

L.N. 90 of 2014

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

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

(Made by the Director of Food and Environmental Hygiene under  
section 55(1) of the Public Health and Municipal Services Ordinance  
(Cap. 132))

### **1. Commencement**

- (1) Subject to subsection (2), this Regulation comes into operation on the expiry of 18 months beginning on the day on which this Regulation is published in the Gazette.
- (2) The following sections come into operation on the expiry of 24 months beginning on the day on which this Regulation is published in the Gazette—
  - (a) section 7 (except in so far as it relates to any infant formula in the new regulation 4C);
  - (b) section 8(2) (except in so far as it relates to any infant formula in the new regulation 5(1AC)).

### **2. Food and Drugs (Composition and Labelling) Regulations amended**

The Food and Drugs (Composition and Labelling) Regulations (Cap. 132 sub. leg. W) are amended as set out in sections 3 to 13.

### **3. Regulation 2 amended (interpretation)**

- (1) Regulation 2(1), definition of *energy*, paragraph (a), after “available carbohydrates”—

**Add**

“(or, if the food is infant formula, total carbohydrates)”.

(2) Regulation 2(1)—

**Repeal the definition of *list of nutrients***

**Substitute**

“*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;”.

(3) Regulation 2(1)—

**Repeal the definition of *nutrient***

**Substitute**

“*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 functions of the body;

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

(b) in Part IV of Schedule 1 and Schedule 6A, includes myo-inositol, L-carnitine and taurine;”.

(4) Regulation 2(1)—

**Repeal the definition of *vitamin A***

**Substitute**

“*vitamin A* (維他命A)—

(a) in 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 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);”.

(5) Regulation 2(1)—

**Add in alphabetical order**

“*folic acid* (葉酸), in relation to any infant formula or follow-up formula, means N-pteroyl-L-glumatic 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;

***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;

***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;

***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 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-

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Tocopherol Equivalent ( $\alpha$ -TE) or International Unit (IU) (with 1 IU as being equivalent to 0.67 mg  $\alpha$ -TE); and

- (b) in relation to any follow-up formula, means alpha-tocopherol compounds, calculated in terms of  $\alpha$ -TE or IU—
  - (i) (for alpha-tocopherol compounds from any natural source) with 1 IU as being equivalent to 0.67 mg  $\alpha$ -TE; or
  - (ii) (for alpha-tocopherol compounds from any synthetic source) with 1 IU as being equivalent to 0.45 mg  $\alpha$ -TE;

**vitamin K** (維他命K), in relation to any infant formula or follow-up formula, means vitamin K1.”.

- (6) After regulation 2(1)—

**Add**

“(1A) In the definition of **follow-up formula** in paragraph (1), 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.

(1B) To avoid doubt, if any product falls within both the definitions of **infant formula** and **follow-up formula** in paragraph (1), it is to be treated for the purposes of these regulations as an infant formula but not a follow-up formula.”.

**4. Regulation 3 amended (standards of composition)**

- (1) Regulation 3—

**Renumber the regulation as regulation 3(1).**

- (2) Regulation 3(1)—

**Repeal**



“The standards”

**Substitute**

“Subject to paragraph (2), the standards”.

(3) After regulation 3(1)—

**Add**

“(2) The item listed in Schedule 1A is exempt from the standards in Part IV of Schedule 1.”.

**5. Regulation 4A amended (labelling of prepackaged food)**

Regulation 4A(1)—

**Repeal**

“Without prejudice to regulations 4 and 4B”

**Substitute**

“Without affecting regulations 4, 4B and 4C”.

**6. Regulation 4B amended (nutrition labelling of prepackaged food and nutrition claim)**

(1) Regulation 4B(1)—

**Repeal**

“Without prejudice to regulations 4 and 4A but subject to paragraphs (2) and (6)”

**Substitute**

“Without affecting regulations 4, 4A and 4C but subject to paragraphs (2), (6) and (7)”.

(2) Regulation 4B(5)—

**Repeal**

“paragraph (6)”

**Substitute**

“paragraphs (6) and (7)”.

