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

Background brief prepared by the Legislative Council Secretariat

Purpose

This paper provides background information on the Administration's legislative proposals to amend the Food and Drugs (Composition and Labelling) Regulations (Cap. 132W) ("the principal Regulations") to govern 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 in Hong Kong, and summarizes the concerns of members of the Panel on Food Safety and Environmental Hygiene ("the Panel") on the legislative proposals.

Background

2. As revealed by the survey of the Centre for Food Safety ("CFS") conducted from May to September 2012, some infant formula products were found to contain iodine at a level not only lower than that prescribed by the Codex Alimentarius Commission ("Codex"), but also below the intake level recommended by the World Health Organization. As iodine deficiency may affect the functioning of the thyroid gland, which may in turn affect the brain development of infants, the survey results have aroused wide public concern over the safety and regulation of formula products.

3. Currently, the safety of formula products and prepackaged food for infants and young children under the age of 36 months is regulated by section 54 of the Public Health and Municipal Services Ordinance (Cap. 132) ("PHMSO"), which stipulates that all food for sale must be fit for human consumption. However, there are no specific provisions in PHMSO 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. The principal Regulations has introduced a mandatory Nutrition Labelling Scheme for prepackaged foods since July 2010 to, inter alia, regulate misleading or deceptive labels and claims, but it does not apply to formula products and prepackaged food for infants and young children under the age of 36 months due to their special nutritional requirements and the separate requirements on nutrition labelling for the above types of food stated in the guidelines published by Codex.

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

4. On 9 June 2014, the Director of Food and Environmental Hygiene, in exercise of the power under section 55(1) of PHMSO, made the Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014 ("the Amendment Regulation"). 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. The key features of the Amendment Regulation are highlighted in the ensuing paragraphs.

Definitions of infant formula, follow-up formula and prepackaged food for infants and young children

5. The proposed 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 proposed definition will also cover formula products labelled with any other words of a meaning similar to "infant formula" or "嬰兒配方產品".

6. As for follow-up formula, the proposed definition 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 six 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.

7. For the purpose of protecting the health of infants under six months, it is also required in the Amendment Regulation that follow-up formula must not be marked or labeled to the effect that the formula is suitable for consumption by persons of any age under six months.

8. As regards 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.

Nutrition labelling of infant formula, follow-up formula and prepackaged food for infants and young children

9. As regards the nutrition labelling of infant formula, the Administration proposes to mandate the labelling of energy value and 29 nutrients ("1+29"), following the relevant Codex standards. According to the Administration, major overseas 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" (i.e. the labelling of energy value and the 33 nutrients) as proposed by the Administration in the public consultation exercise. For follow-up formula, the Administration proposes mandating the labelling of energy value and 25 nutrients ("1+25"), following the requirements laid down in the relevant Codex standards.

10. With respect to prepackaged food for infants and young children, it is proposed to mandate the labelling of energy value and four 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. According to the Administration, the relevant Codex standards do not require all prepackaged food for infants and young children to be labelled with its sodium content. However, as there is evidence suggesting that Chinese people are particularly susceptible to dietary salt-induced high blood pressure, excessive intake of sodium should be avoided at a young age.

Nutritional composition of infant formula

11. For the nutritional composition of infant formula, the Administration proposes to mandate that infant formula must contain energy and 33 nutrients ("1+33") in accordance with the Codex standards. The level of energy and each nutrient must fall within the range specified in the relevant Codex standards as specified in the proposed Divisions 1 and 2 of Part IV of Schedule 1 to the principal Regulations. The Amendment Regulation also mandates that certain nutrients must follow the proportion requirements in accordance with the concerned Codex standards. Due to the extensive use of taurine and DHA in infant formula available in the Hong Kong market, the Administration also

proposes to require infant formula composing of these two substances to follow the relevant Codex standards in terms of maximum value and proportion respectively. Since an excessive intake of fluoride may increase the risk of dental fluorosis, it is also proposed to regulate fluoride in infant formula.

Exemptions under the Amendment Regulation

12. Under the Amendment Regulation, formula for special medical purposes for infants and young children are proposed to be exempted from the nutritional composition and nutrition labelling requirements. Infant formula and follow-up formula packed in a container with a total surface area of less than 250 cm² are also proposed to be exempted from the nutrition labelling requirements.

