

**For Discussion
on 12 March 2013**

LegCo Panel on Food Safety and Environmental Hygiene

**Legislative Proposals Relating to Formula Products and
Foods Intended for Infants and Young Children
under the Age of 36 Months**

PURPOSE

This paper sets out the Government's proposals to amend the Food and Drugs (Composition and Labelling) Regulations (Cap. 132W) to prescribe nutritional composition for infant formula and nutrition labelling for infant formula, follow-up formula and foods intended for infants and young children under the age of 36 months.

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 feeding¹. We must therefore ensure that infant formula is safe and nutritionally adequate. To assist parents to make informed food choices, it is also important to provide nutrition information on labels of formula products and foods intended for infants and young children.

3. In light of the findings in a survey conducted by the Centre for Food Safety (CFS) in 2012 that certain infant formula products are deficient in iodine and the urgency of protecting the health of infants and young children, the Administration considers that priority should be accorded to the introduction of legislation governing formula products and

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

foods intended for infants and young children under the age of 36 months in the following areas -

- (a) Codex Alimentarius Commission (Codex)² requirement for nutritional composition i.e. energy and 33 nutrients as specified by Codex (“1+33”) of infant formula before complementary feeding is introduced. In particular, the level of energy and each nutrient must fall within the range specified by Codex (if available);
- (b) nutrition labelling requirement for infant formula before complementary feeding is introduced, by listing the energy and 33 nutrients which are required to be present in infant formula as specified by Codex;
- (c) nutrition labelling requirement for follow-up formula for infants and young children under the age of 36 months by listing the energy and 25 nutrients as specified by Codex (“1+25”);
- (d) nutrition labelling requirement for foods intended for infants and young children under the age of 36 months by listing the energy and nutrients required for such foods as specified by Codex; and
- (e) commencement of the proposed legislation after a suitable grace period.

4. A public consultation exercise was conducted from 20 November 2012 to 21 January 2013. In addition to the above proposals, the public was also consulted on the views of (i) labelling of sodium content in non-cereal-based foods for infants and young children; and (ii) tackling the issue of regulating nutrition and health claims at a later stage in the coming year.

5. When formulating the legislative proposals, we have adopted the Codex principles, taking into account international practices. This will ensure that our legislative proposals are on par with the international standards. Since most formula products and foods intended for infants and young children under the age of 36 months in the local market are imported

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

from overseas, we believe that such approach will strike a balance between the protection of health of infants and young children and the need to maintain stable supply of formula products and foods for infants and young children.

PUBLIC CONSULTATION

6. The legislative proposals were discussed in a joint meeting of the Legislative Council (LegCo) Panel on Food Safety and Environmental Hygiene and Panel on Health Services on 20 November 2012. To seek views from members of the public, trade and other stakeholders on the legislative proposals, a two-month public consultation exercise was launched on the same day.

7. The views and comments received by the Administration are summarized in the ensuing paragraphs.

General comments

8. In general, traders and members of the public welcomed the Codex-based approach and supported the legislative proposals. Nonetheless, a trader was concerned about the possible impact on the food choice.

Nutritional composition of infant formula

9. Traders and members of the public generally supported the proposal on regulating the nutritional composition of infant formula.

10. Most traders suggested that the Administration should adopt the concept of Guidance Upper Levels³ (GULs) as in the Codex Standard on Infant Formula and Formulae for Special Medical Purposes Intended for Infants (Codex STAN 72-1981) for guidance purpose and that GULs should not be set as the statutory upper limit of nutrient contents in infant formula.

³ For certain nutrients in infant formula where the maximum level cannot be set due to insufficient information for a science-based risk assessment, Codex has established Guidance Upper Levels (GULs). The purpose of GULs is to provide guidance to manufacturers for manufacturing infant formula. GULs are values derived on the basis of meeting nutritional requirements of infants with an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress.

11. As for formula for special medical purposes intended for infants (FSMP), which are formula products specially manufactured to meet the special nutritional requirements of infants with specific disorders, diseases or medical conditions and to be used under medical supervision, some traders suggested that FSMP should either be exempted or be allowed to deviate from the nutritional composition requirement set for regular infant formula.

