



Submission by FCHK, in response to public consultation of proposed regulatory framework on nutrition and health claims on IF, FF, and prepacked foods for IYC under the age of 36 months in HK

frieslandcampina.com to: claims_consultation@fehd.gov.hk 17/4/2015 12:09

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Submission by FrieslandCampina (HK) Ltd_Final.pdf

Attn: Centre for Food Safety,
From: FrieslandCampina Hong Kong

Dear Sir,

On behalf of FrieslandCampina, I would like to express our word of thanks to the Centre for Food Safety (CFS) for the continuous communication with the industry for the discussion of the proposed regulatory framework of nutrition and health claims on formula products and prepackaged foods for infants and young children aged under 36 months in Hong Kong. Enclosed please find the submission from our end for your consideration.

We appreciate continuous and transparent communication that is taking place between the Government and the industry at all stages of the legislation development and review process up to the point of the final submission of the legislation for Legislation Council approval. As a responsible member of the industry, please be assured that we will cooperate with the CFS to provide constructive input with the aim of enabling smooth implementation when the legislation is put in force.

Should there be any questions, please feel free to contact myself (yyho@frieslandcampina.com) or Ms Doris Chan, our Regulatory Affairs Manager (yyho@frieslandcampina.com) for further discussion.

Yours faithfully,
Natalie

Natalie Yuen
Senior Manager, Public Affairs and Communicaitons

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FrieslandCampina (Hong Kong) Ltd.
菲仕蘭(香港)有限公司

Centre for Food Safety

(Re: 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)

Food and Environmental Hygiene Department
43/F, Queensway Government Offices,
66 Queensway, Hong Kong

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

**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**

FrieslandCampina commends and supports the efforts of the Hong Kong SAR Government to create a clear and transparent regulatory framework to govern nutrition and health claims on infant formula, follow-up formula and prepackaged foods for infants and young children under the age of 36 months marketed in Hong Kong by companies in our industry. The purpose of this submission is to both endorse the positions, comments and inputs submitted by the Hong Kong Infant and Young Child Nutrition Association (named as "HKIYCNA" below), and to provide additional perspective on the proposed framework based on our experience operating in more than 30 countries around the world.

FrieslandCampina has had a presence in Hong Kong for more than 77 years and we are proud to be a responsible member of the Hong Kong business community. As a global company that places regulatory compliance as a top priority, we believe that it is important for the Government to align local legislation with international practices and standards and, as such, we are able to share our experience complying with relevant regulations in the European Union (EU) and other relevant jurisdictions.

As we indicated in our submissions to the Working Group on the Regulation of Nutrition and Health Claims on Formula Products and Food for Infants and Young Children in Hong Kong of the Centre For Food Safety and to the Legislative Council in July 2014 and February 2015 respectively, we believe that the legislation is an issue that centers on determining the best approach to protect the interests of consumers, while also preserving the right of consumer and care-giver to access to factual and scientifically substantiated information that consumers require to make informed product-purchasing decisions for their families and babies.



After reviewing the Consultation Document, the following are our response to the proposed framework. These comments are based on four key areas of focus – legislation approach, approval mechanism, technical advice, and implementation timeline and grace period.

Legislation Approach

- a) FrieslandCampina (We) endorses regulation through legislation – as long as the application of that legislation ensures higher consumer protection, ensures a level playing field for all companies in our industry in Hong Kong and eliminates any possibility of confusion in the market if the regulations are to be applied on a voluntary basis;
- b) We also believe that regulation must recognize the rights of responsible companies to carry out their business activities in Hong Kong in a manner that is consistent with Hong Kong's commitment to respect global practices and free-market principles. As such, it is paramount that the local regulation aligns with international practices;
- c) In this regard, we encourage the Government to maintain a continuous and transparent dialogue with industry throughout the legislation process, and to consider inputs from the industry on pending topics including approval mechanisms, technical aspects as well as legislation enforcement, in order to ensure smooth implementation when the legislation takes effect;
- d) We believe an inclusive approach to product claims is the best means of providing consumer access to information, and ensuring that parents have access to accurate, factual, and scientifically substantiated nutrition information that they require when considering the purchase of products covered by the regulations;
- e) To ensure a level playing field as articulated in (a) above, we strongly advocate that all imported products, including unofficially imported ones, regardless of their importation channels, should be covered by the regulations. To this end, an effective enforcement mechanism is essential to determining the party responsible for the importation and sale of any non-complying products;

