

# Proposed Regulatory Framework

**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**

# Background

- What are “**Nutrition claims**” and “**health claims**”?
- \* Representations which state, suggest or imply particular nutrition properties, or that a relationship exists between a product and health
  - \* Widely used in **formula products** (including infant formula (IF), follow-up formula (FF)) and **prepackaged foods for infants and young children (IYC)**

# Background : Nutrition Claim

Claim	Description	Example
<b>Nutrition claim</b>		
Nutrient content claim	Describes the level of a nutrient contained in a food	<ul style="list-style-type: none"> <li>• Contains choline ( 144mg/100g )</li> <li>• With DHA</li> </ul>
Nutrient comparative claim	Compares the nutrient levels and/or energy value of two or more foods	<ul style="list-style-type: none"> <li>• More vitamins, minerals and fibre</li> <li>• Extra iron</li> <li>• Increased DHA level by 3 times (compared to its original formula)</li> </ul>

# Background: Health Claim

Claim	Description	Example
<b>Health claim</b>		
Nutrient function claim	Describes the physiological role of the nutrient in growth, development and normal functions of the body	<ul style="list-style-type: none"> <li>Phospholipids (PhD) are essential for the function of brain cells</li> </ul>
Other function claim	Concerns specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body <i>(note: relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health)</i>	<ul style="list-style-type: none"> <li>Probiotics helps to maintain a healthy digestive system</li> </ul>
Reduction of disease risk claim	Relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition	<ul style="list-style-type: none"> <li>Fortified with an appropriate level of iron to reduce the risk of anaemia</li> </ul>

# Background

- For infants and young children, nutrition is particularly essential for their growth and health. The superiority of breastfeeding is widely recognized
  - \* WHO recommends that infants be exclusively breastfed for the first 6 months of life. Mothers should continue to breastfeed their children beyond the age of 6 months, until they are 2 years of age or older, while at the same time providing them with safe and appropriate complementary foods to meet their evolving nutritional requirements
- It is of paramount importance to prevent practices which would discourage breastfeeding, and to provide parents with accurate and appropriate information on formula products and IYC foods to facilitate informed choice
- Nutrition and health claims, if properly applied, may help promote a healthy diet. However, false, misleading and inappropriate making and application of these claims can cause harm to human health

# Background : Existing Regulation

- **“Nutrition Labelling Scheme” under the Food and Drugs (Composition and Labelling) Regulation**
  - \* Regulates **nutrient content claims, nutrient comparative claims and nutrient function claims** on **prepackaged foods for persons aged 36 months or above**
  - \* Does not cover nutrition and health claims on formula products and IYC foods
- **The Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014**
  - \* Enacted on 22 October 2014
  - \* Only cover :
    - **Nutritional composition** for IF
    - **Nutrition labelling** of IF, FF and IYC foods
- **Public Health and Municipal Services Ordinance and Trade Descriptions Ordinance**
  - \* Regulate misleading claims and false descriptions
  - \* Lack specific provisions on nutrition and health claims on formula products and IYC foods

# Background : International Scene

- **Codex:** Established in 1963 by FAO of United Nations and WHO to develop food standards, guidelines and related texts such as code of practice for protecting the health of consumers and ensuring fair trade practices in the food trade. Membership comprises >180 countries at present.
- **Nutrition and health claims:** shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation
- **Nutrition claims:** should be consistent with national nutrition policy and only nutrition claims that support national nutrition policy should be allowed
- **Health claims:** should be consistent with national health policy, including nutrition policy, and support such policies where applicable
- Notwithstanding the principles set by Codex, national authorities of different jurisdictions have established different requirements in light of their national situation as well as nutrition and health policies when it comes to the regulation of nutrition and health claims on formula products and IYC foods



# Proposed Regulatory Framework



# Purpose

- The purposes of proposed regulatory framework are:
- \* To better protect the health of infants and young children under the age of 36 months; and
  - \* To facilitate effective regulatory control over nutrition and health claims on formula products and IYC foods

