have to consider the need to provide for an appeal mechanism for the aggrieved applicants. Having made reference to overseas practices, we notice that other jurisdictions do not always have in place a formal appeal mechanism dedicated for claim applications, although applicants may resort to other channels to petition to the relevant authorities. For instance, in EU, applicants will be allowed to provide comments on the opinion issued by the European Food Safety Authority before the European Commission makes the final decision on whether to approve the claim. On the other hand, in Australia and New Zealand, applicants can apply to the Administrative Appeals Tribunal for a review of the Food Standards Australia New Zealand's decision to reject the claim. As for our case, even if a dedicated appeal mechanism is considered warranted, we would need to give due consideration to the practicality of identifying and recruiting for the appeal panel adequate number of appropriate experts who are sufficiently authoritative and capable of re-examining the decisions made by the experts serving under our proposed approval mechanism.

4.34 Once a claim has been included in the list of approved claims, the applicant and other traders may make the claim on the relevant product as well as products in the same product category, so long as the specified conditions have been fulfilled. The benefit of such a mechanism is that it is simple to operate.

Revising the List of Approved Claims

4.35 The list of approved claims should be subject to review on a need basis, as the emergence of significant new evidence may alter previous conclusions about the relationship between the nutrient/constituent and its function or health benefit. We propose that the list be reviewed either upon application by the trade, or when such new evidence has come to the knowledge of the relevant authority through other channels.

Other Issues

Definition of Claims

4.36 As the definition and categorisation of nutrition and health claims vary in the international arena, we suggest clearly defining different types of claims to be governed by the regulatory framework to facilitate effective enforcement.

4.37 We propose to define key terms (such as “nutrition claims” and “health claims”) in relation to formula products and IYC foods in a way consistent with Codex, so as to promote harmonisation of local and international standards. Specifically, nutrient function claim is currently defined as a nutrition claim under Cap. 132W, but Codex defines it as a health claim. We propose revising the relevant definition in Cap. 132W in accordance with the Codex definition, such that nutrient function claims would be defined as a health claim under our proposed regulatory framework.

Exemptions

4.38 Currently, certain declarations/presentations on general prepackaged food are not considered as nutrition claims under the NL Scheme.¹⁴ Many of such declarations/presentations are made in the labelling to meet existing statutory requirements. For instance, the mentioning of nutrient content of ingredients is not considered a nutrition claim under the NL Scheme as this is a requirement under Cap. 132W. Another example is the declaration of nutrients required to be labelled under the NL Scheme (such as protein, sugars and sodium, etc.). We propose that similar arrangements be made for formula products and IYC foods in regulating health and nutrition claims.

¹⁴ Section 5 of Schedule 5, Cap. 132W is relevant.

4.39 There are also views that formula for special medical purposes (FSMP) for infants and young children should be exempted from the proposed regulatory framework. FSMP, normally used under medical supervision, are meant for infants and young children with special nutrient requirements. There are views that information such as statements relating to the nutritional composition of an FSMP for specific health purpose (e.g. phenylalanine-free powder for dietary management of infants and young children with documented phenylketonuria) provide healthcare professionals and parents with useful information, and should therefore be allowed. According to the trade, FSMP serves a multi-destination niche market and its manufacturers may have little commercial incentive to re-label their products for different markets. Reference could also be drawn to the fact that FSMP is currently exempted from nutritional composition and nutrition labelling requirements under the Food and Drugs (Composition and Labelling) (Amendment) (No.2) Regulation 2014.

Establishing a Set of NRVs for Infants and Young Children

4.40 NRVs are reference values used in nutrition labelling for comparing nutrient contents among different foods. Footnote 12 is relevant. They are often called upon as reference when the relevant authorities establish the conditions for different nutrition claims (e.g. whether the amount of nutrients in the food can be considered as “high”, “low”, “free”, “more”, “less”, etc.). In our case, it would be useful if we could refer to a set of NRVs derived specifically for infant and young children under the age of 36 months when establishing the conditions for claims eventually allowed under our proposed regulatory framework. At present, Hong Kong has not developed NRVs for this age group. Such NRVs are also not developed by Codex nor by Mainland China. We may need to consider whether it is necessary to develop a set of local NRVs for the purpose of establishing relevant claim conditions. In doing so, we may make reference to NRVs developed in other jurisdictions. We may also need to solicit support from experts to develop these values.

