



Presentation Outline

- What are functional foods?
 - ILSI SEAR relevant activities
 - Attributes and characteristics
 - Foods with health claims
- Status of Health Claims in SEA Countries
 - Indonesia, Malaysia, Philippines & Singapore
- Functional foods in other countries
- Harmonization Opportunity



Relevant Functional Foods Activities Supported by ILSI SEA Region

- ILSI SEA Region started working on the areas of functional foods since 1995
 - Organized First International Conference on East-Perspectives on Functional Foods: Science, Innovations and Claims in 1995
 - Subsequently, about <u>15</u> other conferences, seminars and workshops addressing issues related to understanding of functional foods
 - 4 regional workshops and 2 expert consultations on functional foods;
 9 regional seminars and workshops on NL and claims;
 4 national capacity building workshops
 - Participated by regulators and government officials from ASEAN and Asian countries, experts and researchers, industry stakeholders

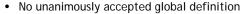


Relevant Functional Foods Activities Supported by ILSI SEA Region

- The series of expert consultations, seminars and workshops on functional foods and claims provided platform to
 - Get updates on international & regional regulatory developments, and national regulatory status and developments
 - Provide platform for discussion on harmonization of regulatory development of these activities in the region
 - Share views and experiences
 - Development of Report publication and Guidelines on Scientific substantiation and safety evaluation
 - · Regulatory and marketing aspects and
 - · Future developments



Functional Foods- Attributes and Characteristics





- A generally accepted understanding is
 - Functional foods are foods that provide health benefits beyond basic nutrition
 - By virtue of physiologically active food components (functional ingredients or bioactive components) present in these foods
 - Bioactive components can either be naturally occurring or added to the food.
 - Similar in appearance to conventional foods and intended to be consumed as part of a normal diet
 - · Not nutraceuticals or supplements (In forms such as capsules,



Southeast

tablet, etc)

Relevant Functional Foods Activities Supported by ILSI SEA Region

- The first Monograph on Functional Foods in Asia (Tee, 2004) was published by ILSI SEA Region
 - · Essential attributes and characteristics
 - Proposed framework and guidelines for the scientific substantiation
 - Guidelines for safety evaluation of functional foods
- Updated second edition of Monograph on Functional Foods will be published in Dec 2017
 - Regulatory status of the various types of health claims permitted in the key SEA countries
 - List of permitted claims included in the available positive lists
 - Regulatory framework for application and review of claim applications, as well as the scientific substantiation requirement





Functional Foods that Provide Health Benefits

- Increased consumer interest and awareness over last few decades on these functional foods and food components that provide health benefits beyond basic nutrition
 - <u>Functional foods</u> and their benefits are mostly communicated through health claims
 - Types of health claims(Codex definition) allowed
 - Nutrient function
 - Other function
 - Reduction of disease risk claims
 - Scientific substantiation required for claims

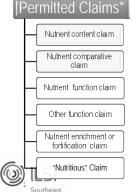


Status of Health Claims (Codex definition) Regulations for Foods in selected SEA Countries



Permitted Health Claims in Malaysia





- Key food regulatory authority-Food Safety and Quality Division(FSQD), MOH Malaysia
- 2003 regulations lay down provisions pertaining to various types of claims
 - Describe the physiological role of the nutrient/other food component in growth, development and normal functions of the body
 - A nutrient/other function claim should not imply that the nutrient cures, treats or protects from diseases

Health Claims Status in SEA

- Different types of health claims are permitted in various SEA countries
 - Nutrient function claims, other function claims and disease risk reduction claims

		Type (s) of Permitted Health Claims	Countries
		Nutrients and Other Function Claims only	Malaysia
<u></u>		Nutrients, other function and disease risk reduction claims	Indonesia, Philippines (no positive list), Singapore
	A	sia Region	

Health Claims in in Malaysia

- Malaysia allows the use of "nutrient" and "other" function claims
- Include both "classical nutrient" and "other food components"
- Adopts a "positive list" approach
 - A total of <u>52</u> claims have been permitted on this list [Reg.18E(14)] and any additional claims should be submitted to MOH with supporting documents for approval
 - 23 nutrient function claims involving 9 vitamins and 5 minerals
 29 other food components
 - Specific conditions required for other function claims, eq
 - Minimum amount of the relevant "food component" that must be present
 - · Additional labelling requirements, if relevant
 - · Restriction to selected foods, if relevant



