

香港擬供**36**個月以下嬰幼兒食用的配方產品  
和食品的立法進展

## Progress on Legislation Relating to Formula Products and Foods Intended for Infants and Young Children under the Age of 36 Months in Hong Kong

業界諮詢論壇

**Trade Consultation Forum**

29.05.2014

# 立法建議

## Legislative Proposals

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- 為加強保障嬰幼兒健康，政府已於2012年11月提出一系列有關擬供36個月以下嬰幼兒食用的配方奶產品和食品的立法建議
- 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.

# 立法建議

## Legislative Proposals

- (1) 為供嬰兒開始餵養補充食品前食用的嬰兒配方，引入營養成分組合規定；
  - (2) 為供嬰兒開始餵養補充食品前食用的嬰兒配方，以及為擬供36個月以下嬰幼兒食用的較大嬰兒配方和食品，引入營養標籤規定；以及
  - (3) 在適當的寬限期屆滿後才實施擬議法例。
- (1) nutritional composition requirement for infant formula before complementary feeding is introduced;
  - (2) nutrition labelling requirement for infant formula, and follow-up formula and foods intended for infants and young children under the age of 36 months; and
  - (3) commencement of the proposed legislation after a suitable grace period.

# 立法建議

## Legislative Proposals

- 為期兩個月的諮詢期已於2013年1月21日完結。整體來說，公眾人士及業界均支持有關立法建議。
- 政府現正草擬有關法例，預計將於2014年提交立法會審議。
- The two-month consultation exercise was concluded on 21 Jan 2013. In general, traders and members of the public supported the legislative proposals.
- The Administration is drafting the amendment regulation and plans to table the amendment at LegCo in 2014.

# 立法建議

## Legislative Proposals

- 中心與業界及提供實驗室服務組共舉行四次技術會議及一次特別會議，討論有關技術事宜。
- 中心亦於業界諮詢論壇與業界討論相關事宜
- Four technical meetings and one special meeting 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 Trade Consultation Forum

# 討論事項

## Discussion

- 1. 產品的定義
- 2. 營養素的定義
- 3. 獲豁免營養標籤的項目
- 4. 較大嬰兒及幼兒配方產品的年齡要求
- 5. 產品規管
- 6. 嬰兒配方產品中氟化物含量的規管
- 7. 營養標籤的規管容忍限
- 1. Product definition
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- 3. Exemption from Nutrition Labelling
- 4. Age limit requirement for follow-up formula
- 5. Product regulation
- 6. Regulation of fluoride content in infant formula
- 7. Tolerance limits of nutrition labelling

# 產品的定義

## Product definition

# 嬰兒配方產品

## Infant Formula

指符合以下說明的產品 —

- (a) 該產品按照其描述或使用指示下，是擬作母乳的替代品食用的，且經特別製造，以在該人獲餵哺適當的補充食品之前，單憑該產品本身即滿足年齡為**12**個月及以下的人的營養需要；或
- (a) a product that, according to its descriptions or instructions for use, is intended for consumption as a substitute for human breast milk that is specially manufactured to satisfy, by itself, the nutritional requirements of persons of any age up to and including 12 months until the introduction of appropriate complementary feeding



# 嬰兒配方產品

## Infant Formula

- (b) 該產品被加上 “infant formula” 或 “嬰兒配方產品” 的標記或標籤，或帶有具類似意思的任何其他文字。
- (b) a product marked or labelled as “infant formula” or “嬰兒配方產品”，or with any other words of similar meaning

# 較大嬰兒及幼兒配方產品

## Follow-up Formula

指符合以下說明的產品 —

- (a) 該產品按照其描述或使用指示下：
  - (i) 被表述為母乳或嬰兒配方產品的替代品；及
  - (ii) 該產品擬供年齡滿6個月但未滿36個月的人，在逐步多元化膳食中，作為液體成分食用；或

- (a) a product that, according to its descriptions or instructions for use, is—
  - (i) represented as a replacement for human breast milk or infant formula; and
  - (ii) intended for consumption as a liquid element in a progressively diversified diet by persons of any age from 6 months to under 36 months; or

