# Submission in Response to Consultation of the Claims Regulation

@mjn.com to: claims_consultation@fehd.gov.hk 17/4/2015 15:43

From: @mjn.com>
To: "claims_consultation@fehd.gov.hk" <claims_consultation@fehd.gov.hk>

1 個附件檔

MJN submission on Claims Regulation Consultation.pdf

To Whom It May Concern,

Please see our submission as attached. Thank you.

Best regards,
Amy Chu
MEAD JOHNSON NUTRITION

Mead Johnson Nutrition
NOURISHING THE BEST START IN LIFE

17 April, 2015

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

Centre for Food Safety
(Attn: Risk Assessment Section)
Food and Environmental Hygiene Department
45/F, Queensway Government Offices
66 Queensway, Hong Kong

**Submissions in Response to Consultation of "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"**

We overall support the initiative taken by the Government to regulate claims on formula and foods for infants and young children (0-36 months) as it will help to ensure that product information to consumers is scientifically substantiated and endorsed according to a consistent, rigorous and well-defined regulatory process.

We generally agree with the five "Overarching Principles" set out by the Government in regulating nutrition and health claims. We would like to emphasize the importance of assuring that these principles are clearly defined and follow international regulatory practice in place in other developed countries, particularly those countries where formula products sold in Hong Kong are imported from.

**REGULATORY FRAMEWORK**

We support the "Inclusive Approach" proposed by the Government as the regulatory framework because it enables consumers to have access to evidence based product information that will allow them to make informed nutrition and product choices. It will also enable to create more consumer trust given only claims that are scientifically substantiated and endorsed through a well-defined regulatory process will be authorized.

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 below section.

The inclusive claim approach has already been successfully implemented for several years in a number of countries, including US, the European Union, Canada, Singapore and Malaysia, and hence can be a good, workable framework for Hong Kong. Since Hong Kong is a unique market with all infant and follow-up formula imported, it is appropriate to consider claims already

allowed overseas as long as they are scientifically substantiated and endorsed by reputable regulatory authorities along with well-defined regulatory processes. Based on experience from other countries, specific conditions for use of a claim (e.g., required minimal intake level) will have to be established. For innovative ingredients or nutritional substances, it is recommended to establish an expert panel review process in line with practice in place in the above mentioned countries/jurisdictions to conduct a scientific assessment of the innovation.

We support the proposal of having a mechanism in place to allow new claims to be approved for use. As a responsible manufacturer, it is our uncompromised commitment to keep abreast with the latest science and continue to improve our products. Simultaneously it is important to be able to communicate the relevant and scientifically substantiated nutrition and health information about our products to our consumers. This requires rigorous, consistent and well-defined regulatory processes that enable to authorize claims.

**SUGGESTIONS ON APPROVAL AND REVIEW MECHANISM OF HEALTH CLAIMS**

In devising a 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. The mechanism should include clear specification of structure and roles, as well as the application, review and appeal processes.

Structure and Roles

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

The role of the expert panel should be focused on providing scientific and risk assessment opinions, and members can consist of independent local and international experts, including pediatricians, nutritionists and food scientists. Since claims and relevant scientific research will most likely not be specific or unique to Hong Kong, it is suggested to consider inviting independent international experts as panel members so that international perspectives and expertise can be brought in. Wherever necessary and appropriate, the cost to involve external or international experts on reviewing specific claim applications can be borne by the applicant.

Mead Johnson Nutrition
NOURISHING THE BEST START IN LIFE

Application Process

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

(a) Applications for claims which are already approved by reputable regulatory bodies in other developed countries: For claims that have undergone stringent scientific assessment and received approval from reputable regulatory bodies in other developed countries, such as the European Union and Singapore, the approval should be qualified through a fast track process. The assessment and approval can be done by the CFS based on supporting documents of approval in other jurisdictions, with notification served to the expert panel. The foci of the assessment should be on whether a submission is valid, the proof of the nutrient level meets the condition specified for the claim, and the Chinese version of the claims reflects the meaning of the original approved claims without distortion. Once the claims are approved by the CFS, a positive list of claims with specific conditions of each claim to be published. Should a company would like to adopt the claims from the positive list, one should be liable to ensure the conditions are fulfilled. With the said process, no pre-market approval would be necessary. The CFS would play the role focusing on monitoring how the claims are being used.