Approval Mechanism

- f) Given that all infant formula, follow-up formula, and pre-packaged foods for infants and young children under the age of 36 months are supplied to Hong Kong through importation, we encourage the Government to adopt a mechanism that is simple to operate and comply with, and is aligned with international product claim review practices;



- g) In this regard, we propose including the following as key features of the approval mechanism:

(i) A bilingual pre-approved list of claims (pre-approved list) for local use:

This is a common practice among the most widely used product claim regulatory systems in the world, this is a common practice among the European Food Safety Authority (EFSA) of the EU, the US Food and Drug Administration (FDA), the Food Standards Australia New Zealand (FSANZ), the Agri-Food & Veterinary Authority of Singapore (AVA) and the National Health and Family Planning Commission of the People's Republic of China (NHFPC). All these regulatory bodies set their own approval systems by launching a pre-approved list of claims, and making reference to their own approval conditions which are primarily claims conditions, and/or claims conditions that leveraging nutrition reference values (NRVs) (such as FSANZ);

We therefore strongly encourage the Government to take reference from these international regulatory authorities, including to consider and accept approved claims by these authorities, and set up a pre-approved list of claims in English and Chinese for the industry to follow and adopt;

We stress the importance of clear communication with the industry on the source of claims on the pre-approved list including the relevant regulatory authorities for approvals and the corresponding condition for making each claim on the list. This will allow the industry to conduct self-monitoring;

The adoption of a pre-approved list would eliminate the approvals process required, and also administrative burden on the Government;

Given there will be a continuous update of claims, we strongly advocate for the government to maintain the pre-approved list as a working file, where the list is regularly updated in line with scientific developments;

(ii) An approval mechanism for claims that are not on the pre-approved list:

For claims that are not included on the pre-approved list, and those that are not approved by any other designated jurisdiction, and/or those approved by some jurisdictions but concurrently rejected by others, we suggest that the government set up an approval mechanism where claim proposals can be submitted, with the latest scientific substantiation and/or data and facts from the last objection, for the government's consideration;

(iii) Openness to new claims resulting from scientific advancements:

Scientific advancement may support new claims that are not yet covered by the pre-approved list of claims, and/or not approved by other regulatory authorities. We believe it is important for the Government to address and recognize scientific advancements and accept new claim proposals that are based on the latest scientific substantiations;

- h) For features (ii) and (iii) above, we recommend that the Government outlines clear approval procedures, the required scientific substantiation and supporting documentation, timeline, and related costs etc. in order to ensure smooth operation of the approval process. The Government should also maintain transparency by publishing the claims that are pending approval in order to provide clarity to the industry;
- i) For all of the above proposed features, we recognize the importance of setting up an independent expert panel to conduct neutral and professional claim reviews based on scientific and fact-based considerations;
- j) We also proposed that the legislation offers an appeal process for rejected claim proposals, and that clarity regarding the procedures and the timeline for the appeal process be clearly set out;
- k) From an administrative standpoint, we believe it is impractical and unnecessary to provide reports and declarations of approvals or rejections of claim proposals in other jurisdictions;

Technical Advice

- l) We understand from clause 4.12 and 4.14 of the Consultation Document that the Government suggests making reference to the Nutrition Labelling Scheme for general prepackaged foods, and to the Dietary Reference Intakes (DRIs) or NRVs for the respective claims for the designated age group of 0-36 months, as a prerequisite for approval of all nutrient content claims, nutrient comparative claims and nutrient function claims. However, the challenge with this recommendation is that the DRIs or NRVs for the designated age group of 0-36 months do not exist;
- m) It is important to note that in the EU and other relevant jurisdictions, such as FSANZ, AVA and NHFPC, the regulatory authorities usually set up claim conditions to regulate the use of claims in their own jurisdictions. We suggest that the Hong Kong Government reference international practices and develop a set of NRV / DRI / claim conditions that are appropriate for the Hong Kong market;



