

Regulations and Guidelines Relating to Functional Foods in South-East Asia

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Outline

- ILSI and Functional Foods – Foods With Added Health Benefits
- Status of Claims in SEA Region
- Status of Claims in USA
- Challenges and Opportunities



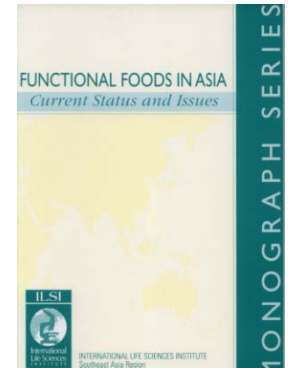
ILSI and Functional Foods

- One of ILSI's 4 global issues
- ILSI provides international forum for information sharing and discussion
 - ILSI SEA Region organized the **1st International Conference on East-West Perspectives on Functional Foods** in 1995
 - Followed by 3 additional global conferences on functional foods organized by ILSI Europe and SEA Region
 - Many other ILSI branches also organized regional and local meetings on functional foods
 - **National Conference on Processed Foods & Beverages for Health: Beyond Basic Nutrition, April 29-30, 2011, New Delhi, India**
 - **ILSI SEA Region: A total of 8 seminars and workshops on related topics**



ILSI SEA Region's Initiatives to Address Functional Foods

- Survey of Current Status of Functional Foods in Asia
 - Definition and regulatory status
 - System for regulatory review and approval of claims
 - Information on scientific substantiation
 - Market situation
- ILSI SEAR's first Monograph – Asian Perspective On Functional Foods published in Dec 2004
 - Asian Position Paper
 - Summary of the survey of functional foods in the Asia
 - Consumers' understanding and expectation in selected countries



Functional Foods

- No official definition of functional foods in SEA countries except **Indonesia**
 - Processed food that contains one or more functional components based on scientific assessment and has certain physiological functions beyond basic functionality; is proven to have beneficial health effect and has no negative effects



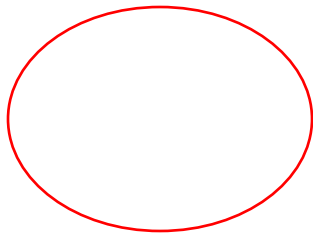
Functional Foods

- In many other parts of world, functional foods are simply refer to foods with claims
- In general, “working” definition is:
 - Foods that have beneficial effects on body functions that go beyond adequate nutritional effects and are relevant to an improved state of health and well-being and/or a reduction of the risk of disease
- Japan was the first to acknowledge this group of foods
 - Foods for Specified Health Uses (FOSHU) in 1991



Functional Foods and Claims

- Nutrition and health claims are usually used as tools by food industry to communicate health benefits of “functional foods” to consumers



National Nutrition Labeling and Claims Regulations

- Every country has its own set of national food regulations including nutrition labeling and claims regulations
 - Differ from country to country
 - Sometimes cause consumer confusion
 - A form of “trade barrier”
- Need for harmonized standards
 - Follow international standards - Codex



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Nutrition Labeling and Claims in SEA Region

- ILSI SEA Region conducts regular survey on nutrition labeling and claims in the region



Nutrition Labeling and Claims in SEA Region

- No harmonized regulations on nutrition labeling and claims in the SEA countries
 - No mandatory labeling for general foods in selected SEA countries except **Malaysia** as per current national regulations
 - Only mandatory labeling for foods for special dietary use, foods that are enriched or fortified and foods making nutrient claims
 - **Thailand:** Also mandatory for some snacks foods such as potato chips, popcorn, extruded snack, biscuit/cracker and filled wafer
 - Voluntary nutrition labeling is permitted but should follow the prescribed format



Are Nutrition Claims (as defined by Codex) Allowed in SEA?

