立法會
Legislative Council

LC Paper No. CB(2)1675/15-16(02)

Ref : CB2/PL/FE

Panel on Food Safety and Environmental Hygiene

Information note prepared by the Legislative Council Secretariat for the meeting on 14 June 2016

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

A survey conducted by the Centre for Food Safety in 2012 revealed that 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 (i.e. infant formula and follow-up formula).

2. 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"). The Amendment Regulation aims to ensure that formula products and prepackaged food for infants and young children under the age of 36 months ("IYC food") 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 who consume such products.

3. The Amendment Regulation provides for:

(a) the standards of nutritional composition of infant formula — 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. Also, certain nutrients must follow the relevant proportion requirements;

(b) the nutrition labelling requirement of infant formula, follow-up formula and IYC foods — the Amendment Regulation mandates the labelling of energy value and 29 nutrients (1+29) for infant formula and the labelling of energy value and 25 nutrients (1+25) for follow-up formula, following the relevant Codex standards. For IYC food, the labelling of energy value and four nutrients, namely protein, fat, carbohydrates and sodium (1+4), as well as vitamins A and D (if they are added to the food) will be required;

(c) items that are exempt from certain requirements — formula for special medical purposes and products with small package size are exempt from the nutritional composition or nutrition labelling requirements, provided that such products are specifically labelled in accordance with the amended Regulation; and

(d) offences and penalties for non-compliance — 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 formula product or IYC food that is not marked or labelled in compliance with the nutrition labelling requirements, commits an offence and is liable to a maximum penalty of a fine of $50,000 and imprisonment for six months.

4. The Amendment Regulation, subject to negative vetting by the Legislative Council, was gazetted on 13 June 2014 and scrutinized by the Subcommittee on Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014 ("the Subcommittee"). The Subcommittee completed scrutiny of the Amendment Regulation in October 2014. An extract from the Subcommittee's report which sets out its deliberations is in the **Appendix**.

5. The requirements on nutritional composition and nutrition labelling of infant formula has come into force since 13 December 2015 (after a grace period of 18 months). The requirements on nutrition labelling of follow-up formula and prepackaged IYC food will take effect on 13 June 2016 (after a grace period of 24 months).

6. The Administration will report on the implementation of the Amendment Regulation at the Panel meeting on 14 June 2016.

Council Business Division 2
Legislative Council Secretariat
7 June 2016

Appendix

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LC Paper No. CB(2)256/14-15

Ref : CB2/SS/8/13

Paper for the House Committee

Report of the Subcommittee on Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014

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Deliberations of the Subcommittee

Length of grace period

9. Members are advised that the results of the public consultation has revealed that while the public advocates a shorter grace period, most traders request a minimum grace period of two years for calibration of the composition of their products and product reformulation etc.. Having considered the views received and the fact that a two-year grace period had been imposed for launching NLS, the Administration has proposed introducing the same grace period of two-years for follow-up formula and prepackaged food for infants and young children, so that the trade will have sufficient time to prepare for the commencement of the Amendment Regulation. As for infant formula, given the fact that infant formula is the sole source of nutrition for infants when breastfeeding is not feasible, a shorter grace period of 18 months is proposed for infant formula for better protection of infants' health.

10. Members in general consider that the Administration should provide the same grace period for infant formula, follow-up formula and prepackaged food for infants and young children under the age of 36 months, but they hold different views on the suitable length of grace period. Hon Vincent FANG and Hon WONG Ting-kwong share the concern of the deputations from the trade that as the Administration has not released the final details of the technical guidance notes, formula products manufacturers will need a longer grace period of 24 months to re-formulate their products and conduct stability study. In their view, the same grace period of 24 months should be provided across the board. Mr FANG has indicated that he will consider moving an amendment to this effect.

11. Dr Helena WONG, however, shares the concern of parents groups and considers that in the interest of protecting infants' health, a shorter grace period of 18 months should be provided for all formula products and prepackaged food for infants and young children. She has also indicated her intention to move an amendment with a view to providing the same grace period of 18 months for all formula products and prepackaged food for infants and young children under the age of 36 months.

