

Nutrients & bioactives: claims & regulatory development in Asia



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Outline of presentation

- **Nutrition and health claims**
 - ❖ **developments in Codex, definitions**
- **Overview of current status and developments of nutrition and health claims in**
 - ❖ **several Southeast Asian countries (Malaysia, Indonesia, Philippines, Singapore, Thailand)**
 - ❖ **China and Japan**
 - ❖ **focus on health claims**
 - **Include nutrients and bioactives (other food biologically active components)**
- **Opportunities for networking in the region**

International developments: Codex guidelines on nutrition and health claims

Codex Alimentarius guide to governments

Food labeling
complete text
(5th edn, 2008)



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Nutrition claims

- **Nutrition claim means any representation which states, suggests or implies that a food has particular nutritional properties**
- **Nutrition claims**
 - ❖ **Nutrient content claim (eg high in vitamin C; free of cholesterol)**
 - ❖ **Comparative claim (eg more protein, less sodium)**

Health claims

- **Health claims means any representation that states, suggests or implies that a relationship exists between a food or a constituent of that food and health, includes**
 - 1. nutrient function claim**
 - 2. other function claim and**
 - 3. reduction of disease risk claims**

Nutrient function claims

- **describes the physiological role of the nutrient in growth, development and normal functions of the body, eg**
 - ❖ **Calcium aids in the development of strong bones and teeth**
 - ❖ **Iron is a factor in red blood cell formation**

Other function claims

- describes specific beneficial effects of the consumption of a food constituent (bioactives) in improving or modifying a physiological function
- Considerable interest in role of bioactive components or functional ingredients in promoting health
- Example:
 - ❖ **Plant sterols helps in lowering blood cholesterol**

Reduction of disease risk claim

- relates the consumption of a food or food constituent (bioactives) to the reduced risk of developing a disease or health related condition
- Example:
 - ❖ **Soy protein reduces risk to heart disease**

Health claims

- **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**
 - ❖ **That is, nutrition and health claims are not permitted for infant formulas and follow-on formulas**

Guidelines for scientific substantiation of claims

- **CCNFSDU started discussion in 2000 the guidelines, continuing in Nov 2008, at step 3**
- **Guidelines to assist governments in their evaluation of health claims for use by industry**
- **Process for substantiation would include a systematic review of the scientific evidence**
 - ❖ **Identify criteria for substantiation**
 - ❖ **Identify the proposed relationship between the food or constituent and the health effect**
 - ❖ **Identify and categories all relevant studies**
 - ❖ **Assess quality of and interpret each study**
 - ❖ **Evaluate if a claimed relationship is substantiated**

Guidelines for scientific substantiation of claims

- **Criteria for substantiation**
 - ❖ **Should primarily be based on evidence provided by well-designed human intervention trials**
 - ❖ **Experimental and animal studies may provide supporting knowledge**
 - ❖ **Evidence should demonstrate a consistent association and with little or no evidence to the contrary**
 - ❖ **Totality of evidence should be identified and reviewed**
- **Specific safety concerns should also be addressed eg known health risks, consumption level from all dietary sources, consumption pattern**

Nutrition & Health claims in Asia

**..... Indonesia, Malaysia,
Philippines, Singapore,
Thailand, China, Japan**

- **Major developments in regulations on nutrition and health claims in the region**
 - ❖ **Food industry can use these claims to convey messages on health benefits of their products to consumers**
 - ❖ **Consumers can gain insight into health benefits of foods or specific nutrients and components**
 - ❖ **Increased interest among regulatory agencies in the region to better regulate these claims; to ensure claims are truthful and not misleading**
- **Countries in the region are continuously monitoring global situation and amending regulations**

- **Status of nutrition and health claims in the region**
 - ❖ **Thanks to input by food regulators in Southeast Asian countries, China and Japan**
 - ❖ **Through series of ILSI SEA Region series of workshops - details in later section**