Brunei	Indonesia	Malaysia	Philippines	Singapore	Thailand	Vietnam
<p>-Yes</p> <p>-Energy value</p> <p>- The amounts of protein, carbohydrate, fat and the amount of any other nutrients for which a nutrition claim is made in respect of the food</p>	<p>-Yes</p> <ul style="list-style-type: none"> • Nutrient Content Claims • Nutrient Comparative Claims <p>- Using NRV Indonesia.</p>	<p>-Yes</p> <p><u>2 types:</u></p> <p>1) Nutrient content claim</p> <p>-Format and criteria similar to Codex except:</p> <p>i) claims on cholesterol: do not link to Sat FA & Trans FA</p> <p>ii) Low sugar claim</p> <p>iii) Content claim for sodium in liquid form</p> <p>2) Nutrient comparative claim</p> <p>- Format and criteria similar to Codex</p> <p>In addition, Claims for enrichment are also permitted</p>	<p>-Yes. Same as Codex</p> <ul style="list-style-type: none"> - Nutrient Content Claim - Nutrient Comparative Claim <p>-But the dietary standard used is not the Codex NRV but the Philippine RENI</p>	<p>Yes</p> <p><u>2 types:</u></p> <p>1) Nutrient content claim</p> <p>- as given in Codex, use RDA in place of NRV</p> <p>- Requirements for protein and energy, and RDAs for vitamins & minerals are given in Regulations. To follow guidelines established by Health Promotion Board for other nutrients</p> <p>2) Nutrient comparative claim</p> <p>- To follow guidelines established by Health Promotion Board</p>	<p>Yes,</p> <p><u>2 types:</u></p> <p>1) Nutrient content claim</p> <p>-Format and criteria similar to Codex but using Thai RDI in place of NRV</p> <p>2) Nutrient comparative claim</p> <p>-Format and criteria similar to Codex</p>	<p>-Yes, claims as to the presence of vitamins and minerals</p> <p><u>2 Types</u></p> <p>1) Nutrient qualitatively content claim</p> <p>2) Nutrient qualitatively comparative claim</p>



Are Health Claims (as defined by Codex) Permitted in SEA?

Brunei	Indonesia	Malaysia	Philippines	Singapore	Thailand	Vietnam
- No	<p>Yes.</p> <p>-Nutrient Function Claims</p> <p>- Other Function Claims</p> <p>-Reduction of Disease Risk Claims</p>	<p>-Yes, nutrient function claims are permitted. They include claims for nutrients as well as “other food components” (similar to other function claims of Codex)</p> <ul style="list-style-type: none"> • Only 52 nutrient and other function claims permitted in a positive list (as of August 2010) • Industry may apply for additional claims through an approval system established by MOH <p>Disease risk reduction claims are not permitted</p>	<p>-Yes</p> <p>-Nutrient Function Claims</p> <p>-Other function claims</p> <p>-Reduction of Disease Risk claims</p>	<p>- Nutrient function claims which are well known in nutrition science may be allowed without further substantiation.</p> <p>-Since April 2009, industry members may apply for use of the five nutrient specific diet-related health claims for their food products which have been endorsed to carry the Healthier Choice Symbol by Singapore’s Health Promotion Board</p> <p>-Since February 2010, industry members may also submit applications to AVA for use of “Other Function Claims”. The applications will be considered by AVA’s Advisory Committee on Evaluation of Health Claims, formed in August 2009.</p>	<p>-Yes</p> <p>- Nutrient function claims when evidence established- positive list with 29 claims.</p> <p>-Additional claims are substantiated and can be applied on a case-by-case basis</p> <p>- Other function and disease risk reduction claims are not permitted at this moment, pending new regulation on health claim.</p>	<p>- Yes. Nutrient function claims are introduced and permitted “Antioxidant nutrients” “Promote... for....”</p> <p>- Industry may apply for additional claims based on MOH approval (mainly functional foods)</p>



Nutrient Function Claims in Singapore

- Protein helps in tissue building and growth
- Low lactose content eases digestion for people who are lactose intolerant
- Enriched with Vitamin D for calcium absorption
- Calcium helps build strong bones and teeth
- Iron is one of the essential minerals vital for life
- Folate helps support fetus' growth and overall development

For more information, please refer to AVA website:

<http://www.ava.gov.sg/FoodSector/FoodLabelingAdvertisement/>



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Health and Nutrition Claims- Singapore

- Nutrient specific diet-related health 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.



