File Ref: FH CR 4/3231/13

LEGISLATIVE COUNCIL BRIEF

Public Health and Municipal Services Ordinance
(Cap. 132)

FOOD AND DRUGS (COMPOSITION AND LABELLING) (AMENDMENT) (NO. 2) REGULATION 2014

INTRODUCTION

On 9 June 2014, the Director of Food and Environmental Hygiene, in exercise of the power under section 55(1) of the Public Health and Municipal Services Ordinance (Cap. 132), made the Food and Drugs (Composition and Labelling) (Amendment) (No.2) Regulation 2014 (the Amendment Regulation) at **Annex A**.

A

JUSTIFICATIONS

Current Legislation

2. The Government is committed to protecting the health of infants and young children. Infants and young children must obtain optimal nutrition from their diet to grow and stay healthy. 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. 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[1]. We must therefore ensure that infant formula is safe and nutritionally adequate.

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[1] Complementary feeding is normally introduced at 6 months of age.

3. Food label enables consumers to obtain specific information on individual food products, including nutrition information. Providing nutrition information on food labels is an important public health tool to promote a balanced diet. The Nutrition Labelling Scheme (the NL Scheme) for prepackaged food products under the Food and Drugs (Composition and Labelling) Regulations (Cap. 132W) (the Regulations) came into force in July 2010. The Scheme covers nutrition labelling[2] and nutrition claims (which include nutrient content claim[3], nutrient comparative claim[4] and nutrient function claim[5]). However, the NL Scheme does not cover formula products and prepackaged food for infants and young children under the age of 36 months as the Codex Alimentarius Commission (Codex)[6] has established different standards for these foods.

4. Section 54 of Cap. 132 stipulates that all food for sale must be fit for human consumption. This covers all food including formula products and prepackaged food for infants and young children under the age of 36 months. However, there are no specific provisions in Cap. 132 governing the requirements and standards of nutritional composition and labelling for formula products and prepackaged food for infants and young children under the age of 36 months.

Need for Regulation

5. A survey conducted by the Centre for Food Safety (CFS) from May to September 2012 covering 63 infant formula products revealed that seven products were found to contain iodine at a level not only lower than

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

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

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

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

6 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.

that prescribed by Codex but also well below the intake level recommended by the World Health Organization. The survey has taken into account the feeding instructions, average infant growth parameters, as well as iodine content in the boiled tap water used for constituting the infant formula. Iodine deficiency may affect the functioning of the thyroid gland. If the normal functions of the thyroid gland are significantly affected, there may be potential impact on the brain development of infants. The finding of iodine deficiency in some infant formula underlines the need to impose regulatory control urgently to protect the health of infants and young children. The Administration therefore decided in 2012 to expedite its work in formulating legislative proposals relating to the nutritional composition and nutrition labelling of formula products and prepackaged food for infants and young children under the age of 36 months. The purpose of the Amendment Regulation is to ensure that the products concerned are properly labelled to reflect the values of important nutrients; and as far as infant formula is concerned, it must be nutritionally adequate, so as to protect the health of infants and young children under the age of 36 months.

Key Features of the Amendment Regulation

6. Codex has developed standards for specific types of formula products (including infant formula and follow-up formula) and prepackaged food for infants and young children under the age of 36 months, including requirements on nutritional composition and nutrition labelling. When formulating details of our proposed composition and labelling requirements, we have made primary reference to the Codex principles and relevant international practices as well as local market and consumption situation. This will ensure that our legislative proposals pay due regard to international standards and local situation. Details of the legislation are explained in ensuing paragraphs.

Definitions of Infant Formula, Follow-up Formula and Prepackaged Food for Infants and Young Children (Sections 3 and 11 of the Amendment Regulation)

7. We propose that the definition of infant formula will cover 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. The age reference of "up to and including 12 months" is proposed because the relevant Codex Standard defines infant as a person not more than 12 months of age. Besides, as some infant formula products are clearly labelled as such, the proposed definition also covers products which are marked or labelled as "infant formula" or "嬰兒配方產品". We also propose to regulate formula products labelled with any other words of a meaning similar to "infant formula" or "嬰兒配方產品" as infant formula.

