Hong Kong
Infant and Young Child
Nutrition Association
香港嬰幼兒營養聯會

致：立法會食物安全及環境衞生事務委員會

對香港供 36 個月以下嬰幼兒食用的嬰兒配方產品及較大嬰兒及幼兒配方產品及預先包裝食物的營養和健康聲稱規管架構公眾諮詢的初步意見

香港嬰幼兒營養聯會（下稱「聯會」/「本會」）由相關業界的主要成員組成。本會成員均為歷史悠久的嬰幼兒配方產品及食品生產及供應商。聯會成員以滿足嬰幼兒的營養需要為目標，故此在產品研發上長期地投放大量資源，供應適合本地嬰幼兒營養需要的產品。

聯會對有關諮詢的初步意見如下：

1) 本會歡迎政府就嬰幼兒配方產品及嬰幼兒食物營養和健康聲稱的規管架構進行諮詢。

基本原則

2) 本會認為對營養和健康聲稱規管應符合清晰、具高透明度、一致及公平的基本原則，因此認同以立法，而非任何自願遵守的方式進行規管。

規管標準、依據及方式

3) 在規管標準和依據方面，本會同意政府認為應該遵循國際慣例的意見。這容許家長在選擇嬰幼兒營養產品時，能夠參考事實及國際上最新的營養科研資訊。同時，由於香港作為國際城市，因此在制訂公共政策時，應秉承並參考國際經驗的做法。而事實上，本會成員所供應的產品均從歐、美、澳、紐及新加坡等地生產及進口，所引用的營養和健康聲稱均具科學佐證及符合有關國家規定。故此香港有需要參考有關國家的規管制度。

4) 聯會欲強調，國際間一直十分重視科研結果及事實基礎，並且遵循一個清晰、開放的規管制度及程序，以處理（包括作出容許或限制）不同產品的各種營養和健康聲稱，而不會一刀切禁止所有聲稱。有關例子包括（如欲了解以下例子的詳細說明，請參考本文件附件。）：

   - 歐洲：歐盟容許嬰幼兒配方產品做出特定的營養和健康聲稱。而有關聲稱需經由專家小組基於科研資料及事實基礎，並透過嚴謹的審批程序予以批准。

- 美國：美國容許嬰幼兒配方產品做出多種營養素含量和健康功能的聲稱。有關聲稱受多種方式規管，有些無需審批，有些需要符合特定條件或規定。

- 中國內地：中國內地容許嬰幼兒配方產品就可選擇性成份作出營養素含量及功能聲稱。有關聲稱需符合特定條件及指定描述。

規管機制及方向

5) 按照以上國際慣例，本會認為政府應參考國際間規管慣例，成立指定專家團隊，訂定規管及審核機制與相關條件；並定期檢討最新的營養和健康聲稱，以確保本港家長能接觸到最新的產品科研及營養資訊。

6) 當具備上述機制後，以包容方式 (Inclusive Approach)規管將得以落實，容許相關產品基於嚴謹事實及營養科研資訊做出特定聲稱。而不是一刀切禁止所有聲稱，這樣會妨礙家長及醫護人員獲得重要產品資訊，不能作出知情選擇。對香港及家長而言，那是一大倒退，既不符合家長的利益，亦不符合國際慣例。長遠而言，那更會阻礙科學研發和產品改良，影響優質嬰幼兒營養產品供港。包容方式的規管架構實更為優勝，可在嚴謹審核基礎上，讓營養資訊在適當、以事實為基礎的規管下流通。這樣便可以保障家長的知情權，讓他們在為孩子選擇營養產品時能作出最佳選擇。

7) 政府的諮詢文件建議嬰幼兒配方產品的營養和健康聲稱所載述的營養素/成分，必須有相關的膳食營養素參考攝入量或營養參考值。本會欲指出，現時並無國際廣泛採納或專為香港設立針對 36 個月以下嬰幼兒的營養參考值，因此建議政府在相關營養參考值設立之前，應允許產品使用合理並具科學佐證的營養聲稱。

豁免

8) 本會認同特殊醫用嬰幼兒配方產品應豁免規管。

時間表及寬限期

9) 本會建議政府在立法工作及審核程序方面提供清晰的時間表。

10) 本會認為於有關法例生效及審核程序正式啟動時，當局將即時面對大量的審核工作，因此我們建議應在有關法例生效及相關機制或審核程序確定後，同時為首批審核申請訂定時間表，並於首批審核程序完成後提供不少於 24 個月的寬限期，讓業界按審核結果配合法例的實施工作，例如是在更改聲稱後重新設計包裝、生產、船運、替換市場產品等。同時，這亦考慮到現時業界正按近期營養成份標籤立法而全面為產品進行重新標籤工作。如果兩者時間相距過短，將令業界實施困難，有機會影響供應，為公眾帶來不便。而若如果政府採取“先訂立、後審議”的立法程序，足夠的寬限期尤其重要。

聯會會進一步研究諮詢文件的細節，擬訂詳細立場及建議。我們希望各界以大部分消費者利益為依歸，參與是次諮詢，並且透過分享業界的最新資訊和專業意見，協助討論及制訂相關政策。

香港嬰幼兒營養聯會
2015 年 2 月 10 日

香港嬰幼兒營養聯會成員包括（按公司英文名稱排列）
- *美國雅培製藥有限公司*
- *達能紐迪希亞生命早期營養品（香港）有限公司*
- *菲仕蘭（香港）有限公司 (嬰幼兒配方產品品牌：美素佳兒)*
- *美贊臣營養品（香港）有限公司*
- *雀巢香港有限公司*
- *惠氏（香港）控股有限公司*

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附件：國際間主要國家/立法機構對處理營養和健康聲稱的安排

