Technical Guidance Notes on

Nutritional Composition and Nutrition Labelling of Infant Formula, Follow-up Formula and Prepackaged Food for Infants and Young Children

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TECHNICAL GUIDANCE NOTES ON NUTRITIONAL COMPOSITION AND NUTRITION LABELLING OF INFANT FORMULA, FOLLOW-UP FORMULA AND PREPACKAGED FOOD FOR INFANTS AND YOUNG CHILDREN

CONTENT

INTRODUCTION

The Government is committed to protecting the health of infants and young children. The Food and Drug (Composition and Labelling) (Amendment) (No.2) Regulation 2014 ("the Amendment Regulation") amends the Food and Drugs (Composition and Labelling) Regulations (Cap. 132W) to provide for regulatory control over infant formula, follow-up formula and prepackaged food for infants and young children. The Amendment Regulation covers nutritional composition requirement of infant formula and nutrition labelling requirement for infant formula, follow-up formula and prepackaged food for infants and young children.

2. In order to assist the trade to comply with the Amendment Regulation, the Centre for Food Safety ("CFS") of the Food and Environmental Hygiene Department ("FEHD") has prepared these Technical Guidance Notes to provide technical information on the requirement and to answer some of the most frequently asked questions, which in turn offer guidance to the trade in formulating their products and making nutrition labels. The members of trade should also make reference to other related guidelines published by the CFS, such as Method Guidance Notes on Nutritional Composition and Nutrition Labelling of Infant Formula, Follow-up Formula and Prepackaged Food for Infants and Young Children, Trade Guidelines on Preparation of Legible Food Label and Trade Guidelines on Serving Size of Prepackaged Food for Nutrition Labelling.

DISCLAIMER

3. The Technical Guidance Notes are not part of the legislation and are intended for general reference only. It should be read in conjunction with the relevant legislation including but not limited to the Amendment Regulation. Information contained in the Technical Guidance Notes may not be exhaustive or complete. Specific issues should be considered on a case by case basis and independent legal advice should be sought in case of doubt. The ultimate authority for interpretation of the legislation rests with the Courts.

BACKGROUND AND OBJECTIVES OF THE AMENDMENT REGULATION

4. Infants and young children must obtain optimal nutrition from their diet to grow and stay healthy. The superiority of breastfeeding in ensuring physical and psychosocial health and well-being of mother and child, as well as the important

impacts of early nutrition on long-term health are widely recognised.

5. Where breast-feeding is not feasible, infant formula 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 feeding. So, prescribing the appropriate composition of infant formula is important to safeguard the health of infants.

6. 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 labelling and nutrition claims. 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")[1] has established different standards for these foods.

7. Providing nutrition information on labels of formula products and foods intended for infants and young children is an important communication tool to assist the parents to obtain specific nutrition information on individual food products.

8. The introduction of the Amendment Regulation aims to (i) protect the health of infants and young children; (ii) assist the parents in making informed food choices; and (iii) encourage food manufacturers to apply sound nutrition principle in the formulation of formula products and foods intended for infants and young children.

9. When preparing the Amendment Regulation, the Administration has made reference to the relevant Codex standards, taking into account international practices. This ensures that the Amendment Regulation is 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, the Administration believes 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.

[1] The Codex Alimentarius Commission (Codex) was established in 1963 by the Food and Agriculture Organization of the United Nations and World Health Organization as an international authority to set food-related standards and guidelines.

DEFINITIONS

10. The Amendment Regulation introduces some newly added or amended definitions, including the following (unless otherwise stated, references to provisions are references to provisions in the amended Food and Drugs (Composition and Labelling) Regulations (Cap. 132W) –

- "folic acid" (葉酸), in relation to any infant formula or follow-up formula, means N-pteroyl-L-glutamic acid.

- "follow-up formula" (較大嬰兒及幼兒配方產品) means —
  (a) a product that, according to its descriptions or instructions for use, is—
    (i) represented as a replacement for human breast milk or infant formula*; and
    (ii) intended for consumption as a liquid element in a progressively diversified diet by persons of any age from 6 months to under 36 months (even if it is also claimed in the descriptions or instructions, if applicable, to be suitable for consumption by persons of any other age); or
  (b) a product marked or labelled as "follow-up formula" or "較大嬰兒及幼兒配方產品", or with any other words of similar meaning.

  * a reference to replacement for human breast milk or infant formula (replacing formula) includes a reference to any product that is a replacement of the replacing formula or any of its subsequent replacements.

- "formula for special medical purposes for infants and young children" (特殊醫用嬰幼兒配方產品) means a product that —
  (a) according to its descriptions or instructions for use, is specially processed or formulated for the dietary management for, and intended for the exclusive or partial feeding of, persons of any age under 36 months (even if it is also claimed in the descriptions or instructions, if applicable, to be suitable for consumption by persons of any age from 36 months onwards)—
    (i) who have limited or impaired capacity to take, digest, absorb or metabolize ordinary food or certain nutrients in it;
    (ii) who have special nutrient requirements that are determined medically; or
    (iii) whose dietary management cannot be achieved only by

consumption of other food for special dietary uses or modification of normal diet; and

(b) may only be used under medical supervision.

- "infant formula" (嬰兒配方產品) means —
  (a) a product that, according to its descriptions or instructions for use, is 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 (even if it is also claimed in the descriptions or instructions, if applicable, to be suitable for consumption by persons of any age over 12 months); or
  (b) a product marked or labelled as "infant formula" or "嬰兒配方產品", or with any other words of similar meaning.

- "list of nutrients" (營養素表) —
  (a) in relation to any prepackaged food to which regulation 4B applies, means a list of nutrients required by section 1 of Schedule 5; and
  (b) in relation to any infant formula, follow-up formula or prepackaged food for infants and young children, means a list of nutrients required by section 1 of Schedule 6A.

- "niacin" (煙酸) —
  (a) in relation to any infant formula, means nicotinamide together with nicotinic acid; and
  (b) in relation to any follow-up formula, means nicotinamide.

- "nutrient" (營養素) —
  (a) means any substance present in food which-
    (i) belongs to, or is a component of, one of the following categories—
      (A) protein;
      (B) carbohydrates;
      (C) fat;
      (D) dietary fibre;
      (E) vitamins;
      (F) minerals; and
    (ii) satisfies any of the following conditions -

(A) the substance provides energy;

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

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

(b) in relation to any infant formula (Part IV of Schedule 1 and Schedule 6A), includes myo-inositol, L-carnitine and taurine.

- "prepackaged food for infants and young children" (預先包裝嬰幼兒食物) means any prepackaged food that, according to its descriptions or instructions for use, is intended for consumption by persons of any age under 36 months (even if it is also claimed in the descriptions or instructions, if applicable, to be suitable for consumption by persons of any age from 36 months onwards), but does not include any infant formula or follow-up formula.