# Different Views



## Codex

- \* Nutrition and health claims **shall not be permitted** for formula products and IYC foods
- \* Except where specifically provided for in relevant Codex standards or national legislation



## Pro-breastfeeding group

- \* Advocates for **more stringent regulation**
- \* Opines that these claims might discourage breastfeeding and mislead parents and care-givers into believing that such food products are superior to breastfeeding



## The trade

- \* Opined that these claims provide useful info to consumers
- \* Considered these claims as an incentive to invest in product development

# Government's Considerations

- ✧ In considering the regulatory framework, the Government has taken into account:
- \* Views aforementioned;
  - \* The current legislation;
  - \* The Codex principles and practices of other jurisdictions;
  - \* Opinion of the Expert Committee on Food Safety; and
  - \* Other factors (including public health concern, implication on food choice, impact on the food trade, availability of resources and implementation issues, etc.)

# Overarching Principles

- 1) **Nutrition claims** (i.e. nutrient content claims and nutrient comparative claims) should be **prohibited** in **IF**
- 2) **Reduction of disease risk claims** should be **prohibited** in **formula products** (i.e. **IF, FF**) and **IYC foods**
- 3) **Nutrition claims** (i.e. nutrient content claims and nutrient comparative claims) and **nutrient function claims** should be **permitted** in **IYC foods**
- 4) Nutrients or constituents permitted to be subjects of claims should be of **high importance to the health of infants and young children**
- 5) **Nutrition and health claims** should **meet specific content conditions**, and **health claims** must be **scientifically substantiated** and have undergone **credible evaluation process**

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- Overarching principles 1 to 3, if accepted, would allow certain claims on certain formula products/IYC foods while prohibiting others
- Together these three principles would set the boundary for the regulatory framework

# Regulatory approaches

- ✧ Within this boundary, there are product-claim combinations which regulatory options are open for discussion :
  - \* Nutrient function claim on IF;
  - \* Nutrition claim (i.e. nutrient content claim and nutrient comparative claim) and nutrient function claim on FF; and
  - \* Other function claim on formula products and IYC foods
- ✧ For these product-claim combinations, there are options for regulatory approaches :
  - \* Inclusive approach ;
  - \* Restriction approach; or
  - \* Taking middle ground
- ✧ The 5 overarching principles aforementioned must be fulfilled, no matter which approach is being chosen

Category of claim	Type of claim	Inclusive approach	Restrictive approach	
Infant formula				
Nutrition claim	Nutrient content claim	Not allowed ( Principle 1 )		
	Nutrient comparative claim			
Health claim	Nutrient function claim	Allowed	Not allowed	(a)
	Other function claim	Allowed	Not allowed	(c)
	Disease risk reduction claim	Not allowed ( Principle 2 )		
Follow-up formula				
Nutrition claim	Nutrient content claim	Allowed	Not allowed	
	Nutrient comparative claim	Allowed	Not allowed	(b)
Health claim	Nutrient function claim	Allowed	Not allowed	
	Other function claim	Allowed	Not allowed	(c)
	Disease risk reduction claim	Not allowed ( Principle 2 )		
IYC foods				
Nutrition claim	Nutrient content claim	Allowed ( Principle 3 )		
	Nutrient comparative claim			
Health claim	Nutrient function claim	Allowed		
	Other function claim			Not allowed
	Disease risk reduction claim	Not allowed ( Principle 2 )		



# Some Arguments For or Against the Product-Claim Combinations<sup>16</sup>

## (a) Nutrient function claim on infant formula (IF)

### Allow

- Trade can inform consumers on nutritional properties of their products

### Not allow

- May mislead parents that IF is superior to breastmilk
- Product with these claim may not have higher nutrient content and more benefits than their counterparts

# Some Arguments For or Against the Product-Claim Combinations<sup>17</sup>

## (b) Nutrition claim and nutrient function claim on follow-up formula (FF)

### Allow

- No legal requirement on composition of these product;  
products with unique nutrients can provide more info to parents
- Trader can distinguish their products from others;  
incentive for research and development