8. We further propose that the definition of follow-up formula will cover products that are:-

(a) represented as a replacement for human breast milk or infant formula, 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; or

(b) 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.

In respect of paragraph 8(a), Section 3(6) of the Amendment Regulation further stipulates that in the definition of follow-up formula, 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.

9. In Hong Kong, follow-up formula products are marketed to infants and young children who are progressively moving away from being fed on human breast milk or infant formula. Follow-up formula can come in different stages targeting at different age groups of infants and young

children under 36 months of age as they grow. Paragraph 8(a) seeks to cover different stages of follow-up formula. Besides, as some follow-up formula products are clearly labelled as such, the proposed definition will also cover products which are marked or labelled as "follow-up formula" or "較大嬰兒及幼兒配方產品". We also propose to regulate products labelled with words of a meaning similar to "follow-up formula" or "較大嬰兒及幼兒配方產品" as follow-up formula. By adopting the term "represented as a replacement for human breast milk or infant formula" (re. paragraph 8(a)), we exclude drinks that we do not intend to regulate as follow-up formula under the Amendment Regulation such as juice and water for infants and young children under the age of 36 months.

10. For the purpose of protecting the health of infants under 6 months, we will also require that 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 (as specified in the proposed item 6A of Schedule 2 to the Regulations). The requirement is in line with World Health Organization's recommendation that infants should only start receiving complementary feeding at 6 months of age. It is also consistent with the minimum age of consumption of follow-up formula adopted in major jurisdictions (e.g. Australia, New Zealand and Mainland China).

11. As for prepackaged food for infants and young children, the proposed definition will cover prepackaged food intended for consumption by persons of any age under 36 months not including infant formula or follow-up formula.

12. As information pertaining to the nature and intended consumers of food products that can be used by infants and young children under 36 months of age is usually set out in product descriptions or instructions for use, we propose to include in the definitions of infant formula, follow-up formula and prepackaged food for infants and young children under 36 months that reference should be made to the descriptions and the instructions for use of a particular product before determining whether it falls within the regulation of the Amendment Regulation.

Products falling under definitions of both Infant Formula and Follow-up Formula

13. Notwithstanding the definitions of infant formula and follow-up formula as elaborated in paragraphs 7 and 8, there are formula products in the Hong Kong market that are intended for use as a sole source of nutrition for infants aged six months or below (i.e. will be covered by the definition of "infant formula" in the Amendment Regulation), and also for consumption by children older than six months alongside complementary feeding (i.e. will be covered by the definition of "follow-up formula" in the Amendment Regulation). As such products can be consumed by infants as their sole source of nutrition, for protection of infants' health, the Amendment Regulation requires such products to be regulated as an infant formula in respect of their composition and labelling (see paragraphs 17 and 22-24 below for details). This will ensure that the product is safe and nutritionally adequate when consumed as an infant formula.

Products intended for children both below 36 months of age and 36 months of age or above

14. As mentioned in paragraphs 3 and 4, the Amendment Regulation aims to regulate nutritional composition and labelling of formula products and prepackaged food for infants and young children under the age of 36 months while the NL Scheme currently takes care of prepackaged food for those 36 months or above. There are however formula products and prepackaged food for infants and young children in the Hong Kong market that are intended for people both below 36 months old and 36 months old or above. Examples of such products are labelled as "from birth onwards", "from 12 months", "for 1-10 years old" etc. For protection of the health of infants and young children under 36 months of age, we propose to regulate the nutritional composition and labelling of such products under the Amendment Regulation (paragraphs 16-24 below refer). But since such products are also for use by people aged 36 months or above, they will continue to be subjected to the requirements under the NL Scheme. To this end, an expression "even if it is also claimed in the descriptions or instructions for use (if applicable) to be suitable for consumption by persons of any age [other than the relevant age range]…" is included in the definitions of infant formula, follow-up formula and prepackaged food for infants and young children.

