

Nutrition and Health Claims for Formula Products and Foods for Infants and Young Children

Results of Public Consultation Exercise and Proposed Regulatory Framework

Centre for Food Safety
July 2015

Issues to Discuss

- Result of consultation exercise
- Proposed regulatory approach

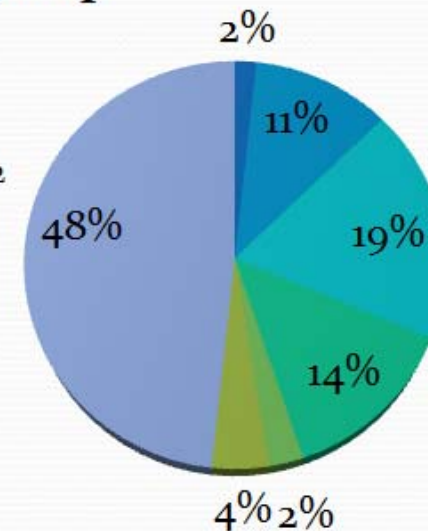
Consultation Exercise

- Consultation period: 6 Jan- 17 Apr 2015
- Written comments received: 131
 - 26 LegCo submission
 - 104 from consultation channel (Email/letter/fax)
 - Including 13 respondents who also submitted written comments to LegCo
 - 1 online petition with 717 supporters
- Vast majority (98%) supports establishment of regulatory framework

Written Comments-- Breakdown by subgroup *

- Overseas government: 2 (Australia; New Zealand MPI)
- Trade: 13
- Interest groups (Child health/ parents/ Consumer Council): 22
- Healthcare professional/Academia: 16
- Media (Newspaper/commentator): 3
- LegCo member/DC member/ Political Parties: 5
- General Public: 57

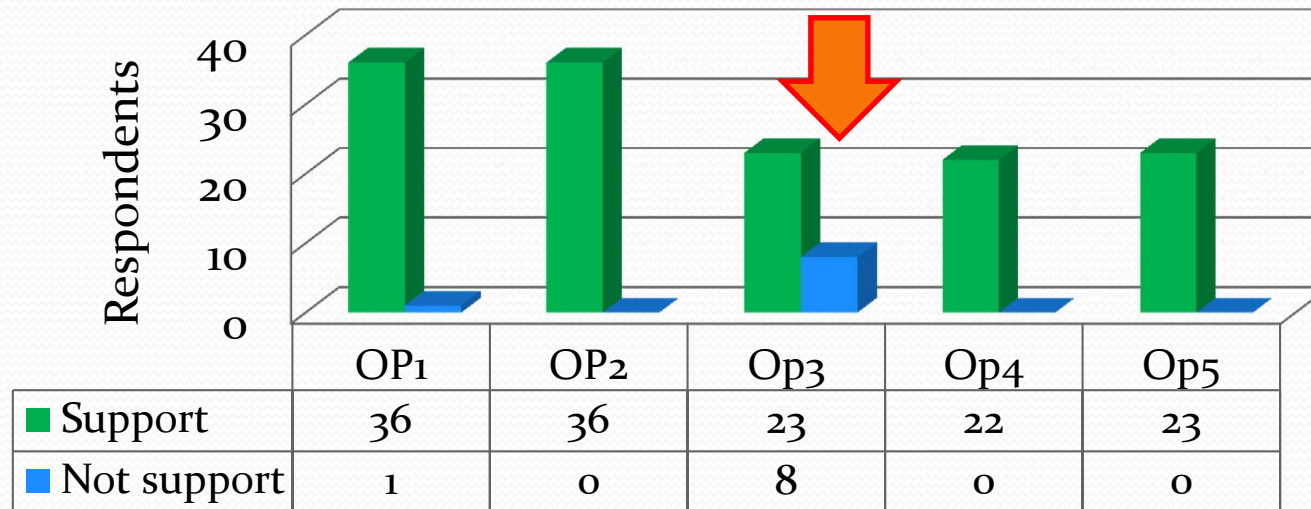
* Submissions from the same organization or individual counted as 1 comment



Overarching Principles (OP)

- 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**

Views on OP



- Not supporting OP3 (8 submissions) :
 - Healthcare professionals, academia, interest groups, general public
- Rationales included:
 - Claims on IYC foods are inappropriate/not necessary
 - Claims on IYC foods are inflated/ misleading
 - Allowing claims cannot facilitate consumers making suitable choices
 - Support WHO Guidelines / Codex recommendations
 - Consensus reached by more than 100 child healthcare professionals

