HKIYCNA - Submission in Response to Public Conultation on Proposed Regulatory Framwork on Nutritionand H

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HKIYCNA Submission on Proposed Regulatory Framework for Nutrit ion and Health Claims.pdf

Hi there

Enclosed the submission from The Hong Kong Infant and Young Child Nutrition Association.

For and on behalf of
the President
The Hong kong Infant and Young Child Nutrition Association

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

BY EMAIL (claims_consultation@fehd.gov.hk) & BY POST

Centre for Food Safety
(Attn: Risk Assessment Section)
Food and Environmental Hygiene Department
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SUBMISSION IN RESPONSE TO PUBLIC CONSULTATION ON 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 36 MONTHS IN HONG KONG

The Hong Kong Infant and Young Child Nutrition Association ("The Association") welcomes the government's initiative to regulate nutrition and health claims on infant formula, follow-up formula and prepackaged foods for infants and young children under the age of 36 months in Hong Kong ("nutrition and health claims").

1. General Principles

The Association believes that any regulation should be transparent. Moreover, it should allow a greater understanding of the science of nutrition and ensure that parents could have access to fact-based and updated nutrition and health information including various scientifically substantiated claims.

2. Views on the Proposed Regulatory Framework

2.1. Supports the Inclusive Approach

The Association agrees with the government's point of view that taking reference to international practices is vital to the success of the local regulation. The majority of Hong Kong's infant and follow-up formulas are imported from various continents and countries, including the European Union, the U.S., Australia / New Zealand, Singapore, etc. More detailed information about the regulatory situations of nutrition and health claims in those jurisdictions can be found in the Appendixes. Since most of the major jurisdictions do allow nutrient content, nutrient function and other function claims especially for follow-up formula and prepackaged food for children under the age of 36 months ("IYC food"), it is the association's recommendation for the Centre of Food Safety ("CFS") to take an inclusive approach so as to be more aligned with international practices.

2.2. Recommends Alternative Conditions for Nutrition Claims

The consultation document suggests that nutrition and health claims on 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 for the respective or appropriate age subgroup.

We think it is important to clarify that nutrition claims and health claims should be allowed based on different conditions since nutrition and health claims are different. Nutrition claims (nutrient content claims and nutrient comparative claims) should be allowed based on pre-determined conditions such as nutrient compositional criteria detailed below, while health claims (nutrient function claims and other function claims) should be allowed following an approval mechanism based on scientific evidence, as detailed in Section 2.3.

As we understand, there are no local NRVs for the age group of 0-36 months in Hong Kong or widely adopted NRVs for this age group internationally for making nutrition claims. With reference to practices in various countries that DRIs or NRVs are not the necessary and the only conditions based on which nutrition claims are allowed, we highly recommend the CFS to adopt alternative conditions for making nutrition claims.

The Association would like to suggest using nutrient compositional criteria as one of the alternatives, which is similar to the current mechanism in China. According to GB13432-2013 National Food Safety Standard Food Labeling of Prepackaged Foods for Special Dietary Use in China, when the content of energy or nutrients in the follow up formula and IYC food complies with the minimum limits or permissible fortified minimal values of the corresponding product standard, nutrition content claims are allowed to make. If such minimum values are not available, basis for nutrition content claims for the interest nutrients in other countries and/or international organizations should be provided.

We recommend the CFS to reference this mechanism and consider nutrients that meet the minimum composition requirements in the relevant Codex standards, or DRIs, or corresponding requirements in other countries for nutrition claims for follow-up formula and IYC foods.

The CFS may also give a consideration to the practice in Singapore, where nutrition claims for energy, protein, carbohydrate, sugar, dietary fibre, total fat, fatty acids, cholesterol, sodium/salt and vitamins/minerals are allowed for general food (including follow-up formula and food for young children) given the products comply with the requirements of the Food Regulations and the nutrient claims guidelines in "A Handbook on Nutrition Labelling" released by Singapore's Health Promotion Board (HPB).

In the event CFS still considers DRIs or NRVs to be the most preferred condition for making nutrition and health claims, they may refer to the

Reference Values for Nutrition Labelling for Foods intended for Infants and Young Children as specified in the Annex VII of the EU Directive 2006/141/EC.

2.3. Proposes An Effective Approval and Review Mechanism for Health Claims under Inclusive Approach

To devise an effective review and approval mechanism on claims for Hong Kong under the Inclusive Approach, the guiding principles should include making it simple, efficient, open, fair and in line with international practices.

