

《2014年食物及藥物(成分組合及標籤) (修訂)(第2號)規例》

FOOD AND DRUGS (COMPOSITION AND LABELLING) (AMENDMENT) (NO. 2) REGULATION 2014

業界諮詢論壇 Trade Consultation Forum 18-11-2015

背景

Background

- 為加強保障嬰幼兒健康，政府於**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產品和食品的立法建議
 - 嬰兒配方產品的營養成分組合
 - 嬰兒配方產品、較大嬰兒及幼兒配方產品及預先包裝嬰幼兒食物的營養標籤

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

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

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- 特區政府於2012年11月20日至2013年1月21日，進行為期兩個月的公眾諮詢。總括而言，業界人士和香港市民都支持有關的立法建議。
 - 中心與業界舉行一連串技術會議以討論有關規管項目的技術問題
 - The consultation exercise was conducted between 20 Nov 2012 and 21 Jan 2013. In general, traders and members of the public supported the legislative proposals
 - A series of technical meetings with the trade and laboratory service providers were held to tackle the various technical issues raised

□ 《2014年食物及藥物(成分組合及標籤)(修訂)(第2號)規例》於2014年6月13日刊憲，並於2014年6月18日提交立法會進行先訂立後審議的程序

□ 立法會於2014年10月完成修訂規例的審議程序

□ 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 in October 2014 the scrutiny of the Amendment Regulation

□ 修訂法例即將實施

■ 嬰兒配方產品的規定

- 將於十八個月寬限期後，
即二零一五年十二月十三日起實施

■ 較大嬰兒及幼兒配方產品
及預先包裝嬰幼兒食物的
規定

- 將於兩年寬限期後，
即二零一六年六月十三日起
實施

□ The Amendment Regulation
will come into force

■ Requirements for **infant
formula**

- on 13 December 2015
(after a grace period of 18
months)

■ Requirements for **follow-up
formula and prepackaged
foods for infants and
young children**

- on 13 June 2016
(after a grace period of 24
months)

《修訂規例》的重點

Key Features of the Amendment Regulation

《2014年食物及藥物（成分組合及標籤）（修訂）（第2號）規例》 Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014 (2)

修訂規例涵蓋

- ❑ 定義
- ❑ 嬰兒配方產品的營養成分組合規定
- ❑ 嬰兒配方產品、較大嬰兒及幼兒配方產品及預先包裝嬰幼兒食物的營養標籤規定
- ❑ 豁免項目
- ❑ 寬限期

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**
- ❑ Exemption
- ❑ Grace Period

定義

Definition

定義

Definition

- 產品的定義
 - 嬰兒配方產品
 - 較大嬰兒及幼兒配方產品
 - 預先包裝嬰幼兒食物
 - 特殊醫用嬰幼兒配方產品
- 營養素的定義
 - 維他命A、維他命C、維他命E、維他命K、煙酸、葉酸
- 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

嬰兒配方產品的營養成分組合規定

Nutritional composition requirement for infant formula

嬰兒配方產品的營養成分組合規定

Nutritional composition requirement for infant formula

- ❑ 嬰兒配方產品必須含有**能量**及**33種營養素**（1+33），而其能量值及各有關營養素含量必須符合修訂規例指定的水平範圍
- ❑ **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

嬰兒配方產品的營養成分組合規定 (2)

Nutritional composition requirement for infant formula (2)

□ (1+33) -

- 能量
- 蛋白質
- 總碳水化合物
- 總脂肪、亞油酸、 α -亞麻酸
- 13 種維他命 (維他命A、D3、E、K、硫胺素、核黃素、煙酸、維他命B6、B12、泛酸、葉酸、維他命C、生物素)
- 12 種礦物質(鐵、鈣、磷、鎂、鈉、氯化物、鉀、錳、碘、硒、銅、鋅)
- 3 種其他物質(膽鹼、肌-肌醇、L-肉鹼)

□ (1+33) -

- Energy
- Protein
- Total Carbohydrates
- Total fat, Linoleic acid, α -Linolenic acid
- 13 Vitamins (A, D3, E, K, Thiamine, Riboflavin, Niacin, B6, B12, Pantothenic acid, folic acid, C, biotin)
- 12 Minerals (Fe, Ca, P, Mg, Na, Cl, K, Mn, I, Se, Cu, Zn)
- 3 Other substances (Choline, Myo-Inositol, L-Carnitine)

嬰兒配方產品的營養成分組合規定 (3)

Nutritional composition requirement for infant formula (3)

