



Abbott Submission

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17/4/2015 16:39

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1 個附件檔



AW150401F.pdf

Dear Sir/Madam,

Please find attached the Abbott submission on the proposed regulation on claims on formula for children under the age of 36 months.

Regards,

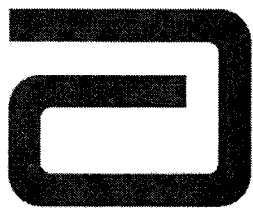
Andrew K. C. Wong
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Abbott Laboratories Ltd

Direct:
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By EMAIL (claims_consultation@fehd.gov.hk)

SUBMISSION ON the PROPOSED REGULATORY FRAMEWORK ON NUTRITION AND HEALTH CLAIMS ON INFANT FORMULA, FOLLOW-UP FORMULA, AND PREPACKAGED FOODS FOR INFANTS AND YOUNG CHILDREN UNDER THE AGE OF 36MONTHS IN HONG KONG

Abbott Laboratories supports breastfeeding and supports the government's initiative to regulate nutrition and health claims for products intended for infant and young children.

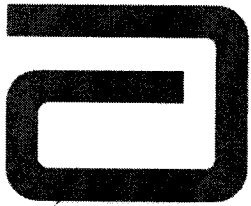
Inclusive approach

Most of the major jurisdictions do allow nutrient content, nutrient function and other function claims on infant formula, follow-up formula, and foods for infants and young children <36 months of age. It is Abbott's recommendation for the bureau to take an **inclusive approach** to be more aligned with the rest of the world and to promote advancements in nutritional research. International practices for the use of product claims put a strong emphasis on scientific substantiation and evidence-based foundation. They follow a clear and open regulatory system and procedures to deal with various nutrition and health claims of different products (including approvals or imposing restrictions), instead of imposing a ban on all claims. Relevant examples include Europe, US, and Mainland China (please refer to the appendix for details).

Nutrition claim for follow up formula

Regarding nutrition claim of essential ingredients for FUF and IYC, we recommend that the Hong Kong government develop a NRV for children under 36 months old either independently or in collaboration with Mainland China. Also, we suggest that nutrition claims with reasonable scientific substantiation be allowed for optional ingredients and for essential nutrients before a NRV is established.

In US, specific nutrient content claims (i.e., content claims communicating the % Daily Value) are allowed for products intended for <2 years of age, including formulas intended for infants and young children (21 CFR 101.13(b)). Additionally, foods intended for young children <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 for this population¹.

In Europe, Annex IV of Commission Directive 2006/141/EC on infant formulae and follow-on formulae lists authorized nutrition (content) claims for infant formulae in Annex IV, indicating that this type of claim is expressly permitted by the Commission.

And in China, nutrition claims for follow up formulas are permitted if the nutrient meets product standard minimum limit or minimum limit specified by other global authority for an approved claim.

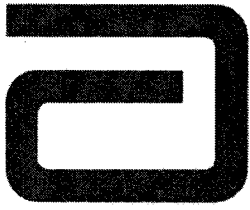
Nutrient function claim and other function claims on infant formula products and IYC foods

As long as it is scientifically substantiated, nutrient function claims and other function claims for IF, FUF and IYC should be allowed. In addition to the benefits listed in 4.20, nutrient function claims and other function claims accommodate innovation and advancements in nutritional research. Human milk contains a variety of nutrients that are not found in infant formulas. Extensive research and development are conducted to provide infant formulas that match the composition or performance of human milk. These provide a safe and nutritious alternative to mothers who are unable or choose not to breastfeed. These formulas are developed using the latest scientific information on infant nutrition. It is important for the consumer to understand the nutritional benefits of the formula and product claims allow for that communication. Health claims also allow the differentiation between the varieties of formulas available on the shelf. Rather than being prohibited, a number of jurisdictions, including EU, US, Codex, Mainland China and Singapore do allow the use of nutrient function claims and other function claims (see Appendix for details).

The European Commission has reviewed and approved the use of a nutrition function claim to highlight the relationship between DHA and eye development in FOF (Commission Regulation No 440/2011) Example: “Docosahexanoic acid (DHA) intake contributes to the normal visual development of infants up to 12 months of age.”). The claim can be used when the product meets the compositional criteria described in the approval.