Nutrition and Health Claims in respect of Formula Products and IYC Foods on Advertisements

4.41 Nutrition and health claims on formula products and IYC foods, while usually present on the packaging of the relevant products, are also commonly found in the form of advertisement in the media, including the Internet. In making purchasing decisions for these products, parents and care-givers are more likely to be influenced by claims channelled through advertisements than the packaging itself as the former channel is much more penetrative. As such, our proposed regulatory framework would govern not only the nutrition and health claims made on the labelling or packaging of formula products and IYC foods, but also those in the advertisements relating to these products.

Grace Period

4.42 We consider it important to have a reasonable grace period before any regulatory control on nutrition and health claims on formula products and IYC foods comes into force. This will allow time for the trade to reformulate their products, modify their packaging, or refine their marketing strategy as necessary, to comply with the new requirements.

4.43 Besides, we propose that traders should, under the proposed mechanism for approving claims (paragraphs 4.29 to 4.35 refer), submit applications to the Government during the grace period in relation to existing claims made on products which are already in the market prior to the coming into force of the proposed regulatory framework to ensure that the sale of these products, subject to the assessment outcome, will not be affected. The actual length of the grace period is therefore also contingent upon the time required for processing such applications to ensure that there will be sufficient time for the relevant authority to process these claim applications before the expiry of the grace period. We shall also take into account views collected during the consultation before finalising the length of the grace period.

CHAPTER 5 VIEWS SOUGHT

5.1 The Government proposes to enhance the regulation of nutrition claims and health claims on formula products and IYC foods by way of legislation. As set out in Chapter 4, the proposed regulatory framework will encompass the following elements —

- (a) the establishment of five overarching principles to delineate the boundary of the regulatory framework and to prescribe conditions that will bind any claims eventually allowed;
- (b) the regulatory options for the product-claim combinations that are within the bounds of the relevant overarching principles;
- (c) the development of a mechanism for establishing and maintaining a list of approved claims and the corresponding conditions;
- (d) the establishment of a mechanism for revising the list of approved claims;
- (e) the provision of clear definition of claims;
- (f) the possible establishment of a set of NRVs specifically for infants and young children; and
- (g) a grace period to allow sufficient time for the trade to comply with the new compliance requirements.

5.2 The Government welcomes your views on the proposed regulatory framework for nutrition and health claims for formula products and IYC foods, especially the issues discussed in paragraphs 4.17 to 4.28 concerning different product-claim combinations. Please send your comments by letter, facsimile or e-mail to the Centre for Food Safety before 17 April 2015 —

Centre for Food Safety
(Attn.: Risk Assessment Section)
Food and Environmental Hygiene Department
43/F, Queensway Government Offices,
66 Queensway,
Hong Kong

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

Facsimile: 2893 3547

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

Enquiry tel. no.: (852) 2867 5699

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

5.4 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.

5.5 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.

5.6 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.

5.7 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 5.2 above.

**Examples of Claims for Orally Consumed Products
in respect of which Advertisement is Controlled
under the Undesirable Medical Advertisements Ordinance (Cap. 231)**

Subject of concern	Examples of prohibited claims
Regulation of blood sugar	<ul style="list-style-type: none">• Regulating blood sugar or glucose• Reducing blood sugar level• Suppressing or reducing the absorption of glucose• Increasing the metabolism of body sugar• Powerfully promoting the health of pancreas• Stimulating the secretion of insulin• Stabilising the index of blood sugar• Helping maintaining a normal pancreas
Regulation of blood pressure	<ul style="list-style-type: none">• Regulating blood pressure• Reducing blood pressure• Relieving the risk of blood pressure• Preventing high blood pressure• Maintain healthy blood pressure
Regulation of blood lipids or cholesterol	<ul style="list-style-type: none">• Regulating blood lipids or cholesterol• Preventing high blood lipids• Balancing blood cholesterol• Helping to maintain normal blood lipids• Helping to maintain the cholesterol at healthy level