- "vitamin A" (維他命 A) —

(a) in relation to any infant formula or follow-up formula (Part IV of Schedule 1 and section 1(1) and (3) of Schedule 6A), means all-trans retinol calculated in terms of Retinol Equivalent (RE) or in International Unit (IU) (with 1 μg RE as being equivalent to 3.33 IU); and

(b) in any other case, means the sum of retinol and beta-carotene contained in the food, calculated in terms of RE (with 6 μg of beta-carotene as being equivalent to 1 μg RE).

- "vitamin C" (維他命 C) —

(a) in relation to any infant formula, means ascorbic acid together with dehydroascorbic acid; and

(b) in relation to any follow-up formula, means ascorbic acid.

- "vitamin E" (維他命 E) —

(a) in relation to any infant formula, means d-alpha-tocopherol, calculated in terms of alpha-Tocopherol Equivalent (α-TE) or International Unit (IU) (with 1 IU as being equivalent to 0.67 mg α-TE); and

(b) in relation to any follow-up formula, means alpha-tocopherol compounds, calculated in terms of α-TE or IU—

(i) (for alpha-tocopherol compounds from any natural source) with 1 IU as being equivalent to 0.67 mg α-TE; or

(ii) (for alpha-tocopherol compounds from any synthetic source) with 1 IU as being equivalent to 0.45 mg α-TE.

- "vitamin K" (維他命 K) in relation to any infant formula and follow-up formula, means vitamin K1.

11. If any product falls within both the definitions of infant formula and follow-up formula, it is to be treated for the purposes of the amended Food and Drugs (Composition and Labelling) Regulations (Cap. 132W) as an infant formula but not a follow-up formula."

COVERAGE AND IMPLEMENTATION TIME FRAME

12. The Amendment Regulation covers infant formula, follow-up formula and prepackaged food for infants and young children as defined.

13. Infant formula, follow-up formula or prepackaged food for infants and young children with description or instruction for use that claims to be suitable for consumption by persons of any age from 36 months onwards should also observe, where applicable, the requirements under the existing Nutrition Labelling Scheme.

14. Except being exempted (as stated in paragraph 15 of these Notes), the Amendment Regulation requires all infant formula to meet nutritional composition requirement and the presence of nutrition label on all infant formula, follow-up formula and prepackaged food for infants and young children. The nutritional composition and nutrition labelling requirements for infant formula will become mandatory from 13 December 2015, after a grace period of 18 months. The nutrition labelling requirement for follow-up formula and prepackaged food for infants and young children will become mandatory from 13 June 2016, after a grace period of two years.

EXEMPTION

15. Under the Amendment Regulation, formula for special medical purposes for infants and young children (FSMP) are exempted from the nutritional composition and nutrition labelling requirements provided that the FSMP comply with the specific

labelling requirements (see Annex I). In addition, infant formula or follow-up formula packed in a container which has a total surface area of less than 250cm^2 and prepackaged food for infants and young children packed in a container which has a total surface area of less than 100cm^2 are exempt from the nutrition labelling requirement.

NUTRITIONAL COMPOSITION

Infant formula

16. Under the Amendment Regulation, infant formula must fulfill the following nutritional composition requirements:

> i) energy value of the infant formula, in a form that is reconstituted or served according to any instructions for use provided, is no less than the minimum specified and no more than the maximum specified in Table 1;
>
> ii) it contains all the nutrients specified in Table 2 and the amount of each nutrient is no less than the minimum, if any, and no more than the maximum, if any, specified for that nutrient; and
>
> iii) it meets the nutritional requirements specified in Table 3

17. In addition, it is recommended, in relation to nutrients without maximum levels specified, to follow the guidance upper levels (GUL)[2], if any, set out in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72- 1981) as shown in Table 2. It is also recommended that infant formula to follow other nutritional requirements set out in CODEX STAN 72- 1981 as shown in Table 4.

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[2] Guidance upper levels (GUL) 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.

Table 1 Energy Value of Infant Formula

	Minimum level per 100 ml	Maximum level per 100 ml
Energy	60 kcal or 250 kJ	70 kcal or 295 kJ

Table 2 Nutrient Content of Infant Formula

Nutrients	Minimum level per 100 kcal	Minimum level per 100 kJ	Maximum level per 100 kcal	Maximum level per 100 kJ	Guidance upper levels per 100kcal	Guidance upper levels per 100kJ
Protein						
Protein (for infant formulae based on cows milk protein)	1.8 g	0.45g	3.0 g	0.7 g	-	-
Protein (for infant formulae based on soy protein isolate)	2.25 g	0.5 g	3.0 g	0.7 g	-	-
Fat						
Total fat	4.4 g	1.05 g	6.0 g	1.4g	-	-
Linoleic acid	300 mg	70 mg	-	-	1400 mg	330 mg
α-Linolenic acid	50 mg	12 mg	-	-	-	-
Carbohydrates						
Total carbohydrates	9.0 g	2.2 g	14.0 g	3.3 g	-	-
Vitamins						
Vitamin A	60 μg RE	14 μg RE	180 μg RE	43 μg RE	-	-
Vitamin D3	1 μg	0.25 μg	2.5 μg	0.6 μg	-	-
Vitamin E	0.5 mg α-TE	0.12 mg α-TE	-	-	5 mg α-TE	1.2 mg α-TE
Vitamin K	4 μg	1 μg	-	-	27 μg	6.5 μg
Thiamine	60 μg	14 μg	-	-	300 μg	72 μg
Riboflavin	80 μg	19 μg	-	-	500 μg	119 μg
Niacin	300 μg	70 μg	-	-	1500 μg	360 μg
Vitamin B6	35 μg	8.5 μg	-	-	175 μg	45 μg

Nutrients	Minimum level per 100 kcal	Minimum level per 100 kJ	Maximum level per 100 kcal	Maximum level per 100 kJ	Guidance upper levels per 100kcal	Guidance upper levels per 100kJ
Vitamin B12	0.1 μg	0.025 μg	-	-	1.5 μg	0.36 μg
Pantothenic acid	400 μg	96 μg	-	-	2000 μg	478 μg
Folic acid	10 μg	2.5 μg	-	-	50 μg	12 μg
Vitamin C	10 mg	2.5 mg	-	-	70 mg	17 mg
Biotin	1.5 μg	0.4 μg	-	-	10 μg	2.4 μg
Minerals						
Iron	0.45 mg	0.1 mg	-		-	-
Calcium	50 mg	12 mg	-		140 mg	35 mg
Phosphorus	25 mg	6 mg	-		100 mg	24 mg
Magnesium	5 mg	1.2 mg	-		15 mg	3.6 mg
Sodium	20 mg	5 mg	60 mg	14 mg	-	-
Chloride	50 mg	12 mg	160 mg	38 mg	-	-
Potassium	60 mg	14 mg	180 mg	43 mg	-	-
Manganese	1 μg	0.25 μg	-	-	100 μg	24 μg
Iodine	10 μg	2.5 μg	-	-	60 μg	14 μg
Selenium	1 μg	0.24 μg	-	-	9 μg	2.2 μg
Copper	35 μg	8.5 μg	-	-	120 μg	29 μg
Zinc	0.5 mg	0.12 mg	-	-	1.5 mg	0.36 mg
Others						
Choline	7 mg	1.7 mg	-	-	50 mg	12 mg
Myo-Inositol	4 mg	1 mg	-	-	40 mg	9.5 mg
L-Carnitine	1.2 mg	0.3 mg	-	-	-	-
Taurine (if added)			12 mg	3 mg	-	-