Formula products primarily intended for adults

15. There are milk products in the Hong Kong market that are primarily intended for adults. Examples of such products are partly-skimmed milk powder / skimmed milk powder that are labelled as "Children under one year of age should not be fed on this milk except under medical advice" but without any other indication that they are intended for persons under the age of 36 months. We do not intend to regulate such products as infant formula or follow-up formula under the Amendment Regulation as they are not intended for use as the sole source of nutrition for infants or formulated for infants and young children under 36 months of age. By making reference to the product descriptions or instructions for use (paragraph 12 refers) of a particular product, CFS will be able to determine whether or not the product falls under the control of the Amendment Regulation.

Nutrition Labelling of Infant Formula, Follow-up Formula, and Prepackaged Food for Infants and Young Children under the Age of 36 Months (Sections 7 and 13 of the Amendment Regulation)

16. To assist parents in making informed food choices for their infants and young children for protection of their health, we propose to mandate nutrition labelling of infant formula, follow-up formula and prepackaged food for infants and young children under the age of 36 months.

(i) Infant formula

17. For infant formula, we propose to mandate the labelling of energy value and 29 nutrients ("1+29"), following the relevant Codex Standards (as specified in the proposed section 1(1) of Schedule 6A to the Regulations). We initially proposed in the public consultation exercise (paragraphs 41-42 below) to mandate the labelling of energy value and the 33 nutrients ("1+33") which are required to be present in infant formula so that the exact components covered in the labelling and composition requirements would be the same (see paragraph 22 below). Further research reveals that major jurisdictions like the European Union, the United States, Australia, New Zealand and Singapore are adopting standards comparable to the Codex standard of "1+29" instead of "1+33". In light of this research finding, we have decided to adopt "1+29". We consider this sufficient for protecting

the health of infants because the four nutrients not required to be labelled will continue to be part of the nutritional composition requirement for infant formula as provided for in the Amendment Regulation.

(ii) Follow-up Formula

18. As regards follow-up formula, we propose mandating the labelling of energy value and 25 nutrients ("1+25"), following the requirements laid down in the relevant Codex Standard (as specified in the proposed section 1(3) of Schedule 6A to the Regulations).

(iii) Prepackaged Food for Infants and Young Children

19. With respect to prepackaged food for infants and young children, we propose to mandate the labelling of such food with energy value and 4 nutrients namely protein, fat, carbohydrates and sodium ("1+4"), as well as vitamin A and vitamin D if they are added to the food, by making reference to the relevant Codex Standards (as specified in the proposed section 1(4) of Schedule 6A to the Regulations).

20. It should be noted that the relevant Codex Standards do not require all prepackaged food for infants and young children to be labelled with its sodium content. However, to protect the health of infants and young children, we have decided to mandate requirement for all such prepackaged food to be labelled with the amount of sodium. It is because there is evidence suggesting that Chinese people are particularly susceptible to dietary salt-induced high blood pressure because of the lack of an efficient mechanism to facilitate kidney excretion of salt (sodium). While sodium is necessary for the proper functioning of the body, prolonged excessive intake of sodium may increase the risk of developing high blood pressure. We therefore consider that excessive intake of sodium should be avoided at a young age. Despite the absence of a relevant Codex requirement, many jurisdictions such as the United States, Australia, New Zealand, and European Union have already required the labelling of sodium content in all food intended for infants and young children.

21. To facilitate easier comprehension of the product labels so as to help consumers make informed food choices for their infants and young children, we propose to standardize the units to be used for energy value and nutrition content expressions by making reference to the relevant

Codex Standards (as specified in the proposed sections 2 and 3 of Schedule 6A to the Regulations). For the same reason, the Amendment Regulation also sets out the format and the language requirements of the nutrition labels (as specified in the proposed section 4 of Schedule 6A to the Regulations), based on the existing NL Scheme.

Nutritional Composition of Infant Formula (Section 9 of the Amendment Regulation)

22. Since 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, we must ensure that infant formula is safe and nutritionally adequate. We therefore mandate that infant formula must contain energy and 33 nutrients (i.e. "1+33") in accordance with the Codex standards. We further mandate that the level of energy and each nutrient must fall within the range specified in the relevant Codex Standard as specified in the proposed Divisions 1 and 2 of Part IV of Schedule 1 to the Regulations.

