Health claims & Scientific Substantiation in SEA - Process & key learnings

E-Siong Tee, PhD
Scientific Director, ILSI SEA Region
(nutrihealth.tes@myjaring.net)

Outline ....
- Summary of health claims status in SEA countries
  - Other function claims
  - Disease reduction claims
- Regulatory framework for review of health claim applications in SEA
  - Expert committees
  - Information required for review
- Scientific substantiation of claims
  - Sharing some lessons
  - Common errors/omissions/weaknesses

Summary of regulatory status of health claims in SEAsia

..... Brunei, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand, Vietnam

Background ....
- Health claims permitted in some countries in SEA region
  - mostly arising from applications from food industry for “other components”
  - other function claims and disease reduction claims
- Regulatory framework, in various forms, exist in SEA to review applications
- Authorities require substantiation of proposed health claims
- Significant interest in the requirements for dossiers, review process, why some applicants are not successful
- Share experiences of the review process and key learnings (especially from perspectives of Malaysia)
Survey of regulations in the SEAsian region
- input by regulators in 9 Southeast Asian countries
- responded to a structured format, including
  - various aspects of nutrition labeling and FOP
  - nutrition claims, nutrient function claims, other function claims and disease risk reduction claims
  - substantiation of health claims
  - regulatory framework
  - definition of claims as given in Codex Alimentarius guidelines
- Supplemented with information from website of regulatory agencies
- Only findings for other function claims and disease reduction claims are presented here

Status of other function claims - other food components, functional ingredients: permitted in 5 countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brunei</td>
<td>Not permitted</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Yes, in new health claims regulations (dietary fibre, plant sterol/stanols)</td>
</tr>
<tr>
<td>Lao PDR</td>
<td>Not permitted</td>
</tr>
<tr>
<td>Malaysia</td>
<td>Yes, 29 claims for variety of other food components; all petitions from industry; positive list</td>
</tr>
<tr>
<td>Myanmar</td>
<td>Not permitted</td>
</tr>
<tr>
<td>Philippines</td>
<td>Yes, according to Codex; no positive list</td>
</tr>
<tr>
<td>Singapore</td>
<td>10 claims for collagen, probiotics, prebiotics, plant sterols; positive list</td>
</tr>
<tr>
<td>Thailand</td>
<td>Not permitted*</td>
</tr>
<tr>
<td>Vietnam</td>
<td>Yes, according to Codex; no positive list</td>
</tr>
</tbody>
</table>

*Thailand has a positive list of permitted probiotic cultures

Status of disease risk-reduction claims: permitted only in 3 countries, for a limited number of nutrients/food components

<table>
<thead>
<tr>
<th>Country</th>
<th>Status</th>
</tr>
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<tbody>
<tr>
<td>Brunei</td>
<td>Not permitted</td>
</tr>
<tr>
<td>Indonesia</td>
<td>7 types of components, positive list</td>
</tr>
<tr>
<td>Lao PDR</td>
<td>Not permitted</td>
</tr>
<tr>
<td>Malaysia</td>
<td>Not permitted</td>
</tr>
<tr>
<td>Myanmar</td>
<td>Not permitted</td>
</tr>
<tr>
<td>Philippines</td>
<td>Yes, according to Codex; no positive list</td>
</tr>
<tr>
<td>Singapore</td>
<td>5 nutrient/food specific claims, positive list</td>
</tr>
<tr>
<td>Thailand</td>
<td>Not permitted</td>
</tr>
<tr>
<td>Vietnam</td>
<td>Not permitted</td>
</tr>
</tbody>
</table>

Positive list of permitted health claims: yes in 3 countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brunei</td>
<td>NA</td>
</tr>
<tr>
<td>Indonesia</td>
<td><a href="http://www.pom.go.id/search/query2.asp?qs_materi=t_hukum">http://www.pom.go.id/search/query2.asp?qs_materi=t_hukum</a> Perundangan&amp;qs_search=pengawasan+klaim&amp;qs_TX=1</td>
</tr>
<tr>
<td>Lao PDR</td>
<td>NA</td>
</tr>
<tr>
<td>Malaysia</td>
<td>Yes, listed in Guide to Nutrition Labelling and Claims (as at December 2010); <a href="http://fsq.moh.gov.my/v4/index.php/component/k2/item/460">http://fsq.moh.gov.my/v4/index.php/component/k2/item/460</a></td>
</tr>
<tr>
<td>Myanmar</td>
<td>NA</td>
</tr>
<tr>
<td>Philippines</td>
<td>Only for probiotic as food supplement</td>
</tr>
<tr>
<td>Singapore</td>
<td>Yes, listed on AVA website: <a href="http://www.ava.gov.sg/FoodSector/FoodLabelingAdsvertisemen">http://www.ava.gov.sg/FoodSector/FoodLabelingAdsvertisemen</a> t/</td>
</tr>
<tr>
<td>Thailand</td>
<td>Positive list of permitted probiotics</td>
</tr>
<tr>
<td>Vietnam</td>
<td>NA</td>
</tr>
</tbody>
</table>
There are no harmonised health claims regulations in SEAsian countries