Product-claim Combinations

- ∞ 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
- ∞ 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
- A larger portion of the respondents (including healthcare professionals, academia, interest groups, general public) urged for restrictive approach
- The trade and the media generally support an inclusive approach

Breakdown of Views **by Written Response** on Product-claim Combinations

		No. of Response	Inclusive	Restrictive
(a) Nutrient function claim on IF		42	12 *	30 ^#
(b) Nutrition claim and nutrient function claim on FF	Nutrient content claim	41	17 *	24 ^#
	Nutrient comparative claim	41	15 *	26 ^#
	Nutrient function claim	40	16 *	24 ^#
(c) Other function claim on IF, FF and IYC	IF	41	12 *	29 ^#
	FF	41	15 *	26 ^#
	IYC	37	15 *	22 ^#

* 23 respondents using the same template only counted as 1 response

^ 4 respondents using the same template only counted as 1 response

#717 supporters of online petition for the restrictive approach only counted as 1 response

Breakdown of Views **by Respondents** on Product-claim Combinations

		No. of Respondents	Inclusive	Restrictive
(a) Nutrient function claim on IF		783	34	749
(b) Nutrition claim and nutrient function claim on FF	Nutrient content claim	782	39	743
	Nutrient comparative claim	782	37	745
	Nutrient function claim	781	38	743
(c) Other function claim on IF, FF and IYC	IF	782	34	748
	FF	782	37	745
	IYC	778	37	741

* Supporters of online petition as well as respondents using the same template were counted as separated responses

Other comments

- Stakeholders generally supported the development of a **mechanism for approving claims**
- Some stakeholders concerned that the Government would likely encounter **problems in evaluation of health claims**
- There were **divergent views on grace period**
 - Interest groups and healthcare professional: short grace period
 - Trade: Longer grace period, e.g., at least 24 months after establishment of the list of approved claims

Proposed Regulatory Approaches

General Considerations

- Local situation
 - The current legislation
 - Public health concern
 - Current market situation and consumer behaviour
 - Implication on food choice
 - Impact on the food trade
 - Availability of resources and implementation issues
- Overseas practice
 - The Codex principles/ WHO recommendation
 - Practices of other jurisdictions
- Results of public consultation
- Breastfeeding policy

Overview of Proposed Regulatory Approaches

- The following proposed approaches :
 - adopted in light of overwhelming public support to breastfeeding promotion
 - have been discussed in the meetings with Expert Committee on Food Safety and Advisory Council on Food and Environmental Hygiene in June 2015, and were supported by the members

Category of claim	Type of claim	Infant Formula (IF)	Follow-up Formula (FF)	IYC Food
Nutrition claim	Nutrient content claim	Not allowed	Not allowed	Allowed
	Nutrient comparative claim	Not allowed	Not allowed	Allowed
Health claim	Nutrient function claim	Not allowed	Not allowed	Allowed
	Other function claim	Not allowed	Not allowed	Allowed
	Reduction of disease risk claim	Not allowed	Not allowed	Not allowed
Medicinal claim		Not allowed	Not allowed	Not allowed

(I) Infant Formula

- Rationale:

- Support by stakeholders
- Essential composition of IF products are being regulated and are similar; nutrition and health claims on IF may be misleading and are not useful in making purchasing decision
- Consumers can still access to various information on product label to make informed choice—
 - Nutrition label
 - Ingredient list
 - Other factual information (e.g., no added sugar, “natural”, “non-GMO”, “organic”, “made with vegetable oil”)
- In line with international practice

Category of claim	Type of claim	Proposed approach
Nutrition claim	Nutrient content claim	Not allowed
	Nutrient comparative claim	Not allowed
Health claim	Nutrient function claim	Not allowed
	Other function claim	Not allowed
	Reduction of disease risk claim	Not allowed

(II) Follow-up Formula

Category of claim	Type of claim	Proposed approach
Nutrition claim	Nutrient content claim	Not allowed
	Nutrient comparative claim	Not allowed
Health claim	Nutrient function claim	Not allowed
	Other function claim	Not allowed
	Reduction of disease risk claim	Not allowed