13. As for prepackaged food for infants and young children, the Administration proposes to model on the requirements under the Nutrition Labelling 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 cm².

Grace period

14. Having considered the results of the public consultation and the fact that a two-year grace period was imposed for launching the Nutritional Labelling Scheme, the Administration proposes to provide the same grace period of two years for follow-up formula and prepackaged food for infants and young children. 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.

Deliberations by the Panel

15. The Panel was briefed on the legislative proposals relating to formula products and prepackaged food for infants and young children under the age of 36 months at its meeting on 12 March 2013. The deliberations and concerns of members are summarized below.

Nutrition labelling requirements of formula products and prepackaged food for infants and young children

16. Some members questioned the need for imposing a nutrition labelling requirement for young children between the age of 12 months and 36 months.

In these members' view, the Administration should consider imposing nutrition labelling requirements for formula products and prepackaged food for infants aged under 12 months only. Some members pointed out that all formula products supplied in Hong Kong were imported from overseas, and the nutrition labelling requirement of "1+33" proposed for infant formula in the consultation exercise was more stringent than the Codex standard of "1+29". These members were concerned about the impact on the supply of formula products to Hong Kong.

17. The Administration explained that in the light of the findings in the survey conducted by CFS in 2012 that certain formula products imported from Japan were deficient in iodine, priority should be accorded to the introduction of legislation governing formula products and prepackaged food for infants and young children under the age of 36 months to safeguard their health. CFS had also conducted another survey before the launch of the public consultation exercise on the legislative proposals. The results of the survey revealed that about 50% of infant formula milk products supplied in Hong Kong had met the proposed nutrition labelling requirement of "1+33", while another 34% had labelled 29 to 32 nutrients. About 80% of formula products for young children under the age of 36 months had met the proposed requirement of "1+25". In the Administration's view, the requirements set out in the legislative proposals were reasonable and there would be adequate supply of formula products meeting the proposed nutrition labelling requirements in Hong Kong.

18. Holding the view that Codex had not imposed any mandatory labelling requirement on sodium in non-cereal-based foods for infants and young children, some members queried the need for imposing such labelling requirement in Hong Kong. Some other members, however, expressed the view that, in addition to sodium, the excessive intake of some nutrients such as potassium might also affect the health of infants and young children under the age of 36 months.

19. According to the Administration, prolonged excessive intake of sodium might increase the risk of developing high blood pressure. The proposed labelling requirement on sodium in non-cereal-based foods for infants and young children sought to assist parents in making informed food choices. Many overseas jurisdictions such as Australia and the European Union had also adopted similar labelling requirements. During the public consultation exercise, members of the public generally supported the labelling of sodium in non-cereal-based foods for infants and young children. Regarding members' concern about the level of potassium in formula products and prepackaged food for infants and young children, the Administration explained that there was presently no such labelling requirement under the Codex standards.

Proposed exemptions

20. Some members expressed the view that exemption should be provided for formula products with a very small sales volume and those formula products which were manufactured to meet special medical needs. According to the Administration, it would look into the relevant views received during the public consultation exercise before finalizing the legislative proposals and the exemption arrangements.

Grace period

21. Concern was raised over the length of the grace period. There was a view that the grace period should not be shorter than two years as the shelf life of formula products was usually about two to three years. Some other members, however, considered a two-year grace period too long and urged the Administration to shorten it to one year. According to the Administration, the Panel's views would be taken into account in determining the suitable length of the grace period when finalizing the legislative proposals.

Regulation of health and nutritional claims

22. Many members were gravely concerned about the regulation of misleading and exaggerated health and nutritional claims made in some formula products advertisements. They urged the Administration to introduce as early as possible legislation regulating such health and nutritional claims. The Administration advised that it would start tackling the issue of regulating nutrition and health claims at a later stage in 2013. The relevant articles of the Hong Kong Code of Marketing and Quality of Formula Milk and Related Products, and Food Products for Infants & Young Children would serve as guidelines with respect to the claims of the formula products.

Relevant papers

23. A list of the relevant papers on the Legislative Council website is in the **Appendix**.

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

Committee	Date of meeting	Paper
Panel on Food Safety and Environmental Hygiene and Panel on Health Service	20.11.2012 (Item II)	Agenda Minutes
Panel on Food Safety and Environmental Hygiene	12.3.2013 (Item IV)	Agenda Minutes

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