Function claims (structure / function) **are permitted** on all foods in the US including infant formulas, for both essential and optional nutrients. The Dietary Supplement Health and Education Act of 1994 (DSHEA) established some special regulatory requirements and

¹<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064916.htm>



procedures for structure/function claims and two related types of dietary supplement labeling claims, claims of general well-being and claims related to a nutrient deficiency disease. Structure/function claims are those that “may describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body.” Although the definition of structure/function claims is established by DSHEA for dietary supplements, the same principles apply to conventional foods.

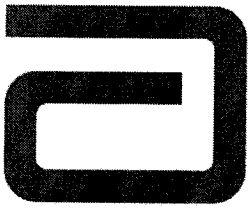
According to GB13432-2013, the China Ministry of Health prohibits content and functional claims for essential nutrients on infant formulas. However, there is no prohibition on content and functional claims for optional nutrients on infant formulas. One must follow the conditions prescribed in the GB, which include meeting a minimum level of such nutrient if established by a relevant Chinese product standard and utilizing the language if listed on the Chinese positive lists. For example, DHA, taurine, GOS/FOS are allowed to have content and functional claims for infant formulas and follow-on formulas. In the case of no minimum exist in the GB, or no such claim exists on the China positive list, one can refer to claims already approved in other jurisdictions provided that all criteria are met by the authorizing authority.

Approval process

If the inclusive approach is adopted, fewer resources may be required by the Hong Kong authority. However if Hong Kong decides to pursue an approval process, we would recommend the Hong Kong government to establish a positive list and take into consideration all the related jurisdictions as reference to approve claims and establish corresponding conditions.

Regarding the mechanism to approve claims and establish corresponding conditions, making reference to well-researched assessments already conducted by other jurisdictions may be a viable way forward. A number of jurisdictions, including EU, Australia, New Zealand, Thailand, Taiwan, Turkey, and Singapore have established a list of pre-approved nutrition and health claims. However, it is concerning given the approval framework in other jurisdictions is so limited. In US, function claims do not require approval (there is no preapproved list); use of these claims is the responsibility of the manufacturer. Structure/function claims must be scientifically substantiated, and cannot be false or misleading.

NRVs for Hong Kong



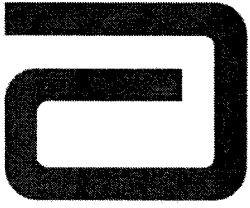
The consultation document suggests that nutrition and health claims on IYC formula products and IYC foods should only be allowed to feature nutrients/constituents for which Dietary Reference Intakes (DRIs) or Nutrient Reference Values (NRVs) have been established. We would like to point out that there is currently no widely adopted NRV list internationally or any specially established list for Hong Kong targeting infants and young children under 36 months. As a result, we recommend the Hong Kong government to develop or work with China to develop a NRV for children under 36 months of age. Establishing DRIs is a very slow process, so disallowing claims until DRIs are established will prevent communication of nutritional benefits associated with infant formula, follow-up formula and IYC foods to consumers and health care professionals. We would suggest that nutrition claims with reasonable scientific substantiation should be allowed before the Government's establishment of the relevant NRV list.

For those ingredients that do not have a DRI or NRV established, we propose that claims should be allowed based on the available science, for example DHA. DHA has been widely studied, has shown benefits, and claims for such have been formally approved in some countries/ jurisdictions. Many jurisdictions including US, EU, China all allow claims for optional ingredients (please see Appendix for details). Not allowing claims for nutrients without DRI or NRV will completely de-incentivize addition of any optional ingredients.

Grace Period

We propose that the Government should provide a clear timetable on the legislative process and claims approval mechanism and procedures.

We believe the Government will receive an overwhelming number of claims approval submissions when the legislation takes effect and the corresponding approval mechanism and procedures are confirmed. In order to ensure and allow sufficient time for the industry to follow the new legislation, we suggest the Government provides a clear timeline and procedures for the first batch of claims approval submissions. In addition a grace period of not less than 24 months for the industry to implement required changes; such as arranging redesigning packaging, manufacturing, shipping, replacing products, etc. This will also take into account the industry's need to conduct comprehensive relabeling of products following the recent nutrition labeling legislation. If the transition period is too short, it will create implementation difficulties for the industry, which may affect the supply and cause inconvenience to the public.



Regarding the grace period, Abbott would recommend to have a minimum 2-years grace period. This is taking into consideration the factors of possible product reformulation / development, manufacturing, testing at various stages, product release, freight and local distribution. The bureau should also take into consideration that the industry is currently undergoing a significant re-labeling exercise due to the recent legislation on composition and labeling. It might create inconvenience for the public and possible stock scarcity if the two changes are expected to be implemented in parallel.

