

**Business Facilitation Advisory Committee  
Wholesale and Retail Taskforce**

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

**Purpose**

This paper aims to introduce the Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014 which will come into effect on 13 December 2015 for the requirements for infant formula and on 13 June 2016 for the requirements for follow-up formula and prepackaged foods for infants and young children.

**Background**

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. We must therefore ensure that infant formula is safe and nutritionally adequate. In addition, 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.

3. Section 54 of Cap. 132 stipulates that all food for sale must be fit for human consumption. This covers all food including formula products (infant formula and follow-up formula) 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 for formula products and prepackaged food for infants and young

children under the age of 36 months before the making of Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014. In addition, the Nutrition Labelling Scheme for prepackaged food products under the Food and Drugs (Composition and Labelling) Regulations (Cap. 132W) does not cover formula products and prepackaged food for infants and young children under the age of 36 months.

4 In light of the finding of iodine deficiency in certain infant formula products in the local market in a survey conducted by the Centre for Food Safety in 2012 and the urgency to protect the health of infants and young children, the Administration proposed that priority should be accorded to the introduction of legislation governing the nutritional composition and nutrition labelling of formula products and prepackaged food for infants and young children under the age of 36 months.

### **Legislation Process**

5. The Administration launched a two-month public consultation exercise between 20 November 2012 and 21 January 2013 to seek the views of the public (including the members of trade) on the legislative proposals. In general, traders and members of the public supported the legislative proposals.

6. The Administration then commenced the drafting of the regulation. A series of technical meetings with the trade were held to tackle various technical issues. In June 2014, the Food and Drugs (Composition and Labelling) (Amendment) (No.2) Regulation 2014 (“the Amendment Regulation”) was published in Gazette and tabled at Legislative Council for negative vetting. The Legislative Council has completed on 22 October 2014 the scrutiny of the Amendment Regulation, which will come into force on 13 December 2015 (after a grace period of 18 months) for the requirements for infant formula and on 13 June 2016 (after a grace period of 24 months) for the requirements for follow-up formula and prepackaged food for infants and young children.

### **Key Features of the Amendment Regulation**

7. When formulating the Amendment Regulation, the Administration had made primary reference to the standards from

Codex Alimentarius Commission (Codex) and relevant international practices as well as local market and consumption situation. This will ensure that our Amendment Regulation pay due regard to international standards and local situation. Key features of the Amendment Regulation are as follows:

### *Definition*

8. The Amendment Regulation stipulates the definition of infant formula, follow-up formula and prepackaged food for infants and young children. Moreover, the Amendment Regulation also stipulates the definition of certain nutrients. In addition, for the purpose of protecting the health of infants under 6 months, we 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.

### *Nutritional Composition*

9. In accordance with the relevant Codex standard, the Amendment Regulation mandates that infant formula must contain energy and 33 nutrients (“1+33”), and the level of energy and each nutrient must fall within the specified range. We also mandate that certain nutrients must follow the proportion requirements in accordance with the concerned Codex Standard. In addition, taurine and DHA, if added to infant formula, are required to follow the requirements on nutritional composition as stipulated in 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.

### *Nutrition Labelling*

10. The Amendment Regulation mandates the nutrition labelling of infant formula, follow-up formula and prepackaged food for infants and young children as follows:

- (a) for infant formula, the Amendment Regulation mandates the labelling of energy value and 29 nutrients (“1+29”), following the relevant Codex Standards,
- (b) for follow-up formula, the Amendment Regulation mandates the labelling of energy value and 25 nutrients (“1+25”), following the relevant Codex Standards, and
- (c) for prepackaged food for infants and young children, the Amendment Regulation mandates 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.

11. In addition, the Amendment Regulation mandates that if the fluoride content of infant formula (in a form that is reconstituted or served according to any instructions for use provided) exceeds 100 µg per 100 kilocalories or 24 µg per 100 kilojoules<sup>1</sup>, the product must be marked or labelled with a statement associated with dental fluorosis—

- (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.

### *Exemption*

12. Formula for special medical purposes for infants and young children can be exempt from the nutritional composition and nutrition labelling requirements, provided that the product is specifically 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).

13. In addition, products with small package size (i.e. infant formula and follow-up formula packed in a container with a total surface area of less than 250 cm<sup>2</sup> and prepackaged food for infants and young children packed in a container with a total surface area of less than 100 cm<sup>2</sup>) can be exempt from the nutrition labelling requirements.

### *Grace Period*

14. The Administration introduced a grace period of 18

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<sup>1</sup> When calculating the fluoride content of infant formula in a form that is reconstituted or served, the Administration will take the instruction for use (including the type and amount of water to be used for reconstitution as recommended by the manufacturer) and the fluoride content of the drinking water in Hong Kong into account. If the product does not have any special recommendation on the type of water to be used or only shows that general drinking water can be used for reconstitution on its instruction for use, fluoride content in water of 0.5mg/L (average fluoride contents of drinking water in Hong Kong were 0.48-0.49 mg/L in 2009-2013) will be used for calculation.

months for the requirements for infant formula and a grace period of 24 months for the requirements for follow-up formula and prepackaged food for infants and young children.

### **Trade facilitation measures**

15. The Centre for Food Safety issued two sets of guidance notes in January 2015 for traders' reference ([http://www.cfs.gov.hk/english/food\\_leg/files/Formula\\_Products\\_for\\_Infants/Technical\\_Guidance\\_Notes\\_e.pdf](http://www.cfs.gov.hk/english/food_leg/files/Formula_Products_for_Infants/Technical_Guidance_Notes_e.pdf) and [http://www.cfs.gov.hk/english/food\\_leg/files/Formula\\_Products\\_for\\_Infants/Method\\_Guidance\\_Notes\\_e.pdf](http://www.cfs.gov.hk/english/food_leg/files/Formula_Products_for_Infants/Method_Guidance_Notes_e.pdf)). These guidance notes discuss in details the technical issues such as tolerance limits, rounding rules and recommended formats of nutrition labelling, and testing methods.

### **Way Forward**

16. The Legislative Council has completed its vetting of the Amendment Regulation in October 2014. The Amendment Regulation will come into force on 13 December 2015 (after a grace period of 18 months) for infant formula and on 13 June 2016 (after a grace period of 24 months) for follow-up formula and prepackaged foods for infants and young children.

17. Members are requested to note the content of this paper and offer comments, if any.

Centre for Food Safety  
Food and Environmental Hygiene Department  
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