**The Scope and Categorisation of Formula Products and IYC Foods Adopted by
Different Authorities**

Authority	Formula products	IYC foods
Codex	Age range: 0 – 36 months <ul style="list-style-type: none"> • Infant formula (0 month – weaning) (first months of life) • Follow-up formula (6 – 36 months) 	Age range: weaning – 36 months <ul style="list-style-type: none"> • Processed cereal-based foods (6 – 36 months) • Canned baby foods (weaning – 36 months)
European Union	Age range: 0 – 12 months <ul style="list-style-type: none"> • Infant formula (birth to weaning) (first months of life) • Follow-on formula (weaning to 12 months) (suitable only by infants over the age of 6 months) 	Age range: 4 – 36 months <ul style="list-style-type: none"> • Processed cereal-based food (4 – 36 months) • Baby food (4 – 36 months)
United States	Age range: 0 – 12 months <ul style="list-style-type: none"> • Infant formula (0-12 months) 	Not specifically defined
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 – 36 months <ul style="list-style-type: none"> • Foods for Infants (4 – 12 months) • Cereal-based foods • Non-cereal-based foods • Formulated supplementary food for young children (12 – 36 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 food for infants and young children (6 – 36 months)
Singapore	Age range: 0 – 6 months <ul style="list-style-type: none"> • Infant formula (0 – 6 months) 	Age range: 6 – 12 months <ul style="list-style-type: none"> • Infants Foods (6 – 12 months)

Definition of Nutrition and Health Claim Adopted by Different Authorities

Authority	Nutrition claim	Health claim
<p>Codex</p>	<p>Nutrition claim means 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. Nutrition claims include the following —</p> <ul style="list-style-type: none"> • Nutrient content claims: A nutrition claim that describes the level of a nutrient contained in a food. (e.g. “source of calcium”, “high in fibre and low in fat”) • Nutrient comparative claims: A claim that compares the nutrient levels and/or energy value of two or more foods. (e.g. “reduced”, “less than”, “fewer”, “increased”, “more than”) 	<p>Health claim means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Health claims include the following —</p> <ul style="list-style-type: none"> • Nutrient function claims, which describe the physiological role of the nutrient in growth, development and normal functions of the body. (e.g. “Nutrient A (naming a physiological role of nutrient A in the body in the maintenance of health and promotion of normal growth and development). Food X is a source of / high in nutrient A.”) • Other function claims, which concern specific beneficial effects of the consumption of food 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.”) • Reduction of disease risk claims, which are 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

Authority	Nutrition claim	Health claim
		or substance A”; “A healthful diet rich in nutrient or substance A may reduce the risk of disease D. Food X is high in nutrient or substance A.”)
European Union	<p>“Nutrition claim” means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to —</p> <p>(a) the energy (calorific value) it (i) provides; (ii) provides at a reduced or increased rate; or (iii) does not provide; and/or</p> <p>(b) the nutrients or other substances it (i) contains; (ii) contains in reduced or increased proportions; or (iii) does not contain.</p>	<p>“Health claim” means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.</p> <p>Reduction of disease risk claim means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.</p>
United States	<ul style="list-style-type: none"> • An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., “low sodium” or “contains 100 calories.” • An implied nutrient content claim is any claim that — <ul style="list-style-type: none"> (a) Describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., “high in oat bran”); or (b) Suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., “healthy, contains 3 grams (g) of fat”). 	<p>“Health claim” means any claim made on the label or in labelling of a food, including a dietary supplement, that expressly or by implication, including third-party references, written statements (e.g., a brand name including a term such as “heart”), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition.</p> <p>Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.</p>
Australia and New Zealand	<p>Nutrition content claim means a claim about —</p> <p>(a) the presence or absence of—</p> <p style="padding-left: 20px;">(i) a biologically active substance; or</p> <p style="padding-left: 20px;">(ii) dietary fibre; or</p>	<p>Health claim means any claim which states, suggests or implies that a food or a property of food has, or may have, a health effect. Health claims include the following —</p> <ul style="list-style-type: none"> • High level health claim means a health

