

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

**5th Technical Meeting with Trade  
28 August 2014**

# Background

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- To better protect the health of infants and young children, the Administration put forward a package of legislative proposals relating to formula products and foods intended for infants and young children under the age of 36 months in November 2012.
- The two-month consultation exercise was concluded on 21 Jan 2013. In general, traders and members of the public supported the legislative proposals.

# Background

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- ❑ A series of technical meetings with the trade and laboratory service providers were held to tackle the various technical issues raised.
- ❑ Other relevant issues were also discussed with the trade in special meeting and Trade Consultation Forum
- ❑ The Government gazetted the Food and Drugs (Composition and Labelling) (Amendment) (No.2) Regulation 2014 (the Amendment Regulation) on 13 June 2014.



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

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

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The Amendment Regulation covers

- ❑ definitions
- ❑ nutritional composition requirement for **infant formula**
- ❑ nutrition labelling requirement for **infant formula, follow-up formula** and **prepackaged foods for infants and young children**
- ❑ marking and labelling of **follow-up formula**
- ❑ exemption

# *Definition*

# Definition

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- Definitions of products
  - Infant formula
  - Follow-up formula
  - Prepackaged food for infants and young children
  - Formula for special medical purposes for infants and young children
- Definitions of nutrients
  - Vitamin A, vitamin C, vitamin E, vitamin K, niacin, folic acid



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# ***Nutritional composition requirement for infant formula***



# Nutritional composition requirement for infant formula


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- ❑ **Infant formula** must contain energy and 33 nutrients (i.e. “1+33”), and the level of energy and each nutrient must fall within the range specified in the Amendment Regulation
- ❑ A maximum level is also set for taurine if it is added to infant formula
- ❑ Certain nutrients must follow the proportion requirements in accordance with the concerned Codex Standard.

# Nutritional composition requirement for infant formula

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- Proportion requirements
  - Ratio of linoleic acid to  $\alpha$ -linolenic acid
  - Ratio of calcium to phosphorus
  - % of lauric and myristic acid, trans fatty acid, eurcic acid of the total content of fatty acids
  - Vitamin E in relation to polyunsaturated fatty acid
  - Ratio of DHA:AA; EPA:DHA (if DHA is added)



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***Nutrition labelling requirement for  
infant formula, follow-up formula  
and prepackaged foods for infants  
and young children***

# Nutrition labelling requirement for infant formula

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- **Infant formula** must label the energy value and content of 29 nutrients (i.e. “1+29”)
  
- If the fluoride content of the product in a reconstituted or served basis exceeds the maximum level stipulated in the concerned Codex standard, the formula must be marked or labelled with a statement—
  - (i) indicating that consumption of the formula may cause dental fluorosis; and
  - (ii) recommending that the risk of dental fluorosis should be discussed with a medical practitioner or health professional.

# Nutrition labelling requirement for follow-up formula

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- **Follow-up formula** must label the energy value and content of 25 nutrients (“1+25”)

# Nutrition labelling requirement for prepackaged foods for infants and young children

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- **Prepackaged foods for infants and young children** must label the energy value and contents of 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.

# Nutrition labelling requirement

- The existing Nutrition Labelling Scheme (i.e. 1+7) will be applicable to **infant formula, follow-up formula or prepackaged food for infants and young children** if it is claimed in its descriptions or instructions for use to be suitable for consumption by persons of any age from 36 months onwards



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# ***Marking and labelling of follow-up formula***



# Marking and labelling of follow-up formula

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- Any container containing **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.

# *Exemption*

# Exemption

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- **Formula for special medical purposes for infants and young children** marked or labelled with required information will be exempted from the requirements of
  - nutritional composition
  - nutritional labelling

# Exemption

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- The required information –

(1) the words “formula for special medical purposes” or “特殊醫用配方產品”， or any other words of similar meaning, in the name of the formula or in a conspicuous place of the package that is not in close proximity to other information on the package;

(2) the words “USE UNDER MEDICAL SUPERVISION” or “在醫生指示下使用”， or any other words of similar meaning, in bold and in a conspicuous place of the package that is not in close proximity to other information on the package;

# Exemption

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- The required information –

(3) a statement stating “For the dietary management of (fill in the disease, disorder or medical condition for which the formula is intended to be used or known to be effective)”, or showing any other words of similar meaning; and

(4) (if the formula poses a health hazard when consumed by a person who does not have the disease, disorder or medical condition stated in the statement) a warning statement and explanation on the hazard in bold and in a conspicuous place of the package that is not in close proximity to other information on the package.

# Exemptions

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- **Infant formula** and **follow-up formula** packed in a container with a total surface area of less than 250 cm<sup>2</sup> will be exempted from the **nutrition labelling requirements**
- **Prepackaged food for infants and young children** packed in a container with a total surface area of less than 100 cm<sup>2</sup> will be exempted from the **nutrition labelling requirements**

Thanks