Nutrition labelling of infant formula, follow up formula and foods intended for infants and young children

12. Traders, Consumer Council and members of the public supported the proposals on regulating the nutrition labelling of infant formula and follow-up formula. Nonetheless, a trader expressed concern that the requirement of “1+33” for infant formula as compared to the energy and 29 nutrients (“1+29”) requirement specified in Codex STAN 72-1981 might constitute a possible trade barrier.

13. For foods intended for infants and young children, while the Consumer Council and members of the public supported the regulation of nutrition labelling, two traders suggested that exemption should be granted to these food products (through extension of the Small Volume Exemption Scheme under the current Nutrition Labelling Scheme or a total exemption of nutrition labelling).

14. Some traders suggested that FSMP be exempted from nutrition labelling requirements. They pointed out that (i) FSMP are unique and due to low volume, these products are used in a number of countries with labels in English to ensure their proper use around the world in accordance with the labelling requirements of several destination countries; (ii) re-labelling of these products may not be necessary, given the small quantity supplied to the Hong Kong market; and (iii) the majority are used in hospitals under medical supervision or doctors’ prescription. In addition, traders also suggested that ready-to-feed (RTF) formula be exempted from nutrition labelling requirements as these products are (i) currently not for sale in the retail market and are only available in hospitals; (ii) the size of each individual RTF container is usually small which makes it nearly impossible to label all required nutrition information in a legible font size.

Grace period

15. The view on grace period from traders and members of the public were quite polarized. Most traders requested a minimum grace period of 24 months for technical reasons (product assessment, product development, manufacturing, supply chain process, and laboratory support) while members of public suggested a shorter grace period (1 year or shorter). The Consumer Council urged that the implementation process be expedited.

Labelling of sodium in non-cereal-based foods for infants and young children

16. The Consumer Council and members of the public generally supported the labelling of sodium in non-cereal-based foods for infants and young children in view of the usefulness of the information and the health concern over excessive sodium intake. However, most traders did not support the idea and pointed out that Codex had not imposed mandatory labelling requirement on sodium in non-cereal-based foods for infants and young children.

Regulation of claims

17. A political party and the Consumer Council were disappointed that the regulation of claims was not included in the current proposal and urged the Government to do so as soon as possible. Some members of the public also urged the Government to regulate claims. On the other hand, traders agreed with the Government's strategy of focusing on nutritional composition and nutrition labelling at the first stage.

Other issues

18. The Consumer Council is of the view that Codex requirements for nutritional composition of follow-up formula and foods intended for infants and young children under the age of 36 months should also be followed.

19. A political party suggested providing health education to the public on choosing suitable formula.

LEGISLATIVE PROPOSALS

20. We receive strong support for our legislative proposals from respondents in the public consultation exercise. Some urged that the proposals should be enacted as soon as possible to protect the health of infants and young children. We will therefore proceed with drafting the legislation for tabling at LegCo in 2013 with details in the ensuing paragraphs.

Key Definitions

21. We intend to define some of the key terms as follows -

- (a) “infant formula” means-
 - (i) a breast-milk substitute prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding; and
 - (ii) including those for special medical purposes.“infant” means a person not more than 6 months of age.

- (b) “follow-up formula” means a food prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin and is intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children up to age of 36 months, including those for special medical purposes.

Nutritional Composition of Infant Formula

22. On nutritional composition for infant formula, we propose to adopt in the law the Codex requirements on “1+33”. We note the trade’s views (paragraph 10 above) that Guidance Upper Limits (GULs) should not be set as the statutory maximum limit of certain nutrients. We note that Codex has established GULs for certain nutrients in infant formula where the maximum level cannot be set due to insufficient information for a science-based risk assessment. The purpose of GULs is to provide guidance to manufacturers for manufacturing infant formula. Without sufficient information for a science-based risk assessment, we agree that we should not set GULs as the maximum statutory limit. We will, however, draw up guidelines in consultation with the trade on this issue.

