



Submission by Wyeth Nutrition Hong Kong

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WNHK_Submission on Proposed Regulatory Framework on Claims (Final).pdf

Dear Sir/ Madam,

In response to the public consultation on the "Proposed Regulatory Framework for 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", I would like to make a submission as attached on behalf of Wyeth Nutrition Hong Kong. The hard copy of the submission will also be posted to the Centre for Food Safety (Centre) in the meanwhile.

We hope that our views will be taken into positive consideration by the Centre and we welcome any opportunity to work with the Centre to develop a suitable regulatory framework that promotes the best interest of consumers, the trade and the whole society.

Should you have any question, please do not hesitate to contact us. Thank you for your attention!

Regards,

Veronica Sze

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Centre for Food Safety
(Attn: Risk Assessment Section)
Food and Environmental Hygiene Department
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SUBMISSIONS IN RESPONSE TO PUBLIC 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”

Wyeth (Hong Kong) Holding Company Limited (Wyeth Nutrition) supports breastfeeding and we recognize that breast milk is the best for babies. For parents who cannot breastfeed, Wyeth Nutrition feels obliged to provide suitable nutritional support for their children’s future healthy outcomes.

In response to 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 36 Months in Hong Kong (Proposed Regulatory Framework) released on 6 January 2015, we would like to put forward our views in this submission for the Centre for Food Safety (CFS)’s consideration.

1. General Principle

Wyeth Nutrition appreciates the Government’s efforts in protecting the health of infants and young children in Hong Kong. We are in support of the objectives of the captioned Proposed Regulatory Framework which aims to facilitate an effective regulatory control on the nutrition and health claims on formula products and prepackaged foods for infants and young children under the age of 36 months (IYC Food). It is believed that the Government’s proposal to put forward a mandatory regulation that is enforceable can help to ensure the compliance by all industry players and ensure a consistency within the market.

In principle, we firmly believe that the ultimate regulatory framework should be science-based, transparent and efficient as these fundamental principle pillars play an essential role in safeguarding the best interest of consumers as well as encouraging the industry to participate in the market with ongoing research and development in nutrition.

2. Support the Overarching Principles

In general, Wyeth Nutrition supports the overarching principles in the proposed regulatory framework. However, to ensure the Government’s effective regulation and enforcement, as well as the industry’s compliance, we recommend that lucid and concrete definitions and examples of key terms such as the definition of “disease” in Principle 2, shall be made correspondingly in the final regulatory framework.

Particularly, for the definition and scope of claims to be covered, we recommend the Government to adopt a consistent scope with that in other current regulations in Hong Kong. According to the Technical Guidance Notes on Nutrition Labelling and Nutrition Claims of The Food and Drugs (Composition and Labelling) Regulations (Cap. 132W), quantitative declaration of a nutrient is not considered as a nutrition claim under the condition that the declaration is expressed in actual amount (e.g. 650 mg omega-3 per serving); while content expressions is also permitted on the label (e.g. 3g total fat per 100g or 30% Calcium NRV per 100 g).

Though we are basically supportive to the overarching principles, a flexible approach is recommended in developing the final regulatory framework. Regarding Principle 1 on nutrition claims in infant formula, we would suggest the Government to consider providing exemptions to the following claims with reference to international practices and current Hong Kong regulations:

	Authorities	Regulations / Standards	Regulatory Situation
1	European Union (EU)	Annex IV of Directive 2006/141/EC	<ul style="list-style-type: none"> Certain nutrition claims related to “lactose only”, “lactose free”, addition of optional ingredients like taurine, fructo-oligosaccharides (FOS) and galacto-oligosaccharides (GOS), and nucleotides are permitted.
2	China	GB 13432-2013 National Food Safety Standard Food Labeling of Prepackaged Foods for Special Dietary Use	<ul style="list-style-type: none"> Content claims for non-essential nutrients are allowed when the minimum limit of those nutrients was fulfilled, e.g. <ul style="list-style-type: none"> DHA: $\geq 0.2\%$ total fatty acid Taurine: $\geq 0.8\text{mg}/100\text{kJ}$ GOS/FOS: $\geq 3\text{g}/100\text{g}$ (solid or powder); $\geq 1.5\text{g}/100\text{ml}$ (liquid); or $\geq 1.5\text{g}/420\text{kJ}$ Lutein: $\geq 30\ \mu\text{g}/100\text{g}$ Nucleotides: $\geq 2\text{mg}/100\text{g}$ Probiotics: $\geq 10^6\text{cfu}/\text{g}$ Choline: $\geq 7.1\text{mg}/100\text{kcal}$ Inositol: $\geq 4.2\text{mg}/100\text{kcal}$ l-carnitine: $\geq 1.3\text{mg}/100\text{kcal}$
3	Australia and New Zealand	Standard 2.9.1 - Infant Formula Products	<ul style="list-style-type: none"> Infant formula products are allowed to make nutrient content claim on the lactose level such as “lactose free” or “low lactose”.