With the continuous evolution of scientific findings, it is evident that new innovations will emerge and as a consequence new claims will be approved overseas. Therefore, we suggest the positive list to be remaining as an open list and allow modification or addition based on the latest science. When there are new claims surfaced and received approval from reputable authorities, manufacturers can submit the claims through this fast track process for review and approval to ensure the positive list is kept abreast to the latest science and consumers will be able to benefit from having the opportunity to learn about the new information and enable them to make an informed choice.

(b) Applications for claims which are approved in some jurisdictions, but are pending or not accepted in other jurisdictions: For claims that have received approval in some jurisdictions, but may be pending or that 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 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) Applications for new claims: For claims that have not been assessed by a reputable regulatory authority, 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.

Mead Johnson Nutrition
NOURISHING THE BEST START IN LIFE

Assessment criteria

A clear set of assessment criteria should be established to help the 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:

(a) Health claims should primarily be based on evidence provided by well-designed human intervention studies
(b) The totality of the evidence should be identified and reviewed
(c) Evidence needs to be weighted
(d) Evidence should demonstrate a consistent association between the food or food constituent and the health effect, with little or no evidence of the contrary
(e) 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
(f) 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
(g) The specific study population in which the evidence was obtained should be representative of the target population.

Revision process

We concur to the consultation document's proposal to put in place a claim revision process. The approved claims 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.

Appeal process

To ensure fair treatment and due process, there is also a need to put in place an appeal process on approval results made by the CFS. 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.

**SUGGESTIONS ON THE CONDITIONS FOR NUTRITION CLAIMS FOR FOLLOW-UP FORMULA**

As follow-up formula is not a breast milk substitute and there are no composition requirements for this category of products in Hong Kong regulations, nutrition claims should be allowed in order for manufacturers to be able to distinguish their products from others and to facilitate consumers making their informed choice.

Since there is no international NRV list established for the age group of 0-36 months, it may be challenging in setting up a Hong Kong specific local NRV list. We therefore support using DRI

for the appropriate age group; Expert recommendations published by FAO/WHO and reference to the composition requirements set out in the relevant Codex standard (CODEX STAN 156-1987) may be used as the bases to develop a list of nutrients for which nutrition claims may be allowed to be made. In addition, we suggest adopting the Commission Directive 2006/141/EC on follow-on-formulae lists authorized nutrition content claims for optional ingredients in Annex IV into the Hong Kong regulation.
For nutrients that are not included in such composed nutrient list or optional ingredients, they should be allowed to state the amount of these nutrients / ingredients content in the product (i.e. Contains XXmg / 100g of Y nutrient or ingredient) which is aligned with the current regulation for general foods.

**EXEMPTION**

We agree with the proposal that FSMP products for infants and young children not be included in the scope of this regulation, because these formulas and foods are specifically formulated for the dietary management of disorders or diseases. Furthermore these FSMP products are to be consumed under medical supervision. It is important for healthcare professionals and care givers to have sufficient on pack and off pack information to reference to. In addition, scientific information including nutrient and health claims should be allowed when communicating with healthcare professionals.

In addition, communication to HCPs on product features and benefits should be allowed in the form of nutrition claims and health claims for both IF and FUF in HCP designed materials.

**GRACE PERIOD**

We are committed to ensuring all our products comply with the applicable regulations. For an effective and implementable transition, we would like to suggest a grace period of 24 months upon the availability of the claim positive list. This would allow manufacturers to conduct assessment of their current labels and make plans to implement the necessary changes accordingly and be compliant. For manufacturers, these changes include, among others, possible product reformulation and quality testing, label revision, printing of new packaging materials, production, commercialization and phasing out of old products in market.

The CFS may also consider international experience as reference in implementation. As an example, when the claim regulation was implemented in the European Union, specific conditions were provided to food business operators with respect to a transition or grace period. The conditions for the grace period were associated with claims previously used or authorized by Member States and submission of a specific claim dossier for these claims. *(Please refer to Article 28 of Regulation (EC) No 1924/2006 of The European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1924-20141213&from=EN for specific details)*

Mead Johnson Nutrition
NOURISHING THE BEST START IN LIFE

**CONCLUSION**

We overall support the CFS in regulating the claims on formula and foods for infants and young children (0-36 months). We would respectfully ask the CFS to consider our position and continue to work with the industry on the technical aspects of the regulation in order to reach the common goal of protecting the health of infants and young children in Hong Kong.

Thank you for your kind attention. Should you need further information, please do not hesitate to contact us.

Yours sincerely,

Amy Chu
Regulatory Affairs Manager
Mead Johnson Nutrition (Hong Kong) Limited