Status of nutrition claims

Country	Nutrition claim
Indonesia	Yes, nutrient content claim, comparative claim; criteria for claim based on NRV Indonesia
Malaysia	Yes, nutrient content claim, comparative claim; format and criteria generally similar to Codex
Philippines	Yes, nutrient content claim, comparative claim; format generally similar to Codex; criteria based on RENI Philippines
Singapore	Yes, nutrient content claim, comparative claim; criteria for claim based on RDA not NRV
Thailand	Yes, nutrient content claim, comparative claim; format generally similar to Codex; criteria based on Thai RDI rather than NRV
China	Yes, nutrient content claim, comparative claim; format and criteria generally similar to Codex
Japan	Yes, nutrient content claim only; format generally similar to Codex; but different criteria used

Status of nutrient function claims

Country	Nutrient function claim
Indonesia	Yes, in new regulations to be enforced; 4 macronutrients (protein, fat, linoleic acid, carbohydrates), 8 vitamins, 3 minerals
Malaysia	23 claims for protein, 9 vitamins, 5 minerals
Philippines	Yes, according to Codex; no positive list
Singapore	26 claims for 3 macro nutrients (protein, lactose, dietary fibre), 7 vitamins, 5 minerals
Thailand	29 claims for protein, dietary fibre, 13 vitamins, 14 minerals
China	60 claims for 8 macronutrients (energy, fat, protein, saturated fat, cholesterol, carbohydrate, sugar, dietary fibre), 6 minerals, 11 vitamins
Japan	17 claims for 12 vitamins, 5 minerals

Status of other function claims

Country	Other function claim
Indonesia	Yes, in new regulations to be enforced; dietary fibre (psyllium, inulin, oat), prebiotic, probiotic, plant sterol and stanol esters
Malaysia	21 claims for other food components (eg inulin, FOS, GOS, GOS+IcFOS mixture, polydextrose, resistant starch, sterol, beta-glucan, soy protein)
Philippines	Yes, according to Codex; no positive list
Singapore	7 claims for probiotics, prebiotics (eg inulin, oligofructose, GOS+IcFOS mixture)
Thailand	Not permitted
China	Not permitted
Japan	FOSHU (797 products approved as at end August 2008)

Status of disease risk-reduction claims

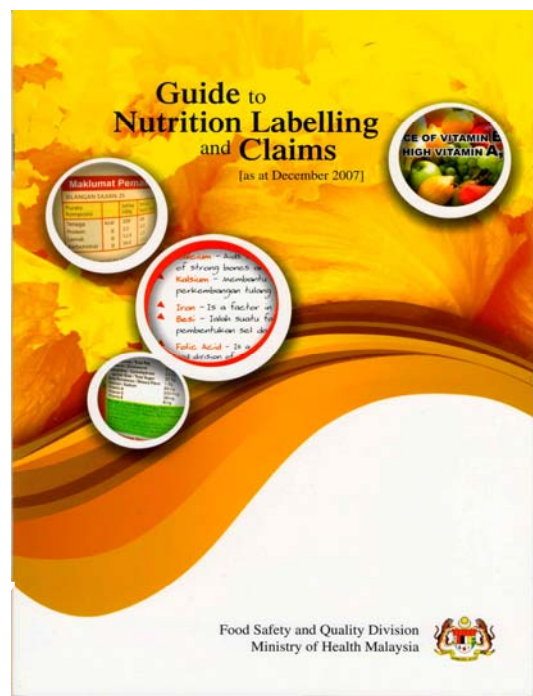
Country	Disease risk-reduction claim
Indonesia	Yes, in new regulations to be enforced; folate, calcium, dietary fibre psyllium, inulin, oat), plant sterol and stanol esters, soy protein, soy isoflavone
Malaysia	Not permitted
Philippines	Yes, according to Codex; no positive list
Singapore	Not permitted
Thailand	Not permitted
China	Not permitted
Japan	Only calcium and osteoporosis and folate and neural tube defect

Examples of other function claims - Malaysia

- **21 other function claims for non-nutrients also permitted, include**
 - ❖ **Several dietary fibres (eg High Amylose Maize Resistant Starch, inulin, GOS, FOS, GOS:FOS (90:10), beta-glucan, polydextrose**
 - ❖ **Sialic acid**
 - ❖ **Soy protein**
 - ❖ **Patented cooking oil blend**
 - ❖ **Bifidobacterium**
- **All arising from petition from industry**

