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Nutritional Composition and Labelling Legislation on Baby Formula

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Report Highlights:

The Hong Kong government tabled an amendment to the Food and Drugs (Composition and Labelling) Regulation on June 18, 2014 with the effect to regulate nutritional composition of infant formula and labelling of infant formula, follow-up formula and prepackaged food for infants and children under the age of 36 months. The amendment will be passed in 28 days automatically if no motion for amendment is moved. The Legislative Council will have a maximum of 49 days in total to discuss the amendment. However, a grace period of 2 years will be provided to new requirements pertaining to follow-up formula and prepackaged food for young children; and 18 months for infant formula. If this new legislative amendment becomes effective, U.S. infant formula which are in compliance with the U.S. standard and catered for the U.S. market may not be able to sell in Hong Kong without first making modifications to composition and labeling.

Background:

Back in 2012, a survey found that some popular formulas in Hong Kong contained iodine at a level lower than that recommended by World Health Organization and that prescribed by Codex. The survey result prompted the Hong Kong government (HKG) quickly to initiate legislative proposals on regulating the composition of baby formula. Given that the existing labeling regulation does not cover formulas and foods for children under 36 months, the HKG decided to include labeling requirements for baby formulas and foods for young children as well in this amendment exercise.

Following a public consultation and briefing for the Legislative Council in early 2013, the Hong Kong Center for Food Safety finalized the proposal by amending the existing Food and Drugs (Composition and Labelling) Regulation and submitted it to the Legislative Council for vetting on June 18, 2014.

The Amendment:

The HKG indicated that the new legislative requirements are primarily based on Codex standard and international standard, with reference to local consumption situation.

Labeling Requirements

The amendment will require the labeling of energy value and 29 nutrients (1+29) for infant formula and the labeling of energy value and 25 nutrients (1+25) for follow up formula. These requirements are in line with Codex standards. Infant formula and follow-up formula refers to formula for babies “up to and including 12 months” and for young children from 6 months to under 36 months respectively.

Moreover, fluoride is not a required nutrient for infant formula. If it is contained in infant formula at a level exceeding 100 ug per 100 kcal or 24 ug per 100 kJ, equivalent to the Codex standard, it is mandatory to include a statement relating to the risk of dental fluorosis.

For prepackaged food for infants and young children, it is proposed to require mandatory labeling 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). All prepackaged food (excluding infant formula or follow-up) food for babies and young children up to the age 36 months are to be covered by this regulation measure.

Unlike Codex, Hong Kong will require prepackaged food for infants and young children to be labelled with sodium content. The HKG explained that this requirement serves to combat salt-induced high blood pressure among the population from an early age. The Hong Kong government paper indicated that many countries such as the U.S., Australia, New Zealand and European Union have also required the labeling of sodium content in all food for infants and young children.

Nutritional Composition Requirement

The proposed amendment will require infant formula to contain energy and 33 nutrients (1+33), at levels and proportions according to Codex standards.

Taurine and decosahexaenoic acid (DHA) are not mandatory nutrients, but if they are added to the formula, they have to be within the maximum level and proportion respectively as stipulated in the amendment and these prescribed levels are in line with Codex.

Exemption

The proposed amendment will exempt formula for special medical purposes for infants and young children from the nutritional composition and labelling requirements on the grounds that the standard composition requirements may not meet the specific needs of these children. Moreover, the proposed amendment exempts products with a small package size from the nutritional labelling requirements.

Time Frame

This legislative amendment for regulating nutritional composition and labeling has been introduced by negative vetting, implying that members can request an extension of vetting period which will not exceed 49 days at a maximum and the amendment will be enacted automatically.

The amendment proposes a grace period of two years for follow-up formula and prepackaged food for infants and young children. However, a shorter grace period of 18 months is proposed for infant formula.

Language

The labeling language could be in either English, Chinese, or both. If both languages are used in the marking or labelling of the infant formula, follow-up formula or prepackage food for infants and young children, the labeling of the nutrient list must be in both the Chinese and English languages.

Expression of Units

The proposed amendment standardizes the expression of units for energy and nutrients. They are to be labelled in an appropriate unit (such as kcal/kJ/g) per 100 g/mL of the infant formula. For follow-up formula and prepackaged food for infants and young children, they can be labelled in units per 100 g/mL or per serving specified in g/mL.

Details

Details of the regulation including the required nutrients are provided in this [link](#).

Impact on U.S. Products

The amendment will have impact on U.S. infant formula. U.S. infant formula produced for the U.S.

domestic market may not meet the Hong Kong new requirements in the context of composition or/and labelling.

The composition requirements for infant formula between the U.S. and Hong Kong are different. The U.S. regulations specify that infant formulas must contain 29 nutrients whereas there are 33 nutrients required in Hong Kong. The four nutrients not listed in 21CFR 107.100 but required in Hong Kong are α -Linolenic acid, total carbohydrates, selenium, and L-Carnitine. Moreover, the minimum nutrient requirements level in the U.S. may be lower than that in the Hong Kong (e.g, thiamine, riboflavin, iron and iodine).

In the area of labeling for infant formula, Hong Kong's proposed amendment requires energy and nutrients to be provided in terms of value per 100 Kcal/kJ and 100 g/ml respectively. In the U.S., the nutrient values are contained in "a statement of the number of fluid ounces supply 100 kilocalories" and "a statement of the amount of each of the (required) nutrients supplied by 100 kilocalories."

Another labeling issue relates to selenium. Hong Kong mandates the labeling of selenium but there is no such requirement in the U.S. yet.

Given the differences in composition and labeling requirements in infant formula between the U.S. and Hong Kong, reformulation of the formula and labeling modification may be needed if U.S. infant formula wants to enter the Hong Kong market.