- (3) Regulation 4B(6)—

**Repeal subparagraphs (a) and (b).**

- (4) Regulation 4B(6)(c)—

**Repeal**

“other”.

- (5) After regulation 4B(6)—

**Add**

“(7) Without affecting paragraph (6), if a prepackaged food (***the food***) is infant formula, follow-up formula or prepackaged food for infants and young children, this regulation applies to the food only if it is claimed in its descriptions or instructions for use to be suitable for consumption by persons of any age from 36 months onwards.”.

**7. Regulation 4C added**

After regulation 4B—

**Add**

**“4C. Nutrition labelling of infant formulae, follow-up formulae and prepackaged food for infants and young children**

- (1) Without affecting regulations 4, 4A and 4B but subject to paragraph (2), any infant formula, follow-up formula or prepackaged food for infants and young children must be marked or labelled with its energy value and nutrient content in compliance with Schedule 6A.
- (2) The items listed in Schedule 6B are exempt from the requirement of paragraph (1).”.

**8. Regulation 5 amended (offences and penalties)**

- (1) Regulation 5(1), after “food or drug which”—

**Add**

“, subject to regulation 3(2),”.

- (2) After regulation 5(1AB)—

**Add**

“(1AC) Any person who advertises for sale, sells or manufactures for sale any infant formula, follow-up formula or prepackaged food for infants and young children that is not marked or labelled in compliance with regulation 4C(1) commits an offence and is liable to a fine at level 5 and to imprisonment for 6 months.”.

- (3) Regulation 5(1B)—

**Repeal**

“food, alters, removes or obliterates the labelling of any food or drug marked or labelled for the purposes of regulation 4, 4A or 4B”

**Substitute**

“food or drug, alters, removes or obliterates the marking or labelling of any food or drug marked or labelled for the purposes of regulation 4, 4A, 4B or 4C”.

- (4) After regulation 5(2)—

**Add**

“(2A) In any proceedings for an offence against paragraph (1AC) in relation to the publication of an advertisement, it is a defence for the defendant to prove that, being a person whose business is to publish, or arrange for the publication of, advertisements, the defendant received the advertisement for publication in the ordinary course of business.”.

- (5) Regulation 5(3)—

**Repeal**

“possession for”.

- (6) Regulation 5(3), English text—

**Repeal**

“would have taken”

**Substitute**

“had taken”.

- (7) After regulation 5(3A)—

**Add**

“(3B) In any proceedings for an offence against paragraph (1AC) in relation to the sale of any infant formula, follow-up formula or prepackaged food for infants and young children that is not marked or labelled in compliance with regulation 4C(1), it is a defence for the defendant to show that, before offering the formula or food for sale, the defendant had taken all reasonable steps to ensure that the formula or food was so marked or labelled.”.

**9. Schedule 1 amended**

- (1) Schedule 1—

**Repeal**

“[regs. 3 & 5 & Sch.”

**Substitute**

“[regs. 2, 3 & 5 & Schs. 1A &”.

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- (2) Schedule 1, Part I, heading—  
**Repeal**  
“AND MILK PRODUCTS”  
**Substitute**  
“, MILK PRODUCTS AND INFANT FORMULAE”.
- (3) Schedule 1, Chinese text, the following provisions—  
(a) Part II, items 14, 15, 16, 18 and 19;  
(b) Part III, Division 2, item 4—  
**Repeal**  
“納” (wherever appearing)  
**Substitute**  
“鈉”.
- (4) Schedule 1, after Part III—  
**Add**

“Part IV

**Energy and Nutritional Composition of Infant  
Formulae**

**Division 1—Energy Value**

|        | Minimum level per 100 mL<br>(in a form that is<br>reconstituted or served<br>according to any instructions<br>for use provided) | Maximum level per 100 mL<br>(in a form that is<br>reconstituted or served<br>according to any instructions<br>for use provided) |
|--------|---|---|
| Energy | 60 kcal or 250 kJ   | 70 kcal or 295 kJ   |