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Permitted "Other Function" Claims Beta-glucan from (state the source) helps lower or reduce cholesterol* B)fidobacterium lactis: Bifidobacterium lactis helps improve a beneficial intestinal microflora* Bifidobacterium lactis may help to reduce the incidence of diarrhoea* Calcium aids in the development of strong bones and teeth DHA and ARA: DHA and ARA may contribute to the visual development of infant* i. Folic acid is essential for growth and division of cells ii. Folate plays a role in the formation of red blood cells iii. Folate helps to maintain the growth and development of the foetus • High Amylose Maize Resistant Starch (HAMRS) helps improve/promote colonic/bowel/intestinal function/environment* Iron: i. Iron is a factor in red blood cell formation ii. Iron is a component of haemoglobin in red blood cell which carry oxygen to all parts of the body

Permitted "Other Function" Claims Magnesium promotes calcium absorption and retention Niacin is needed for the release of energy from protein, fats and carbohydrates Oat soluble fibre (beta-glucan): Oat soluble fibre (beta-glucan) helps to lower the rise of blood glucose provided it is not consumed together with other food* Oligosaccharide mixture containing 90% (wt/wt) GOS and 10% (wt/wt) IcFOS: Oligosaccharide mixture containing 90% (wt/wt) GOS and 10% (wt/wt) IcFOS is prebiotic* i. Oligosaccharide mixture containing 90% (wt/wt) GOS and 10% (wt/wt) IcFOS is bifidogenic* iii.Oligosaccharide mixture containing 90% (wt/wt) GOS and 10% (wt/wt) IcFOS helps increase intestinal bifodobacteria and helps maintain a good intestinal environment* v.Oligosaccharide mixture containing 90% (wt/wt) GOS and 10% (wt/wt) IcFOS helps to improve the gut/intestinal immune systems of babies/infants*

Permitted "Other Function" Claims Inulin and oligofructose (fructo-oligosaccharide): i.Inulin helps increase intestinal bifidobacteria and helps maintain a good intestinal environment* ii.Oligofructose (fructo-oligosaccharide) helps increase intestinal bifidobacteria and helps maintain a good intestinal environment* iii.Inulin is bifidogenic* iv.Oligofructose (fructo-oligosaccharide) is bifidogenic* v.Inulin is prebiotic* vi.Oligofructose (fructo-oligosaccharide) is prebiotic* lodine is essential for the formation of thyroid hormone Isomaltulose Isomaltulose is slowly hydrolysed to glucose and fructose, and therefore it provides longer lasting energy compared to sucrose* ii. Isomaltulose is a slowly release source of energy compared to sucrose* iii. Isomaltulose provides longer lasting energy compared to sucrose* iv. Isomaltulose is slowly hydrolysed to glucose & fructose, compared with sucrose Lutein As a predominant macular pigment in the retina, lutein is able to filter blue ight and may protect the eye*

Pe	ermitted "Other Function" Claims
[Oligofructose-inulin mixture containing 36-42% oligofructose (DP 2-10) and 50-56 % inulin (DP >10) helps to increase calcium absorption and increase bone mineral density when taken with calcium rich food* Patented cooking oil blend helps to increase HDL cholesterol and improve
ŀ	HDL/LDL cholesterol ratio* Plant sterol or plant stanol helps lower or reduce cholesterol* Plant sterol ester helps lower or reduce cholesterol*
-	Polydextrose i. Polydextrose is bifidogenic* ii. Polydextrose helps increase intestinal bifidobacteria and helps maintain a good intestinal microflora*
[Protein - i. Protein helps build and repair body tissues ii. Protein is essential for growth and development iii. Protein provides amino acids necessary for protein synthesis
[-	Resistant dextrin / Resistant maltodextrin is a soluble dietary fibre that helps to regulate / promote regular bowel movement especially of people with a tendency to constipation*

Permitted "Other Function" Claims

Vitamin D -

i.Vitamin D helps the body utilise calcium and phosphorus

ii.Vitamin D is necessary for the absorption and utilization of calcium and phosphorus