2.3.1. Structure and Roles

While it is expected that the CFS will take the core responsibility to administer the mechanism of claims approval and regulation implementation, it is important that an independent expert panel should be formed to provide independent scientific assessment and review on claims applications, and play an advisory role for the CFS. Appointing an independent expert panel for a scientific review is a common practice of reputable regulatory bodies, like that in the European Union and Singapore. It allows claims applications to undergo a stringent assessment process based on scientific research and substantiation, so that evidence-based and scientifically substantiated nutrition and product information can reach consumers and facilitate their informed choices.

Members of the expert panel can consist of independent local and international experts, including pediatricians, nutritionists and food scientists. By including overseas experts, international perspectives and expertise can be brought in and thus a balanced and comprehensive view can be ensured. Wherever necessary and appropriate, the cost to involve external or international experts on reviewing specific claim applications can be borne by the applicant.

2.3.2. Approval Process

In order to make the approval mechanism simple and efficient, the Association agrees with the CFS' suggestion to put claim applications into specific categories with different approval processes. It is important that the relevant process and procedures are clearly defined and documented.

(a) Establish a pre-approved positive list

For claims that have undergone stringent scientific assessment and received approval from reputable regulatory bodies in other developed countries, such as EU and Singapore, we suggest the Government to refer to the approved claims to develop a pre-approved list of claims in English and Chinese for the adoption in Hong Kong, and provide the conditions of each claims on the list for the industry's reference. With such a list, the industry could conduct self-assessment, follow and adopt the claims on the pre-approved list. It is not necessary for the Government to conduct pre-approval assessment for claims of this kind and therefore the administrative process can be streamlined. Consequently the Government should focus on monitoring of claims being used.

(b) Approval for claims which are accepted in some jurisdictions but pending for approval or not yet accepted in other jurisdictions

For claims that have received approval in some jurisdictions, but may be pending for approval or have not been accepted under certain circumstances in some other jurisdictions, an

independent scientific assessment by the expert panel should be conducted upon receipt of such applications. The expert panel should review all supporting facts on scientific substantiation from both sides, especially including the newer and the latest scientific information available since assessment, in order to make a fair and evidence based judgment/assessment. Applicant should be allowed to provide further data and facts for clarification where needed.

(c) Approval for new claims

For claims that have not been assessed in other jurisdictions, a full and detailed scientific assessment should be conducted by the expert panel. All available documents on the claim's relevant scientific substantiation should be referred to and reviewed.

(d) Alternative process for application of new claims

Hong Kong could also consider the innovative approach taken recently in Australia / New Zealand whereby in addition to using claims from a positive pre-approved list, manufacturers have the option of self-substantiating new nutrient function health claims provided set requirements are met. These requirements include a systematic review of claim evidence. The regulator is notified and holds a record of such claims on a list. Further detail on this approach and claim assessment criteria can be found in ANZ Nutrition and Health Claims Standard 1.2.7. Manufacturers are still required to submit disease-risk reduction health claims for specific pre-market approval by the regulator.

2.3.3. Assessment Criteria

A clear set of assessment criteria should be established to help CFS and the expert panel process claim applications openly and consistently. Codex CAC/GL 23-1997 can be served as a principle for reference which includes:

i. Health claims should primarily be based on evidence provided by well-designed human intervention studies
ii. The totality of the evidence should be identified and reviewed
iii. Evidence needs to be weighted
iv. Evidence should demonstrate a consistent association between the food or food constituent and the health effect, with little or no evidence of the contrary
v. Nutrient function claims may be substantiated based on generally accepted authoritative statements by recognized expert scientific bodies that have been verified and validated over time
vi. The quantity of the food or food constituent and pattern of consumption required to obtain the claimed effect should reasonably be achieved as part of a balanced diet
vii. The specific study population in which the evidence was obtained should be representative of the target population.

2.3.4. Appeal Process

It is also recommended to put in place an appeal process on the approval results. It will be more efficient if the appeal process is basically administrative in nature, in the form of an appeal committee or board, with an independent review of the application process.

2.3.5. Revision Process

We concur to the consultation document's proposal to put in place a claim revision process. The approved claim list should be subject to review on a need basis, upon application, or when relevant new evidence has come to the knowledge of the CFS or the expert panel.

2.4. Suggests A Sufficient Grace Period

It is the association's recommendation to have a minimum 2-year grace period on top of the time required to complete the pre-approval process before the official effective date of the regulation. This is taking into consideration the factors of possible product reformulation / development, manufacturing, testing at various stages, product release, freight and local distribution.

The CFS should also take into the consideration that the industry is currently undergoing a significant re-labeling exercise due to the recent regulation amendment on composition and labeling. It might create inconvenience for the public and possible stock scarcity if the implementation of the two regulations is closely scheduled one after another one.