Health and Nutrition Claims- Singapore

- Nutrient specific diet-related health claims:
 - A healthy diet rich in whole grains⁺, 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 - Malaysia

- Some examples of function claims:
 - Oat soluble fiber (β -glucan) help lower / reduce cholesterol
 - Plant sterol / plant stanol helps lower / reduce cholesterol -only for milk, milk product, soya milk and soya drink only with some additional labeling requirement)
 - Soy protein help to reduce cholesterol
 - Vitamin E protects the fat in body tissues from oxidation
 - Vitamin A is essential for the functioning of the eye
 - Zinc is essential for growth



Is There a Regulatory Framework or System for the Approval of New Nutrition and Health Claims?

Brunei	Indonesia	Malaysia	Philippines	Singapore	Thailand	Vietnam
<p>- Yes, done case by case through formal applications to Director General of Health Services</p>	<p>-Yes</p> <p>-- Must submit scientific substantiations of claim to be reviewed by an evaluator group and expert group (if needed).</p> <p>-Based on the result of the review, evaluators and experts give recommendation to BPOM.</p> <p>-Based on such recommendation BPOM publishes the approval/ reject letter.</p> <p>Today, BPOM is preparing the Guidelines.</p>	<p>-Yes, an approval system has been established by Food Safety & Quality Control Division, MOH to review applications for new claims submitted by industry.</p> <p>-Applications are reviewed by an Expert Group on Nutrition, Health Claims & Advertisement (established in 1996)</p> <p>-Information required in the forms include physiological role, chemical and physical properties, processing method, safety evaluation, scientific substantiation</p> <p>- The working group also looks into harmonization of other function claim that already approved by other countries especially ASEAN</p>	<p>-Not an established documented framework but a very simple system.</p> <p>-Applications are reviewed by evaluators.</p> <p>-For nutrient function claims, whose nutrient function is established and the supporting documents came from recognized references, and the level also conform to standard (source/high) they are just discussed among the evaluators.</p> <p>- But for other function claims and disease risk reduction claims, the evaluations are elevated/referred to the consultants.</p>	<p>Applications for use of nutrient specific diet-related health claims should be submitted to AVA or HPB. Details on the requirements and application process can be found at the following URL: http://www.ava.gov.sg/FoodSector/FoodLabelingAdvertisement/</p> <p>Applications for use of of new nutrient function and other function claims as defined by Codex should be submitted to AVA.</p>	<p>-Yes, an approval framework based on risk analysis</p> <p>-Must submit scientific substantiations of claim</p> <p>-All substantiations are reviewed by an expert group</p> <p>-Expert's viewpoints are considered by Thai FDA for approval</p>	<p>-Yes</p> <p>- Applications are reviewed by experts</p> <p>-Laboratory analysis of nutrient content if necessary</p> <p>- Approved by giving certificate to companies or industry</p>



What Kinds of Evidences Are Required to be Submitted for the Substantiation of New Health Claims?

Brunei	Indonesia	Malaysia	Philippines	Singapore	Thailand	Vietnam
-	<p>-Scientific evidence data, especially clinical study that published in peer reviewer scientific journal.</p> <p>- Nutrient function claim should be supported by at least 1(one) clinical trial (<i>Randomized Controlled Trials</i>)</p> <p>- For reduction of disease risk claim should be supported by at least 3 (three) clinical trial (<i>Randomized Controlled Trials</i>)</p>	<p>-Data from human intervention trails (RCTs) are preferred; data from at least 5 human trials are required</p> <p>- In addition, experimental and epidemiological studies may be included to support the application</p> <p>- Reviews and meta-analysis publications may also be included</p> <p>-Studies should preferably be from a variety of organizations</p> <p>-Published in refereed journals</p>	<p>-The consultants would require substantiation other than scientific data depending on the claim.</p> <p>- Evidence from well designed human intervention studies. These should be peer reviewed, published and can be reproduced.</p>	<p>Types of evidence include the followings:</p> <ol style="list-style-type: none"> Human studies: <ol style="list-style-type: none"> Experimental intervention studies eg. RCT, RT Observational studies eg. cohort studies, case-control studies, cross-sectional studies Non-human studies eg. animal, <i>ex vivo</i>, <i>in vitro</i> studies Systematic reviews such as pooled analysis, meta-analysis Contradictory information Recommendations by food safety authorities of major developed countries on the use of the proposed claims. 	<p>- Human Intervention Study (Clinical trials) of final product must be submitted.</p>	<p>-Data on value of nutritive content</p> <p>-Results of clinical intervention studies</p> <p>-If necessary, the local clinical trial would be needed</p> <p>- Review of meta analysis results</p> <p>- Publications in the journals</p>