There are significant differences

- other function claims permitted in 5 countries
  - Indonesia, Malaysia, Philippines, Singapore, Vietnam
  - relate to several bioactive components eg several dietary fibres and non-digestible oligosaccharides, plant sterols, PUFAs
- Disease risk reduction claims are considered higher level claims and are permitted only in 3 countries
  - Indonesia, Philippines and Singapore
  - and only for a few nutrients or bioactive compounds or food

Regulatory framework for review of health claims in SEAsia

..... Indonesia, Malaysia, Singapore,

Regulatory system related to claims differ considerably

- 3 countries adopt a positive-list approach
- claims not on the listed are not permitted, but industry may apply on a case-by-case basis
- approval based on scientific substantiation of proposed claim

Each claim has to be accompanied by scientific substantiation which will be reviewed by a panel of experts appointed by the regulatory agency
- Experts from various agencies and expertise

Examples of expert committees

- National Agency for Drug and Food Control, Indonesia
- Expert Group on Nutrition, Health Claims and Advertisement – Food Safety & Quality Division, MOH Malaysia; meet every month to review applications and other regulatory matters
- Advisory Committee for Evaluation of Health Claims – Agri-Food and Veterinary Authority, Singapore
- and a variety of approaches by Philippines Food and Drug Administration, Thailand Food and Drug Administration, Vietnam National Institute for Food Control

Similar requirements in the application forms from the 3 countries – Indonesia, Malaysia, Singapore
Use application form in Guide Book to assist industry and enforcement officers understand nutritional labeling and claims regulations

Revised December 2010


APPLICATION FOR USE OF HEALTH CLAIMS FOR FOOD INTENDED FOR SALE IN SINGAPORE

Part A: Applicant Information

Company Name: ____________________________
Address: ____________________________
Contact Person Name: ____________________________
Company Name (if different from above): ____________________________
Address (if different from above): ____________________________
E-mail: ____________________________
Telephone: ____________________________
Fax: ____________________________

Part B: Summary of Proposed Claim

Types of claims (please tick where relevant):

- Nutrient function claim
- Other function claim
- Disease risk reduction claim

http://www.ava.gov.sg/AVA/Templates/AVA-GenericContentTemplate.aspx?NRMODE=Published&NRNODEGUID=%7bB96B0EC2-1D1E-4448-9C29-ABD9702B474%7d&NRORIGINALURL=%2fFoodSector%2fFoodLabelingAdvertisement%2f&NRCACHEHINT=Guest#FbFoodForSale

Malaysia -

Applying for new health claims – other function claims (Regulation 18E)

*general principles are same for other countries*

For a compound to make a health claim, it must be a permitted “added nutrient”

- Regulation 26 of Food Regulations 1985 regulates the use of “added nutrients” to foods
- “added nutrients” includes any mineral, vitamin, amino acid, fatty acid, nucleotide or other food components which, when added singly or in combination to food, improves the nutritional value of the food
- “other food components” include various non-nutrients or “functional ingredients” with proven physiological effects beneficial to health
- If is not in this list, an application has to be submitted for approval for use prior to application for health claim

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**TWELFTH SCHEDULE**

(Regulation 26)

**PERMITTED ADDED NUTRIENT**

<table>
<thead>
<tr>
<th>TABLE I</th>
</tr>
</thead>
<tbody>
<tr>
<td>The following added nutrients are permitted in food:</td>
</tr>
</tbody>
</table>

1. **Vitamin and Mineral**
   - Pantothenic acid
     - Calcium pantothenate
     - D - pantothenic acid
     - D - pantethenyl alcohol
     - Panthenol
   - Iron (III) - Casein Complex
   - Iron (Fe)
     - Carbonyl iron
     - Electrolytic iron
     - Ferric ammonium citrate
     - Ferric caseinate
     - Ferric citrate

4. **Nucleotides**
   - Adenosine 5’ - monophosphate
   - Cytidine 5’ - monophosphate
   - Guanosine 5’ - monophosphate
   - Inosine 5’ - monophosphate
   - Uridine 5’ - monophosphate

5. **Other food components**
   - Inulin (except in infant formula)
   - Oligofructose/Fructo-oligosaccharide (except in infant formula)
   - Sialic acid (from milk)
   - Plant sterols or plant stanols or phytosterols or phystanols comprising mainly of sitosterol, campesterol, stigmasterol and other related plant sterol
Main information required for new “added nutrient” application

- Basic information eg
  - chemical structure and properties and physical properties of the nutrient
  - stability in the foods serving as vehicles
  - bioavailability
  - analytical method
  - physiological role
- Safety evaluation important as it is a novel ingredient
- Benefits of adding the nutrient to the food
  - Provide clear scientific evidence

… new added nutrient application

- Name the food (s) to which the nutrient is to be added
  - Preferably, provide a table of the list the foods and indicate the approximate amount that will be added to each of the foods listed
- Provide an estimate of the daily intake of the nutrient, eg from various food sources containing the nutrient. Indicate if there is safety concern if this nutrient is added to the foods proposed

