Functional foods with health benefits - approaches around the globe

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Introduction
- no uniform use of terminology, but generally accepted understanding
- focused on health claims and their scientific substantiation

ILSI a main driving force in R&D
- ILSI SEA Region work on harmonised approach to functional foods
- Major projects in ILSI Europe, especially in scientific substantiation of health claims
- ILSI North America focus on scientific evidence
Outline of presentation

- Worldwide regulatory developments in health claims
  - Codex guidelines on health claims
  - Health claims in selected Asian countries
  - EU Directive on health claims, 2006
  - USFDA approaches to health claims
- Way ahead
  - Continue efforts in providing scientific evidence for substantiation
  - Better consumer understanding
  - Continue opportunities to net work
Introduction ....

Increased interest in bioactive components beyond basic nutrients
Great deal of attention given to potential health significance of components other than nutrients that are found in foods.

Much interest in these bioactive or functional components as they are believed to be able to serve physiological roles beyond provisions of basic nutrient requirements.
- e.g. ability to promote general well being or even reduce the risk of chronic diseases.

Foods containing such components have been termed “functional foods”.
- Such components may be termed “functional components” or “bioactive components”.
There is no unanimously accepted global definition of functional foods
- the term “functional foods” is also currently not used in any of the relevant regulations or legal systems

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) present in these foods

The approach by regulatory agencies towards these foods is therefore focused on
- health claims permitted and
- their scientific substantiation
ILSI a main driving force ....

ILSI SEA Region work on harmonised approach to functional foods
ILSI SEA Region has been in the forefront of scientific activities for more than 15 years to promote a harmonized development of functional foods in the region.


Subsequently, a series of six seminars and workshops has been organized since 2003:
- the latest being in September 2010
- participated by officials of regulatory agencies in SEAsia, as well as research scientists in the Asia Pacific region.
These meetings provided a platform for sharing of views and experiences:
- scientific substantiation and safety evaluation
- regulatory and marketing aspects and
- future developments

Be familiarised with international and regional regulatory developments.

Provide regular updates of national regulatory status and developments.

Provide avenues for harmonising regulatory development of these activities in the region.
Over the years, a number of documents have been published resulting from these scientific activities:

- Monograph on functional foods
- Suggested framework and guidelines for the scientific substantiation
- And safety evaluation of functional foods

Guidance for regulatory agencies in the region
ILSI a main driving force ....

Major projects of ILSI Europe on scientific substantiation of functional foods
Major projects to facilitate the substantiation of health claims of functional foods
Numerous scientific meetings (seminars, workshops) on various aspects
In 1999, the FUFOSE (European Commission Concerted Action on Functional Food Science in Europe) was completed,
  - to assess the science-based required for scientific evidence for claims
Building on this, PASSCLAIM (Process for the Assessment of Scientific Support for Claims on Foods) was completed, 2001-2005
  - provided a generic tool with principles for assessing the scientific support for health-related claims
To test the PASSCLAIM developed criteria, two activities have been carried out:
- the antioxidant actions of polyphenols and ingredients to maintain oral/dental health
- PROCLAIM aimed to provide guidelines for a standardised, evidence-based approach to build scientific data to support a health claim
- The GNP (Good Nutrition Practice) system is promoted so that human intervention studies performed will result in proof of safety and efficacy, which is of high quality, reliable, ethical and retraceable.
Numerous publications in the area of functional foods

http://www.ilsi.org/Europe/Pages/Publications.aspx
Studies on functional foods in ILSI North America
- Given emphasis on examining the scientific evidence for various foods and food components.
- Effect of **flavonoids** on human health, analysis of population intake data linking dietary flavonoids and cardiovascular outcomes
  - understand the level of flavonoid intake that produces a health effect.
- Effect of food components on mental energy (including cognition, mood & motivation)
  - e.g. caffeine, ginko, ginseng, n-3 PUFA, glucose
- Gut microbes and health (**probiotics and prebiotics**)
Numerous publications on functional foods

A review of the epidemiologic evidence concerning the reproductive health effects of caffeine consumption: A 2000–2009 update

Jennifer David Peck\textsuperscript{a,}\textsuperscript{b}, Alan Leviton\textsuperscript{b}, Linda D. Cowan\textsuperscript{a}

\textsuperscript{a} University of Oklahoma Health Sciences Center, College of Public Health, USA
\textsuperscript{b} Harvard Medical School, Children’s Hospital, Neuroepidemiology Unit, One Apple Street, Boston, MA 02215, USA