Furthermore, as stated in CODEX Standard 72-1981, “Sucrose, unless needed, and the addition of fructose as an ingredient should be avoided in infant formula, because of potential life-threatening symptoms in young infants with unrecognized hereditary fructose intolerance.” We thus suggest that the nutrition claims of “sucrose free” should be allowed, though this is not a mandatory requirement under the Food and Drugs (Composition and Labelling) (Amendment) (No.2) Regulation 2014 (Cap.132W).

3. Adopt an Inclusive Approach to Facilitate Informed Choice

As acknowledged by the Government, factually accurate claims can provide consumers with useful information for selecting suitable products. Under the supervision of the overarching principles, it is convinced that the claims approved to be made under the regulatory framework will be sound and trustworthy. To facilitate parents' informed choices and with the above understanding, Wyeth Nutrition is in support of an inclusive approach which allows the industry to communicate evidence-based nutrition information with parents in need.

In the meanwhile, given follow-up formula and IYC foods are of similar nature that are consumed as complementary foods by young children, same standards for permitting claims that meet with specific conditions should be applied to the two categories.

Some international practices of adopting an inclusive approach consistently for formula products and IYC foods are listed below for the CFS's reference.

	Authorities	Regulations / Standards	Regulatory Situation
1	EU	Regulation (EC) No 1924/2006 on nutrition and health claims made on foods	<ul style="list-style-type: none"> Selected nutrition claims listed in the Annex, such as the source of fibre and the source of protein, are allowed for both follow-up formula and IYC foods, provided the fulfillment of criteria for making such claims. Health (function) claims are allowed for both follow-up formula and IYC foods (Articles 13 and 14 that taken into account European Food Safety Authority (EFSA)'s Scientific Opinion on the composition of these products). Nutrients related to these allowed claims include alpha-linolenic acid, iron, iodide, magnesium, vitamins A, B1, B2, B5, C, D, zinc, selenium and DHA.
2	China	GB 13432-2013 National Food Safety Standard Food Labeling of Prepackaged Foods for Special Dietary Use	<ul style="list-style-type: none"> Nutrient function claims on fibre for infant formula are permitted. Nutrition and function claims for both follow-up formula and IYC foods are allowed. For follow up formulas for 6-36 months, function claims for energy, protein, fat, DHA (6-12 months only), vitamins A, D, E, B2, B6, B12, C, Niacin, Folic Acid, Pantothenic Acid, Calcium, Magnesium, Iron, Zinc , Iodine and fibre are allowed.

3	Singapore	<p>A Handbook on Nutrition Labelling” by Singapore’s Health Promotion Board (HPB);</p> <p>Regulations 251 to 254 of the Food Regulations;</p> <p>A Guide to Food Labelling and Advertisement by the Agri-Food & Veterinary Authority (AVA)</p>	<ul style="list-style-type: none"> • Nutrient function claims and other function claims for infant formula, foods for infant and young children are permitted for the followings: <ul style="list-style-type: none"> ○ Choline helps support overall mental functioning ○ Docosahexaenoic acid (DHA) and arachidonic acid (ARA) are important building blocks for development of the brain and eyes in infant ○ Nucleotides are essential to normal cell function and replication, which are important for the overall growth and development of infant ○ Taurine helps to support overall mental and physical development ○ Zinc helps in physical development ○ Prebiotic blend (Galacto-oligosaccharides and long chain Fructo-oligosaccharide), zinc, and iron support the child’s natural defences ○ Nucleotides support body’s natural defences
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The inclusive approach would encourage the industry to continue ongoing investment in research and development in hopes of bringing consumers more innovative scientific-based products. On the contrary, a restrictive or over-constrictive approach fully denies the positive function that accurate claims plays and inevitably ignores the needs to make informed choices of those parents who have to use formula products and IYC foods to support their children’s nutritional needs. Without adequate information as provided by claims, consumers may be left single-handed to select suitable products and thus may pick less nutritious alternatives finally.