- 如嬰兒配方產品有加入牛磺酸及二十二碳六烯酸(DHA)，必須分別符合最高含量及比例規定
- 某些營養素必須符合比例規定
- Maximum level and proportion requirement are also set for taurine and DHA respectively if they are added to infant formula
- Certain nutrients must follow the proportion requirements

嬰兒配方產品、較大嬰兒及幼兒配方產品及
預先包裝嬰幼兒食物的營養標籤規定

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

嬰兒配方產品的營養標籤規定

Nutrition labelling requirement for infant formula

- ❑ 嬰兒配方產品的標籤須標示其能量值及29種營養素（1+29）的含量
- ❑ **Infant formula** must label the energy value and content of 29 nutrients (i.e. “1+29”)

嬰兒配方產品的營養標籤規定 (2)

Nutrition labelling requirement for infant formula (2)

□ (1+29) -

- 能量
- 蛋白質
- 總碳水化合物
- 總脂肪
- 13 種維他命 (維他命A、D3、E、K、硫胺素、核黃素、煙酸、維他命B6、B12、泛酸、葉酸、維他命C、生物素)
- 12 種礦物質 (鐵、鈣、磷、鎂、鈉、氯化物、鉀、錳、碘、硒、銅、鋅)
- 1種其他物質(膽鹼)

□ (1+29) -

- Energy
- Protein
- Total Carbohydrates
- Total fat
- 13 Vitamins (A, D3, E, K, thiamine, riboflavin, niacin, B6, B12, pantothenic acid, folic acid, C, biotin)
- 12 Minerals (Fe, Ca, P, Mg, Na, Cl, K, Mn, I, Se, Cu, Zn)
- 1 Other substance (Choline)

嬰兒配方產品的營養標籤規定 (3)

Nutrition labelling requirement for infant formula (3)

- 如嬰兒配方產品的氟化物含量(調製後或供食用的形式)超出訂明的上限(每100千卡超過100微克或每100千焦超過24微克)，該產品須標示一項有關氟斑牙的陳述
- If the fluoride content of the product in a reconstituted or served basis exceeds the maximum level stipulated in the Amendment Regulation (exceeds 100 µg per 100 kilocalories or 24 µg per 100 kilojoules), the formula must be marked or labelled with a statement associated with dental fluorosis

較大嬰兒及幼兒配方產品的營養標籤規定

Nutrition labelling requirement for follow-up formula

- 較大嬰兒及幼兒配方產品的標籤須標示其能量值及25種營養素（1+25）的含量
- Follow-up formula must label the energy value and content of 25 nutrients (i.e. “1+25”)

較大嬰兒及幼兒配方產品的營養標籤規定 (2)

Nutrition labelling requirement for follow-up formula (2)

□ (1+25) -

- 能量
- 蛋白質
- 碳水化合物
- 總脂肪
- 13 種維他命 (維他命A、D、E、K、硫胺素、核黃素、煙酸、維他命B6、B12、泛酸、葉酸、維他命C、生物素)
- 9 種礦物質 (鐵、鈣、磷、鎂、鈉、氯化物、鉀、碘、鋅)

□ (1+25) -

- Energy
- Protein
- Carbohydrates
- Total fat
- 13 Vitamins (A, D, E, K, thiamine, riboflavin, niacin, B6, B12, pantothenic acid, folic acid, C, biotin)
- 9 Minerals (Fe, Ca, P, Mg, Na, Cl, K, I, Zn)

預先包裝嬰幼兒食物的營養標籤規定

Nutrition labelling requirement for prepackaged foods for infants and young children

□ 預先包裝嬰幼兒食物的標籤須標示

- 能量值
- 蛋白質、總脂肪、碳水化合物及鈉的含量
- 維他命A和D（如有加入的話）的含量

□ Prepackaged foods for infants and young children must label

- the energy value
- the contents of protein, total fat, carbohydrates and sodium
- the contents of vitamin A and vitamin D if they are added to the food

豁免項目

Exemption

特殊醫用嬰幼兒配方產品的豁免

Exemption for Formula for special medical purposes for infants and young children

- 特殊醫用嬰幼兒配方產品如按《修訂規例》加上**特定標籤**，可獲豁免遵從
 - 營養成分組合規定
 - 營養標籤規定
- **Formula for special medical purposes for infants and young children (FSMP)** marked or labelled with **required information** will be exempted from the requirements of
 - **nutritional composition**
 - **nutrition labelling**