- **Permitted “other function claims” include**
 - ❖ **..... helps reduce / lower cholesterol**
 - ❖ **..... helps increase intestinal bifidobacteria / bifidogenic /prebiotic and helps to maintain a good intestinal environment**
 - ❖ **.... helps to lower to rise in blood glucose**
 - ❖ **.... helps to improve intestinal immune system of babies**
- **Specific conditions required for other function claims, eg**
 - ❖ **Minimum amount of the relevant “food component” that must be present**
 - ❖ **Additional labelling requirements, if relevant**
 - ❖ **Restriction to selected foods, if relevant**

All function claims contained in revised Guide Book to assist industry and enforcement officers understand new regulations



- ❖ **Industry may apply for new function claims using prescribed forms**
- ❖ **All applications reviewed by Expert Committee on Nutrition, Health Claims and Advertisement, MOH**
 - ❖ **Members comprised experts from multi government agencies**
 - ❖ **Information on 18 items required, including scientific data to substantiate proposed claim, preferably based on human intervention trials**
- ❖ **If approved by Expert Committee, application shall be submitted to higher level Technical Committee on Food Regulations for endorsement**
- ❖ **Final approval shall be given by Deputy Director-General of Health. All companies can use the claims once they are published as government gazettes**

Examples of other function claims - Singapore

➤ Probiotics

- ❖ Helps to maintain a healthy digestive system
- ❖ Helps in digestion.
- ❖ Helps to maintain a desirable balance of beneficial bacteria in the digestive system.
- ❖ Helps to suppress/fight against harmful bacteria in the digestive system, thereby helping to maintain a healthy digestive system

Examples of other function claims - Singapore

➤ Prebiotics

- ❖ Prebiotic promotes the growth of good Bifidus bacteria to help maintain a healthy digestive system.
- ❖ Inulin helps support growth of beneficial bacteria/good intestinal flora in the gut.
- ❖ Oligofructose stimulates the bifido-bacteria, resulting in a significant increase of the beneficial bifidobacteria in the intestinal tract. At the same time, the presence of less desirable bacteria is significantly reduced



Health claims in Japan

- In Japan, health claims are permitted only for foods for specified health use (FOSHU)
- Legalized in 1991, it was meant to be an expansion of the 'health' food market
- defined FOSHU as foods officially approved to claim their physiological effects on the human body
- pre-marketing approval system set up: each food has to be proven to promote health on a case-by-case basis based on clinical trials
 - ❖ Up till August 2008, over 797 products have been approved

Progress of Nutrition and Health Claims on Food in Japan

year	Types of Claims			
1991 1994	Foods for Specified Health Use (FOSHU) regulation system (by MHLW)			
1997 ↓ 2000	Nutrition labeling standards (Nutrient content claims, Nutrient comparative claims)			
2001	Food with health claims (FHC)			
	Foods with Nutrient Function Claims (FNFC) (5 minerals and 12 vitamins)	Foods for Specified Health Use (FOSHU)		
2005	Food with health claims (FHC)			
	Foods with Nutrient Function Claims (FNFC)	Foods for Specified Health Use (FOSHU)		
		Ordinary FOSHU	New Type FOSHU	
			Standardized FOSHU	Reduction of disease risk

Foods for Specified Health Use (FOSHU)

Seal of approval for other FOSHU	Seal of approval for Qualified FOSHU
	
<p>Example of a claim: Ingredient X (functional ingredient) improves gastrointestinal condition</p>	<p>Example of a claim: This product contains XX and, although supporting evidence has not necessarily been established, this product might be possibly suitable for condition YY.</p>

Main FOSHU products approved and the relevant ingredients

Type of FOSHU	Principal ingredients exhibiting health functions
Improve gastrointestinal conditions	Oligosaccharides, bifidobacteria, lactic acid bacteria, dietary fiber & ingestible dextrin, polydextrose, guar gum, psyllium seed coat, etc.
Related to high blood cholesterol level	Chitosan, soybean protein, degraded sodium alginate
Related to high blood sugar levels	Indigestible dextrin, wheat albumin, guava tea polyphenol, L-arabiose, etc.
Related to high blood pressure	Lactotripeptide, casein dodecanepptide, tochu leaf glycoside (geniposidic acid), sardine peptide, etc.