4. Establish a Positive List of Approved Health Claims with Simple Mechanism

We support the Government’s proposal on establishing a list of approved health claims by taking reference to the current practices in overseas jurisdictions, with clear guidance and a simple and short processing time mechanism.

Taking reference to international practices such as the health claims approval mechanism in Australia and New Zealand (Standard 1.2.7 - Nutrition, Health and Related Claims by Food Standards Australia New Zealand (FSANZ)), we recommend the Government to develop a list of pre-approved health claims in advance to the legislation of the regulatory framework. This could be done by considering those health claims already approved in other overseas jurisdictions such as EU, US, China, Canada, Australia and New Zealand, Singapore or Malaysia and other international bodies such as EFSA, without any application needed from the Trade. Traders will be able to make these health claims if they are included in the list of pre-approved claims and the conditions specified are fulfilled.

For health claims that have not yet been included in the pre-approved list and are wished to be made by the Trade, we suggest that the Government could take reference to the mechanism applied by FSANZ of Australia/New Zealand to develop an efficient mechanism for the submission of health claims for approval by the Trade and the assessment of claims by the Government. Under FSANZ's mechanism, those claims which were not in the pre-approved list are allowed to be made based on the self-substantiation of a food-health relationship. Traders have to notify FSANZ before making a health claim based on a self-substantiated food-health relationship, which is established in accordance with detailed requirements of systematic review process set out in Standard 1.2.7 and the published "Guidance on establishing food-health relationships for general level health claims".

We support that health claims submitted for approval shall be scientifically substantiated and introduced with clear and consistent principles and requirement. The level of science outlined in the Annex of Codex Guidelines for Use of Nutrition and Health Claims CAC/GL 23-1997 can serve as a good reference, such as:

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

For the assessment of such claims, we recommend the Government to establish an expert committee to provide scientific and technical advices to the CFS in relation to the requirements and approval of such claims.

5. Maintain the Openness of the List of Approved Health Claims

Keeping abreast of the latest development in the science arena, the list of approved health claims shall remain open, i.e. a transparent review over the list on a regular basis, such as annually, shall be conducted to revisit the validity of current approved claims and to consider the needs of enriching the list when new scientific evidence emerges. Similar to assessing health claims that have not yet included in the pre-approved list, we suggest the Government could consider establishing an expert committee to provide recommendations to CFS in relation to any health claim revision.

During the ongoing review, a multi-party dialogue including the regulators, experts, the Trade and/or consumers are strongly encouraged so as to ensure that compelling decisions can be made upon fruitful communications among all relevant stakeholders.

6. Allow Alternative Content Conditions for Nutrition and Health Claims

Regarding specific content conditions for nutrition and health claims, as the Government has also acknowledged the fact that a set of local Nutrient Reference Values (NRVs) for 0-36 months is not available at this moment, the CFS is considering to develop a set of local NRVs. This added with the fact that there is no widely adopted NRV list internationally. We thus would like to recommend CFS to consider adopting alternative conditions for making nutrition and health claims.

We would like to suggest using compositional requirements 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, for follow up formula and IYC Food, when the content of energy or nutrients in the product complies with the minimum limits or permissible fortified minimal values of the corresponding product standard, content claim can be made. For such minimum values is not available, basis for the content claim for the interest nutrients in other country and/or international organization should be provided. To apply the mechanism to Hong Kong, we recommend the CFS to consider adopting the compositional requirements of nutrients under the amended Cap. 132W as the criteria for nutrition claims for infant formula, and nutrients that meet the minimum composition requirements in the relevant Codex standards or corresponding requirements in other countries for nutrition claims for follow-up formula and IYC foods.