Flavonoids and Heart Health: Proceedings of the ILSI North America Flavonoids Workshop

Flavonoids and Heart Health: Proceedings of the ILSI North America Flavonoids Workshop, May 31–June 1, 2005, Washington, DC\textsuperscript{1–4}

John W. Erdman, Jr.\textsuperscript{a}, Douglas Balentine\textsuperscript{a}, Lenore Arab\textsuperscript{a}, Gary Beecher\textsuperscript{b}, Johanna T. Dwyer\textsuperscript{c}, John Folts\textsuperscript{d}, James Harnly\textsuperscript{e}, Peter Hollman\textsuperscript{f}, Carl L. Keen\textsuperscript{g}, G. Mazza\textsuperscript{h}, Mark Messina\textsuperscript{i}, Augustin Scalbert\textsuperscript{j}, Joseph Vita\textsuperscript{k}, Gary Williamson\textsuperscript{l}, and Jerri Lynn Burrowes\textsuperscript{m}

Functional Foods for Health Prom. Obesity
2005
Guest Editors: Anderson P, Milner J.

Do specific dietary constituents and supplements affect mental energy? Review of the evidence.

Gorby HE, Brownwell AM, Falk MC
Life Sciences Research Organization, Bethesda, Maryland, USA.

Functional foods for health promotion: microbes and health

Extended abstracts from the 11th Annual Conference on Functional Foods for Health Promotion, April 2008

Authors: Walker, W Allan\textsuperscript{a}; Martens, Eric C\textsuperscript{a}; Sherman, Philip M\textsuperscript{a}; Lampe, Johanna W\textsuperscript{a}; Hullar, Meredith A\textsuperscript{j}; Wu, Christine D\textsuperscript{a}

Source: Nutrition Reviews, Volume 67, Number 1, January 2009, pp. 40–48(9)

ILSI Caffeine Monograph
2002
Journal: Food and Chemical Toxicology
Supported by the Caffeine Working Group
Worldwide regulatory developments in health claims ....

Codex Alimentarius
Discussed at various meetings of Codex, eg the Exec Committee, Codex Committee for Asia, and the Codex Committee on Nutrition and Foods for Special Dietary Uses since 2001

Proposal for an expert consultation to determine if Codex could lead in functional foods discussions

Codex did not approve new work on functional foods; felt that this could be discussed under health claims
Codex Alimentarius Commission guidelines on nutrition claims were revised in 2004 with the addition of health claims, which include:

- nutrient function claims,
- other function claims and
- disease risk reduction claims

the latter two are of relevance to functional foods/components

Guidelines on nutrition and health claims amended by addition of annex on Recommendations on scientific substantiation of health claims, in 2009
Worldwide regulatory developments in health claims

Asia ....

..... Brunei, Indonesia, Malaysia, Philippines, Singapore, Thailand, Vietnam, China, Japan
- Major developments in regulations on nutrition and health claims in the region
- Review of status of health claims in the region
  - presentation only covers other function claims and disease risk reduction claims
  - input by food regulators in 7 Southeast Asian countries, China and Japan
  - through series of ILSI SEA Region series of workshops, the latest being 20 Sept 2010
  - through websites of regulatory authorities
<table>
<thead>
<tr>
<th>Country</th>
<th>Other function claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brunei</td>
<td>Not permitted</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Yes, in functional foods regulation 2005 (now being revised) (e.g. prebiotic, probiotic, plant sterol/stanols)</td>
</tr>
<tr>
<td>Malaysia</td>
<td>29 claims for variety of other food components (eg dietary fibres, non-digestible oligosaccharides, sterol, soy protein, DHA/AA, lutein, soy protein, bifidobacteria). All petitions from industry</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</td>
</tr>
<tr>
<td>Thailand</td>
<td>Not permitted</td>
</tr>
<tr>
<td>Vietnam</td>
<td>Yes; no positive list</td>
</tr>
<tr>
<td>China</td>
<td>Not permitted</td>
</tr>
<tr>
<td>Japan</td>
<td>FOSHU (over 800 products approved to date)</td>
</tr>
<tr>
<td>Country</td>
<td>Disease risk-reduction claim</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
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<td>Not permitted</td>
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</tr>
<tr>
<td>Malaysia</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, ie Ca/Vit; Na; sat fat/trans fats; fibre; whole grains, fruits &amp; veggies</td>
</tr>
<tr>
<td>Thailand</td>
<td>Not permitted</td>
</tr>
<tr>
<td>Vietnam</td>
<td>Yes; no positive list</td>
</tr>
<tr>
<td>China</td>
<td>Not permitted</td>
</tr>
<tr>
<td>Japan</td>
<td>Only calcium and osteoporosis and folate and neural tube defect</td>
</tr>
</tbody>
</table>
All the countries in ASEAN, do provide for additional health claims to be made
- except for Brunei