	Type	Age (month)	Nutrient content claim	Nutrient comparative claim	Nutrient function claim	Other function claim	Reduction of disease risk claim	Remarks
Codex	Infant Formula	0-w (first months of life)	**Codex Alimentarius "Guidelines for use of nutrition and health claims (CAC/GL 23-1997)"** <u>Types of claim and definitions:</u> • Nutrition claims: include nutrient content claim and nutrient comparative claim • Health claims: include nutrient function claims, other function claims and reduction of disease risk claims. *"Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation."*					• Definition of "infant formula" and "follow-up formula" in Codex • "Infant formula" means a breast-milk substitute 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. • "Follow-up formula" means a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children.
	Follow-up Formula	6-36						

	Type	Age (month)	Nutrient content claim	Nutrient comparative claim	Nutrient function claim	Other function claim	Reduction of disease risk claim	Remarks

EU	Infant Formula	0 – w (first months of life)	O	X	O	O	O	• Definition of "infant formulae" and "follow-on formulae"
								  • "Infant formulae" means foodstuffs intended for particular nutritional use by infants during the first months of life and satisfying by themselves the nutritional requirements of such infants until the introduction of appropriate complementary feeding
								  • "Follow-on formulae" means foodstuffs intended for particular nutritional use by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants
								
								• Annex IV of Commission Directive 2006/141/EC on infant formulae and follow-on formulae lists authorised nutrition (content) claims for infant formulae in Annex IV, indicating that this type of claim is expressly permitted by the Commission. (not only optional ingredients – e.g., lactose)
								
								• Annex IV of Commission Directive 2006/141/EC also lists authorized health claim (disease risk reduction claim) for infant formula.
								
								• Commission Regulation No 440/2011 demonstrates that specific nutrition and health (function) claims are permitted for follow-on formulae, as evidenced by an express approval for a DHA function claim. Example: "Docosahexanenoic acid (DHA) intake contributes to the normal visual development of infants up to 12 months of age."

	Follow-on Formula	W – 12 (suitable only for infants over the age of 6 months)	O	O	O	O	O	

	Type	Age (month)	Nutrient content claim	Nutrient comparative claim	Nutrient function claim	Other function claim	Reduction of disease risk claim	Remarks
USA	Infant Formula	0-12	O	X	O	O	O	• In USA, only infant formula is defined in regulations which govern 0-12 months. • Specific nutrient content claims (*i.e.*, content claims communicating the % Daily Value for essential nutrients) are allowed for products intended for <2 years of age, including infant and follow-on formulas (21 CFR 101.13(b)(3)). • Foods intended for <2 years of age can utilize any infant formula claims provided for in 21 CFR 107 (e.g., "with iron"), "unsweetened" and "unsalted" taste claims, and "sugar free" and "no added sugar" claims for dietary supplements for this population.[1] • Function claims (structure / function) are permitted on all foods in the U.S., including infant formula and follow-up formulas (follow-up formulas are classified as infant formulas when targeted to infants (0-12 months) and as conventional foods if targeted to young children (1-3 years), for both essential nutrients and optional ingredients. The legal basis for structure / function claims is predicated in the definition of a drug according to the Food, Drug, and Cosmetic Act, which has been in effect since 1938. The Act (Sec 201(g)(C)) defines a drug as "articles (other than food) intended to affect the structure or any function of the body of man ….." Thus, the statute recognizes that foods affect the structure / function of
	Follow-up Formula		O	X	O	O	O	

[1] http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064916.htm

								the body, and claims are made on this basis. FDA has further elaborated on the allowance of such claims on food products in industry letters and other public documentation.[2,3] • All foods are permitted to utilize health claims (disease risk reduction claims) if U.S. FDA has reviewed and either codified a regulation authorizing such claim without qualification or if U.S. FDA has reviewed and issued a letter of enforcement discretion for the claim, with specific qualifications required. One such claim is currently permitted on infant formula. It is a qualified health claim (disease risk reduction claim) based on an FDA letter of enforcement discretion.[4]

[2] http://www.fda.gov/food/guidanceregulation/ucm053425.htm

[3] http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm111447.htm

[4] http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm256731.htm

	Type	Age (month)	Nutrient content claim	Nutrient comparative claim	Nutrient function claim	Other function claim	Reduction of disease risk claim	Remarks
Mainland China	Infant Formula	0-6	O	X	X	O	X	• Content and function claims for optional ingredients on infant formulas are allowed.[5, 6] • To make a content or function claim in accordance with GB13432-2013[6], the formula must first provide the minimum level of such nutrient (if established by a relevant Chinese product standard) [5,6,7], and then must utilize authorized language[8]. For example, DHA, taurine, dietary fibre are allowed to have content and function claims for infant formulas and follow-on formulas[9]. In the case where no minimum level of the nutrient exists in the relevant product standard, or no such claim exists on the China positive list, one can then refer to claims already approved in other jurisdictions; provided that all criteria are met by the authorizing authority.[6, 9]
	Follow-up Formula	6-36	O	O* * Not allowed from July 2015	O	O	X	

[5] GB 10765-2010 http://www.shfda.gov.cn/spaqbz/GB%2010765-2010%20 婴儿配方食品.pdf

[6] GB 13432-2013 http://www.nhfpc.gov.cn/ewebeditor/uploadfile/2014/05/20140505140531583.pdf

[7] GB 10767-2010 http://www.shfda.gov.cn/spaqbz/GB%2010767-2010%20 较大婴儿和幼儿配方食品.pdf

[8] GB 28050-2011 http://www.shfda.gov.cn/spaqbz/GB28050-2011%20 预包装食品营养标签通则.pdf

[9] GB 13432-2013 Q&A http://www.nhfpc.gov.cn/sps/s3594/201409/dc38ac8f1c154bb5aaa616e3a8da1061.shtml