23. With regard to the trade’s suggestion (paragraph 11 above) to exempt formula for special medical purposes intended for infants (FSMP) or allow FSMP to deviate from the nutritional composition requirement, we are looking into this issue to see whether there are grounds for exemption.

24. We have not proposed to impose nutritional composition requirement on follow-up formula and foods for infants and young children for the following reasons –

- (a) infants and young children who have begun complementary feeding are no longer solely dependent on milk formulae or the abovementioned foods for infants and young children for nutrients;
- (b) conventional child statistics has indicated satisfactory child growth and there is no data to reflect specific nutritional deficiencies;
- (c) Codex composition standard for follow-up formula was set over 20 years ago and follow-up formula has undergone significant development over the years. Codex has just started the process of reviewing this set of standard; and
- (d) balanced nutrition for children growth should be achieved by parental and caregiver education on the appropriate food intake.

Nutrition Labelling of Infant Formula, Follow-up Formula, and Foods intended for Infants and Young Children under the Age of 36 Months

25. We propose to mandate nutrition labelling of infant formula, follow-up formula and foods intended for infants and young children under the age of 36 months to help parents and caretakers make informed food choice for their infants and young children as follows -

- (a) *infant formula*: we propose to mandate the labelling of “1+33” which should be present in infant formula as specified by CODEX STAN 72 – 1981. We have carefully considered the trade’s view to only include the “1+29” requirement instead⁴ (paragraph 12 above). Our considered view is that since we have proposed to

⁴ Codex only requires labelling of the content of 29 of the 33 nutrients considered to be essential in infant formula.

mandate infant formula to fulfil the “1+33” nutritional composition requirements under Codex (paragraph 3(a) above), it follows that the energy and the 33 nutrients should all be labelled. Otherwise, consumers will not be able to gain full knowledge of the nutritional composition of the infant formula concerned;

(b) *follow-up formula*: we propose mandating labelling of follow-up formula with “1+25”, following the Codex requirements laid down in CODEX STAN 156 - 1987; and

(c) *food intended for infants and young children under the age of 36 months*: we propose to mandate the labelling of food intended for infants and young children under the age of 36 months with energy, protein, fat and carbohydrates, as well as other specified nutrients applicable to certain food categories, following the Codex requirements laid down in CODEX STAN 73 – 1981 and CODEX STAN 74 – 1981.

26. Regarding the suggestion of granting exemption from nutrition labeling requirements (paragraph 13 above) in respect of foods intended for infants and young children, we cannot accept such suggestion from the perspective of safeguarding the health of infants and young children. Granting such an exemption will defeat the purpose of this new piece of regulation.

27. We are looking into the issue of whether formula for special medical purposes intended for infants (FSMP) should be exempted from nutrition labelling requirements (paragraphs 14 and 23 above). We are examining the case of ready-to-feed (RTF) formula to see whether they should be exempted from the nutritional labelling requirements and will arrive at a position when we have completed the analysis.

Grace Period

28. The Administration notes that there are diverse views expressed by members of the public and the trade in terms of the length of grace period. The Administration is looking into it with regard to the trade and laboratories’ readiness for the proposed changes, aspiration of the general public, etc before finalizing the duration of the grace period.

Labelling of sodium in non-cereal-based food for infants and young children

29. Sodium is necessary for the proper functioning of the body. However, prolonged excessive intake of sodium may increase the risk of developing high blood pressure. There is evidence suggesting that Chinese people are particularly susceptible to dietary salt-induced high blood pressure because we lack an efficient mechanism to facilitate kidney excretion of salt (sodium). Excessive intake of sodium should be avoided at a young age. Although Codex only requires sodium to be labelled in processed cereal-based foods intended for infants and young children under the age of 36 months, many jurisdictions such as the United States, Australia, New Zealand, and European Union have also required labelling of sodium content in other foods intended for infants and young children. This requirement is also supported by members of the public. Hence we propose to mandate the labelling of sodium content in both processed cereal-based foods and non-cereal based foods intended for infants and children under the age of 36 months.

VIEWS SOUGHT

30. Members' views are sought on paragraphs 21-29 above.

**Food and Health Bureau
Food and Environmental Hygiene Department
Centre for Food Safety
March 2013**