FSMP exemption

Abbott supports the bureau's intention to exempt FSMP formula from the regulation on claims. The FSMP products that Abbott imports into Hong Kong are niche products for specific patient populations and are formulated to meet very special medically determined needs and are used under the supervision of the physician. The majority of these products are used in the hospital setting. Specific nutrition or medical claims are needed to provide information relevant to the health care practitioner and/or caregiver to ensure appropriate understanding and use of the formula.

Abbott Laboratories Limited

17 April 2015

AW150401F

Appendix: Regulatory Framework on Nutrition and Health Claims in Different Authorities

		Age (month)	Nutrition claim		Health claim		
			Nutrient Content Claim	Nutrient comparative claim	Nutrient function claim	Other function claim	Reduction of disease risk claim
Codex	IF	0-w (first months of life)	x	x	x	x	x
	FUF	6-36	x	x	x	x	x
	IYC	6-36 (processed cereal-based foods); w-36 (canned baby food)	x	x	x	x	x
EU	IF	0-w (first months of life)	o Claims are listed within the infant formula 2006/141 EC.	x	x	x	o EU currently allows claims related to reduction of risk to allergy to milk protein.
	FUF	w-12 (suitable only for infants over the age of 6 months)	o 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)	o	o	o	o Allowed per the approved allergy health claim for infant formula and it should imply that it is likely possible for any product <36 months).
	IYC	4-36	o	o	o	o	o

USA	IF	0-12	○ The claim 'infant formula with iron' is required by regulation for formulas with more than 1 mg iron per 100 kcal. Lactose-free would be permitted if product contains no lactose. Other claims on added ingredients are permitted if no DRI / DV are established.	x	○ US allows. The manufacturer is responsible to confirm if the claim complies with the regulation and that substantiation is based on competent and reliable scientific evidence.	○ US allows. The manufacturer is responsible to confirm if the claim complies with the regulation and that substantiation is based on competent and reliable scientific evidence.	○ US allows the use of disease risk reduction claim (from a positive list) if the product meets the requirements of the regulation. Currently, the only disease risk reduction claim permitted on infant formula is a qualified health claim describing the relationship between hydrolyzed protein and a reduced risk of allergy. Although these types of claims are not prohibited, they are subject to a rigorous review and must demonstrate significant scientific agreement for approval
	FUF	NA FUF (for infants >12 mos of age) is considered as conventional foods and conventional foods allow the use of nutrient function claim.	○	○	○	○	○

	Food for infants and toddlers	<24	○ Allowed though nutrient content and nutrient comparative claims are limited for foods intended for children <2 years of age	○ Allowed though nutrient content and nutrient comparative claims are limited for foods intended for children <2 years of age	○	○	○ US does allow.
	General food	25-36	○	○	○ Allowed if the product is targeted for over 2 years	○	○ US does allow.
Australia and New Zealand	IF	0-4/6	x	x	x	x	x
	FUF	6-12	x	x	x	x	x
	IYC	4-36	○ Permitted per local regulation Std 2.9.3.	○	○ Permitted as per local regulation Std 2.9.3 and in line with Std 1.2.7 Nutrition, Health and Related Claims.	○	○
Mainland China	IF	0-6	○ The new China framework (GB13432) allows content claims for optional ingredients as long as ingredients in the product reach the minimal value.	x	x	○ Allowed in China. MOH has published an approved list of functional claims allowed for infant formula for non-essential nutrients in Sep 2014. A formal petition mechanism has not yet been established to add new claims.	x No application policy for approving reduction of disease risk claim.

	FUF	6-36	○ Permitted if the nutrient meets product standard minimum limit or minimum limit specified by other global authority for an approved claim.	○	○ Allows the use of nutrient function claim as long as comply with the requirement and conditions of nutrient content claims and nutrient comparative claims; need to follow specific wording in GB 28050.	○ MOH has published an approved list of functional claims allowed for infant formula for non-essential nutrients in Sep 2014. A formal petition mechanism has not yet been established to add new claims.	x No application policy for approving reduction of disease risk claim.
	IYC	6-36	○	○	○	x	x No application policy for approving reduction of disease risk claim.
Singapore	IF	0-12	○	○	○ Singapore allows selected claims (e.g. "nucleotides support body's natural defenses")	○	○ No claim currently exists in the list that can be used in IF
	FUF				NA; covered under infant food		
	IYC				NA; covered under general food		
	General food	13-36	○	○	○	○	○