Plans to Amend Current Regulations on Nutrition and Health Claims

- No new plans for Malaysia ,Singapore & Vietnam
- Indonesia
 - Draft regulations on Guidelines for Nutrition and Health Claims Control on Food Label and Advertisement
- Philippines:
 - Planning mandatory nutrition labeling
- Thailand
 - In the process of drafting of health claim regulation



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Functional Foods in USA

- No official definition of functional foods
- Allow nutrition and health claims which are defined by two laws
 - Nutrition Labeling and Education ACT (NLEA) in 1990
 - Dietary Supplement Health and Education Act (DSHEA) in 1994



Types of Claims Allowed in US

- Nutrient content claims
- Structure function claims
- Qualified health claims
- Health claims



USA - Health Claims

- Health claims describe a relationship between a food, food component, or dietary supplement ingredient, and reducing risk of a disease or health related condition
- Substantiation: “Significant scientific agreement” among qualified experts, based on totality of evidence
 - Requires a strong, relevant, consistent body of evidence that is not likely to be reversed by new and evolving science
 - Clinical trials of the substance that is the subject of the claim, not the exact product on which the claim appears
 - If the product is not tested, the claim may need to refer to the substance rather than the product



Health Claims in USA

- Approved health claims:
 - **Calcium , Vitamin D and osteoporosis:** Food or supplements must be high in calcium and Vitamin D.
 - **Sodium and hypertension :** Foods must qualify as “low sodium”.
 - **Dietary lipids and cancer:** Foods must qualify as “low fat” or, in the case of meat and poultry, as “extra lean”.
 - **Saturated fat and cholesterol and risk of coronary heart disease:** Foods must qualify as “low saturated fat,” “low cholesterol,” and “low fat” or, in the case of meat and poultry, as “extra lean”.



Health Claims in USA

- Approved health claims:
 - **Fiber containing grain, fruits and vegetables and risk of cancer** : Grain products, fruits, or vegetables must qualify both as “low fat” and as “good sources” (without fortification) of dietary fiber.
 - **Grains, fruits and vegetable products that contain fiber, particularly soluble fiber, and risk of coronary heart disease**: Fruits, vegetables, or grain products must qualify as “low saturated fat,” “low cholesterol,” and “low fat” and provide at least 0.6 grams of soluble fiber per serving.



Health Claims in USA

- Approved health claims:
 - **Fruits and vegetables (containing one or more of Vitamin A, C and dietary fiber) and risk of cancer:** Fruits and vegetables must qualify as “low fat” and as “good sources” of vitamin A, C or dietary fiber.
 - **Folate and Neural Tube defects :** Foods must qualify as “good sources” of folate (40 mcg per serving) and contain no more than the recommended intakes of Vitamin A or D.
 - **Plant sterol/stanol esters and risk of coronary heart disease:** Foods must have at least 0.65 g plant sterol esters per serving of spreads and dressing or 1.7 grams plant stanol esters per serving; must be low in sat. fat and cholesterol.