Vitamin E protects the fats in body tissues from oxidation

Zinc is essential for growth

For all the above claims, words/sentences of similar meaning can also be used

Permitted Health Claims in Singapore



- Key food regulatory authority-
 - Agri-Food & Veterinary Authority Singapore(AVA)
- Three types of health claims are allowed:
 - Nutrient & other function claims
 - To be considered based on available scientific evidence
 - Reduction of disease risk claims
 - Only 5 approved claims
 - No misleading statements or claims including those for therapeutic or prophylactic actions





http://www.ava.gov.sg/docs/default-source/tools-andresources/fesources-forbusinesses/aguidetofoodlabellingandadvertisementsverioniuly/_off?sfvrsn=2

Disease Risk Reduction Claims in Malaysia

- <u>Disease risk reduction claims are not permitted in Malaysia</u>
- There are several prohibitions:
 - Claims related to the suitability of a food for use in the prevention, alleviation, treatment or cure of a disease, disorder or particular physiological condition are not allowed
- Discussions among industry, consumer bodies and professional bodies
 - Most of the stakeholders agreed with the conditions
 - Not misleading
 - Supported by clinical trial
 - To develop new mechanism/system
 - · Advertisement need to be controlled
 - · Enforcement to be strengthened



Nutrient Function Claims - Singapore

Nutrient function claim may be allowed if the following criteria are met:

- •The particular nutrient mentioned is present in an amount that either meets the requirements of the Food Regulations (ie. 1/6 of daily allowances for vitamins and minerals), or requirements of the nutrient claim guidelines established by Health Promotion Board
- •The product carrying the claim should also be labeled in accordance with requirements of Food Regulations for use of nutrition claims
- •The approved claims must not be truncated or reworded to deviate from original meaning
- •A total of 143 function claims have been approved
 - 3 macronutrients, 15 vitamins, 9 minerals and 13 food constituents



Function Claims in Singapore

- Some examples:
 - Protein
 - Protein helps in tissue building and growth
 - Protein provides the essential amino acids needed to aid in the building and maintenance of body tissues
 - Lactose
 - Low lactose content eases digestion for people who are lactose intolerant
 - · Low lactose content allows easier digestions
 - Dietary Fibre
 - · Dietary fibre aids in digestive system



Function Claims in Singapore

- Examples of other function claims :
 - Prebiotics*
 - Prebiotic promotes the growth of good Bifidus bacteria to help maintain a healthy digestive system
 - Taurine(claim only for food for children up to 6 years of age)
 - Taurine helps to support overall mental and physical development
 - Collagen
 - Collagen is a protein in connective tissues found in skin, bones and muscles

* Need to specify the name(s) of the probiotic or prebiotic whenever a claim is made in relation to that probiotic or prebiotic.



Southeast Asia Region

Function Claims in Singapore

- Some examples of nutrient function claims :
 - Folate (claims for foods for pregnant women)
 - Folate helps support foetus' growth and overall development.
 - Folate plays a role in the formation of red blood cells
 - Folate, taken before and during early pregnancy, helps in the mental/normal and overall development of foetus.
 - Folic acid is essential/important for growth and division of cells
 - Vitamin K and D(combined vitamins claims)
 - Vitamins K and vitamin D work synergistically on bone metabolism to improve bone strength/ build strong bones



Newest "Other Function Claim" in Singapore

- New other function claim gazetted permitted from April 2017
- "(3) In the case of prepacked foods that have added to it barley beta-glucan and meet the criteria in paragraph (4), the following claim may be made in a label:
 - "Barley beta-glucans have been shown to lower/reduce blood cholesterol. High blood cholesterol is a risk factor in the development of coronary heart disease.".
- Cholesterol, saturated fatty acids and trans fatty acids present in the food are within specific levels
- A statement : effect that consumption of at least 3 g of barley beta-glucans in a day has been shown to lower blood cholesterol levels
- NIP to state the amounts of barley beta-glucan, cholesterol, saturated fatty acids and trans fatty acids



