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GAIN Report

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Proposed Regulations on Claims on Formula Products

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Agriculture in the News

Dairy and Products

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Sanitary/Phytosanitary/Food Safety

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Report Highlights:

Pursuant to WTO notification, the Hong Kong government has proposed legislation to further regulate nutrition and health claims on products for children under 36 months, such as infant and toddler formulas and prepackaged foods. Under consideration are regulations that grant government additional control over the utilization of nutrition and health claims on products intended for the very young.

Background

In recent years, the Hong Kong government (HKG) has signaled its intent to bring more regulatory structure to products that have a potential health and nutritional impact on young children. In 2014, Hong Kong passed legislation regulating nutritional composition and labelling of formula and food for children under the age of 36 months that will be effective in 2016. (See [Gain report HK1424](#).)

In January 2015, pursuant to WTO notification G/TBT/NHKG/47, the Hong Kong government invited comments on new regulations to govern nutrition and health claims on infant and follow-up formula and pre-packaged foods for children under 36 months. The regulation would control use of such claims in both packaging and advertising. The objectives stated for the additional regulations are increased protection of the health of infants and young children and to facilitate effective regulatory control over nutrition and health claims for products intended for the very young. In addition, sources relate Hong Kong health officials are targeting the control of nutrition/health claims on products that caregivers could provide as substitutes for breastfeeding, an activity that the government promotes for nutritional care of young children.

The Proposed Framework

According to the consultation paper, the proposed regulation of nutrition and health claims would include claims for nutrient content, nutrient comparison, nutrient function, disease risk reduction and other functional claims.

The proposed framework is summarized in the table below. Items marked with an “Ö” or “x” have already been determined as allowed or prohibited; those with a “?” are subject to discussion under the proposed regulation.

	Nutrient Content Claims (e.g. contains choline 144mg/100gm)	Nutrient Comparison Claims (e.g. increased DHA level by 3 times)	Nutrient Function Claims (e.g. PHD are essential for the function of brain cells)	Other Function Claims (e.g. probiotics helps to maintain a healthy digestive system”	Disease Claims (e.g. fortified with an appropriate level of iron to reduce the risk of anaemia”
Infant Formula	x	x	?	?	x
Follow-up Formula	?	?	?	?	x
Pre-packaged food for	√	√	√	?	x

children under 36 months of age					
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Notes: “√” stands for allowed; “x” stands for prohibited; “?” stands for subject to open discussion

- Nutrients or constituents permitted to be the subjects of claims should be important for infants and young children.
- Nutrient claims should meet specific content conditions; and
- Health claims should be scientifically substantiated and have undergone credible evaluation process.

The HKG will provide a mechanism whereby traders must first apply, very likely on a cost recovery basis, for approval to use a nutrition/health claim on a food product for young children. The approval process will include an assessment mechanism whereby those claims with previous approvals by a foreign food safety authority would receive “fast track” consideration, provided the applicant supplies relevant supporting documents. No application which has been rejected by a foreign food authority will be accepted by Hong Kong authorities. Applications for claims without prior foreign approval are expected to encounter a lengthy HKG approval consideration.

Hong Kong will establish a list of nutrition/health claims which have been approved and will be available for common use provided sellers can comply with conditions established for use with the claim.

Exemption

Formulas for special medical purposes will be exempt from these provisions given they are generally provided under medical supervision.

Grace Period

The HKG will provide a transition period prior to implementation of any new regulation but the duration has not been announced. Applications for nutrition/health claim consideration would be accepted during the grace period with priority given to claims already in use on products prevailing in the market.

Public Views

In general, breastfeeding groups and the infant formula industry expressed support for the initiative to regulate nutrition and health claims on formula and food for young children. The breastfeeding groups favor stronger regulation of claims to avoid confusion about whether formula is better than breast milk. Industry advocates flexibility in urging the government to allow claims that are currently open for discussion as providing more information to consumers to determine the appropriate choice for their children. In addition, the industry supports mandatory regulation versus voluntary guidelines to ensure an equal marketing platform for all entrants.

The industry also expressed concern over the setting of conditions for making nutrient claims. In the consultation paper, the HKG stated that these claims have to be made with reference to Nutrient Reference Values (NRVs), which are used to compare nutrient contents among different food products. However, the industry questioned the practicality of this approach because there are no domestic, regional or internationally adopted NRVs, such as Codex, for infants and young children.

Comments

The public comment period closed April 17, 2015 but specific concerns could still be directed to our office at ATOHongKong@fas.usda.gov.