Submission on Proposed Regulatory Framework on Nutrition and Health Claims - Fonterra HK Ltd

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Fonterra_HK Claims Submission.pdf

Dear Sir/Madam,

Enclosed please find the comment from Fonterra (Hong Kong) Ltd over the topic of Proposed Regulatory Framework on Nutrition and Health Claims on Infant formula. Should you have any queries relating to this submission, please feel free to contact me.

Thank you.

Regards,

Henry Cheng MSc
Regulatory & Nutrition Manager

Fonterra Brands (Hong Kong) Ltd.

Fonterra Brands (Hong Kong) Ltd

Submission on the Proposed Regulatory Framework on Nutrition and Health Claims on Infant Formula, Follow-up Formula, and Pre-packaged Foods for Infants and Young Children Under the Age of 36 Months in Hong Kong

15th April 2015

Company Overview

Fonterra is a farmer-owned dairy company based in New Zealand, and the world's second largest processor of milk, collecting more than 22 billion litres from five countries each year, with manufacturing sites in 10 countries. It has a long history in the manufacture of paediatric nutrition, with more than 50 years of experience in producing world class infant and toddler formulas for children all around the world. Fonterra produce formula and ingredients for large multinational and major regional paediatric companies and is one of the world's largest contract manufacturers of paediatric nutrition formula and ingredients.

Fonterra is a co-operative, owned and led by 10,500 New Zealand farmers and supported by more than 20,000 staff in 140 countries across Australasia, Asia, Africa, the Middle East and Latin America. Fonterra produces more than two million tonnes of dairy ingredients, specialty ingredients, foodservice products and consumer products every year.

As a market leader, Fonterra owns six global brands, including Anchor™, Anlene™ and Anmum™, and supplies dairy products to many of the world's largest consumer and foodservice brands.

Drawing on generations of dairy expertise, Fonterra is one of the largest investors in dairy-based research and innovation in the world.

General Comments

As a manufacturer and importer of infant formula from New Zealand, Fonterra strongly supports the protection of breastfeeding and recommendations from the WHO and Codex. We welcome the proposed regulatory framework to enhance the regulation of nutrition and health claims on formula products, post the introduction of the Food and Drug (Composition and Labeling) (Amendment) (No.2) Regulation last year.

1. - Fonterra supports the 5 overarching principles and inclusive approach

Of the regulatory options presented, Fonterra supports the inclusive approach, which allows health claims in infant formula, and both nutrition and health claims on follow-up formula, and believes this is an appropriate way to govern the use of claims for paediatric formula products. We support the inclusive approach for the following reasons:

1.1 Informed consumer decisions

Fonterra supports a regulatory framework that empowers mothers to make informed decisions on infant feeding, and believes the inclusive approach best recognizes the importance of adequate information to support such decisions. An appropriate claims framework will ensure infant and young children receive the best nutrition appropriate to their needs particularly when consumers choose not to seek the advice of a medical professional.

1.2 Encouraging Innovation and investment in research and development

The inclusive approach continues to encourage manufacturers to innovate and invest in research and development to consistently improve their products and offer greater benefit to infant health through allowing the display of validated claims on-pack[1]. This incentivizes manufacturers to continue to invest in research and development to support new beneficial ingredients for paediatric formula.

1.3 Similarity of approach with other well-regarded jurisdictions

This approach is comparable to a number of other jurisdictions which also recognizes the valid role of nutrition and health claims on paediatric products. For example, the EU, Mainland China, Malaysia and Singapore permit the use of claims on formula from 6 month old, and Australia and New Zealand (ANZ), under certain conditions, also allow health claims on products suitable for young children from 12 month old.

2. Regulatory Framework to approve the use of claims

2.1 Development of a Positive List of Claims through recognition of existing claim approvals granted in other markets

Fonterra supports the adoption of a positive list of pre-approved claims in both Chinese and English which outlines conditions required to make the claim. We suggest HK recognize claims that have already been approved from jurisdictions where robust scientific assessment of claims is in place and include these in a Schedule of the proposed HK Claim Standard. These, for example, could include existing claim approvals from Singapore, Malaysia, Mainland China, EU, US, ANZ[2] among others. Manufacturers could then use claims directly from the pre-approved list without going through additional government assessment. This reduces administrative burden. An appropriate mechanism would need to be put in place to update the positive list of claims, and recognition given that the list is not exhaustive e.g. if a recognized jurisdiction pre-approved a new claim, then this claim could automatically be considered pre-approved in Hong Kong.

[1] Fonterra estimates, for example, it can cost at least $15mil develop and commercialize a new probiotic ingredient with health benefit.

[2] The link to ANZ Claims can be found in Schedule 1-3 of Standard 1.2.7

2.2 Assessment Procedure for new claims not on pre-approved list

2.2.1 Statutory timelines for processing and review of new claims not on the pre-approved list could be outlined in the proposed Claims Regulation. For example, in ANZ under the new Nutrition, Health and Related Claims Standard 1.2.7, ten months is allowed for the Regulator to review and approve new claims, from date of submission (see Appendix 1).