Health Claims in USA

- Approved health claims:
 - **Soluble fiber from oats or psyllium and risk of coronary heart disease:** Products must provide at least 0.75 grams of soluble fiber from whole oats or 1.7 grams of soluble fiber from psyllium seed husk per serving and qualify as “low saturated fat,” “low cholesterol,” and “low fat”
 - **Soybean protein and coronary heart disease :** Products must be low fat and cholesterol and contain at least 6.25 g of soy protein per serving
 - **Dietary Noncariogenic Carbohydrate Sweeteners and Dental Caries :** Sugar free, and when a fermentable carbohydrate is present, the food must not lower plaque pH below 5.7 by bacterial fermentation



Health Claims in USA

- Approved health claims based on authoritative statements by Federal Scientific Bodies:

Statement published by NAS, NIH, CDC, Surgeon General, Food and Nutrition Services, etc to be submitted to FDA

- **Potassium and risk of high blood pressure and stroke:** Products must be good sources of potassium and low in sodium, total fat, sat. fat and cholesterol.
- **Whole grains foods and risk of heart disease and certain cancer :** Products must contain 51 % or more whole grain ingredient by wt per serving and low fat
- **Fluoridated Water and Reduced Risk of Dental Carries:** Bottled water meeting the standards of identity and quality
- **Saturated Fat, Cholesterol, and Trans Fat, and Reduced Risk of Heart Disease:** Low saturated fat -Low cholesterol, bear quantitative *trans* fat labeling, contain less than 0.5 g *trans* fat per RACC, contain less than 6.5 g total fat



Qualified Health Claims in US

- FDA may allow qualified health claims to be made when the evidence is **not well enough established** to meet the **significant scientific agreement standard** required for FDA to issue an authorizing regulation
- Qualifying language is included as part of the claim to indicate that the evidence supporting the claim is limited
- Both conventional foods and dietary supplements may use qualified health claims
 - **Include a disclaimer**



Disclaimers for QHC

- “Although there is scientific evidence supporting the claim, the evidence is not conclusive”
- “Some scientific evidence suggests ..however, FDA has determined that this evidence is limited and not conclusive”
- “Very limited and preliminary scientific research suggests...FDA concludes that there is little scientific evidence supporting this claim”



Qualified Health Claims in US

- Qualified Claims About Cancer Risk
 - Selenium and cancer
 - Antioxidant Vitamins & Cancer
 - Calcium and Colon/Rectal Cancer & Calcium and Recurrent Colon/Rectal Polyps
 - Tomatoes and/or Tomato Sauce & Prostate, Ovarian, Gastric, and Pancreatic Cancers
 - Green tea and cancer



Qualified Health Claims in US

- Qualified Claims About Cardiovascular Disease Risk
 - Nuts & Heart Disease
 - Walnuts & Heart Disease
 - Omega-3 Fatty Acids & Coronary Heart Disease
 - B Vitamins & Vascular Disease
 - Monounsaturated Fatty Acids From Olive Oil
 - Unsaturated Fatty Acids from Canola Oil and Reduced Risk of Coronary Heart Disease
 - Corn Oil and Corn Oil-Containing Products and a Reduced Risk of Heart Disease



Qualified Health Claims Examples

- Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive
- Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease. FDA evaluated the data and determined that, although there is scientific evidence supporting the claim, the evidence is not conclusive



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Functional Foods and Claims – Challenges

- Expensive and time consuming for food industry
 - R&D, Scientific Substantiation
- Different regulations in the region
 - Lack of definition
 - Review process of claims is different
- Consumer understanding varies
 - Lack of data on how consumers understand and utilize such information



Functional Foods and Claims – Challenges

- Need for effective communication on labeling and claims information to consumers
 - Lack of resources to carry out educational activities or research
- Enforcement
 - Information provided is factual



Opportunities for Functional Foods and Claims

- Long history of functional foods and ingredients in Asia
- Consumers are asking for healthier and innovative food products
 - Food companies compete to develop healthier alternatives
 - Functional foods
- Regulatory agencies are aware of the challenges faced by industry
 - Willing to discuss with the industry via different platforms
 - Developing clearer regulations



Overall Summary

- Functional foods are foods that provide health benefits beyond basic nutrition
- Claims are used to communicate benefits of functional foods to consumers
- No harmonized nutrition labeling and claims regulations in SEA region
- Challenges and opportunities in the development of functional foods and claims



Thank You !



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