Authority	Nutrition claim	Health claim
	<ul style="list-style-type: none"> (iii) energy; or (iv) minerals; or (v) potassium; or (vi) protein; or (vii) carbohydrate; or (viii) fat; or (ix) the components of any one of protein, carbohydrate or fat; or (x) salt; or (xi) sodium; or (xii) vitamins; or <p>(b) glycaemic index or glycaemic load; that does not refer to the presence or absence of alcohol, and is not a health claim.</p>	<p>claim that refers to a serious disease or a biomarker of a serious disease.</p> <ul style="list-style-type: none"> • General level health claim means a health claim that is not a high level health claim.
<p>Mainland China</p>	<ul style="list-style-type: none"> • 營養聲稱： 對食品營養特性的描述和聲明，如能量水平、蛋白質含量水平。營養聲稱包括含量聲稱和比較聲稱。 • 營養成分功能聲稱： 某營養成分可以維持人體正常生長、發育和正常生理功能等作用的聲稱。 	<p>(Not applicable)</p>
<p>Singapore</p>	<p>A nutrient claim suggests/implies that a food has a nutritive property. This property may be general or specific and it can be stated positively or negatively. This property may refer to —</p> <ul style="list-style-type: none"> (i) Energy; (ii) Salt, sodium or potassium; (iii) Amino acids, carbohydrates, cholesterol, fats, fatty acids, dietary fibre, protein, starch or sugars; or (iv) Any other nutrients. 	<ul style="list-style-type: none"> • Nutrient function claims describe the physiological role of the nutrient in growth, development and normal functions of the body. • Other function claims refer to claims concerning specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on relating to a positive contribution to health or to the improvement of a function or to modifying or preserving health. • Nutrient specific diet-related health claims refer to 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.

Regulatory Control on Nutrition and Health Claims in Different Authorities

	Type	Age (month)	Nutrient content claim	Nutrient comparative claim	Nutrient function claim	Other function claim	Reduction of disease risk claim
Codex	IF	0–w (first months of life)	×	×	×	×	×
	FF	6–36	×	×	×	×	×
	IYC	6–36 (processed cereal-based foods); w-36 (canned baby food)	×	×	×	×	×
EU	IF	0–w (first months of life)	○	×	×	×	○
	FF	w–12 (suitable only for infants over the age of 6 months)	○	○	○	○	○
	IYC	4–36	○	○	○	○	○
USA	IF	0–12	○	×	×	×	×
	FF	NA	NA	NA	NA	NA	NA
	Food for infants and toddlers	<24	○	×	—	—	×
	General food	25–36	○	○	○	○	○
Australia and New Zealand	IF	0–4/6	○	×	×	×	×
	FF	6–12	○	×	×	×	×
	IYC	4–36	○	—	○	○	○
Mainland China	IF	0–6	×	×	×	×	×
	FF	6–36	○	○*	○	×	×
	IYC	6–36	○	○*	○	×	×

	Type	Age (month)	Nutrient content claim	Nutrient comparative claim	Nutrient function claim	Other function claim	Reduction of disease risk claim
Singapore	IF	0–12	×	×	○	○	×
	FF	NA	NA	NA	NA	NA	NA
	IYC	6–12	×	×	○	○	×
	General food	13–36	○	○	○	○	○

Legend

IF : Infant formula

FF : Follow-up formula

IYC : Food for infant and young children

w : Weaning

NA : No food/information fits in this category

×

 : Not allowed

○

 : Allowed (some with specific requirements)

—

 : Not mentioned

*

 : Not allowed from July 2015

Regulatory Approaches Adopted in Different Jurisdictions

European Union (“EU”)

According to the Commission Directive 2006/141/EC on infant formulae and follow-on formulae, infant formulae (birth to weaning) may only bear specific nutrition claims (e.g. lactose only, lactose free) and health claims including reduction of disease risk claims (reduction of risk to allergy to milk protein) provided that the condition warranting the claims are met.