23. We also mandate that certain nutrients must follow the proportion requirements in accordance with the concerned Codex Standard (the proposed Division 3 of Part IV of Schedule 1 to the Regulations refers). Besides, due to the extensive use of taurine and DHA in infant formula available in the Hong Kong market, we also propose to require infant formula composed of these two substances to follow the relevant Codex standards in terms of maximum value and proportion respectively, notwithstanding the fact that they are not part of the 33 nutrients required to be present in infant formula.

24. Fluoride is also not one of the 33 nutrients required to be present in infant formula. However, since an excessive intake of fluoride may increase the risk of dental fluorosis, we propose to regulate fluoride in infant formula by requiring infant formula to be labelled with a statement associated with dental fluorosis[7], if the fluoride content of the product (in a

[7] The statement would :-
(a) indicate that consumption of the formula may cause dental fluorosis; and
(b) recommend that the risk of dental fluorosis should be discussed with a medical practitioner or health professional.

form that is reconstituted or served according to any instructions for use provided) exceeds the maximum level stipulated in the corresponding Codex standard (as specified in the proposed section 1(2) of Schedule 6A to the Regulations).

25. We have not proposed to impose nutritional composition requirement on follow-up formula and prepackaged food for infants and young children for the following reasons –

(a) infants and young children who have begun complementary feeding are no longer solely dependent on formula or prepackaged food for infants and young children for nutrients;

(b) conventional child statistics has indicated satisfactory child growth and there is no data to reflect specific nutritional deficiencies;

(c) Codex composition standard for follow-up formula was set over 20 years ago and follow-up formula has undergone significant development over the years. Codex has just started the process of reviewing the composition standard; and

(d) balanced nutrition for children growth should be achieved by educating parents and caregivers on the appropriate food intake.

Exemptions

Nutritional Composition and Nutrition Labelling Requirements for Formula for Special Medical Purposes (Sections 4, 7, 10 and 13 of the Amendment Regulation)

26. Formula for special medical purposes for infants and young children (FSMP) are formula products specially manufactured to meet the special nutrition requirements or dietary management need of infants and young children with specific disorders, diseases or medical conditions (e.g. maple syrup urine disease or phenylketonuria), and to be used under medical supervision.

27. In view of the special nature of FSMP, we consider it infeasible to prescribe a pre-set nutritional composition for FSMP as their formulation is varied to fit different medical purposes arising from disease(s), disorder(s) or medical condition(s). For instance, an FSMP intended for the dietary management of infants suffering from hyperlipoproteinaemia type 1 has to be formulated to contain a total fat level lower than the relevant Codex requirement for infant formula. We therefore propose to exempt FSMP from the nutritional composition requirements to be imposed on infant formula (as specified in the proposed regulation 3(2) and Schedule 1A to the Regulations).

28. As FSMP may be serving a multi-destination niche market, it may not be commercially viable for the concerned supplier/manufacturer to re-label its product just to satisfy the requirements of the Hong Kong market, which is comparatively small. We therefore further propose in the Amendment Regulation to exempt FSMP from the concerned nutrition labelling requirements, provided that the product is specifically labelled in accordance with Schedule 6B to the Regulations (the proposed regulation 4C(2) refers). Schedule 6B requires FSMP to be labelled as "formula for special medical purposes" or "特殊醫用配方產品", and "USE UNDER MEDICAL SUPERVISION" or "在醫生指示下使用", and with a statement stating that it is for the dietary management of a particular disease, disorder or medical condition (or any other words of similar meaning). This will ensure the continuous and stable supply of FSMP to Hong Kong. We do not consider that such an exemption will compromise the safe use of FSMP, as most FSMP are not available in the local retail market, and such products are used under medical supervision.