# 較大嬰兒及幼兒配方產品

## Follow-up Formula

- (b) 該產品被加上“follow-up formula”或“較大嬰兒及幼兒配方產品”的標記或標籤，或帶有具類似意思的任何其他文字
- \*較大嬰兒及幼兒配方產品的定義中，提述母乳或嬰兒配方產品的替代品(替代配方產品)包括提述任何產品作為替代配方產品的替代品或任何其後的替代品。
- (b) a product marked or labelled as “follow-up formula” or “較大嬰兒及幼兒配方產品”，or with any other words of similar meaning
- \*In the definition of follow-up formula, a reference to replacement for human breast milk or infant formula (replacing formula) includes a reference to any product that is a replacement of the replacing formula or any of its subsequent replacements.

# 預先包裝嬰幼兒食物

## Prepackaged food for infants and young children

- 指符合以下說明的預先包裝食物：該食物按照其描述或使用指示下，是擬供年齡未滿**36**個月的人食用；但不包括嬰兒配方產品及較大嬰兒及幼兒配方產品
- any prepackaged food that, according to its descriptions or instructions for use, is intended for consumption by persons of any age under 36 but does not include any infant formula or follow-up formula;

# 營養素的定義

## Nutrient definition

# 營養素的定義

## Nutrient definition

### □ 葉酸

- 就嬰兒配方產品或較大嬰兒及幼兒配方產品而言，指N-蝶酰-L-谷氨酸

### □ 維生素A

- 就嬰兒配方產品或較大嬰兒及幼兒配方產品而言，指按視黃醇當量或國際單位計算的所有反式視黃醇(以1微克視黃醇當量相等於3.33國際單位計)

### □ Folic acid

- in relation to any infant formula or follow-up formula, means N-pteroyl-L-glumatic acid

### □ Vitamin A

- in relation to any infant formula or follow-up formula, means all-trans retinol, calculated in terms of Retinol Equivalent (RE) or International Unit (IU) (with 1 µg RE as being equivalent to 3.33 IU)

# 營養素的定義

## Nutrient definition

### □ 維生素E

- 就嬰兒配方產品而言，指按 $\alpha$ -生育酚當量或國際單位計算的d- $\alpha$ -生育酚(以1國際單位相等於0.67微克 $\alpha$ -生育酚當量計算)

### □ Vitamin E

- in relation to any infant formula, means d-alpha-tocopherol, calculated in terms of alpha-Tocopherol Equivalent ( $\alpha$ -TE) or International Unit (IU) (with 1 IU as being equivalent to 0.67 mg  $\alpha$ -TE)

# 營養素的定義

## Nutrient definition

### □ 維生素E

- 就較大嬰兒及幼兒配方產品而言，指按 $\alpha$ -生育酚當量或國際單位計算的 $\alpha$ -生育酚化合物 —
  - (i) (來自天然成分的 $\alpha$ -生育酚化合物)以1國際單位相等於 0.67微克 $\alpha$ -生育酚當量；或
  - (ii) (人工合成的 $\alpha$ -生育酚化合物)以1國際單位相等於0.45微克 $\alpha$ -生育酚當量

### □ Vitamin E

- in relation to any follow-up formula, means alpha-tocopherol compounds, calculated in terms of alpha-Tocopherol Equivalent ( $\alpha$ -TE) or International Unit (IU)—
  - (i) (for alpha-tocopherol compounds from any natural source) with 1 IU as being equivalent to 0.67 mg  $\alpha$ -TE; or
  - (ii) (for alpha-tocopherol compounds from any synthetic source) with 1 IU as being equivalent to 0.45 mg  $\alpha$ -TE;



# 獲豁免營養標籤的項目

## Exemption from Nutrition Labelling

# 獲豁免營養標籤的項目

## Exemption from Nutrition Labelling

- 加上規定的標記或標籤的特殊醫用嬰幼兒配方產品
- 以總表面面積小於**250**平方厘米的容器包裝的任何嬰兒配方產品或較大嬰兒及幼兒配方產品
- 以總表面面積小於**100**平方厘米的容器包裝的任何預先包裝嬰幼兒食物。
- Formula for special medical purposes for infants and young children marked or labelled with required information
- Any infant formula or follow-up formula packed in a container that has a total surface area of less than 250 cm<sup>2</sup>
- Any prepackaged food for infants and young children packed in a container that has a total surface area of less than 100 cm<sup>2</sup>