2. As stipulated in the Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children, whilst claims not specifically prohibited may generally be made for the products in question (i.e. processed cereal-based foods and baby foods for infant and young children; not applicable to milks intended for young children) in conformity with the rules applicable for all foodstuffs, such claims should, where appropriate, take into account the compositional criteria specified in the Directive. The nutrition claim and conditions applying to general food are laid down in Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods. This Regulation also stipulated that health claims shall be prohibited unless they comply with the general and specific requirements and are authorised. Meanwhile, nutrition claims are only permitted if they are listed in the Regulation and are in conformity with the conditions set out. A list of EU-authorized nutrition and health claim, including those applicable to infant and young children foods are available.

3. However, it is noted that the Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control shall repeal 2006/141/EC, 2006/125/EC and relevant directives from the

date of application of the delegated acts, which shall be adopted by 20 July 2015. The Commission shall be empowered to adopt delegated acts, with respect to the specific requirements on labelling, presentation and advertising of food (i.e. infant formula and follow-on formula, processed cereal-based food and baby food), including the authorisation of nutrition and health claims in relation thereto.

United States (“US”)

4. In the US, only a statement/claim in relation to iron content as specified in the 21 Code of Federal Regulations (“CFR”) Part 107 are allowed in infant formula (0-12 months). As stipulated in 21 CFR Part 101.13, except for “a statement that describes the percentage of a vitamin or mineral in the food in relation to a Reference Daily Intake” that may be made on food intended specifically for use by infants and children less than 2 years of age (not applicable to infant formula), nutrient content claims in these products are generally not allowed in the US. In addition, 21 CFR 101.14 state that no health claim may be made on food unless the label does not represent or purport that the food is for infants and toddlers less than 2 years of age except if the claim is approved by the authority, with the request of the trade through a petition mechanism or specifically provided as below —

- Health claims: calcium, vitamin D, and osteoporosis.
- Health claims: dietary lipids and cancer.
- Health claims: sodium and hypertension.
- Health claims: dietary saturated fat and cholesterol and risk of coronary heart disease.
- Health claims: fiber-containing grain products, fruits, and vegetables and cancer.
- Health claims: fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.
- Health claims: fruits and vegetables and cancer.
- Health claims: Folate and neural tube defects.

- Health claims: dietary noncariogenic carbohydrate sweeteners and dental caries.
- Health claims: Soluble fiber from certain foods and risk of coronary heart disease.
- Health claims: Soy protein and risk of coronary heart disease.
- Health claims: plant sterol/stanol esters and risk of coronary heart disease.

Australia and New Zealand

5. As stipulated in Standard 1.2.7 Nutrition, Health and Related Claims of the Food Standards Code, a nutrition content claim or health claim must not be made about an infant formula product (0-12 months). However, under Standard 2.9.1 Infant Formula Products, claims relating to lactose free and low lactose are permitted in infant formula products provided that the words “lactose free” and “low lactose” is part of the name of lactose free formula and low lactose formula respectively.

6. Approved nutrition content claim or health claim may be made on other infant food and food for young children, provided that the product satisfies the conditions laid down in Standard 1.2.7. In addition, under Standards 2.9.2 Foods for Infants and 2.9.3 Formulated Meal Replacement and Formulated Supplementary Foods, food for infants (4-12 months) and formulated supplementary foods for young children (12-36 months) may respectively bear nutrient content claims on protein and/or selected vitamins and minerals provided that specific conditions are fulfilled.