### Not allow

- FF often resembles their sister IF products;  
claims on FF may imply similar feature on IF, hence undermine breastfeeding
- FF often follow Codex standard on composition;  
products with claims may not have additional health benefit
- WHO considered FF unnecessary and unsuitable as breastmilk replacement

# Some Arguments For or Against the Product-Claim Combinations<sup>18</sup>

## (c) Other function claim on formula products (FP) and IYC foods

### Allow

- No legal requirement on declaring the content of non-nutrient constituents; these claims can provide more info to parents
- Incentive for research and development

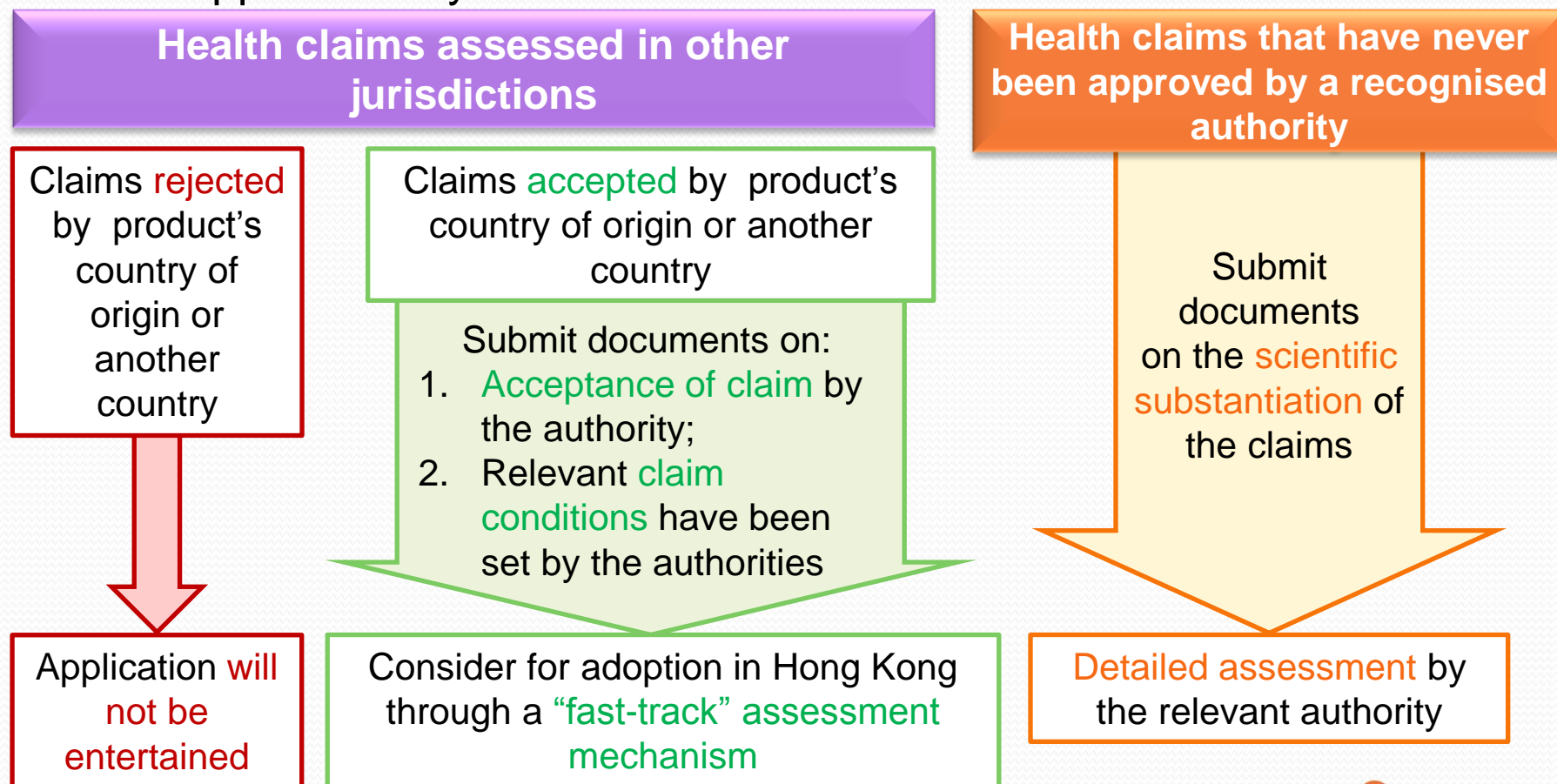
### Not allow

- These claims are not related to essential nutrients; may divert parents' attention from essential nutrients
- May give wrong impression to parents that foods for other function claims are better than regular food and interfere child's progression to an adult diet