12. The Administration has reiterated its explanation on why different grace periods are proposed for infant formula, follow-up formula and prepackaged food for infants and young children under the age of 36 months. It has further advised that CFS has provided the provisional draft of the technical guidance notes to the trade and the finalized version of the notes will be released after the completion of scrutiny of the Amendment Regulation. It has also stressed that in order to protect the health of infants and young children, the Administration will only consider proposing a shorter grace period of 18 months if the same grace period should be provided across the board.

13. As mentioned in paragraph 8 above, the period for amending the Amendment Regulation expired at the Council meeting of 22 October 2014 without being extended. Members note that it is technically not feasible for the Subcommittee or any Member to amend the Amendment Regulation.

Nutritional composition and nutrition labelling requirements for infant formula, follow-up formula and prepackaged food for infants and young children

14. Members have expressed concern that it has become increasingly popular for some parents to buy formula products directly from overseas markets via online purchasing agents. They have asked the Administration whether these online purchasing activities are subject to the regulation of the Amendment Regulation. The Administration has advised that under the Amendment Regulation, any person who advertises for sale, sells or manufactures for sale any infant formula that does not conform to the nutritional composition requirements in the Amendment Regulation, or any infant formula, follow-up formula or prepackaged food for infants and young children that does not comply with the nutrition labelling requirements in the Amendment Regulation, commits an offence. The provisions are applicable to conducting sales and advertising for sale on the Internet. However, the provisions do not regulate conduct outside the Hong Kong jurisdiction.

15. Members have also enquired whether the labels indicating energy value and 33 nutrients will comply with the nutrition labelling requirement under the

Amendment Regulation and whether the trade is required to reprint these labels. According to the Administration, presently there is no legislation requiring infant formula to indicate its "1+33" nutrition composition. The Administration proposes, through the Amendment Regulation, to require infant formula to be labelled with a list of nutrients setting out "1+29", and the composition requirement on the relevant product is "1+33". The new section 1(7) of Schedule 6A stipulates that 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. Therefore, the labels of products indicating energy value and 33 nutrients should have conformed to the Amendment Regulation and no re-printing is required.

16. In response to the concern raised by Dr Hon Helena WONG about the tolerance limits adopted for formula products, the Administration has advised that in enforcing labelling requirements, CFS allows some discrepancies between "values on nutrition labels" and "values from testing and measurement" since nutrients in food may degrade during the shelf-life period. It is proposed that the same tolerance limits as the existing NLS for nutrition labelling of infant formula, follow-up formula and prepackaged food for infants and young children be adopted. The tolerance limit for nutrients which may have a positive effect on the body is set at no less than 80% of the labelled values while that of nutrients which may have a negative effect on the body is set at no more than 120% of the labelled values. For added vitamins and minerals, the tolerance limits are set at no less than the labelled values. As for vitamin A and vitamin D, since both insufficient intake and excessive intake have negative effect on the body, the tolerance limits of their nutrition labels will be set at 80-180% of the labelled values.

Regulation of fluoride content in infant formula

17. Members note that if fluoride is contained in infant formula at a level exceeding 100 µg per 100 kcal or 24 µg per 100 kJ, equivalent to the Codex standards, it is mandatory to include a statement associated with dental fluorosis as specified in the new section 1(2) of Schedule 6A. 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.

18. Members are concerned that if fluoride is present in infant formula, and when combined with fluoridated tap water in Hong Kong, excessive fluoride intake may occur. It is suggested that the Administration should consider requiring infant formula products be marked or labelled with a statement

indicating the recommended daily dosage limit of fluoride to alert consumers about the risk of dental fluorosis.

19. The Administration has advised that in drafting the Amendment Regulation, CFS has sought advice from the Dental Service under the Department of Health, which advised that there is no international recommendation for the maximum intake level of fluoride by infants. Nonetheless, most of the adolescents and children in Hong Kong do not have dental fluorosis. According to Codex, fluoride should not be added to infant formula. However, fluoride is naturally present and in any case its level shall not exceed 100 µg per 100 kcal or 24 µg per 100 kJ in infant formula as prescribed by Codex. The Administration has further advised that many major jurisdictions such as the United States, Singapore, and the Mainland have neither regulated the fluoride content of infant formula products nor required the fluoride content to be labelled.

20. Noting that the European Union ("EU") has made labelling requirement for fluoride in infant formula, Dr Helena WONG has asked why the Administration did not follow the practice adopted by EU in this regard. To facilitate parents to make an informed choice and to safeguard infants' health, she holds a strong view that the Administration should conduct a study on the fluoride content in infant formula currently on sale in Hong Kong.

