

**For discussion
on 14 June 2016**

LegCo Panel on Food Safety and Environmental Hygiene

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

Purpose

This paper updates Members on the implementation of the Food and Drugs (Composition and Labelling) (Amendment) (No.2) Regulation 2014 (the Amendment Regulation).

Background

2. The Government is committed to protecting the health of infants and young children. It is necessary for infants and young children to obtain optimal nutrition from their diet to grow and stay healthy. The superiority of breastfeeding in ensuring the physical and psychosocial health and well-being of mothers and children, as well as the important impact of early nutrition on long-term health, are widely recognised. Where breastfeeding is not feasible, infant formula is the only processed food which wholly fulfils the nutritional requirements of infants during their first months of life until the introduction of appropriate complementary feeding¹. We need to ascertain that infant formula is safe for consumption and nutritionally adequate.

3. Food labels enable consumers to obtain specific information about 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

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

(Composition and Labelling) Regulations (Cap. 132W) came into force in July 2010. The NL Scheme, however, does not cover formula products and prepackaged food for infants and young children under the age of 36 months.

4. To better protect the health of infants and young children, the Government introduced the Amendment Regulation to regulate the nutritional composition and nutrition labelling of formula products and prepackaged food for infants and young children under the age of 36 months. The Codex Alimentarius Commission (Codex)² 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. In mapping out the regulatory details, we have made reference to the Codex principles and relevant international practices, as well as the local market and consumption situation so as to ensure that the legislation pays due regard to international standards and the local situation.

5. The Legislative Council completed vetting of the Amendment Regulation in October 2014. The Amendment Regulation stipulates different grace periods for the regulation of different food products for infants and young children. The provisions on nutritional composition and nutrition labelling of infant formula took effect on 13 December 2015 after the expiry of a grace period of 18 months from the gazette date³. The nutrition labelling requirements for follow-up formula and prepackaged food for infants and young children will come into operation on 13 June 2016 after a grace period of two years.

² Codex was established in 1963 by the Food and Agriculture Organization of the United Nations and the World Health Organization as an international authority to set food-related standards and guidelines.

³ The Amendment Regulation was gazetted in June 2014.

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

6. In the Amendment Regulation, “infant formula”, “follow-up formula” and “prepackaged food for infants and young children” are defined as follows:

“Infant formula” 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.

“Follow-up formula” means-

- (a) a product that, according to its descriptions or instructions for use, is represented as a replacement⁴ 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 (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.

⁴ 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.

“Prepackaged food for infants and young children” 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.

7. Regarding nutritional composition, infant formula must contain energy and 33 nutrients (1+33)⁵, and the energy value and content of each nutrient must fall within the range specified in the Amendment Regulation. Certain nutrients must also follow the relevant proportion requirements. In addition to the 33 nutrients, the Amendment Regulation requires infant formula composed of taurine and docosahexaenoic acid (DHA) to follow the relevant standards in terms of maximum value and proportion respectively. Furthermore, since an excessive intake of fluoride may increase the risk of dental fluorosis, the Amendment Regulation mandates that infant formula be labelled with a statement associated with dental fluorosis, if its fluoride content exceeds the stipulated maximum level.

8. Regarding nutrition labelling, the Amendment Regulation requires the labelling of energy value and 29 nutrients (1+29)⁶ for infant formula, and the labelling of energy value and 25 nutrients (1+25)⁷ for follow-up formula. Prepackaged food for infants and young children must be labelled with its

⁵ An infant formula must contain energy and 33 nutrients (protein, total fat, linoleic acid, α -linolenic acid, total carbohydrates, vitamin A, vitamin D3, vitamin E, vitamin K, thiamine, riboflavin, niacin, vitamin B6, vitamin B12, pantothenic acid, folic acid, vitamin C, biotin, iron, calcium, phosphorus, magnesium, sodium, chloride, potassium, manganese, iodine, selenium, copper, zinc, choline, myo-inositol and L-carnitine).

⁶ The nutrition label of an infant formula must indicate the energy value and the content of 29 nutrients (protein, total fat, total carbohydrates, vitamin A, vitamin D3, vitamin E, vitamin K, thiamine, riboflavin, niacin, vitamin B6, vitamin B12, pantothenic acid, folic acid, vitamin C, biotin, iron, calcium, phosphorus, magnesium, sodium, chloride, potassium, manganese, iodine, selenium, copper, zinc and choline).

⁷ The nutrition label of a follow-up formula must indicate the energy value and the content of 25 nutrients (protein, total fat, available carbohydrates, vitamin A, vitamin D, vitamin E, vitamin K, thiamine, riboflavin, niacin, vitamin B6, vitamin B12, pantothenic acid, folic acid, vitamin C, biotin, iron, calcium, phosphorus, magnesium, sodium, chloride, potassium, iodine and zinc).

energy value and the content of four nutrients, namely protein, fat, carbohydrates and sodium (1+4), as well as vitamins A and D (if they are added to the food).

9. Formula for special medical purposes for infants and young children is exempted from the nutritional composition and nutrition labelling requirements, provided that such products are specifically labelled in accordance with the Amendment Regulation. Modelling on the existing NL Scheme, the Amendment Regulation also exempts products packed in small packages (i.e. formula products packed in a container with a total surface area of less than 250 cm² or prepackaged food for infants and young children packed in a container with a total surface area of less than 100 cm²) from the nutrition labelling requirements.

Enforcement

10. For the period from 13 December 2015 when the requirements on nutritional composition and nutrition labelling of infant formula came into effect to 31 May 2016, the Centre for Food Safety (CFS) examined the nutrition labels of 44 infant formulae. All were found with satisfactory results. CFS also collected 40 samples for nutrient content analysis. While 10 samples are awaiting test results, the rest of the samples were found to comply with the legal requirements. In addition, CFS collected 20 samples for fluoride testing, all with satisfactory results. The fluoride content of these products did not exceed the maximum level stipulated in the Amendment Regulation.

Publicity and Education

11. CFS has held a series of technical meetings with the trade and other relevant stakeholders in preparation for the implementation of the new requirements. CFS has also produced technical guidelines covering the technical issues involved for reference by the trade. Through posters, online slogan advertising, as well as its publications and electronic and social platforms, CFS has raised public awareness of the Amendment Regulation. In addition, CFS has prepared leaflets highlighting the legal

requirements and the nutritional characteristics and nutrition labels of formula products and food for infants and young children, with a view to facilitating caregivers of infants and young children to have a better understanding of the nutrition labelling and nutritional composition of these products. The leaflets are available to the public at venues including hospitals as well as maternal and child health centres network and district offices of the Food and Environmental Hygiene Department. They are also distributed to the trade. CFS will continue to step up publicity and education through various channels.

Advice Sought

12. Members are invited to note and comment on the content of this paper.

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