Table 3 Nutritional Requirements of Infant Formula

1. The ratio of linoleic acid to α-linolenic acid must be at least 5:1 and not more than 15:1.
2. The ratio of calcium to phosphorus must be at least 1:1 and not more than 2:1.
3. The combined content of lauric acid and myristic acid must not exceed 20% of the total content of fatty acids.
4. The content of trans fatty acids must not exceed 3% of the total content of fatty acids.
5. The content of erucic acid must not exceed 1% of the total content of fatty acids

6. The content of vitamin E must in any case not be less than 0.5 mg α-TE/g polyunsaturated fatty acids, as adapted to the number of fatty acid double bonds in the formula using the following factors of equivalence— (a) 0.5 mg α-TE/g linoleic acid (18:2 n-6); (b) 0.75 mg α-TE/g α-linolenic acid (18:3 n-3); (c) 1.0 mg α-TE/g arachidonic acid (20:4 n-6); (d) 1.25 mg α-TE/g eicosapentaenoic acid (20:5 n-3); (e) 1.5 mg α-TE/g docosahexaenoic acid (22:6 n-3).
7. If there is any docosahexaenoic acid (DHA) added— (a) the content of arachidonic acid must not be less than that of DHA; and (b) the content of eicosapentaenoic acid must not exceed that of DHA.

Table 4 Other Recommended Nutritional Requirements for Infant Formula

1. For equal energy value, the formula contains an available quantity of each essential and semi-essential amino acid at least equal to that contain in the reference protein (Essential and semi essential amino acids contents in breast milk as defined in Annex I of CODEX STAN 72-1981).
2. The content of phospholipids does not exceed 300mg/100kcal (72mg/100kJ).
3. If there is added DHA, its content does not exceed 0.5% of total fatty acid.
4. Fluoride should not be added to infant formula.

Follow-up formula

18. It is recommended that follow-up formula should fulfill the nutritional composition requirements set out by the jurisdiction or country where the product is originated or the nutritional composition requirements as set out in Codex Standard for Follow-up Formula (CODEX STAN 156-1987).

Prepackaged food for infants and young children

19. It is recommended that prepackaged food for infants and young children should fulfill the nutritional composition requirements set out by the jurisdiction or country where the product is originated or the nutritional composition requirements as set out in Codex Standard for Canned Baby Foods (CODEX STAN 73-1981) and Codex Standard for Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981).

NUTRITION LABELLING

Information on the Nutrition Label

20. Under the Amendment Regulation, nutrition label must include information on energy value and the content of certain specified nutrients as summarized in paragraphs 23, 25 and 26 below. Additional information on other nutrients may voluntarily be included in the nutrition label provided that such information is not false, misleading or deceptive in any respect as to the nutritional or dietary value of the infant formula, follow-up formula or prepackaged food for infants and young children.

21. Under the Amendment Regulation, there are two options given for labelling carbohydrates content on the nutrition label of follow-up formula or prepackaged food for infants and young children– (i) to set out the content of "available carbohydrates"[3]; or (ii) to set out the content of "total carbohydrates". If the latter option is chosen, the content of dietary fibre must also be set out, preferably underneath the amount of total carbohydrates (see the example in paragraph 43). In case the term "carbohydrates" is used on nutrition labels of follow-up formula or prepackaged food intended for infants and young children, it will be assumed that the term refers to "available carbohydrates".

22. Names or abbreviations that are commonly known to consumers are considered acceptable in nutrition labelling. Table 5 lists some of the common names and abbreviations of nutrients, the use of which are acceptable.

Table 5 Common names and abbreviation of selected nutrients

Information	Common Names and Abbreviation
Energy	"Calories" / "Kilojoules" (When "Calories" or "Kilojoules" is used instead of the term "Energy", the term must match with declaration of energy in the corresponding unit of energy.)

[3] Available carbohydrates is defined as the amount of total carbohydrates excluding the amount of dietary fibre.

Available carbohydrates	"Carbohydrates, Available" / "Carbohydrates"/ "Available Carb" / "Carb, Available" / "Carb" / "Available CHO" / "CHO"
Total carbohydrates	"Carbohydrates, Total" / "Total Carb" / "Carb, Total" / "Total CHO" / "CHO, Total"
Total fat	"Fat" / "Fat, Total"
Dietary fibre	"Dietary fiber" / "Total dietary fibre" / "Total dietary fiber" / "Fibre" / "Fiber"
Thiamine	"Thiamin" / "Vitamin B1" / "Vit. B1"
Riboflavin	"Vitmain B2" / "Vit. B2"
Niacin	"Vitamin B3" / "Vit. B3"
Vitamin B12	"Cobalamin" / "Vit. B12"
Pantothenic acid	"Pantothenate"/ "Vitamin B5" / "Vit. B5"
Folic acid	"Folate" / "Folacin" / "Vitamin B9" / "Vit. B9"
Iodine	"Iodide"

Infant formula

23. Under the Amendment Regulation, nutrition label of infant formula must include information on energy value and the content of the following 29 nutrients:

(i) Protein;
(ii) Total fat;
(iii) Total carbohydrates;
(iv) Vitamin A;
(v) Vitamin D3;
(vi) Vitamin E;
(vii) Vitamin K;
(viii) Thiamine;
(ix) Riboflavin;
(x) Niacin;
(xi) Vitamin B6;
(xii) Vitamin B12;
(xiii) Pantothenic acid;
(xiv) Folic acid;

(xv) Vitamin C;
(xvi) Biotin;
(xvii) Iron;
(xviii) Calcium;
(xix) Phosphorus;
(xx) Magnesium;
(xxi) Sodium;
(xxii) Chloride;
(xxiii) Potassium;
(xxiv) Manganese;
(xxv) Iodine;
(xxvi) Selenium;
(xxvii) Copper;
(xxviii) Zinc; and
(xxix) Choline.