2.2.2 Substantiation requirements the manufacturer must follow to submit an application for a new claim should be listed in the proposed Claims Standard. For example, a systematic review on the food health relationship that underpins the claim could be undertaken according to a set format.

Criteria for Systematic Review to Support Claim, adapted from ANZ Standard 1.2.7 Schedule 6	
(a)	A description of the food or property of food, the health effect and the proposed relationship between the food or property of food and the health effect.
(b)	A description of the search strategy used to capture the scientific evidence relevant to the proposed relationship between the food or property of food and the health effect, including the inclusion and exclusion criteria.
(c)	A final list of studies based on the inclusion and exclusion criteria.
(d)	A table with key information from each included study.
(e)	An assessment of the quality of each included study based on set consideration criteria
(f)	An assessment of the results of the studies as a group
(g)	A conclusion based on the results of the studies, including the amount of food required to achieve the health effect

2.2.2. A - Nutrient Reference Value's

NRVs are not always necessarily required to establish minimum conditions for content claims e.g. nutrients such as probiotics/ DHA do not have NRVs. For vitamins and minerals, claim conditions could be based on proportion of other countries RDI's could be used (e.g. USA, ANZ values) until such time as Codex or Hong Kong or China develop their own NRVs. With respect of health claims, it is the amount of nutrient in the product where benefit must be demonstrated and for which the claim is made, not necessarily the amount in relation to a %NRV.

2.2. 2. B - Additional Mechanism to allow self-substantiation for nutrient function health claims – experience from recently developed ANZ Claims review

In addition to a positive list of pre-approved claims, we suggest a mechanism to allow companies to **self-substantiate health claims** (specifically nutrient function health claims and not disease risk reduction health claims) provided strict substantiation requirements are met, as outlined in Section 2.2.2, including the undertaking of a systematic review of evidence related to the food-health relationship that underpins the claim. This reduces administrative burden, and still prevents the misuse of health claims as strict criteria must still be met, and the Regulator will still have oversight of the claims manufacturers make.

- The substantiation requirements would be comparable to the substantiation requirements for claims submitted for pre-approval.
- The regulator would be notified of the claim, and the systematic review available upon request.

- This innovative approach of self-substantiation has been undertaken in Australia and New Zealand for 'general level health claims' (those that are comparable to Hong Kong's nutrient function health claim). However self-substantiation is not an option for health claims that relate to disease risk reduction. This is outlined in the ANZ Food Standards Code, Standard 1.2.7 *Nutrition, Health and Related Claims,* paragraph 17 (4) (b) and substantiation requirements in Schedule 6[3].

2.2.3 Appropriate guidance materials should be available detailing how claims in particular health areas may be substantiated. Guidance documents as published by EFSA[4], ANZ[5] etc could be used as a reference for how to substantiate select claims.

2.2.4 Establishment of a health claims scientific advisory group/ expert panels. External panels with well-recognised expertise in the particular area of research should be invited to review claims. Such panels could leverage expertise of Universities and other well recognized researchers, both nationally and internationally.

3. Transition Period

We suggest both a claim assessment period and grace period are allowed after the new Hong Kong claims regulation being vetted by the Legislative Council and enacted. This then allows the establishment of an approved claim list, and manufacturers to comply and make labelling changes as required. We suggest in Hong Kong a six month period is allowed for claim assessment/ development of a positive list of claims, and then a two year minimum grace period is allowed for manufacturers to comply. We note in ANZ when the Nutrition, Health and Related Claim Standard 1.2.7 was recently updated, manufacturers were given a three year transition period following the Standards gazettal.

Summary

Fonterra is supportive of the proposed inclusive approach to nutrition and health claim regulation for paediatric products. We believe this is an appropriate claims framework that will enable consumer choice and continue to encourage innovation and investment in scientific research as well as ensure infant and young children receive the best nutrition appropriate to their needs. It is suggested claims that have already been approved by well-regarded regulatory jurisdictions should be adopted onto a positive list of pre-approved claims. We recommend a supporting mechanism for new claim review and approval is developed and clear guidance outlined on substantiation requirements of claims. Additionally we suggest an option of self-substantiation of new nutrient function health claims, with the same substantiation requirements of claims that require Regulator pre-approval. An adequate transition period should be allowed for manufacturers to comply with any new rules. Fonterra welcomes the opportunity to work with the government through ongoing dialogue and create an environment that protects & promotes breastfeeding and healthy diets in infants and young children in Hong Kong.

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[3] Standard 1.2.7. Nutrition, Health and Related Claims. http://www.comlaw.gov.au/Details/F2014C01191

[4] http://www.efsa.europa.eu/en/nda/ndaguidelines.htm

[5] http://www.foodstandards.govt.nz/publications/Pages/Guidance-on-establishing-food-health-relationships-for-general-level-health-claims.aspx

If there are any queries relating to this submission, please contact:

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Yours faithfully,

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