The CFS may also consider international experience as reference in implementation. As an example, when the claim regulation was implemented in the European Union, there was a short grace period to submit claim dossier. Beyond this, there was an additional grace period during which only claims that were being submitted for review could remain being used, independent of the outcome of the assessment. Those which were not submitted for review had to be removed immediately.

3. Conclusion

To conclude, the Association believes that the final regulation should be developed based on internationally recognized principles of openness, efficiency, inclusion and alignment with practices in other jurisdictions, in order to best address the nutritional needs of children in need in such a modern and international society as Hong Kong.

The Hong Kong Infant and Young Child Nutrition Association
17 April 2015

Abbott Laboratories Limited
Danone Nutricia Early Life Nutrition (Hong Kong) Limited
Fonterra Brands (Hong Kong) Limited
FrieslandCampina (Hong Kong) Limited
Mead Johnson Nutrition (Hong Kong) Limited
Nestle Hong Kong Limited
Snow Brand Hong Kong Company Limited
Wyeth (Hong Kong) Holding Company Limited

Appendix 1: Summary of Nutrition and Health Claims in Other Jurisdictions

Europe

Annex IV of Commission Directive 2006/141/EC on infant formula and follow-on formula lists authorised nutrition (content) claims for optional ingredients in Annex IV, indicating that this type of claims is expressly permitted by the Commission. Annex IV of Commission Directive 2006/141/EC also lists one authorized health claim (disease risk reduction claim) for infant formula. Though there are limited health and nutrition claims authorised by the Comimssion for infant and follow-on formulae, this directive clearly indicates the acceptance of these specific types of claims. In addition, Commission Regulation No 440/2011 demonstrates that nutrition (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."

Mainland China

According to GB13432-2013, the Ministry of Health prohibits nutrition content and function claims for essential nutrients on infant formula. However, there is no prohibition on content and function claims for optional ingredients on infant formula. To make a content or function claim in accordance with GB13432-2013, the formula must first provide the minimum level of such nutrient (if established by a relevant Chinese product standard), and then must utilize authorized language (if such language is listed on the Chinese positive list). For example, DHA, taurine, GOS/FOS are allowed to have content and function claims for infant formulas and follow-on formulas. 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.

U.S.A

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)). Additionally, 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-on formulas (follow-on formulas are classified as conventional foods), 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 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]

In addition, 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]

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

[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

Australia and New Zealand

A new Standard (Standard 1.2.7) to regulate nutrition content claims and health claims on food labels and in advertisements became law on 18 January 2013 with 3 years grace period for food industries to make changes to ensure they are following the new rules.

According to the standard, approved nutrition content claims or permitted general level and high level health claims may be made on milk formula for young children (12-36 months) when the product satisfied specific conditions in Schedule 1-3 laid down in Standard 1.2.7. General level and high level health claims are comparable to Hong Kong's nutrient function health claims, and disease risk reduction health claims, respectively.

Also, under Standard 2.9.1 Infant Formula Products, claims relating to lactose free and low lactose are permitted in infant formula products (0-12 months) including infant formula and follow-on formula that provided the words "lactose free" and "low lactose" is part of the name of lactose free formula and low lactose formula respectively.

General level health claim (similar to Hong Kong's health claim) can base their claim on a food-health relationship that is either:

- pre-approved by FSANZ as listed in Schedule 3 of Standard 1.2.7 (there are more than 200 health claims on this pre-approved list), or
- self-substantiated, provided the claim has been established in accordance with the requirements set out in Schedule 6 of Standard 1.2.7.

Food businesses self-substantiating a food-health relationship so they can make a general level health claim, must notify FSANZ of the relationship before making the claim on food labels or in advertisements for food. FSANZ maintains a list of the notified food-health relationships, which is a public record of food businesses chosen to self-substantiate a food-health relationship to underpin a general level health claim.

Codex

The Codex Alimentarius Guidelines for Use of Nutrition and Health Claims specifies, in Article 1.4, that "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." Thus, Codex does not apply a blanket prohibition, but does allow for local regulatory agencies to develop their own policies on this matter.

Appendix 2: Regulatory Control on Nutrition and Health Claims in Different Authorities as According to Information Collected by HKIYCNA

	Type	Age (month)	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)	Prohibited by Codex unless specifically authorized by relevant Codex standards or by the local authority				
	FF	6-36					
EU	IF	0 – w (first months of life)	O	X	O	O	O
	FF	W – 12 (suitable only for infants over the age of 6 months)	O	O	O	O	O
USA	IF	0-12	O	X	O	O	O
	FF		O	X	O	O	O
Mainland China	IF	0-6	O	X	X	O	X
	FF	6-36	O	O	O	O	X
Australia and New Zealand	IF	0-4 to 6	O	X	X	X	X