Main FOSHU products approved (2)

Type of FOSHU	Principal ingredients exhibiting health functions
Related to dental hygiene	Palatinose, maltitose, erythrytol, etc.
Cholesterol plus gastro-intestinal conditions, triacylglycerol plus cholesterol	Degraded sodium alginate, dietary fiber from psyllium seed husk, etc.
Related to mineral absorption	Calcium citrated malate, casein phosphopeptide, heme iron, fructo-oligosaccharide, etc.
Related to osteoporosis	Soybean isoflavone, MBP (milk basic protein), etc.
Related to triacylglycerol	Medium chain fatty acid, etc.

Summary status of nutrition & health claims

- **There are considerable differences in the permitted nutrition and health claims**
 - ❖ **Nutrition claims are permitted in all the countries reviewed**
 - ❖ **All countries allow nutrient function claims**
 - ❖ **Other function claims are permitted in all countries, except in China and Thailand. The claims relate to several bioactive components including several dietary fibres and non-digestible oligosaccharides, and plant sterols**
 - ❖ **Disease risk reduction claims are considered higher level claims and are permitted only in a few countries, namely Indonesia, Philippines and Japan, and only for a few nutrients or bioactive compounds**

Opportunities for networking among countries in the region

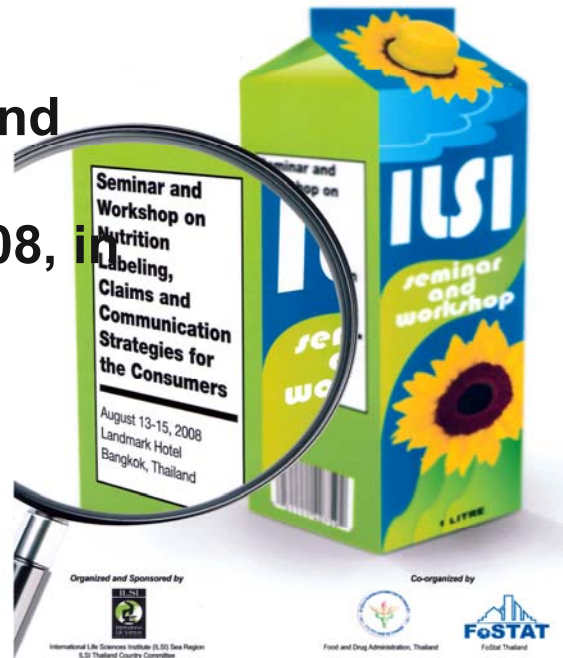
.... through a series of ILSI SEA Region's Workshops 2001-2008 to address Issues Related To Nutrition Labeling and Claims



Series of ILSI workshops 2001-2008

- **participated by officials of regulatory agencies in SEAsia, research scientists in China, Japan, Korea, Australia/New Zealand**
- **Be familiarised with international and regional regulatory developments**
- **Provide regular updates of national regulatory status and developments**
- **Share experiences in evaluating scientific data submitted for substantiation of claims**
- **provide avenues for harmonising development of these activities in the region**
- **Latest seminar and workshop 13-15 August 2008, Bangkok**

**Latest seminar and
workshop
13-15 August 2008, in
Bangkok**



Seminar programme:

- ❖ **Regional Country Updates on Nutrition Labeling and Claims Regulations: Australia/New Zealand, Indonesia, Malaysia, Philippines, Singapore, Thailand, Vietnam (also Japan, Korea)**
- ❖ **Nutrient profiling in Europe and practical considerations by food industry**
- ❖ **Effective Communication of Nutrition Information on Food Labels: include data on consumer perception, attitude on food labels**
- ❖ **Understanding Consumer Behaviour -The Thai Experience: include data on Thai food consumption; efforts to increase awareness of consumers**

Workshop discussion topics:

- ❖ Guidelines for scientific substantiation and regulatory framework for nutrition and health claims -current usage in the region
- ❖ Similarities and differences in nutrition and health claims in the region
- ❖ Consumer research -needs and challenges in understanding the consumer for regulators
- ❖ Nutrient Profiling – new to the region, no discussions yet on its use as a screening tool when making health claims
- ❖ Front of pack signposting – new to the region, being discussed in some countries

Examples of Front-of-pack (FOP) sign posting schemes in Europe