Section 9

**Division 2—Nutrient Content**

| Item                 | Nutrient   | Minimum level          |                         | Maximum level   |               |
|----------------------|--|------------------------|-------------------------|-----------------|---------------|
|                      |  | per<br>100 kcal        | per<br>100 kJ           | per<br>100 kcal | per<br>100 kJ |
| <b>Protein</b>       |  |                        |                         |                 |               |
| 1.                   | Protein (for infant formulae based on cows milk protein)   | 1.8 g                  | 0.45 g                  | 3.0 g           | 0.7 g         |
| 2.                   | Protein (for infant formulae based on soy protein isolate) | 2.25 g                 | 0.5 g                   | 3.0 g           | 0.7 g         |
| <b>Fat</b>           |  |                        |                         |                 |               |
| 3.                   | Total fat  | 4.4 g                  | 1.05 g                  | 6.0 g           | 1.4 g         |
| 4.                   | Linoleic acid  | 300 mg                 | 70 mg                   | —               | —             |
| 5.                   | $\alpha$ -Linolenic acid                                   | 50 mg                  | 12 mg                   | —               | —             |
| <b>Carbohydrates</b> |  |                        |                         |                 |               |
| 6.                   | Total carbohydrates  | 9.0 g                  | 2.2 g                   | 14.0 g          | 3.3 g         |
| <b>Vitamins</b>      |  |                        |                         |                 |               |
| 7.                   | Vitamin A  | 60 $\mu$ g RE          | 14 $\mu$ g RE           | 180 $\mu$ g RE  | 43 $\mu$ g RE |
| 8.                   | Vitamin D3   | 1 $\mu$ g              | 0.25 $\mu$ g            | 2.5 $\mu$ g     | 0.6 $\mu$ g   |
| 9.                   | Vitamin E  | 0.5 mg<br>$\alpha$ -TE | 0.12 mg<br>$\alpha$ -TE | —               | —             |

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| Item | Nutrient         | Minimum level   |               | Maximum level   |               |
|------|------------------|-----------------|---------------|-----------------|---------------|
|      |                  | per<br>100 kcal | per<br>100 kJ | per<br>100 kcal | per<br>100 kJ |
| 10.  | Vitamin K        | 4 µg            | 1 µg          | —               | —             |
| 11.  | Thiamine         | 60 µg           | 14 µg         | —               | —             |
| 12.  | Riboflavin       | 80 µg           | 19 µg         | —               | —             |
| 13.  | Niacin           | 300 µg          | 70 µg         | —               | —             |
| 14.  | Vitamin B6       | 35 µg           | 8.5 µg        | —               | —             |
| 15.  | Vitamin B12      | 0.1 µg          | 0.025 µg      | —               | —             |
| 16.  | Pantothenic acid | 400 µg          | 96 µg         | —               | —             |
| 17.  | Folic acid       | 10 µg           | 2.5 µg        | —               | —             |
| 18.  | Vitamin C        | 10 mg           | 2.5 mg        | —               | —             |
| 19.  | Biotin           | 1.5 µg          | 0.4 µg        | —               | —             |
|      | <b>Minerals</b>  |                 |               |                 |               |
| 20.  | Iron             | 0.45 mg         | 0.1 mg        | —               | —             |
| 21.  | Calcium          | 50 mg           | 12 mg         | —               | —             |
| 22.  | Phosphorus       | 25 mg           | 6 mg          | —               | —             |
| 23.  | Magnesium        | 5 mg            | 1.2 mg        | —               | —             |
| 24.  | Sodium           | 20 mg           | 5 mg          | 60 mg           | 14 mg         |
| 25.  | Chloride         | 50 mg           | 12 mg         | 160 mg          | 38 mg         |
| 26.  | Potassium        | 60 mg           | 14 mg         | 180 mg          | 43 mg         |
| 27.  | Manganese        | 1 µg            | 0.25 µg       | —               | —             |
| 28.  | Iodine           | 10 µg           | 2.5 µg        | —               | —             |
| 29.  | Selenium         | 1 µg            | 0.24 µg       | —               | —             |
| 30.  | Copper           | 35 µg           | 8.5 µg        | —               | —             |