Mainland China

7. In Mainland China, formula and foods for infants and young children shall fulfil the labelling requirements as stated in GB13432-2004 General Standard for the Labelling of Prepackaged Foods for Special Dietary Uses (《預包裝特殊膳

食用食品標籤通則》)。 The Standard also stipulates that nutrient content claims that are allowed, and lays down specified conditions for making nutrient comparative claims and nutrient function claims. Claims regarding the prevention, alleviation, treatment or cure of a disease are, on the other hand, prohibited. In GB13432-2014《食品安全國家標準—預包裝特殊膳食用食品標籤》, which will come into force on 1 July 2015, nutrient content claim, nutrient comparative claim and nutrient function claim regarding essential nutrients on infant formula (0-6 months) are not allowed to be made. In addition, conditions for making nutrient comparative claims have not been established. For other health claims, regulatory control are stipulated under《保健食品註冊管理辦法(試行)》, in which application for each product, including food for infant and young children, has to be submitted to the authority for approval before marketing. A list of authorised products with respective health claim, including those for infant and young children, is available.

Singapore

8. In Singapore, nutrient claims are not allowed in infant formula (0-6 months) and food for infant and children below the age of 2. Regarding nutrient function claim, there is a list of acceptable nutrient function claims specific to infant formula, infant's food and foods for young children (up to 6 years of age) as well as a list of acceptable nutrient function claims for all foods. Singapore has also listed out acceptable other function claim for all foods. Food manufacturers and importers may submit applications to the authorities for use of specific disease risk claims (e.g. A healthy diet with adequate calcium and vitamin D, with regular exercise, helps to achieve strong bones and may reduce the risk of osteoporosis. X is a good source of / high in / enriched in / fortified with calcium) for food including those for 1 year old and above. Only food products that have been first approved by Health Promotion Board in Singapore to carry Healthier Choice Symbol may be considered for application of use of these health claims. However, these claims have not been allowed for formula milk and infant foods.

**Mechanisms for Evaluating Nutrition and Health Claims
Adopted in Different Jurisdictions**

European Union (“EU”)

To obtain authorisation for a new health claim or amend the existing list on health claims made on foods, the manufacturer must submit an application to the Member State concerned, which will forward it to the European Food Safety Authority (“EFSA”) for scientific assessment. EFSA shall issue its opinion within 5 months from the date of receipt of the request, and such time limit may be extended for 1 more month if considered necessary. The Commission then makes a decision on the use of the claim on the basis of the EFSA’s opinion within 2 months of receiving opinion from EFSA. In total, it may take 7-8 months from the receipt of application to approval for a new health claim. Currently, EFSA does not charge a fee for its scientific evaluations. However, this practice is under review by the EU decision-makers.

2. According to Commission Regulation (EC) 353/2008 on establishing implementing rules for applications for authorisation of health claims, each application shall cover only one relationship between a nutrient or other substance, or food or category of food, and a single claimed effect. Technical rules for the preparation and presentation of the application for health claims are promulgated.

3. EFSA’s Panel on Dietetic Products, Nutrition and Allergies (“NDA Panel”) is responsible for verifying the scientific substantiation of the health claims. The NDA Panel comprises 20 highly qualified risk assessment experts from a number of European nationalities with expertise in a range of relevant fields, such as human nutrition, infant nutrition, human medicine, exposure assessment, food consumption, dietary surveys, nutrient requirements, nutritional epidemiology, food allergy and intolerance, toxicology, clinical immunology, and nutritional biochemistry.

4. On the other hand, for nutrition claims, similar petition mechanism has not been described in the Regulation. However, it was stated that amendments to the positive list could be adopted in accordance with specific regulatory procedure and, where appropriate, after consulting EFSA. Where appropriate, the Commission shall involve interested parties, in particular food business operators and consumer groups, in order to evaluate the perception and understanding of the claims in question.