Disease Risk Reduction Claims in Singapore

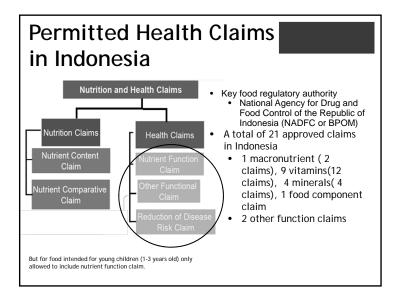
- As of April 2009, food manufacturers may submit applications to AVA or HPB for use of the following nutrient specific diet-related health claims (reduction of disease risk claims):
 - A healthy diet with adequate calcium and vitamin D, with regular exercise, helps to achieve strong bones and may reduce the risk of osteoporosis. (Name of food) is a good source of/high in/enriched in/fortified with calcium.
 - A healthy diet low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Name of food) is sodium free/ low in/ very low in/ reduced in sodium.
 - A healthy diet low in saturated fat and trans fat, may reduce the risk of heart disease. (Name of food) is free of/ low in saturated fats, trans fats
 - A healthy diet rich in whole grains¹, fruits and vegetables that contain dietary fibre, may reduce the risk of heart disease. (*Name of food*) is low/ free of fat and high in dietary fibre.
 - A healthy diet rich in fibre-containing foods such as whole grains, fruits and vegetables may reduce the risk of some types of cancers. (Name of food) is free/ low in fat and high in dietary fibre.



Nutrient Function Claims in Indonesia-Examples

Protein	Protein helps in the development and repair of body tissue. Protein is an essential component in children growth and development.
Dietary Fibre	Soluble dietary fiber (Psyllium, beta glucan from oats, inulin from chicory and pectin from fruit) can help maintain / preserve the function of the digestive tract.
Vitamin A	Vitamin A may help in maintaining outer linings surface integrity (eyes, digestive tract, respiratory tract, and skin).
Vitamin B1/ Thiamine	Vitamin B1 plays a role as a co-enzyme for converting carbohydrate into energy.
Vitamin B2/ Riboflavin	Vitamin B2 plays a role as a co-enzyme for converting carbohydrate into energy.
Vitamin B3/ Niacin	Niacin is a co-factor in formation of energy and tissue formation reactions.





Other Function Claims in Indonesia

Dietary fibre

- Soluble dietary fiber (Psyllium, beta glucan from oats, inulin from chicory and pectin from fruit) can help lower blood cholesterol levels if accompanied by a diet of low saturated fat and low cholesterol.
- Insoluble food fiber can help facilitate bowel movements (laxative), if accompanied by drinking enough water.



Disease Risk Reduction Claims in Indonesia

- No positive list on disease risk reduction
- Proposed claim statements should be submitted to Head of Food Products Standardization Directorate for assessment



Health Claim in Philippines

- Conditions for Health claims:
 - Based on current relevant and scientific facts and the level of proof is sufficient to support the claimed effect and the relationship to health
 - Acceptable to the competent authority where the food is sold
 - Claimed benefit should arise from the consumption of a reasonable quantity of the food or food constituent
 - If the claimed benefit is attributed to a nutrient with established reference value, the food should be:
 - · Source of or high in the nutrient/constituent
 - . Low in or reduced in or free of the nutrient/food constituent
 - Only those essential nutrients for which Nutrient Reference Values (or recently established DRI) have been established should be the subject of a nutrient function claim

Southeast Asia Region

Permitted Health Claims in Philippines



- Key food authority-Food and Drug Administration
- The rules on any use of nutrition claims or health claims in food shall be covered by the rules of B.C. 2007-002 (Guidelines on the Use of Health and Nutrition Claims in Food) based on the Codex Guidelines
- Types of health claims allowed:
 - Nutrient function and other function claims
 - Disease reduction risk claims
 - No positive list is available



Although at present most of the applications and approval were nutrient function claims.