| Item | Nutrient           | Minimum level   |               | Maximum level   |               |
|------|--------------------|-----------------|---------------|-----------------|---------------|
|      |                    | per<br>100 kcal | per<br>100 kJ | per<br>100 kcal | per<br>100 kJ |
| 31.  | Zinc               | 0.5 mg          | 0.12 mg       | —               | —             |
|      | <b>Others</b>      |                 |               |                 |               |
| 32.  | Choline            | 7 mg            | 1.7 mg        | —               | —             |
| 33.  | Myo-Inositol       | 4 mg            | 1 mg          | —               | —             |
| 34.  | L-Carnitine        | 1.2 mg          | 0.3 mg        | —               | —             |
| 35.  | Taurine (if added) | —               | —             | 12 mg           | 3 mg          |

### Division 3—Other Requirements

1. The ratio of linoleic acid to  $\alpha$ -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  $\alpha$ -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  $\alpha$ -TE/g linoleic acid (18:2 n-6);
- (b) 0.75 mg  $\alpha$ -TE/g  $\alpha$ -linolenic acid (18:3 n-3);
- (c) 1.0 mg  $\alpha$ -TE/g arachidonic acid (20:4 n-6);
- (d) 1.25 mg  $\alpha$ -TE/g eicosapentaenoic acid (20:5 n-3);
- (e) 1.5 mg  $\alpha$ -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.”.

**10. Schedule 1A added**

After Schedule 1—

**Add**

**“Schedule 1A**

[reg. 3]

**Item Exempt from Part IV of Schedule 1**

1. Any formula for special medical purposes for infants and young children that is marked or labelled with—
- (a) 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;
  - (b) 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;

- (c) 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
- (d) (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.”.

**11. Schedule 2 amended (marking and labelling of foods and drugs)**

Schedule 2, after item 6—

**Add**

“6A. Follow-up formula.

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.”.

**12. Schedule 3 amended (marking and labelling of prepackaged foods)**

Schedule 3, Chinese text, section 2(5)(a), after “其”—

**Add**

“本”.

**13. Schedules 6A and 6B added**

After Schedule 6—

**Add**

**“Schedule 6A**

[regs. 2 & 4C &  
Sch. 6B]

**Nutrition Labelling of Infant Formulae, Follow-up  
Formulae and Prepackaged Food for Infants and  
Young Children**

**1. List of nutrients**

- (1) Any infant formula must be legibly marked or labelled with a list of nutrients setting out—
  - (a) the energy value of the formula; and
  - (b) the content of the following nutrients contained in the formula—
    - (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.
- (2) If the fluoride content of any infant formula (in a form that is reconstituted or served according to any instructions for use provided) exceeds 100 µg per 100 kcal or 24 µg per 100 kJ, the formula must be marked or labelled with a statement—
- (a) indicating that consumption of the formula may cause dental fluorosis; and
  - (b) recommending that the risk of dental fluorosis should be discussed with a medical practitioner or health professional.
- (3) Any follow-up formula must be legibly marked or labelled with a list of nutrients setting out—
- (a) the energy value of the formula; and

- (b) the content of the following nutrients contained in the formula—
- (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.

- 
- (4) Any prepackaged food for infants and young children must be legibly marked or labelled with a list of nutrients setting out—
- (a) the energy value of the food; and
  - (b) the content of the following nutrients contained in the food—
    - (i) protein;
    - (ii) total fat;
    - (iii) available carbohydrates;
    - (iv) sodium;
    - (v) vitamin A (if added); and
    - (vi) vitamin D (if added).
- (5) Without affecting subsections (1), (3) and (4), the content of any other nutrient contained in the infant formula, follow-up formula or prepackaged food for infants and young children may also be set out in the list of nutrients.
- (6) For the purposes of subsections (3)(b)(iii) and (4)(b)(iii)—
- (a) available carbohydrates may be marked or labelled on the list of nutrients as “carbohydrates” or “碳水化合物”;
  - (b) the content of total carbohydrates may be set out in the list of nutrients in substitution of the content of available carbohydrates if the content of dietary fibre is also set out in the list of nutrients.
- (7) Other information may be set out in a list of nutrients if the 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.