United States (“US”)

5. Any interested person may petition the Food and Drug Administration (“FDA”) to issue a regulation regarding a health claim. FDA will publish a final rule, within 540 days of the date of receipt of the petition, that either authorises use of the health claim or explains why the agency has decided not to authorise one. Similarly, interested parties may petition the agency to authorise synonyms or new nutrition claims (nutrient content claims and nutrient comparative claims) under the procedures described in the regulation. However, unlike health claims, structure/function claims are not subject to FDA review and authorisation. The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims.

Australia and New Zealand

6. A new Standard, namely Standard 1.2.7 Nutrition, Health and Related Claims, became law on 18 January 2013. According to the Standard, a nutrition content claim or health claim must not be made about an infant formula product, including infant formula, follow-on formula and infant formula products for special dietary use.

7. Food businesses wanting to make a general level health claim can either (i) base their claims on one of the more than 200 pre-approved food-health relationships in the Standard, or (ii) self-substantiate the claim in accordance with

detailed requirements set out in the Standard. For the latter case, food businesses must undertake its own systematic review and notify the Food Standards New Zealand Australia (“FSANZ”) of the relationship prior to making the claim on food labels or in advertisements for food. FSANZ will maintain a list of the notified food-health relationships. FSANZ will seek scientific and technical advice from Health Claims Scientific Advisory Group related to health claims (excluding high level health claim variations and relevant applications and proposals) if needed. The Advisory Group comprises seven core members.

8. On the other hand, high level health claims must be based on a food-health relationship pre-approved by FSANZ. There are currently 13 pre-approved food-health relationships for high level health claims listed in the Standard. However, food businesses can apply to make a change to the list of high level health claims or to add a general level health claim in accordance to procedures and requirements stated in the Standard and relevant guidelines. These applications will be considered by the High Level Health Claims Committee. The Committee provides recommendations to FSANZ in relation to draft high level health claim variations and/or the application or proposals, and it comprises seven core members. The core members for the Advisory Group and the Committee are currently the same. It is anticipated that some 10 months will be required to process each application, counting from the receipt of proposal to the making of final decision. Regulations for recovering the cost of processing applications relating to high level health claims are not yet made. Until then, FSANZ cannot charge fees for these applications.

Mainland China

9. In Mainland China, according to 《保健食品註冊管理辦法（試行）》， products with health claims, including food for infant and young children, need to be approved before marketing. For domestic food, the petition shall be submitted to provincial food and drug authorities, and it may take 145 days from the receipt of petition to final approval. For imported food, the petition shall be submitted to

national food and drug authorities, and it may take 130 days from the receipt of petition to final approval. The application procedure and dossier as well as time requirements are formulated in the regulation.

10. The China Food and Drug Administration (“CFDA”) is responsible for approving the food with health claims and designating laboratories which provide associated testing service. A total of 27 categories of relevant health functions are listed in the CFDA website. All the food with health claims shall be evaluated case by case. In doing so, CFDA will organise experts in the field of food, nutrition, medicine, pharmacology and other professionals to evaluate the food and health claims. Currently, CFDA does not charge any fees for such applications.

Singapore

11. Local food manufacturers and importers may submit applications to the Agri-Food and Veterinary Authority (“AVA”) or the Health Promotion Board (“HPB”) for use of nutrient specific diet-related health claims. Only food products that have been first approved by HPB to carry the Healthier Choice Symbol may be considered for application of use of these health claims. HPB will conduct pre-market evaluation of applications that are concurrently submitted with applications for the Healthier Choice Symbol. AVA will conduct pre-market evaluation of separate applications. To assist industry members who wish to apply for the use of new nutrient function and other function claims, the guidance information, application form and checklist are promulgated.

12. In Singapore, tasks relating to claim evaluation are performed by AVA’s Advisory Committee on Evaluation of Health Claims, which was formed in August 2009. The Committee comprises reputable scientific experts with relevant professional training and experience from government bodies, tertiary institutions, and industry associations. It is responsible for establishing a framework and principles for evaluation of health claims, evaluating the claim applications, as well

as providing advice and update on relevant scientific developments and legislation relating to evaluation of health claims.