24. If the fluoride content of infant formula (in a form that is reconstituted or served according to any instructions for use provided) exceeds 100 μg per 100 kilocalories or 24 μg per 100 kilojoules, the formula must be marked or labelled with a statement—

(i) indicating that consumption of the formula may cause dental fluorosis; and

(ii) recommending that the risk of dental fluorosis should be discussed with a medical practitioner or health professional.

Follow-up formula

25. Under the Amendment Regulation, nutrition label of follow-up formula must include information on energy value and the content of the following 25 nutrients:
(i) Protein;
(ii) Total fat;
(iii) Available carbohydrates;
(iv) Vitamin A;
(v) Vitamin D;
(vi) Vitamin E;
(vii) Vitamin K;
(viii) Thiamine;
(ix) Riboflavin;
(x) Niacin;
(xi) Vitamin B6;

(xii) Vitamin B12;
(xiii) Pantothenic acid;
(xiv) Folic acid;
(xv) Vitamin C;
(xvi) Biotin;
(xvii) Iron;
(xviii) Calcium;
(xix) Phosphorus;
(xx) Magnesium;
(xxi) Sodium;
(xxii) Chloride;
(xxiii) Potassium;
(xxiv) Iodine; and
(xxv) Zinc.

Prepackaged food for infants and young children

26. Under the Amendment Regulation, nutrition label of prepackaged food for infants and young children must include the information on energy value and the content of the following 6 nutrients:
(i) Protein;
(ii) Total fat;
(iii) Available carbohydrates;
(iv) Sodium;
(v) Vitamin A (if added); and
(vi) Vitamin D (If added).

Nutrient Content Expression

27. All nutrient content expressions, whether mandatory or voluntary, must be accurate and truthful.

28. Energy value and the content of nutrients referred to in paragraphs 23, 25 and 26 above should be expressed in absolute numbers. They can be rounded up in accordance with paragraphs 40 below. Ranges, including maximum (e.g. <0.3mg) and minimum (e.g. >9g) are not acceptable.

Infant formula

29. Energy value must be expressed in kilocalorie (kcal) or kilojoule (kJ) or both -
    (i) per 100g of the formula (in a form ready for sale); or
    (ii) per 100mL of the formula (in a form ready for sale, or in a form that is reconstituted or served according to any instructions for use provided).

30. The amount of protein, total fat and total carbohydrates must be expressed in gram (g) -
    (i) per 100g of the formula (in a form ready for sale); or
    (ii) per 100mL of the formula (in a form ready for sale, or in a form that is reconstituted or served according to any instructions for use provided).

31. The content of other nutrients must be expressed in an appropriate unit -
    (i) per 100g of the formula (in a form ready for sale); or
    (ii) per 100mL of the formula (in a form ready for sale, or in a form that is reconstituted or served according to any instructions for use provided).

Follow-up formula

32. Energy value must be expressed in kilocalorie (kcal) or kilojoule (kJ) or both -
    (i) per 100g of the formula (in a form ready for sale);
    (ii) per 100mL of the formula (in a form ready for sale, or in a form that is reconstituted or served according to any instructions for use provided); or
    (iii) per suggested serving as specified in gram(g) or milliliter(mL)

33. The amount of protein, total fat and available carbohydrates must be expressed in gram (g) -
    (i) per 100g of the formula (in a form ready for sale);
    (ii) per 100mL of the formula (in a form ready for sale, or in a form that is reconstituted or served according to any instructions for use provided); or
    (iii) per suggested serving as specified in gram(g) or milliliter(mL)

34. The content of other nutrients must be expressed in an appropriate unit -
    (i) per 100g of the formula (in a form ready for sale);
    (ii) per 100mL of the formula (in a form ready for sale, or in a form that is reconstituted or served according to any instructions for use provided); or
    (iii) per suggested serving as specified in gram(g) or milliliter(mL)

35. In addition, content of nutrients in infant formula and follow-up formula may further be expressed on a per 100kcal or per 100kJ basis.

Prepackaged food for infants and young children

36. Energy value must be expressed in kilocalorie (kcal) or kilojoule (kJ) or both
    (i) per 100g of the food (in a form ready for sale);
    (ii) per 100mL of the food (in a form ready for sale, or in a form that is reconstituted or served according to any instructions for use provided); or
    (iii) per suggested serving as specified in gram(g) or milliliter(mL)

37. The amount of protein, total fat and available carbohydrates must be expressed in gram (g) -
    (i) per 100g of the food (in a form ready for sale);
    (ii) per 100mL of the food (in a form ready for sale, or in a form that is reconstituted or served according to any instructions for use provided); or
    (iii) per suggested serving as specified in gram(g) or milliliter(mL)

38. The content of other nutrients must be expressed in an appropriate unit -
    (i) per 100g of the food (in a form ready for sale);
    (ii) per 100mL of the food (in a form ready for sale, or in a form that is reconstituted or served according to any instructions for use provided); or
    (iii) per suggested serving as specified in gram(g) or milliliter(mL)

39. For energy value and nutrient content expression of follow-up formula and prepackaged food for infants and young children, "per suggested serving" may be presented as "per suggested serving of product as sold" or "per suggested serving of product as consumed".

Units and Rounding Rules of Declared Value in Nutrition Label

40. To present energy value on nutrition labels, either kcal or kJ should be used. Protein, carbohydrates and fat content should be declared in gram (g). As for nutrient content declaration of other nutrients referred to in paragraphs 23, 25 and 26 above, metric units (g, mg, μg) are recommended. It should be noted that the recommended units for vitamin A and vitamin E are μg Retinol Equivalent (RE) and mg α-Tocopherol Equivalent (TE) respectively. The energy value and nutrient contents of

infant formula, follow-up formula and prepackaged food for infants and young children can be rounded according to Table 6 with examples illustrated in Table 7 below.

Table 6 Rounding Rules for Labelling of Selected Nutrients

	Unit	Round to	Definition of "0" (per 100g/mL of food as sold)
Energy	kcal or kJ	1	≤ 4 kcal or ≤ 17 kJ
Protein	g	0.1	≤ 0.5g
Carbohydrates (Available or Total)	g	0.1	≤ 0.5g
Dietary Fibre	g	0.1	≤ 1.0g
Fat	g	0.1	≤ 0.5g
Sodium	mg	1	≤ 5mg
Vitamins, Minerals and Choline	g, mg or µg	Round to two significant figures	-

Table 7 Examples for Rounding of Nutrient Content

	Value before rounding	Value after rounding
Energy	463.5kcal	464kcal
Protein, Carbohydrates (Available or Total), Fat	18.64g	18.6g
Dietary Fibre	0.73g	0.7g
Sodium	263.8mg	264mg
Calcium	333mg	330mg
Vitamin B12	0.0676µg	0.068µg
Choline	20.5mg	21mg

Nutrition Labelling Format

41. The nutrition information must be presented in tabular format and the nutrition label must be placed in a conspicuous place on the package. Notwithstanding the aforesaid, the trade has an option to use linear format for prepackaged food for infants and young children if the total surface area of the package is less than 200cm^2.