- n) The Government should clearly outline the development timeline, and enforce the new legislation only when the local claim conditions for the age group of 0-36 months and the pre-approved list of claims are available. In the interim, the Government should continue the current practice of accepting claims that are scientifically substantiated;
- o) We also strongly encourage the Government to ensure that the industry had the opportunity to express its views on the development of the relevant technical guidelines for the new regulatory framework and that the technical guidelines be made available either before or on the day the legislation is published;

Implementation Timeline and Grace Period

- p) We agree with the proposal to include this new regulatory framework as subsidiary legislation to the current Cap 132W legislation;
- q) Based on our industry experience in compliance with product labelling legislation, we can foresee that a process based on negative vetting may result in a shortened grace period for implementation and compliance considering that there may be potential challenges related to the time required for official reviews and discussion in the Legislative Council and delays in the launch of finalized technical guidelines. We also understand that the treatment of every single subsidiary legislation might be different. To this end, we request that this new regulatory framework adopts a positive vetting approach;
- r) We propose a two-tiered implementation of the regulations:
The First Tier implementation should commence when the legislation details, the bilingual pre-approved list of claims and the corresponding claim conditions for Hong Kong and the technical guideline have been finalized and published, with a grace period for industry compliance of at least 24 month to allow sufficient time for implementation by the industry;

The Second Tier implementation refers to those claim approval applications under features (ii) and (iii) above that are not covered by the pre-approved list of claims where approval process is necessary. From a practical and administrative standpoint, we suggest that the Government set a clear time-frame, procedures and requirements for the relevant approval process that followed by a grace period be granted for industry implementation of at least 24 months from the date the approval result is released;
- s) Based on international practices, we note that the grace period for claims legislation can extend up to 3 years (e.g. FSANZ). In the case of Hong Kong, we believe that a grace period



of 24 months for implementation purpose by the industry is a reasonable timeline for the industry on recipe review and reformulation, revise labeling artwork design and production, address changes in pre-export inspection procedures by government authorities in the manufacturing country, ship products, and carry out the necessary phase-in and phase-out procedures at the retail levels;

- t) We believe the industry's current action of product re-labeling in response to the recent legislation for formula products and foods for IYC on composition and labeling should be considered, which might create confusion for the public and possible stock scarcity if the implementations if the two legislations are closely scheduled;
- u) Supply stability reassurance at the retail level is important. This is the reason we suggest the Government to consider the requirement of supply stability and common accessibility of milk formula products supply to the Hospital Authority Tender under Clause 4.1 (i). There are total nine key products supply to the Tender since 2015 April that represents over 90% of total market share. To this end, we suggest to give priority to products supply to the Tender in the assessment process in order to protect the interest of consumer and babies.

FrieslandCampina is committed to manufacturing and selling high-quality products in a manner that is responsible and in compliance with local regulations and codes. This commitment is demonstrated by the sophisticated processes applied to the manufacture of our products and the stringent standards we apply to all aspects of our operations.

We thank the Government and the Panel for providing us with an opportunity to provide our perspective on the Consultation Document. We support any regulation that ensures uniform practices by the industry as well as preserves the interests of consumer to access factual and scientifically substantiated information. We appreciate the continuous and transparent communication that is taking place between the Government and the industry at all stages of the legislation development and review process up to the point of the final submission of the legislation for Legislation Council approval. As a responsible member of the industry, please be assured that we will cooperate with the Government and the panel to provide constructive input to the Centre for Food Safety for the formulation of the approval mechanisms and technical guidelines with the aim of enabling smooth implementation when the legislation is put in force.

FrieslandCampina (Hong Kong) Limited
April 17, 2015