21. The Administration has explained that the 2012 survey found that 10 products were provided with nutrition labels showing their fluoride content. The fluoride content limits of all these 10 products were found to have complied with the Codex Standard (i.e. not more than 100 µg per 100 kcal). In the Administration's view, the suggested regulatory control has already struck a proper balance between providing sufficient information for parents to make an informed choice and international regulatory practices.

22. To ensure the compliance of the infant formula products in the market with the requirements under the Amendment Regulation, the Administration has advised that CFS will, upon implementation of the Amendment Regulation, take samples of infant formula products in the market for examination of their fluoride content. In the interest of better protection of infants' health, members have requested the Administration to consider conducting these sampling tests after the enactment of the Amendment Regulation. At the Subcommittee's request, the Administration has agreed to report to the Panel on Food Safety and Environmental Hygiene ("the FSEH Panel") on the results of the sampling tests.

Legibility of the nutrition labels

23. Ms Cyd HO has raised concern about the legibility of the nutrition labels, considering that the Administration should review the principal Regulations and if necessary, introduce legislative amendments to ensure their legibility.

24. The Administration has explained that under the principal Regulations, all prepackaged food shall be legibly labelled unless otherwise exempted. According to the advice of the Department of Justice, in enforcing the relevant provisions of the principal Regulations, the department concerned should apply the general rule of statutory interpretation and the word "legible" must be construed in its ordinary and natural meaning, i.e. clear enough to read. Hence, the Administration considers that the existing provisions are sufficient for the department concerned to take effective enforcement actions. The Administration has further advised that CFS has issued the "Trade Guidelines on Preparation on Legible Food Label" in May 2012 to assist the trade in providing clear and legible information on the food labels. CFS has tightened up its enforcement strategy since 1 October 2014, taking into account that the trade has become very familiar with and capable of strictly abiding by the requirements stipulated in the relevant provisions of the principal Regulations. If CFS identifies any non-compliance with the requirements, including the legibility requirement, CFS will initiate prosecutions immediately without allowing any time for compliance.

25. At the request of the Subcommittee, the Administration has agreed to update the FSEH Panel on enforcement actions, if any, taken by the Administration against non-compliant cases relating to nutritional composition and nutrition labelling requirements for formula products and prepackaged food for infants and young children under the age of 36 months.

Exemptions under the Amendment Regulation

26. Some members including Hon KWOK Wai-keung and Hon TANG Ka-piu have expressed concern about the granting of exemptions for FSMP and prepackaged food for infants and young children with total surface area of package size of less than 100 cm^2. Members note the Administration's explanation that FSMP are specially manufactured and be used under medical supervision. Given the market size for FSMP is small, manufacturers may not export FSMP products to Hong Kong if they are required to comply with the labelling requirements. The Administration proposes to exempt products packed in a container with a small surface area from the nutritional labelling requirements because such container is too small to be labelled by the trade with all the required nutrition information in a legible font size. CFS has

earlier conducted inspections on retail outlets selling food for infants and young children and no prepackaged food for infants and young children with packages of total surface area of less than 100 cm^2 is found to be on sale in the market.

Penalties for non-compliance

27. Dr Hon Helena WONG considers that the maximum penalty level provided under the proposed new subsection (1AC) of regulation 5 of the principal Regulations should be raised from level 5 to level 6 so as to achieve sufficient deterrent effect. She has indicated that she has the intention to move an amendment to this effect if the scrutiny period could be extended to 12 November 2014 by resolution.

28. The Administration has stressed that in determining the penalties for non-compliance with the Amendment Regulation, the Administration has taken into account the relativity between such penalties and others relating to the food labelling requirements. Under the Amendment Regulation, 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 the nutrition labelling requirements, commits an offence and is liable to a fine at level 5 (i.e. $50,000) and imprisonment for six months. In the Administration's view, the penalties and the associated criminal liability imposed on the offenders can achieve a deterrent effect.

29. Having regard to members' view, the Administration has advised that it will conduct a comprehensive review of the food safety-related penalties under PHMSO and its subsidiary legislation, as well as the Food Safety Ordinance (Cap. 612) ("FSO") in 2015. The Administration has also agreed to report the outcome of the study to the FSEH Panel.

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