# Proposed Regulatory Mechanism for health claims

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- A list of approved health claims would be established by way of application by the trade



[Note: Application fee calculated on a cost recovery basis will likely apply]

# Proposed Regulatory Mechanism for health claims

- Once a claim has been included in the list of approved claim, the applicant and other traders may make the claim on the **relevant product** and products in the **same product category** as long as the **specified conditions** are fulfilled (e.g. content of nutrient/substance in the product is within the required level, appropriate wording/presentation is used)
- For claims that are rejected by the Centre for Food Safety for the inclusion in the list, we will have to consider the need to provide for an appeal mechanism for the applicant
- The list should be subject to review on a need basis

# Exemption: Formula for Special Medical Purposes (FSMP)

- FSMP is currently exempted from nutritional composition and nutrition labelling requirements under the Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014 (if several conditions satisfied)
- We propose that exemption should be granted to FSMP for infants and young children under the proposal regulatory framework. The rationales are :
  - \* FSMP is normally used under medical supervision
  - \* Useful information to healthcare professional/ parents
  - \* FSMP serves a multi-destination niche market and its producers may have little commercial incentive to re-label their products for different markets

# Nutrient Reference Values (NRV)

- NRVs are reference values used in nutrition labelling. They are used to compare nutrient contents among different foods
- In establishing conditions for nutrient claims (e.g. “high”, “low”, “free”, “more”, “less”, etc.), NRVs are often needed as reference
- Codex has not established NRVs for infants and young children
- Local NRVs do not exist and Mainland China also does not have NRVs for children under the age of 36 months
- If local NRVs are considered necessary, we may need to solicit support from experts to develop these values as appropriate



# Grace Period

- ❧ A reasonable grace period before any regulatory control on nutrition and health claims comes into force will allow time for the **trade** to reformulate their products, modify their packaging, or refine their marketing strategy as necessary, to comply with the new requirements
- ❧ Traders should submit applications to the Government during the grace period in relation to existing claims made on products that are already in the market. There should be sufficient time for the **relevant authority** to process these claim applications before the expiry of the grace period
- ❧ **We shall take into account views collected during the consultation before finalising the length of the grace period**

# Summary

- The Government proposes to enhance the regulation of nutrition claims and health claims on formula products and IYC foods by way of legislation
- The proposed regulatory framework will encompass the following elements :
  1. the establishment of **five overarching principles** to delineate the boundary of the regulatory framework and to prescribe conditions that will bind any claims eventually allowed;
  2. the **regulatory options for the product-claim combinations** that are within the bounds of the relevant overarching principles;
  3. the development of a mechanism for establishing and maintaining a **list of approved claims** and the corresponding conditions;
  4. the establishment of a mechanism for revising the list of approved claims;
  5. the provision of clear definition of claims;
  6. the possible establishment of **a set of NRVs specifically for infants and young children**; and
  7. a **grace period** to allow sufficient time for the trade to comply with the new compliance requirements.

# Views Sought

- A **3-month consultation** is launched with a view to collecting comments from the public on the proposed regulatory framework
- Please send your comments by letter, facsimile or e-mail to the **Centre for Food Safety** before **17 April 2015**
  - Centre for Food Safety (Attn.: Risk Assessment Section)
  - Food and Environmental Hygiene Department
  - 43/F, Queensway Government Offices, 66 Queensway, HK
  - (Re: 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)
- \* Facsimile: 2893 3547
- \* E-mail address: [claims\\_consultation@fehd.gov.hk](mailto:claims_consultation@fehd.gov.hk)
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