42. Regardless of the size and/or format of the nutrition label, an appropriate heading is needed. It is recommended that headings such as "Nutrition Label", "Nutrition Information" or "Nutrition Facts" be displayed. Furthermore, it is suggested that the terms "per 100g", "per 100mL" or "per serving" be placed at an appropriate position in the nutrition label (see examples in Annex II).

43. There are no legal requirements in the order of nutrients. However, when declaring the amount and/or types of carbohydrates or total carbohydrates, it is suggested that the following order can be used –

Carbohydrates (or available carbohydrates)
Dietary fibre

or

Total carbohydrates
- Dietary fibre

44. Nutrition label can be written in the English Language, the Chinese Language (simplified or traditional) or in both languages, but numbers may be expressed in Arabic numerals. However, the nutrition label must be in both English and Chinese languages if both languages are used in the marking or labelling of the infant formula, follow-up formula and prepackaged food for infants and young children.

Compliance and Tolerance Limits

45. Under the routine surveillance programme, the Administration verifies the accuracy of nutrient values on nutrition labels. Depending on the type of nutrients, the declared values have different tolerance limits (Table 8). The tolerance limits are only applicable to declared values on nutrition label but not to the nutrition composition requirements.

Table 8 Tolerance Limits for Declaration of Energy Level or Nutrient content on nutrition label

Energy / Nutrients	Tolerance Limits
Energy, Total Fat, Saturated Fatty Acids, Trans Fatty Acids, Cholesterol, Sodium, Sugars	≤ 120% declared value
Protein, Polyunsaturated Fatty Acids, Monounsaturated Fatty Acids, Carbohydrates (Available or Total), Starch, Dietary Fibre, Soluble Fibre, Insoluble Fibre, Individual Component of Fibre	≥ 80% declared value
Vitamins and Minerals (Other than Vitamin A, Vitamin D and added vitamins and minerals), Choline	≥ 80% declared value
Vitamin A and Vitamin D (including added ones)	80%-180% declared value
Added Vitamins and Minerals (other than Vitamin A and Vitamin D)	≥ declared value

46. Measurement uncertainty is a quantitative indicator of the analytical variability of a test result and has not been taken into consideration when corresponding tolerance limits were set. Since measurement uncertainty and tolerance limit are independent of each other, the measurement uncertainty will be dealt with separately in the event of compliance checking.

MARKING AND LABELLING

47. Under the Amendment Regulation, any container containing follow-up formula must not be marked or labelled to the effect that the formula is suitable for consumption by persons of any age under 6 months.

Centre for Food Safety
Food and Environmental Hygiene Department
January 2015

Annex I

Exemption from Nutritional Composition and Nutrition Labelling Requirements

Formula for special medical purposes for infants and young children (FSMP) can be exempted from the nutritional composition and nutrition labelling requirements provided that such product is marked or labelled with:

(1) the words "formula for special medical purposes" or "特殊醫用配方產品", or any other words of similar meaning, in the name of the formula or in a conspicuous place of the package that is not in close proximity to other information on the package;

(2) the words "USE UNDER MEDICAL SUPERVISION" or "在醫生指示下使用", or any other words of similar meaning, in bold and in a conspicuous place of the package that is not in close proximity to other information on the package;

(3) a statement stating "For the dietary management of (fill in the disease, disorder or medical condition for which the formula is intended to be used or known to be effective)", or showing any other words of similar meaning; and

(4) (if the formula poses a health hazard when consumed by a person who does not have the disease, disorder or medical condition stated in the statement) a warning statement and explanation on the hazard in bold and in a conspicuous place of the package that is not in close proximity to other information on the package.

Annex II

Examples of Recommended Formats of Nutrition Labelling

(A) Infant Formula

(1) Labels showing energy value and nutrient contents per 100g or 100mL of the formula (in a form ready for sale) in English

Nutrition Information		
	Unit	Per 100g or Per 100mL
Energy	kcal or kJ	
Protein	g	
Total fat	g	
Total carbohydrates	g	
Vitamins		
Vitamin A	µg RE	
Vitamin D3	µg	
Vitamin E	mg α-TE	
Vitamin K	µg	
Thiamine	µg	
Riboflavin	µg	
Niacin	µg	
Vitamin B6	µg	
Vitamin B12	µg	
Pantothenic acid	µg	
Folic acid	µg	
Vitamin C	mg	
Biotin	µg	
Minerals		
Iron	mg	
Calcium	mg	
Phosphorus	mg	
Magnesium	mg	
Sodium	mg	
Chloride	mg	
Potassium	mg	
Manganese	µg	
Iodine	µg	
Selenium	µg	
Copper	µg	
Zinc	mg	
Others		
Choline	mg	
Insert other nutrient(s) to be declared	g, mg or ug	

(2) Labels showing energy value and nutrient contents per 100mL of the formula (in a form that is reconstituted or served according to any instructions for use provided) in English

Nutrition Information		
	Unit	Per 100mL of prepared formula
Energy	kcal or kJ	
Protein	g	
Total fat	g	
Total carbohydrates	g	
Vitamins		
Vitamin A	μg RE	
Vitamin D3	μg	
Vitamin E	mg α-TE	
Vitamin K	μg	
Thiamine	μg	
Riboflavin	μg	
Niacin	μg	
Vitamin B6	μg	
Vitamin B12	μg	
Pantothenic acid	μg	
Folic acid	μg	
Vitamin C	mg	
Biotin	μg	
Minerals		
Iron	mg	
Calcium	mg	
Phosphorus	mg	
Magnesium	mg	
Sodium	mg	
Chloride	mg	
Potassium	mg	
Manganese	μg	
Iodine	μg	
Selenium	μg	
Copper	μg	
Zinc	mg	
Others		
Choline	mg	
Insert other nutrient(s) to be declared	g, mg or ug	

(3) Labels showing energy value and nutrient contents per 100g of the formula (in a form ready for sale) and per 100mL of the formula (in a form that is reconstituted or served according to any instructions for use provided) in English or in both Chinese and English