- Rationales:
 - Result of public consultation called for restrictive approach
 - In today's market, there is no clear distinction between IF and FF in terms of packaging, branding and labelling
 - nutrition and health claims on FF would lead parents and caregivers to believe that IF products from the same brand are superior to breastfeeding
 - The unique situation of Hong Kong:
 - The amount of promotion of formula products seen in HK is rarely found in other city
 - A study conducted by DH in 2010 found a high prevalence of unbalanced diet in young children with an over consumption of formula milk → might be result of intensive marketing drive
 - Many parents believed that FF had added nutrients that promotes the brain development of children not found in other foods
 - Some professionals considered evidence was lacking to support that claims of those products have actual additional benefit to health
 - WHO considered FF unnecessary for infants and young children; nutrition and health claims on FF are mainly useful in promotion and marketing of FF
 - Prohibiting nutrition and health claims on FF is in line with the Codex principles and WHO recommendations

(III) IYC food

Category of claim	Type of claim	Proposed approach
Nutrition claim	Nutrient content claim	Allow
	Nutrient comparative claim	Allow
Health claim	Nutrient function claim	Allow
	Other function claim	Allow
	Reduction of disease risk claim	Not allowed

- Rationale:
 - During the weaning period, infant and young children can consume a wide variety of food
 - Individual IYC food products are not their main source of nutrition
 - They can take general food instead of IYC foods
 - General foods are currently allowed to make nutrition claims and health claims
 - Reasonable to allow these claims to be made on IYC foods as well, if specific claim conditions have been fulfilled
 - Nutrition and health claims on IYC are generally allowed overseas when specific conditions are met, .e.g.-
 - Nutrition claims and nutrient function claims are allowed in jurisdictions such as EU, Australia, New Zealand, Mainland China
 - A limited number of other function claims have been accepted in places such as Singapore

Medicinal Claims

- During the consultation exercise, concerns were raised regarding the use of medicinal claims on formula products and IYC foods
- At present, some products bearing medicinal claims are not regulated as medicine/ proprietary Chinese medicines, or controlled by UMAO
- It is proposed to take the opportunity to specify the prohibition of medicinal claims on formula products and IYC foods in the proposed regulatory framework

Other issues

- Exemption:
 - Proposed to exempt FSMP for infants and young children from the regulation on nutrition and health claims, provided that specific labelling requirements have been fulfilled
- Grace period:
 - nutrition and health claims would not be allowed in infant and follow-up formula
 - the production, shipping and marketing patterns, the lead-time between placement of order and delivery in Hong Kong is around 15 – 18 months
 - a grace period of 18 months is proposed for the trade to clear their existing stocks
 - For IYC foods, time is needed to process the claim applications. It is proposed to allow a minimum of two years for traders to adequately prepare themselves for the new compliance requirements

Other issues

- Grace period for advertisement:
 - During the consultation process, a question was raised on
 - whether a similar transitional arrangement is warranted for advertisements;
 - if so, how long the grace period should be.
 - Of note is that the lead time for production of advertisement is shorter than 18 months.
 - Nevertheless, the advertisement would often carry the images of the products in question.
 - We would further consult the stakeholders before finalising our position on this in the law drafting process.

Progress and Way Forward

- Reported to LegCo Panel and sought their comments on 14 July and plan to table the legislative proposal to LegCo for discussion in the coming year
- CFS conducts technical meeting with trade to discuss relevant technical details
 - First technical meeting :
 - Conducted on 8 July 2015
 - Issues discussed:
 - Result of public consultation and proposed regulatory approach;
 - Nutrition and health claims on IYC foods;
 - Approval mechanism for health claims

Summary of 1st Technical Meeting – Nutrition claim

- It is proposed to establishing pre-approved lists of nutrient content claims and nutrient comparative claims to be allowed in IYC foods, making reference to those claims accepted overseas and the corresponding claim conditions, with the following proposed criteria-
 - The claim is of high importance to the health of local infants and young children; and
 - Appropriate claim conditions can be established.

Summary of 1st Technical Meeting – Health claims approval mechanism

- It is proposed to establish a list of approved health claims by way of application by the trade
 - to establish a “fast-track” mechanism for certain health claims that have been accepted overseas
 - For those claims that were not assessed overseas, traders would need to submit relevant documents on the scientific substantiation of the claims to CFS for detailed evaluation.
 - The assessment will mainly base on Codex's recommendation on the substantiation of health claim as provided in Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)
 - CFS would need to identify and recruit a pool of experts who have no conflict of interest in this area and are able to provide expert advice on the scientific substantiation of health claims in concern

Progress and Way Forward

- More technical meetings with relevant trade representatives to continue
- All interested trade representatives are welcome to register for the technical meeting

~ Thank you ~