## **2. Energy value expression**

- (1) The energy value to be set out in a list of nutrients for any infant formula must be expressed in kilocalorie (kcal) or kilojoule (kJ), or both—
  - (a) per 100 g of the formula (in a form ready for sale); or
  - (b) per 100 mL 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).
- (2) The energy value to be set out in a list of nutrients for any follow-up formula or prepackaged food for infants and young children must be expressed in kilocalorie (kcal) or kilojoule (kJ), or both—
  - (a) per 100 g of the formula or food (in a form ready for sale);
  - (b) per 100 mL of the formula or food (in a form ready for sale, or in a form that is reconstituted or served according to any instructions for use provided); or
  - (c) per suggested serving as specified in gram (g) or millilitre (mL).

## **3. Nutrient content expression**

- (1) The content of nutrients referred to in section 1(1)(b) of this Schedule to be set out in a list of nutrients for any infant formula must be expressed (for protein, total fat and total carbohydrates) in gram (g) or (for the other nutrients) in an appropriate unit—
  - (a) per 100 g of the formula (in a form ready for sale); or
  - (b) per 100 mL 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).

- 
- (2) The content of nutrients referred to in section 1(3)(b) or (4)(b) of this Schedule to be set out in a list of nutrients for any follow-up formula or prepackaged food for infants and young children must be expressed (for protein, total fat and available carbohydrates) in gram (g) or (for the other nutrients) in an appropriate unit—
- (a) per 100 g of the formula or food (in a form ready for sale);
  - (b) per 100 mL of the formula or food (in a form ready for sale, or in a form that is reconstituted or served according to any instructions for use provided); or
  - (c) per suggested serving as specified in gram (g) or millilitre (mL).
- (3) Without affecting subsections (1) and (2), the content of nutrients referred to in section 1(1)(b) or (3)(b) of this Schedule to be set out in a list of nutrients for any infant formula or follow-up formula may further be expressed (for protein, total fat, total carbohydrates and available carbohydrates) in gram (g) or (for the other nutrients) in an appropriate unit—
- (a) per 100 kcal of the formula; or
  - (b) per 100 kJ of the formula.

#### **4. Format of list of nutrients**

- (1) Subject to subsection (2), a list of nutrients for any infant formula, follow-up formula or prepackaged food for infants and young children must be presented in tabular form in a conspicuous place of the package with an appropriate heading.



- (2) A list of nutrients for prepackaged food for infants and young children may be presented in linear form if the total surface area of the package is less than 200 cm<sup>2</sup>.
- (3) The marking or labelling for the purposes of this Schedule must be in—
  - (a) the English language;
  - (b) the Chinese language; or
  - (c) both languages.
- (4) However, numbers may be expressed in Arabic numerals.
- (5) A list of nutrients must be in both the English and Chinese languages if both languages are used in the marking or labelling of the infant formula, follow-up formula or prepackaged food for infants and young children.

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## Schedule 6B

[reg. 4C]

### Items Exempt from Schedule 6A

1. Any formula for special medical purposes for infants and young children that is marked or labelled with—
  - (a) 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;
  - (b) 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;

- (c) 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
  - (d) (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.
2. Any infant formula or follow-up formula packed in a container that has a total surface area of less than 250 cm<sup>2</sup>.
  3. Any prepackaged food for infants and young children packed in a container that has a total surface area of less than 100 cm<sup>2</sup>.”.

Vivian LAU  
Director of Food and  
Environmental Hygiene

9 June 2014

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### Explanatory Note

This Regulation amends the Food and Drugs (Composition and Labelling) Regulations (Cap. 132 sub. leg. W) (*principal Regulations*) to provide for—

- (a) the standards of composition of infant formulae;
  - (b) the nutrition labelling requirements of infant formulae, follow-up formulae and prepackaged food for infants and young children;
  - (c) the items that are exempt from the standards or requirements; and
  - (d) the offences and penalties for non-compliance with the standards or requirements.
2. The Regulation also makes certain textual amendments to the principal Regulations.