Regulatory Framework and Scientific Evidence required in SEA Region for Health Claims



Survey on Status of Nutrition Labeling and Claims Regulations in Southeast Asia

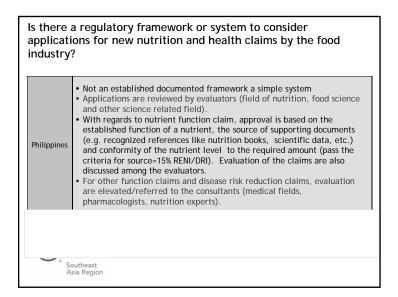
- Prior to each NL and claims workshop, structured surveys were conducted, with the latest one done in May 2016
- Information gathered from SEA regulators which covers
 - Different aspects of nutrition labeling
 - Mandatory vs voluntary, nutrients to be declared, NIP formats, expressions against reference, presence of tolerance levels. etc
 - Nutrition and health claims
 - Definition, availability of positive list, regulatory framework, scientific substantiation, etc





Is there a regulatory framework or system to consider applications for new nutrition and health claims by the food industry? An approval system has been established by FSQD Division, MOH to review applications for new claims submitted by industry. All applications are reviewed by an Expert Working Committee on Nutrition, Health Claims & Advertisement. All applications must be made in the forms prescribed by MOH Malaysia with complete documents. There are three (3) types of forms: 1. Application for addition to the permitted added nutrient list 2. Application for the nutrition claims 3. Application for addition to the NRV list Information required in the forms include physiological role, chemical and physical properties, processing method, safety evaluation, scientific substantiation.

Is there a regulatory framework or system to consider applications for new nutrition and health claims by the food industry? Yes. Application form is available • Shall be supported by scientific substantiations of claim which will be reviewed by an evaluator group and/ or expert group (if needed) Indonesia ·Based on the result of the review, evaluators and experts provide recommendation to NADEC •Based on such recommendation, NADFC will publish approval/reject letter. Applications for use of new nutrient function and other function claims as defined by Codex can be submitted to AVA using official application form. Singapore Guidance information, application form and checklist for application are also posted at the following URL: http://www.ava.gov.sg/explore-by-sections/food/labelling-packaginginformation/labelling-guidelines-for-food-importers-manufacturers



What kind of evidence is required to be submitted by the industry for the substantiation of new health claims?

Indonesia	 Scientific evidence data, especially clinical study which has been published in peer reviewer scientific journal.
	All applications for claims must be accompanied by scientific data to substantiate the proposed claim:
Malaysia	Data from human intervention trials are preferred; the data should include both positive and negative findings(totality) Epidemiological and experimental studies and review papers may be included as supportive evidences The studies cited must be appropriate for the intended target group Studies should include those conducted by other organizations or institutions Publications cited should be published in refereed journals
Philippines	 The consultants would require substantiation other than scientific data depending on the claim. Evidence from well designed human intervention studies. These should be peer reviewed, published and reproduced.
	CI



How about functional foods in other countries?



What kind of evidence is required to be submitted by the industry for the substantiation of new health claims?

 AVA made reference to Codex document, "Recommendations on the Scientific Substantiation of Health Claims" for evidence required to justify for use of new nutrient function and other function health claims, Types of evidence include the followings:
 Human studies:

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- a) Experimental intervention studies e.g. RCT, RT
- b) Observational studies e.g. cohort studies, case-control studies, cross-sectional studies
- 2. Non-human studies e.g. animal, ex vivo, in vitro studies
- 3. Systematic reviews such as pooled analysis, meta-analysis
- 4. Contradictory information
- 5. Recommendations by food safety authorities of major developed countries on the use of the proposed claims.



Other Countries-Vietnam

- Vietnam: Circular No. 43/2014/TT-BYT dated November 24, 2014 on Regulating the Management of Functional Food
 - Functional foods are defined as
 - Supplemented foods means ordinary foods supplemented with micronutrients and other elements conducive to the health such as vitamins, minerals, amino acids, fatty acids, enzymes, probiotics, prebiotics and other biologically active substances
 - Health supplements, Food supplements, & Dietary supplements
 - Foods for special medical purposes or medical foods
 - Food for special dietary uses



Other Countries- Vietnam

- Vietnam: Circular No. 43/2014/TT-BYT dated November 24, 2014 on Regulating the Management of Functional Food
 - Health claims for functional foods:
 - a) Shall be made only when the active substance's content in the product reaches 10% RNI or above and is proven with specific scientific evidence
 - b) For those without RNI, health claims shall be made only when are proven with scientific evidence or level of such ingredients are in line with recommendations from published scientific documents
 - c) Health claims must be clear, consistent, and suitable for the target users and dosage $\,$
 - No available positive list