The CFS may also take reference 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) when the products comply with the requirements of the Food Regulations and the nutrient claims guidelines in "A Handbook on Nutrition Labelling" by Singapore's Health Promotion Board (HPB). Health claims are allowed for infant and follow-up formula and IYC food as laid down in the Guide to Food labelling and Advertisement by the Agri-Food & Veterinary Authority (AVA) when the particular nutrients mentioned is present in an amount meets the requirement of the Food Regulations, with a few specific content conditions for some nutrients, such as nucleotides and prebiotic blend in infant food and foods for children (up to 6 years of age), to be met.

In case the CFS would like to keep adopting NRVs as the condition for making nutrition and health claims, we suggest that the CFS could take reference to the Reference Values for Nutrition Labelling for Foods Intended for Infants and Young as specified in the Annex VII of the EU Directive 2006/141/EC, which is used for follow-on formula that in addition to numerical information, information on vitamins and minerals included in Annex VII can be expressed as a percentage of the reference values given therein, per 100ml of the product ready for use.

In addition, as it is noted that all the health claims allowed in overseas jurisdictions are for the nutrient or food constituent, but not for a specific food product, we suggest the CFS to apply the same principle when setting the conditions for nutrient and health claims.

7. Offer Exemption on FSMP

Currently, under the Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014, formula for special medical purposes (FSMP) for infants and young children, which are used under medical supervision and for special dietary management of a disease, disorder or medical condition, is required to be marked or labelled as such and are exempted from nutritional composition and labelling requirement. We therefore suggest the same exemption be made for FSMP in the final regulatory framework for nutrition and health claims.

8. Provide Sufficient Grace Period for Compliance

In response to the new requirements under the regulatory framework, it is foreseen that a series of actions such as label development is needed to be performed by the manufacturers. Wyeth Nutrition is committed to ensure our products' compliance with local regulatory requirements. Given complex labeling and stock procedures will be involved, a reasonable and sufficient grace period, such as two years on top of the time required for the actual approval process, is strongly recommended to ensure a full compliance of regulation by all products in the market, especially if the effectiveness of the upcoming regulation will be started on the date when it is published in the Gazette.

In addition, the Government's early release of some agreed principles or guidelines like the specific conditions for making claims will be helpful to facilitate the Trade's compliance.

9. Conclusion

To conclude, Wyeth Nutrition appreciates the Government's initiatives to protect the health of infants and young children in Hong Kong and supports the development of the captioned regulatory framework. We support the overarching principles and an inclusive approach in regulating the nutrition and health claims of formula products and IYC foods in Hong Kong. We will be grateful if the above views and recommendations will be taken into positive consideration by the Government. We look forward to maintaining a continuous communication with the Government and we welcome any opportunity to work with CFS in developing a suitable and well-balanced legislation for the benefits of infants and children in Hong Kong

Wyeth (Hong Kong) Holding Company Limited

16 April 2015

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References:

1. 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. The European Union
2. Commission Directive 2006/141/EC of 22 December 2006 on infant formula and follow-on formula and amending Directive 1999/21/EC. The European Union
3. GB 13432-2013 National Food Safety Standard Food Labeling of Prepackaged Foods for Special Dietary Supplies. The Ministry of Health of the People's Republic of China
4. GB 10765-2010 National Food Safety Standard Infant Formula. The Ministry of Health of the People's Republic of China
5. Standard 1.2.7 - Nutrition, Health and Related Claims. Food Standards Australia New Zealand
6. Standard 2.9.1 - Infant Formula Products. Food Standards Australia New Zealand
7. Guidance on establishing food-health relationships for general level health claims. Version 1.1 September 2013. Food Standards Australia New Zealand
8. Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants Codex Standard 72-1981
9. Codex Guidelines for Use of Nutrition and Health Claims CAC/GL 23-1997
10. A Handbook on Nutrition Labelling. Health Promotion Board of Singapore
11. Regulations 251 to 254 of the Food Regulations. The Agri-Food & Veterinary Authority of Singapore
12. A Guide to Food labelling and Advertisement. The Agri-Food & Veterinary Authority of Singapore
13. Technical Guidance Notes on Nutrition Labelling and Nutrition Claims of The Food and Drugs (Composition and Labelling) Regulations Cap. 132W
14. Food and Drugs (Composition and Labelling) (Amendment) (No.2) Regulation 2014