Nutrition Labelling Requirements for Products with Small Package Size (Section 7 and 13 of the Amendment Regulation)

29. We propose to exempt in the Amendment Regulation infant formula and follow-up formula packed in a container with a total surface area of less than 250 cm^2 from the nutrition labelling requirements (the proposed regulation 4C(2) and Schedule 6B to the Regulations refer). We consider container with this surface area or smaller to be too small to be labelled with all the required nutrition information in a legible font size. Most of these products are ready-to-feed (RTF) formula which is liquid

formula designed for just-born infants. They are usually used in hospitals and are currently not available in the local retail market.

30. As for prepackaged food for infants and young children, as the amount of nutrition information required to be labelled is similar to that required under the NL Scheme, we propose to model on the requirements under the NL Scheme and exempt such food from the proposed nutrition labelling requirement if it is packed in a container with a total surface area of less than 100 cm^2 (the proposed regulation 4C(2) and Schedule 6B to the Regulations refer).

31. If the products mentioned in paragraphs 29 and 30 above in small size are packed together and sold in a container with a total surface area of equal or more than the exemption limit, they will not be exempted and nutrition labels have to be affixed at the outer packaging of the products as required by the Amendment Regulation. This is also in line with the NL Scheme.

Grace Period (Section 1 of the Amendment Regulation)

32. We propose in the public consultation document (paragraph 41 below) that to allow sufficient time for the trade to prepare for the changes and for the necessary laboratory equipment and techniques on the testing of the relevant nutrients to be in place, we will allow a suitable grace period before implementing the proposed legislation. Results of the public consultation revealed that while the public advocated a shorter grace period, most traders requested a minimum grace period of two years to get prepared for the legislation. The trade considered a longer grace period necessary on the following grounds:-

(a) the trade needs to perform calibration of the composition of their products with the new requirements to ensure compliance with the Amendment Regulation;

(b) calibration results may require their products to be reformulated. Product reformulation involves product development, trial production and stability tests, as well as re-labelling of the products;

(c) as formula products and most prepackaged food for infants and young children are not manufactured in Hong Kong, they need to be shipped to Hong Kong upon production; and

(d) the trade needs sufficient time to phase out old products that do not comply with the new requirements before introducing new ones into the market.

33. Having considered the trade's views and the fact that we also imposed a two-year grace period for launching the NL Scheme, we suggest introducing the same grace period of two years for follow-up formula and prepackaged food for infants and young children.

34. However, given infant formula is the sole source of nutrition for infants, a shorter grace period of 18 months is proposed for infant formula for better protection of infants' health.

Penalty (Section 8 of the Amendment Regulation)

35. Any person who advertises for sale, sells or manufactures for sale any infant formula which does not conform to the nutritional composition requirements, or any infant formula, follow-up formula or prepackaged food for infants and young children that is not marked or labelled in compliance with the nutrition labelling requirements, will commit an offence. The maximum penalty for committing the offence will be a fine at level 5 ($50,000) and imprisonment for six months. The penalty is in line with that relating to the NL Scheme.

Regulation of Claims

36. We note that there were calls for early regulation of health and nutrition claims relating to formula products and prepackaged food for infants and young children under the age of 36 months during the public consultation. At present, there is still a lack of international consensus on the regulation of claims. In view of the complexity and controversies concerning the regulation of claims, more time would be needed for consultation among stakeholders and the public before a consensus can be reached. To avoid delay in the more urgent task of regulating nutritional composition of infant formula and nutrition labelling of infant formula,

follow-up formula and prepackaged food for infants and young children under the age of 36 months, the Administration therefore decided to tackle the issue of regulating claims at a later stage. CFS is studying the local and international situations on the use of nutrition and health claims in the products concerned. In light of the study, the Administration will examine the possible strategies on regulating such claims in 2014.

THE AMENDMENT REGULATION

A 37. The Amendment Regulation at **Annex A** amends the Regulations. The main provisions of the Amendment Regulation are as follows –

(a) Section 1 provides for the commencement of the Amendment Regulation (paragraphs 32-33 above refer).

(b) Section 2 provides that the Regulations are amended as set out in Sections 3 to 12.