# 較大嬰兒及幼兒配方產品 的年齡要求

## Age limit requirement for follow-up formula

# 較大嬰兒及幼兒配方產品的年齡要求

## Age limit requirement for follow-up formula

- 世衛建議嬰兒出生後首六個月應以純母乳餵哺，並繼續母乳餵哺至兩歲或更長時間，同時接受營養充足和安全的補充食品。
- WHO recommends exclusive breastfeeding up to 6 months of age, with continued breastfeeding along with appropriate complementary foods up to two years of age or beyond.

# 較大嬰兒及幼兒配方產品的年齡要求

## Age limit requirement for follow-up formula

- 較大嬰兒及幼兒配方產品於食品法典委員會及其他地方(澳洲及中國)均被定義為適合六個月或以上嬰幼兒的食品
- Follow-up formula was defined in Codex and other jurisdictions (Australia and China) that it is for the diet of the infants aged from 6 months.

# 較大嬰兒及幼兒配方產品的年齡要求

## Age limit requirement for follow-up formula

- “較大嬰兒及幼兒配方產品不得加上表明該產品適合供年齡未滿6個月的人士食用的標記或標籤”
- **“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”**

# 產品規管

## Product regulation

# 產品規管

## Product regulation

主要擬供成人食用的奶類產品 (如：半脫脂奶粉 / 脫脂奶粉)

- 標示為“除由醫生指導外不應用以餵哺一歲以下之嬰兒”
- 如產品沒有任何標示指明擬供**36**個月以下的人士食用，則不會受修訂規例規管

milk products that are primarily intended for adults. (e.g. partly-skimmed milk powder / skimmed milk powder )

- labelled as “Children under one year of age should not be fed on this milk except under medical advice”
- Would not be regulated under the Amendment Regulation if the product does not have any other indication that they are intended for persons under the age of 36 months.



# 嬰兒配方產品中氟化物含量的規管

## Regulation of fluoride content in infant formula

# 嬰兒配方產品中氟化物含量的規管

## Regulation of fluoride content in infant formula

- 根據食品法典委員會的標準 CODEX STAN 72 – 1981, 氟化物不應添加到嬰兒配方產品。嬰兒配方產品在飲用時的氟化物含量不應超過100 微克/100 千卡 或 24 微克/100 千焦
- 嬰兒配方產品的氟化物含量如超過上述水平，須附有字句提醒消費者有關氟斑牙的風險
- According to CODEX STAN 72 – 1981, fluoride should not be added to infant formula. Its level should not exceed 100 µg/100 kcal or 24 µg/100 kJ in the infant formula prepared ready for consumption
- Infant formula having exceeding the above mentioned level of fluoride to bear some sorts of statements to remind consumers on the risk of dental fluorosis

# 嬰兒配方產品中氟化物含量的規管

## Regulation of fluoride content in infant formula

- (a) 示明食用該配方產品可導至氟斑牙；及
- (b) 建議應與醫生或衛生專業人員討論氟斑牙的風險。
- (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.

# 營養標籤的規管容忍限

## Tolerance limits of nutrition labelling

# 營養標籤的規管容忍限

## Tolerance limits of nutrition labelling

- 為嬰幼兒配方產品和食品的能量和營養素標示值制定一套規管容忍限
- To establish a set of tolerance limits for declared value of energy and nutrients on the nutrition label for formulae and foods for infants and young children

# 國際間的情況

## Overseas situation

- 營養標籤的規管容忍限在國際間並沒有共識，尤其對於添加的維他命及礦物質含量
- 食品法典委員會並沒有在相關標準中提供營養標籤的建議規管容忍限
- There is no internationally recognized tolerance limits for declaration of nutrition information on food labels, particularly for added vitamins and minerals content
- Recommended tolerance limits have not been provided in relevant Codex standards.