Nutrition Information			
	Unit	Per 100g	Per 100mL of prepared formula
Energy	kcal or kJ		
Protein	g		
Total fat	g		
Total carbohydrates	g		
Vitamins			
Vitamin A	μg RE		
Vitamin D3	μg		
Vitamin E	mg α-TE		
Vitamin K	μg		
Thiamine	μg		
Riboflavin	μg		
Niacin	μg		
Vitamin B6	μg		
Vitamin B12	μg		
Pantothenic acid	μg		
Folic acid	μg		
Vitamin C	mg		
Biotin	μg		
Minerals			
Iron	mg		
Calcium	mg		
Phosphorus	mg		
Magnesium	mg		
Sodium	mg		
Chloride	mg		
Potassium	mg		
Manganese	μg		
Iodine	μg		
Selenium	μg		
Copper	μg		
Zinc	mg		
Others			
Choline	mg		
Insert other nutrient(s) to be declared	g, mg or ug		

Nutrition Information 營養資料			
	Unit 單位	Per 100g 每100克	Per 100mL of prepared formula 每100毫升沖調好的配方產品
Energy 能量	kcal or kJ 千卡或千焦		
Protein 蛋白質	g 克		
Total fat 總脂肪	g 克		
Total carbohydrates 總碳水化合物	g 克		
Vitamins 維他命			
Vitamin A 維他命 A	µg RE 微克視黃醇當量		
Vitamin D3 維他命 D3	µg 微克		
Vitamin E 維他命 E	mg α-TE 毫克α-生育酚當量		
Vitamin K 維他命 K	µg 微克		
Thiamine 硫胺素	µg 微克		
Riboflavin 核黃素	µg 微克		
Niacin 煙酸	µg 微克		
Vitamin B6 維他命 B6	µg 微克		
Vitamin B12 維他命 B12	µg 微克		
Pantothenic acid 泛酸	µg 微克		
Folic acid 葉酸	µg 微克		
Vitamin C 維他命 C	mg 毫克		
Biotin 生物素	µg 微克		
Minerals 礦物質			
Iron 鐵	mg 毫克		
Calcium 鈣	mg 毫克		
Phosphorus 磷	mg 毫克		
Magnesium 鎂	mg 毫克		
Sodium 鈉	mg 毫克		
Chloride 氯化物	mg 毫克		
Potassium 鉀	mg 毫克		
Manganese 錳	µg 微克		
Iodine 碘	µg 微克		
Selenium 硒	µg 微克		
Copper 銅	µg 微克		
Zinc 鋅	mg 毫克		
Others 其他			
Choline 膽鹼	mg 毫克		
Insert other nutrient(s) to be declared **填入其他標示的營養素**	g, mg or ug 克、毫克或微克		

(4) Labels showing energy value and nutrient contents per 100g of the formula (in a form ready for sale), per 100mL of the formula (in a form that is reconstituted or served according to any instructions for use provided) and per 100 kcal or 100kJ of the formula in English

Nutrition Information				
	Unit	Per 100g	Per 100mL of prepared formula	Per 100kcal or Per 100kJ
Energy	kcal or kJ			
Protein	g			
Total fat	g			
Total carbohydrates	g			
Vitamins				
Vitamin A	µg RE			
Vitamin D3	µg			
Vitamin E	mg α-TE			
Vitamin K	µg			
Thiamine	µg			
Riboflavin	µg			
Niacin	µg			
Vitamin B6	µg			
Vitamin B12	µg			
Pantothenic acid	µg			
Folic acid	µg			
Vitamin C	mg			
Biotin	µg			
Minerals				
Iron	mg			
Calcium	mg			
Phosphorus	mg			
Magnesium	mg			
Sodium	mg			
Chloride	mg			
Potassium	mg			
Manganese	µg			
Iodine	µg			
Selenium	µg			
Copper	µg			
Zinc	mg			
Others				
Choline	mg			
Insert other nutrient(s) to be declared	g, mg or ug			

(B) Follow-up Formula

(1) Labels showing energy value and nutrient contents per 100g or 100ml of the formula (in a form ready for sale) in English

Nutrition Information		
	Unit	Per 100g or Per 100mL
Energy	kcal or kJ	
Protein	g	
Total fat	g	
Available carbohydrates	g	
Vitamins		
Vitamin A	μg RE	
Vitamin D	μg	
Vitamin E	mg α-TE	
Vitamin K	μg	
Thiamine	μg	
Riboflavin	μg	
Niacin	μg	
Vitamin B6	μg	
Vitamin B12	μg	
Pantothenic acid	μg	
Folic acid	μg	
Vitmain C	mg	
Biotin	μg	
Minerals		
Iron	mg	
Calcium	mg	
Phosphorus	mg	
Magnesium	mg	
Sodium	mg	
Chloride	mg	
Potassium	mg	
Iodine	μg	
Zinc	mg	
Insert other nutrient(s) to be declared	g, mg or ug	

(2) Labels showing energy value and nutrient contents per suggested serving in English

Nutrition Information		
	Unit	Per 160mL serving
Energy	kcal or kJ	
Protein	g	
Total fat	g	
Available carbohydrates	g	
Vitamins		
Vitamin A	μg RE	
Vitamin D	μg	
Vitamin E	mg α-TE	
Vitamin K	μg	
Thiamine	μg	
Riboflavin	μg	
Niacin	μg	
Vitamin B6	μg	
Vitamin B12	μg	
Pantothenic acid	μg	
Folic acid	μg	
Vitmain C	mg	
Biotin	μg	
Minerals		
Iron	mg	
Calcium	mg	
Phosphorus	mg	
Magnesium	mg	
Sodium	mg	
Chloride	mg	
Potassium	mg	
Iodine	μg	
Zinc	mg	
Insert other nutrient(s) to be declared	g, mg or ug	

(3) Labels showing energy value and nutrient contents per 100g of the formula (in a form ready for sale) and per suggested serving in English or in both Chinese and English (Labelling carbohydrates as "total carbohydrates")

Nutrition Information			
	Unit	Per 100g	Per 160mL serving
Energy	kcal or kJ		
Protein	g		
Total fat	g		
Total carbohydrates	g		
- Dietary Fibre	g		
Vitamins			
Vitamin A	μg RE		
Vitamin D	μg		
Vitamin E	mg α-TE		
Vitamin K	μg		
Thiamine	μg		
Riboflavin	μg		
Niacin	μg		
Vitamin B6	μg		
Vitamin B12	μg		
Pantothenic acid	μg		
Folic acid	μg		
Vitamin C	mg		
Biotin	μg		
Minerals			
Iron	mg		
Calcium	mg		
Phosphorus	mg		
Magnesium	mg		
Sodium	mg		
Chloride	mg		
Potassium	mg		
Iodine	μg		
Zinc	mg		
Insert other nutrient(s) to be declared	g, mg or ug		