(c) Section 3 defines certain terms used in the Regulations, including infant formula, follow-up formula and prepackaged food for infants and young children (paragraphs 7-9 and 11-14 above refer).

(d) Section 11 adds item 6A under Schedule 2 to stipulate that 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 (paragraph 10 above refers).

(e) Section 6 adds a new regulation 4B(7) to the Regulations to state clearly that infant formula, follow-up formula or prepackaged food for infants and young children is also required to comply with the requirements stipulated in Regulation 4B (i.e. the existing NL Scheme) if it is claimed to be suitable for consumption by persons of any age from 36 months onwards (paragraph 14 above refers).

(f) Section 7 adds a new regulation 4C to the Regulations which –

(i) requires infant formula, follow-up formula and prepackaged food for infants and young children to be marked or labelled with their energy value and nutrient content in compliance with Schedule 6A (paragraphs 16-21 above refer); and

(ii) exempts products in Schedule 6B, including FSMP that are marked or labelled in accordance with corresponding requirements and products with small package size, from the requirements in (i) above (paragraphs 28-31 above refer).

Schedules 6A and 6B are added through Section 13.

(g) Section 9 adds Part IV of Schedule 1 to the Regulations, setting out the nutritional composition requirements of infant formula (paragraphs 22-24 above refer). Sections 4 amends regulation 3 of the Regulations to the effect that FSMP that are marked or labelled in accordance with Schedule 1A will be exempted from the nutritional composition requirements (paragraphs 26-27 above refer).

Schedule 1A is added through Section 10.

(h) Section 8 amends regulation 5 of the Regulations to provide that any person who advertises for sale, sells or manufactures for sale:-

(i) any infant formula which does not conform to the nutritional composition requirements stipulated in Part IV of Schedule 1 of the Regulations; or

(ii) any infant formula, follow-up formula or prepackaged food for infants and young children which does not comply with the labelling requirements stipulated in regulation 4C of the Regulations

commits an offence. Contravention of the requirements may be subject to a maximum penalty of a fine at level 5 and imprisonment for 6 months (paragraph 35 above refers).

(i) Sections 5 and 12 provides for technical amendments to regulation 4A and Schedule 3 of the Regulations respectively.

LEGISLATIVE TIMETABLE

38. The legislative timetable is as follows –

Publication in the Gazette	13 June 2014
Tabling at the Legislative Council for negative vetting	18 June 2014

IMPLICATIONS OF THE PROPOSAL

39. The Amendment Regulation is in conformity with the Basic Law, including the provisions concerning human rights. It will not affect the binding effect of the principal Ordinance.

40. The Regulation has financial, civil service, economic and sustainability implications as set out in **Annex B**. The Regulation has no environmental and productivity implication.

B

PUBLIC CONSULTATION

41. We launched a two-month public consultation exercise from 20 November 2012 to seek the views of the public on the legislative proposals. We received strong support for our legislative proposals from respondents in the public consultation exercise. Some urged that the proposals should be enacted as soon as possible to protect the health of infants and young children. Specific views on various parts of the legislative proposals have been addressed in the Amendment Regulation as appropriate and are covered in the paragraphs above.

42. The legislative proposals were discussed at a joint meeting of the Legislative Council Panel on Food Safety and Environmental Hygiene (FSEH Panel) and Panel on Health Services on 20 November 2012. We reported the results of public consultation and received the support of the FSEH Panel on the legislative proposals on 12 March 2013.

PUBLICITY

43. A press release will be published and a spokesperson will be made available to answer any press enquiries.

ENQUIRIES

44. Any enquiries on this brief may be addressed to Mr Jeff LEUNG, Principal Assistant Secretary for Food and Health (Food)1 at 3509 8925.

Food and Health Bureau
Food and Environmental Hygiene Department
June 2014

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

Contents

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-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 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 &".

