The Hong Kong Government (HKG) has set up a working group on the regulation of nutrition and health claims on formula and food for infants and young children under the age of 36 months. Industry representatives are invited to this working group and asked to provide current health claims on these products circulating in the market, with particular information on the approving authorities and scientific justification with respect to the approved claims. It assures the trade that the information provided would not be used for existing labeling enforcement purposes. The working group is set up with a view to evaluating whether there is a need and how to further regulate claims on formula products and food for babies and young children. U.S. Industry interested to submit claims approved for use in the U.S. to the Hong Kong Food Safety Center may provide information via ATO Hong Kong office.
General Information:

Currently, there is no specific regulation on health claims on all foods. For formulas and foods catered for young children under 36 months of age, there are no specific regulations both for health claims and nutrition claims.

More than 80 percent of prepackaged food in Hong Kong is imported from all over the world. There exists a variety of nutrition and health claims on foods and advertisements. Claims are generally subject to regulation under Section 61- False Labeling and Advertisement of Food or Drugs of Chapter 132 Public Health and Municipal Services Ordinance and the Trade Description Ordinance. However, there are no claims conditions specified in these Ordinances and the successful prosecution on false claims poses a challenge to the government.

Hong Kong’s nutritional labeling regulation which became effective in 2010 does provide regulation on nutrition claims with specifics listed on the nutritional labeling regulation. However, Hong Kong’s nutritional labeling regulation does not cover formulas and foods for children under 36 months and other foods for special dietary uses.

Realizing the need to step up regulation on formulas and foods for children under 36 months of age, the Hong Kong government (HKG) had already completed consultations on its legislative proposal and is planning to introduce the regulation to Legislative Council for discussion this year. While the proposed regulation will cover the nutritional composition and nutritional labeling of the products in question, it will not include any provisions governing nutrition and health claims. The HKG explained that they wanted to introduce mandatory regulation on the nutrition and labeling of formulas and food products as early as possible and the inclusion of regulations on claims will inevitably delay the legislation process given the complexity of the claims issue.

Moreover, the future Hong Kong Code of Marketing and Quality of Formula Milk and Related Products, and Food Products for Infants & Young Children will consist of some provisions on claims, but will be voluntary in nature. The HKG has not yet had a set time frame for introducing the Code. The proposed voluntary guidelines on claims are as follows:

Infant formula
- No claim is allowed

Follow-up formula
- Nutrition claim is not allowed
- Health claim is allowed

Infant and young children foods
- Nutrition claim on 4 groups of nutrients (sugars, sodium, vitamins and minerals) is allowed
- Health claim is allowed
A Survey on Claims:

According to a survey conducted by the Hong Kong Center and Food Safety Center in 2012 covering more than 100 popular prepackaged food samples intended for infants and young children under the age of 36 months, 28 percent of the samples were found to bear one or more nutrition or health claim. The government document commented that some of the claims are related to the function of nutrients or food components, such as vitamin E and immunity, choline and eye development, probiotic and immunity as well as probiotic and allergy that do not have adequate internationally recognized evidence of scientific substantiation.

Regulatory Control Review:

In view of the void in the existing regulatory regime over health claims and nutrition claims on formulas and foods for children under 36 months of age and the prevalence of claims on food products, the HKG has set up a working group to explore the possible strategies on enhancing regulatory control. Through the working group, the HKG invited the trade to provide information on nutrition claims and health claims which are currently in use on these products. Between November 2013 and January 2014, the government received a total of 147 claims, each may be related to more than one substance and/or health effects.

According to the claims submitted by the trade, individual traders had already made nutrition claims on vitamins, minerals and some other nutrients. Popular health claims make reference to DHA, ARA, prebiotics, vitamins and minerals. The HKG mostly wanted the trade to tell them whether these claims have been approved by other government authorities and the scientific justification for the approval. Such information, however, is rarely provided in the trade’s submission.

It is believed that the HKG is exploring possible mechanisms to impose regulatory control on claims for formulas and foods for children under the age of 36 months. One likelihood is that they will have a list of preapproved claims and will provide the trade with a mechanism to apply for claims approval in the future provided that the applicant provides scientific justification or/and overseas authorities’ judgment on these claims. However, the HKG maintained that they are prepared to hear comments from the industry so that any future policy will strike a balanced approach on public health protection and trade.

Recommended Action for the U.S. Industry:

While the HKG does not have a timetable for any legislative process, the direction is toward regulatory control in the future. The government will send officials to Europe this year to learn about their regulatory regime on nutrition and health claims.

It is advisable that the U.S. industry provide claims approved and allowed to be used on U.S. products to the HKG with scientific justification. The submission will allow the HKG to consider including U.S. claims on its future approved list for claims in the event of regulatory control. The acceptance of the U.S. claims by the Hong Kong food safety authority will remove one potential
trade barrier for U.S. products exploring the Hong Kong market. Moreover, the use of nutrition/health claims could be an effective marketing tool, influencing consumption choice. The HKG is planning to complete this exercise of collecting claims available in the market by the end of this summer. Industry interested to submit claims approved for use in the U.S. to the Hong Kong Food Safety Center may provide information in the following table format via ATO Hong Kong office at atohongkong@fas.usda.gov

<table>
<thead>
<tr>
<th>Claims Permitted</th>
<th>Permitted claim statements</th>
<th>Claim condition</th>
<th>Product group</th>
<th>Target age group</th>
<th>Approval country/authority</th>
<th>Approval status (1-4)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>DHA, an omega-3 fatty acid, supports the normal physical development of the brain, eyes and nerves primarily in children under two year of age</td>
<td>--</td>
<td>children food</td>
<td>&lt;2 years</td>
<td>Canada</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Good source of calcium</td>
<td>≥137.5mg per serving</td>
<td>foods for infants</td>
<td>0-12m</td>
<td>Australia</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

** Approval status:
1. Adopted from a pre-approved list of claims
2. Approved by overseas authority upon product-specific application
3. The product label on which the claim is found has been vetted and accepted by overseas authority
4. Others (pls. specify)

Note:
(i) The purpose of this form is to collect information on the use of nutrition and health claims on prepackaged food in overseas countries.

(ii) The information will be used to facilitate discussion on possible strategies on enhancing the control of nutrition and health claims on formula products and foods intended for infants and young children under the age of 36 months in Hong Kong.

(iii) Please provide details on claims, statements and presentations related to nutrients and/or health, which are currently in use on formula and foods for infants and young children below age of 36 months in the U.S. (including those on product package, website, and advertisement).