# 嬰幼兒配方產品和食品營養標籤的規管容忍限

## Tolerance Limits for nutrition labelling of formulae and foods for infants and young children

<b>USA</b> 美國	<ul style="list-style-type: none"> <li>• 添加的維他命及礦物質： 不少於標示值</li> </ul>	<ul style="list-style-type: none"> <li>• added vitamins and minerals : ≥ declared value</li> </ul>
<b>Mainland China</b> 中國	<ul style="list-style-type: none"> <li>• 維他命及礦物質： 不少於標示值的<b>80%</b></li> </ul>	<ul style="list-style-type: none"> <li>• vitamins and minerals : ≥80% of declared value</li> </ul>
<b>Taiwan</b> 台灣	<ul style="list-style-type: none"> <li>• 維他命： 標示值的<b>80%-180/250/300%*</b></li> <li>• 礦物質： 標示值的<b>80%-150/200%*</b> (* 視乎不同維他命及礦物質而定)</li> </ul>	<ul style="list-style-type: none"> <li>• Vitamins: 80%-180/250/300%*</li> <li>• Minerals: 80%-150/200%* (* depending on the vitamin/mineral)</li> </ul>
<b>Germany</b> 德國@	<ul style="list-style-type: none"> <li>• 添加的維他命： 標示值的<b>70/80%-150%#</b> (# 視乎不同維他命而定)</li> </ul>	<ul style="list-style-type: none"> <li>• added vitamins : 70/80%-150%# (# depending on the vitamin)</li> </ul>
<b>Netherlands</b> 荷蘭@	<ul style="list-style-type: none"> <li>• 維他命:標示值的 <b>80% - 200%</b></li> <li>• 礦物質:標示值的 <b>80% - 150%</b> (天然存在，添加或總含量?)</li> </ul>	<ul style="list-style-type: none"> <li>• vitamins: 80% - 200%</li> <li>• minerals: 80% - 150% (naturally present, added or both?)</li> </ul>

@ 資料由業界提供

Information provided by trade members

# 營養標籤的規管容忍限

## Tolerance limits of nutrition labelling

- 現行採用於一般預先包裝食物的規管容忍限

能量/營養素	規管容忍限
能量、總脂肪、飽和脂肪酸、反式脂肪酸、膽固醇、鈉、糖	≤ 標示值的 120%
蛋白質、多元不飽和脂肪酸、單元不飽和脂肪酸、碳水化合物、澱粉質、膳食纖維、可溶性纖維、不可溶性纖維、纖維的個別組成部分	≥ 標示值的 80%
維他命及礦物質(維他命 A、維他命 D 及添加的維他命及礦物質除外)	≥ 標示值的 80%
維他命 A 及維他命 D (包括添加的)	標示值的 80% 至 180%
添加的維他命及礦物質(維他命 A 及維他命 D 除外)	≥ 標示值

- Tolerance limits currently in use for general prepackaged foods in Hong Kong

Energy/ Nutrients	Tolerance Limits
Energy, Total fat, Saturated fatty acids, Trans fatty acids, Cholesterol, Sodium, Sugars	≤ 120% declared value
Protein, Polyunsaturated fatty acids, Monounsaturated fatty acids, Carbohydrates, Starch, Dietary fibre, Soluble fibre, Insoluble fibre, individual component of fibre	≥ 80% declared value
Vitamins and minerals (other than Vitamin A, Vitamin D and added vitamins and minerals)	≥ 80% declared value
Vitamin A and Vitamin D (including added ones)	80% - 180% declared value
Added vitamins and minerals (other than Vitamin A and Vitamin D)	≥ declared value



# 營養標籤的規管容忍限

## Tolerance limits of nutrition labelling

- ❑ 嬰幼兒配方產品和食品應至少採用與預先包裝食物一樣的規管容忍限
- ❑ 德國及荷蘭對於添加的維他命及礦物質採用的規管容忍限(由業界提供的資料)是包含上下限
- ❑ 建議採納現行採用於一般預先包裝食物的規管容忍限
- ❑ Formula products and foods for infants and young children should at least adopt the same set of tolerance limits for general prepackaged foods
- ❑ The tolerance limits used in Germany and Netherlands for added vitamins and minerals (as provides by trade) adopt a range approach
- ❑ It is proposed to adopt the same set of tolerance limits currently in use for general prepackaged foods in Hong Kong

# 歡迎提供意見及討論

## For comments and discussion