China Health Foods-27 Approved Claims

- 1) Enhancing immune function
- . 2) Anti-oxidative function
- 3) Assisting memory improvement function
- 4) Alleviating eye fatigue function
- 5) Facilitating lead excretion function
- 6) Moistening and cleaning throat function.
- 7) Improving sleep function
- 8) Facilitating milk secretion function
- 9) Alleviating physical fatigue function
- 10) Enhancing anoxia endurance function
- 11) Assisting irradiation hazard protection
- 12) Improving child growth and
- development function
 13) Increasing bone density function



- 14) Improving nutritional anemia function
- 15) Assisting the protection against chemical injury of liver function
- 16) Eliminating acne function
- 17) Eliminating skin chloasma function
- 18) Improving skin water content function
- 19) Improving skin oil content function
- 20) Regulating gastrointestinal tract flora function
- · 21) Facilitating digestion function
- 22) Facilitating feces excretion function
- 23) Assisting protection against gastric mucosa damage function
- 24) Weight control function
- 25) Assisting blood lipids reduction function
- 26) Assisting blood sugar reduction function
- 27) Assisting blood pressure reduction function

Other Countries- China



- China: "Functional foods" are also known as "Health Foods"
 - A food that has <u>special health functions</u> or able to supply vitamins or minerals. It is suitable for the consumption by special groups of people, and has the function of regulating human body, but is not used for therapeutic purposes. And it shall not have any harmful effects whether acute or sub-acute or chronic.
 - Health claims (except disease risk reduction claims) are permitted for health foods
- Since 2003, health foods are regulated in China on individual product basis, including application, expert review and final approval by China FDA



Harmonization Opportunity



Health Claims in SEA- Conclusion

- No harmonized health claims regulations in SEA countries
- Significant differences in the permitted nutrition and health claims
 - Nutrient function claims permitted in
 - Indonesia, Malaysia, Philippines, Singapore and Thailand
 - Other function claims permitted in the following countries
 - Indonesia, Malaysia, Philippines, Singapore
 - Disease risk reduction claims permitted in only 3 countries



Indonesia, Philippines, Singapore

Southeast Asia Region

Potential Areas for Harmonization

- Expressing 4 core nutrients (energy, protein, CHO and fat) on NIP, potentially extending to a maximum of 7 nutrients, according to Codex
- Expressing nutrients as amount per 100 ml/g AND per serving size
- Use of Codex NRV in nutrition labeling and nutrient content claims
- Express CHO excluding dietary fibre in the NIP and use fiber content in energy calculations
- Use Codex guidelines regarding only declaring optional vitamins and minerals when the presence is at least 5% of the relevant NRV
- Nutrients declaration tolerance levels and compliance
- Adopt a common list of nutrient function claims for ASEAN



Why is Harmonization Needed?



- These labeling and claims differences :
 - Cause confusions among consumers
 - Potential barriers to trade as it is challenging to have so many different sets of labels
- Continue to work with authorities and key stakeholders
 - At Nov 2013's 8th Workshop, it was agreed that some areas under NIP/Nutrient Declaration could be harmonized
 - Discussion continued at 9th Workshop in Aug 2015
 - A workshop was held to discuss the 7 potential areas for harmonization in May 2016



Outcome from May 2016 Workshop

- List of nutrient functions claims compiled
 - All similar nutrient function claims approved in at least 3 out of the 4 countries were separately listed and could potentially be considered as a common list of permitted nutrient function claims in ASFAN
 - Allow countries to compare and decide if they would like to standardize the wordings for permitted common claims or if they would like to adopt the claims which are currently not permitted in their countries
 - Reported and shared at ACCSQ's PFPWG



Prepared Foodstuff Product Working Group

- The Prepared Foodstuff Product Working Group (PFPWG)
 was established in 2003 under ASEAN Consultative
 Committee on Standards & Quality (ACCSQ) with one of the
 key responsibilities to identify areas for possible
 harmonization
- Established a subsidiary Task Force on Harmonization of Prepared Foodstuff Standards in 2008, which addresses harmonization of standards for food additives, contaminants, food contact materials, etc.



Thank You!

Any Questions?



ILSI SEA Region will continue to facilitate the discussion on functional foods, labeling and claims

 10th Seminar and Workshop will be held in 3rd Quarter of 2018!
 Please join us!