其他豁免項目

Other Exemptions

- 嬰兒配方產品及較大嬰兒及幼兒配方產品如包裝在總表面面積小於250 平方厘米的容器內，可獲豁免遵從營養標籤規定
- 預先包裝嬰幼兒食物如包裝在總表面面積小於100 平方厘米的容器內，可獲豁免遵從營養標籤規定
- Infant formula and follow-up formula packed in a container with a total surface area of less than 250 cm² 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 cm² will be exempted from the nutrition labelling requirements

寬限期

Grace Period

寬限期

Grace Period

- 嬰兒配方產品的營養成分組合及營養標籤規定，將於十八個月寬限期後，即二零一五年十二月十三日起實施
- 較大嬰兒及幼兒配方產品及預先包裝嬰幼兒食物的營養標籤規定將於兩年寬限期後，即二零一六年六月十三日起實施
- nutritional composition and nutrition labelling requirements for **infant formula** will come into operation on 13 December 2015 (after a grace period of 18 months)
- nutrition labelling requirements for **follow-up formula** and **prepackaged food for infants and young children** will come into operation on 13 June 2016 (after a grace period of 24 months)

便利業界措施

Trade Facilitation Measures

- 技術指引及檢測方法技術指引
 - 於2015年1月出版供業界參考
 - 詳細討論有關技術問題，當中包括：規管容忍限、數據修整方法、營養標籤的建議格式示例及檢測方法

http://www.cfs.gov.hk/tc_chi/food_leg/files/Formula_Products_for_Infants/Technical_Guidance_Notes_c.pdf

http://www.cfs.gov.hk/tc_chi/food_leg/files/Formula_Products_for_Infants/Method_Guidance_Notes_c.pdf



- Technical Guidance Notes and Method Guidance Notes
 - issued in January 2015 for traders' reference
 - technical issues such as tolerance limits rounding rules and recommended formats of nutrition labelling, and testing methods

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/Method_Guidance_Notes_e.pdf

謝謝

Thank you

□ 特設網頁

http://www.cfs.gov.hk/tc_chi/food_leg/food_leg_Formula_Products_for_Infants.html

嬰幼兒配方產品和食品的規例

《2014年食物及藥物(成分組合及標籤)(修訂)(第2號)規例》

立法會已於2014年10月完成《2014年食物及藥物(成分組合及標籤)(修訂)(第2號)規例》的審議程序。有關《規例》規管嬰兒配方產品的營養成分組合、以及嬰兒配方產品、較大嬰兒及幼兒配方產品及預先包裝嬰兒食物營養標籤。嬰兒配方產品的營養成分組合及營養標籤規定將於十八個月寬限期後，即二零一五年十二月十三日起實施。而較大嬰兒及幼兒配方產品及預先包裝嬰兒食物營養標籤規定將於兩年寬限期後，即二零一六年六月十三日起實施。

- 《2014年食物及藥物(成分組合及標籤)(修訂)(第2號)規例》
- 指引
- 技術會議(二零一二年十一月-進行中)
- 業界(提供實驗室服務組)技術會議(二零一二年十二月-進行中)
- 香港營養標籤及營養聲稱講座

《2014年食物及藥物(成分組合及標籤)(修訂)(第2號)規例》

新聞公報-政府建議規管嬰幼兒配方產品及預先包裝食物營養成分組合和營養標籤

《2014年食物及藥物(成分組合及標籤)(修訂)(第2號)規例》(2014年第90號法律公告)

□ Designated Website

http://www.cfs.gov.hk/english/food_leg/food_leg_Formula_Products_for_Infants.html

Regulation for Formula Products and Foods for Infants and Young Children

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

The Legislative Council has completed its vetting of the Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014 in October 2014. The Regulation comprises requirements on nutritional composition of infant formulae and nutrition labelling of infant formulae, follow-up formulae and prepackaged food for infants and young children. The requirements on nutritional composition and nutrition labelling of infant formulae will come into operation on 13 December 2015 after a 18-month grace period. The requirements on nutrition labelling of follow-up formulae and prepackaged food for infants and young children will come into operation on 13 June 2016 after a two-year grace period.

- Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014
- Guidelines
- Technical meeting (November 2012 - ongoing)
- Technical Meeting with Laboratory Service Providers (December 2012 - ongoing)
- Seminar on Nutrition Labelling and Claims in Hong Kong

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

Press Release - Government proposes to regulate nutritional composition and nutrition labelling of formula products and prepackaged food for infants and young children

Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014 (L.N. 90 of 2014)