Nutrition Information **營養資料**			
	Unit 單位	Per 100g 每100克	Per 160mL serving 每160毫升食用分量
Energy 能量	kcal or kJ 千卡或千焦		
Protein 蛋白質	g 克		
Total fat 總脂肪	g 克		
Total carbohydrates 總碳水化合物	g 克		
- Dietary Fibre 膳食纖維	g 克		
Vitamins 維他命			
Vitamin A 維他命 A	µg RE 微克視黃醇當量		
Vitamin D 維他命 D	µg 微克		
Vitamin E 維他命 E	mg α-TE 毫克 α -生育酚當量		
Vitamin K 維他命 K	µg 微克		
Thiamine 硫胺素	µg 微克		
Riboflavin 核黃素	µg 微克		
Niacin 煙酸	µg 微克		
Vitamin B6 維他命 B6	µg 微克		
Vitamin B12 維他命 B12	µg 微克		
Pantothenic acid 泛酸	µg 微克		
Folic acid 葉酸	µg 微克		
Vitamin C 維他命 C	mg 毫克		
Biotin 生物素	µg 微克		
Minerals 礦物質			
Iron 鐵	mg 毫克		
Calcium 鈣	mg 毫克		
Phosphorus 磷	mg 毫克		
Magnesium 鎂	mg 毫克		
Sodium 鈉	mg 毫克		
Chloride 氯化物	mg 毫克		
Potassium 鉀	mg 毫克		
Iodine 碘	µg 微克		
Zinc 鋅	mg 毫克		
Insert other nutrient(s) to be declared **填入其他標示的營養素**	g, mg or ug 克、毫克或微克		

(4) Labels showing energy value and nutrient contents per 100g of the formula (in a form ready for sale), per suggested serving and per 100 kcal or 100kJ of the formula in English

Nutrition Information				
	Unit	Per 100g	Per 160mL serving	Per 100kcal or Per 100kJ
Energy	kcal or kJ			
Protein	g			
Total fat	g			
Available carbohydrates	g			
Vitamins				
Vitamin A	μg RE			
Vitamin D	μg			
Vitamin E	mg α-TE			
Vitamin K	μg			
Thiamine	μg			
Riboflavin	μg			
Niacin	μg			
Vitamin B6	μg			
Vitamin B12	μg			
Pantothenic acid	μg			
Folic acid	μg			
Vitamin C	mg			
Biotin	μg			
Minerals				
Iron	mg			
Calcium	mg			
Phosphorus	mg			
Magnesium	mg			
Sodium	mg			
Chloride	mg			
Potassium	mg			
Iodine	μg			
Zinc	mg			
Insert other nutrient(s) to be declared	g, mg or ug			

(C) Prepackaged food for infants and young children

(1) Labels showing energy value and nutrient contents per 100g or 100mL of the food (in a form ready for sale) in English

Nutrition Information	
	Per 100g or Per 100mL
Energy	kcal or kJ
Protein	g
Total fat	g
Available carbohydrates	g
Sodium	mg
Insert other nutrient(s) to be declared	g, mg or μg

(2) Labels showing energy value and nutrient contents per suggested serving in English (Labelling carbohydrates as "total carbohydrates)

Nutrition Information	
	Per 10g serving
Energy	kcal or kJ
Protein	g
Total fat	g
Total carbohydrates	g
- Dietary fibre	g
Sodium	mg
Insert other nutrient(s) to be declared	g, mg or μg

(3) Labels showing energy value and nutrient contents per 100g or 100mL of the food (in a form ready for sale) and per suggested serving in English (Food with added vitamin A and vitamin D)

Nutrition Information		
	Per 100g or Per 100mL	Per 10g serving
Energy	kcal or kJ	kcal or kJ
Protein	g	g
Total fat	g	g
Available carbohydrates	g	g
Sodium	mg	mg
Vitamin A	μg RE	μg RE
Vitamin D	μg	μg
Insert other nutrient(s) to be declared	g, mg or μg	g, mg or μg

(4) Linear format (e.g. showing energy value and nutrient contents per 100g or 100mL of the food (in a form ready for sale)) in English

Nutrition Information Per 100g or Per 100mL

Energy xx kcal or kJ, **Protein** xx g, **Total fat**, xx g, **Available carbohydrates**, xx g, **Sodium** xx mg, **Insert other nutrient(s) to be declared** xx g, mg or μg

Annex III

FREQUENTLY ASKED QUESTIONS

1. What are the examples of "formula for special medical purposes for infants and young children"?

Formula for infants and young children with metabolic diseases (e.g. maple syrup urine disease or phenylketonuria) and for specific groups of infants and young children such as premature infants or babies with lactose intolerance, are considered as formula for special medical purposes for infants and young children. Formula for special medical purposes for infants and young children should be marked or labelled as stated in Annex I in order to be exempted from the nutritional composition and nutrition labelling requirements in the Amendment Regulation. It should be noted that the presentation of the product as formula for special medical purposes for infants and young children needs to observe the relevant provisions in the Amendment Regulation and where applicable, other laws of Hong Kong including the Undesirable Medical Advertisements Ordinance (Cap. 231).

2. Can a follow-up formula be specified for persons at any age between 4 months or above and under 9 months?

No. Under the Amendment Regulation, follow-up formula must not be marked or labelled to the effect that the formula is suitable for consumption by persons of any age under 6 months.

3. If a prepackaged food is specified for persons at any age between 1 year or above and under 5 years, how will it be regulated?

As such product is claimed to be suitable for consumption of persons aged both at or above and under 36 months, it will be regulated as both prepackaged food for infants and young children (provided that it is not an infant formula or follow-up formula as defined) and general prepackaged food. That means it should observe the relevant nutrition labelling requirements in the Amendment Regulation and the existing Nutrition Labelling Scheme. Nutrient contents needed to be declared for prepackaged food for infants and young children in the Amendment Regulation and for general prepackaged food in the Nutrition Labelling Scheme are as follows:

Nutrient contents needed to be declared for prepackaged food for infants and young children in the Amendment Regulation	Nutrient contents needed to be declared for general prepackaged food in the Nutrition Labelling Scheme
Energy	Energy
Protein	Protein
Total fat	Total Fat
Available carbohydrates	Saturated fatty acids
Sodium	Trans fatty acids
Vitamin A (if added)	Available carbohydrates
Vitamin D (if added)	Sugars
	Sodium
	Nutrients involved in nutrition claim (s)

If such product is a follow-up formula as defined, it should observe relevant nutrition labelling requirements in the Amendment Regulation and the existing Nutrition Labelling Scheme.

4. How can I know that vitamin A or vitamin D is added to a prepackaged food for infants and young children?

Vitamin A (or its other forms such as retinol and β-carotene) or vitamin D (or its other forms such as cholecalciferol and ergocalciferol) should be listed in the ingredient list if they are added.

5. Is there any requirement on the protein content of infant formula which based on sources other than cows milk protein and soy protein isolate (e.g. goats milk protein)?