Main information required for new health claim application

- The basic information required for “added nutrient” application
- Propose a minimum level that the nutrient must be present before the function claim can be made
  - Provide scientific justification why this level is proposed
  - Usually this is the level at which the nutrient is effective in bringing about the proposed function claim (eg lowering blood cholesterol)

... new health claim application

- Provide sound scientific evidences for the claim
  - All available literature including both positive and negative findings on the proposed claim must be provided
  - Randomised, placebo-controlled, double-blind human trials
  - Epidemiological and experimental studies and reviewed papers may be included as supportive evidences
  - Studies should include those conducted by other organizations or institutions
  - Result of all these studies should be published in refereed journals
  - Submit a copy of all the scientific publications cited in this section
Examples of some errors/weaknesses in submissions – lessons to be learnt

actual examples of dossiers submitted, but products and compounds have been generalised

personal opinion & views

General errors

- Inadequately prepared dossier
  - too brief description of all required items in form
  - skimpy information/ data presented
- Poorly explained section on substantiation of claims eg
  - mere listing of publications
  - summaries of studies should be provided to facilitate expert committee members reviewing the dossier
  - point out how findings substantiate the claims
- Insufficient scientific data to substantiate
  - Proper literature search to be done
  - Totality of evidence presented

Specific errors/weaknesses

- Wordings of the proposed claim do not match the findings of the studies
- Publications provided are not relevant to the study
- Extrapolated beyond the findings, eg
  - findings are for a specific aspect of immune function, eg gut immune function
  - but the proposed claim is: “compound x helps to improve immune function”
- Gut immune function is only a specific aspect of immune function
  - and may not be extrapolated to bring about beneficial effect to overall immune function
The compound used in the study does not match the compound that is the subject of the claim, eg
- the claim refers to a specific compound x extracted from a particular plant
- but the substance used in the study is an entire aqueous extract of the plant

The plant extract contains compound x as well as many other compounds
- beneficial effects cannot be attributed only to compound x

The food vehicle for the compound does not match the intended claim, eg
- the claim is for a compound x in milk and dairy products
- but the studies submitted had used different food matrix, eg soya milk

The claim is only applicable for the food vehicle used in the study
- It cannot be ascertained that the compound x is still effective in other matrices
- If the claim is intended for different foods, studies should be done using the compound contained in different matrices, eg beverage, cereals, milk products, etc

Several applications received using studies carried out using “pure” compounds
- More like a supplement, consumed with water or a beverage
  - it cannot be ascertained that the compound is still bioavailable and effective when combined in a food matrix
- Studies should be carried out using the compound of interest added to food
  - The regulation deals with food, not supplements
- If the claim is intended for different foods, studies should be done using the compound contained in different matrices
- Several novel ingredients have started off as supplements and not yet used in many food products

Study compounds include compound x plus other biologically active components
- eg to study the prebiotic effect of compound x, other undigestible carbs are also given
- eg to study effect of one PUFA, a mixture of PUFAs are given

Findings confounded by other compounds present; beneficial effects obtained cannot be attributed solely to compound x
- Study compound characteristics not presented
  - could be for proprietary reasons
  - difficult to be approved because no distinguishing feature(s), not unique to the compound in the claim
- A few applications for whole foods
  - eg nutrient fortified formulations
  - Similarly, no clear unique characteristics
Study findings extrapolated to general population
- eg subjects in the studies were infants
- but the claim extrapolated to include older children and teenagers
- It cannot be ascertained that the beneficial effect seen in the study subjects will be similarly observed in other age/physiological groups

Inappropriate scientific data cited
- eg publications were mostly citing usage of compound x in treatment of subjects
- but the application is for improving specific physiological condition in apparently healthy population

Wordings for claims bordering on disease reduction
- eg lowering blood pressure, prevent constipation, diarrhoea
- diseases risk reduction claims not permitted
- Claims linked to diseases not permitted

Concluding thoughts

Health claims in place in SEA for a decade
- In Malaysia, system started in 2005
- applications still being reviewed by MOH regularly

Concerns with difficulty in preparation and submission of dossiers
- Especially smaller companies

Concerns that the requirements for substantiation is too stringent
- is there a need for such stringent requirements “for other function claims”?
- in view that these are food claims, not drugs
Many Asian functional foods have been used for many years as part of local cultures
- no proper documentation of health benefits
- what is the best approach to permitting some claims and yet not misleading?
- how much evidence is enough?
- need to identify all beneficial components?

Framework for health claims only in 3 countries in SEA

Health claims may be permitted in a few other countries, but no clear review system in place
- Need for clear transparent framework in all countries
- Relevant experts, reviewing applications regularly

The series of ILSI SEA Region seminars and workshops will continue to be organised
- to facilitate continued sharing of progress, of experience in area of nutrition labeling and claims
- including sharing of process for substantiation of claims
- Workshop in the afternoon can discuss some of the concerns and issues raised and learnings from this seminar

Thank you!