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

Division 2—Nutrient Content

Item	Nutrient	Minimum level		Maximum level	
		per 100 kcal	per 100 kJ	per 100 kcal	per 100 kJ
	Protein				
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
	Fat				
3.	Total fat	4.4 g	1.05 g	6.0 g	1.4 g
4.	Linoleic acid	300 mg	70 mg	—	—
5.	α-Linolenic acid	50 mg	12 mg	—	—
	Carbohydrates				
6.	Total carbohydrates	9.0 g	2.2 g	14.0 g	3.3 g
	Vitamins				
7.	Vitamin A	60 μg RE	14 μg RE	180 μg RE	43 μg RE

Item	Nutrient	Minimum level		Maximum level	
		per 100 kcal	per 100 kJ	per 100 kcal	per 100 kJ
8.	Vitamin D3	1 μg	0.25 μg	2.5 μg	0.6 μg
9.	Vitamin E	0.5 mg α-TE	0.12 mg α-TE	—	—
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	—	—
	Minerals				
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	—	—

Item	Nutrient	Minimum level		Maximum level	
		per 100 kcal	per 100 kJ	per 100 kcal	per 100 kJ
28.	Iodine	10 μg	2.5 μg	—	—
29.	Selenium	1 μg	0.24 μg	—	—
30.	Copper	35 μg	8.5 μg	—	—
31.	Zinc	0.5 mg	0.12 mg	—	—
	Others				
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 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.".

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^2.

(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.

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^2.

3. Any prepackaged food for infants and young children packed in a container that has a total surface area of less than 100 cm^2.".

Director of Food and Environmental Hygiene

9 June 2014

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.

Annex B

IMPLICATIONS OF THE PROPOSAL

FOOD AND DRUGS (COMPOSITION AND LABELLING) (AMENDMENT) (NO. 2) REGULATION 2014

Financial and Civil Service Implications

Upon implementation of the Amendment Regulation after expiry of the grace period, the Centre for Food Safety (CFS) has to conduct surveillance through checking the nutrition labels of infant formula, follow-up formula and prepackaged food for infants and young children available in the market. CFS will also collect food samples of these products for chemical analysis to be conducted by the Government Laboratory (GL) to verify their compliance with the composition requirements and labelling requirements as appropriate. CFS will also need to arrange public education programme to enhance public awareness of the new requirements to help the public make informed food choices for their children. These implementation work will entail additional workload for CFS and GL.

2. To facilitate the preparation of the implementation of the Amendment Regulation, a funding of $2.3 million is provided in 2014-15 and $3.0 million in a full year for GL to strengthen its analytical services. The resource requirements of CFS and GL will be reviewed during the grace period having regard to future surveillance plan.

Economic Implications

3. The proposal would better protect the health of infants and young children in Hong Kong. At the same time, it would entail some compliance costs for the trade, as the trade would need to undertake preparatory work for complete compliance with the Amendment Regulation, including laboratory testing, minor product reformulation and hence re-labelling if necessary. Yet the costs are expected to be largely one-off and not significant. Since the proposed regulation is devised with

reference to Codex standards, prevailing international practice and local market situation, the infant formula, follow up formula and prepackaged food for infants and young children in the Hong Kong market should not have too much problem in complying with the proposed composition and labelling requirements.

4. Indeed, CFS conducted two surveys on the infant formula and follow-up formula available in the local market in 2012. The survey on nutritional composition revealed that among the 56 infant formula products tested, 40 (71%) of them complied with the "1+33" nutritional composition requirement. As for the survey on nutrition labelling, among the 62 infant formula products studied, 46 (74%) of them have already labelled "1+29". Meanwhile, among the 51 follow-up formula products studied, 40 (78%) of them have already labelled "1+25". Besides, a survey conducted by CFS on prepackaged food for infants and young children in early 2014 revealed that more than 70% (603 out of 827 samples) of prepackaged food for infants and young children complied with the proposed nutrition labelling requirement.

Sustainability Implications

5. The proposal is in line with the sustainability principle of pursuing policies which promote and protect the physical and mental health of the people of Hong Kong. The nutritional composition requirements would strengthen the Government's capability to ensure food safety. The nutrition labelling requirements would regulate misleading or deceptive labels and provide useful nutrition information for parents of infants and young children to make informed food choices, thereby facilitating parents to provide a balanced diet for their infants and young children.