The Amendment Regulation makes reference to the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981) and includes nutritional composition requirements of infant formula, including the protein content for infant formula based on cows milk protein and soy protein isolates. As there is no specific requirement in CODEX STAN 72-1981 on the protein content of the infant formula based on sources other than cows milk protein and soy protein isolate and no international consensus on such requirement, protein content of the infant formula based on sources other than cows milk protein and soy protein isolate

is not covered by the nutritional composition requirement in the Amendment Regulation. Nevertheless, it is recommended that the protein content of such formula should fulfill the requirement set out by the jurisdiction or country where the product is originated.

6. What other words are deemed to have similar meaning with "formula for special medical purposes" (特殊醫用配方產品) and "USE UNDER MEDICAL SUPERVISION"（在醫生指示下使用）in the labelling requirements for exemption of formula for special medical purposes for infants and young children (FSMP) from the nutritional composition and nutrition labelling requirements?

The table below (which is not exhaustive) lists out some words that are considered to be of similar meaning with "formula for special medical purposes" (特殊醫用配方產品) and "USE UNDER MEDICAL SUPERVISION" (在醫生指示下使用):

	Words with similar meaning
formula for special medical purposes (特殊醫用配方產品)	- Formula for special medical uses - Special medical purpose formula - Special medical use formula - 特殊醫療用途配方產品
USE UNDER MEDICAL SUPERVISION (在醫生指示下使用)	- USE UNDER MEDICAL ADVICE - USE UNDER SUPERVISION OF A MEDICAL PROFESSIONAL - USE AS DIRECTED BY A MEDICAL PROFESSIONAL - 在醫生監督下使用 - 在醫護人員指導下使用

7. What kinds of product would be considered as infant formula in the Amendment Regulation?

Formula product which is 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, or marked or labelled as "infant formula" (嬰兒配方產品) or with any other words of similar meaning would be considered as infant formula. For instance, formula product which is marked or labelled as "infant milk", "new-born formula", "new-born milk", "初生嬰兒配方奶粉" or "嬰兒配方奶粉" would be considered as infant formula and should observe nutritional composition and nutrition labelling requirements for infant formula in the Amendment Regulation.

8. What kinds of product would be considered as follow-up formula in the Amendment Regulation?

Formula product which is represented as a replacement for human breast milk or infant formula (including its replacement or subsequent replacement), and intended for consumption as a liquid element in a progressively diversified diet by persons of any age from 6 months to under 36 months would be considered as follow-up formula. Formula product that marked or labelled as "follow-up formula" (較大嬰兒及幼兒配方產品) or with any other words of similar meaning would also be considered as follow-up formula. For instance, formula product which is marked or labelled as "follow-on formula", "follow-on milk", "growing-up formula", "growing-up milk", "toddler formula", "toddler milk", "較大嬰兒配方奶粉", "幼兒助長配方奶粉" or "幼兒成長配方奶粉" would be considered as follow-up formula and should observe nutrition labelling requirements for follow-up formula in the Amendment Regulation.

Products like fruit juice, vegetable juice, instant powdered drink or fresh milk will generally not be considered as "follow-up formula". However, it should be noted that prepackaged food which is intended for consumption by persons of any age under 36 months (excluding infant formula and follow-up formula) would be considered as prepackaged food for infants and young children and should observe relevant nutrition labelling requirements in the Amendment Regulation.

9. Some milk products intended for consumption by adults would be labelled as "Children under one year of age should not be fed on this milk except under medical advice". Will this type of product be covered by the Amendment Regulation?

This type of product would generally not be covered by the Amendment Regulation provided that it does not have any specific indication that it is intended for persons under the age of 36 months. If it has any indication (e.g. product description or instruction for use) that it is intended for consumption by persons under the age of 36 months, it would be regulated by the Amendment Regulation and should observe the relevant nutritional composition and/or nutrition labelling requirements.

10. Certain nutrients have different definitions in infant formula/follow-up formula and general prepackaged food. If a product is considered as follow-up formula and general prepackaged food, and makes claims on such nutrients, how should the content of such nutrients be labelled?

According to the Amendment Regulation, folic acid, niacin, vitamin A, vitamin C, vitamin E and vitamin K have different definitions in infant formula/follow-up formula and general prepackaged food. If a product is considered as follow-up formula and general prepackaged food, and makes claims on such nutrients, the contents of such nutrients-should be labelled according to the Amendment Regulation and the existing Nutrition Labelling Scheme. To avoid doubt, it is recommended to clearly label the content of such nutrients according to their definition in follow-up formula and general prepackaged food. The example below shows the recommended way to label such nutrients in aforesaid scenario.

Nutrition Information	
	Per 100g
----	----
----	----
Folic acid (N-pteroyl-L-glutamic acid) Folic acid	xx µg xx µg DFE
Niacin Nicotinamide	xx µg xx µg
Vitamin A (all-trans retinol) Vitamin A (retinol and beta-carotene)	xx µg RE xx µg RE
Vitamin C (ascorbic acid) Vitamin C	xx mg xx mg
Vitamin E (alpha-tocopherol compounds) Vitamin E	xx mg α-TE xx mg α-TE
Vitamin K Vitamin K1	xx µg xx µg
----	----

11. How will the Administration calculate the fluoride content of infant formula in a form that is reconstituted or served?

Ultrapure water will be used when testing the fluoride content of infant formula. When calculating the fluoride content of infant formula in a form that is reconstituted or served, the Administration will take the instruction for use (including the type and amount of water to be used for reconstitution as recommended by the manufacturer) and the fluoride content of the drinking water in Hong Kong into account. If the product does not have any special recommendation on the type of water to be used or

only shows that general drinking water can be used for reconstitution on its instruction for use, fluoride content in water[4] of 0.5mg/L will be used for calculation.

For example, 13g infant formula powder required 90ml water to make up 100ml infant formula with energy value of 65kcal. If the tested fluoride content of the infant formula powder using ultrapure water is 150µg/100g, according to the following equation,

Fluoride content of reconstituted infant formula (µg /100kcal) =

$$\left[\frac{(A \times B \div 100) + (C \times D)}{E}\right] \times 100$$

A= fluoride content of infant formula powder (µg/100g)
B= infant formula powder used during reconstitution of 100mL infant formula (g)
C= fluoride content of water (mg/L)
D= water used during reconstitution of 100mL infant formula (mL)
E= energy value in 100mL reconstituted infant formula (kcal)

the fluoride content of reconstituted infant formula will be 99.2µg/100kcal, which does not exceed 100µg/100kcal. As a result, the infant formula is not required to be labelled with a statement associated with dental fluorosis.

[4] The average fluoride contents of drinking water in Hong Kong were 0.48-0.49 mg/L in 2009-2013