Each claim has to be accompanied by scientific substantiation which will be reviewed by a panel of experts appointed by the regulatory agency

Examples of expert committees
- Tim Mitra Bestari - Indonesia
- Expert Group on Nutrition, Health Claims and Advertisement – Malaysia
- Advisory Committee on Evaluation of Health Claim – Singapore
- and a variety of approaches in Philippines, Thailand and Vietnam
Health claims in Japan ....

- Japan has been said to be “originator” of functional foods; but the term is not used in its legal system
- 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
  - Over 800 products have been approved
### Progress of Nutrition and Health Claims on Food in Japan

<table>
<thead>
<tr>
<th>Year</th>
<th>Types of Claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>1991</td>
<td>Foods for Specified Health Use (FOSHU) regulation system (by MHLW)</td>
</tr>
<tr>
<td>1997</td>
<td>Nutrition labeling standards (Nutrient content claims, Nutrient comparative claims)</td>
</tr>
<tr>
<td>2000</td>
<td>Food with health claims (FHC)</td>
</tr>
<tr>
<td>2001</td>
<td>Foods with Nutrient Function Claims (FNFC) (5 minerals and 12 vitamins)</td>
</tr>
<tr>
<td>2005</td>
<td>Food with health claims (FHC)</td>
</tr>
<tr>
<td></td>
<td>Foods for Specified Health Use (FOSHU)</td>
</tr>
<tr>
<td></td>
<td>Ordinary FOSHU</td>
</tr>
<tr>
<td></td>
<td>Standardized FOSHU</td>
</tr>
<tr>
<td></td>
<td>Reduction of disease risk</td>
</tr>
<tr>
<td></td>
<td>Qualified FOSHU</td>
</tr>
</tbody>
</table>
### Main FOSHU products approved and the relevant ingredients

<table>
<thead>
<tr>
<th>Type of FOSHU</th>
<th>Principal ingredients exhibiting health functions</th>
</tr>
</thead>
<tbody>
<tr>
<td>To modify gastrointestinal conditions</td>
<td>Oligosaccharides, lactose, bifidobacteria, lactic acid bacteria, dietary fiber &amp; ingestible dextrin, polydextrose, guar gum, psyllium seed coat, etc.</td>
</tr>
<tr>
<td>Related to high blood cholesterol level</td>
<td>Chitosan, soybean protein, degraded sodium alginate</td>
</tr>
<tr>
<td>Related to high blood sugar levels</td>
<td>Indigestible dextrin, wheat albumin, guava tea polyphenol, L-arabiose, etc.</td>
</tr>
<tr>
<td>Related to high blood pressure</td>
<td>Lactotripeptide, casein dodecanepptide, tochu leaf glycoside (geniposidic acid), sardine peptide, etc.</td>
</tr>
</tbody>
</table>
### Main FOSHU products approved (2)

<table>
<thead>
<tr>
<th>Type of FOSHU</th>
<th>Principal ingredients exhibiting health functions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Related to dental hygiene</td>
<td>Palatinose, maltitose, erythrytol, etc.</td>
</tr>
<tr>
<td>Cholesterol plus gastrointestinal conditions, triacylglycerol plus cholesterol</td>
<td>Degraded sodium alginate, dietary fiber from psyllium seed husk, etc.</td>
</tr>
<tr>
<td>Related to mineral absorption</td>
<td>Calcium citrated malate, casein phosphopeptide, heme iron, fructo-oligosaccharide, etc.</td>
</tr>
<tr>
<td>Related to osteoporosis</td>
<td>Soybean isoflavone, MBP (milk basic protein), etc.</td>
</tr>
<tr>
<td>Related to triacylglycerol</td>
<td>Medium chain fatty acid, etc.</td>
</tr>
</tbody>
</table>
Worldwide regulatory developments in health claims ....

..... European Union
- on nutrition & health claims made on foods
- entered into force on 19 January 2007
- to be applied from 1 July 2007

Article 13: Health claims
- the role of a nutrient or other substance in growth, development and the functions of the body, or
- psychological and behavioural functions; or
- slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet
Article 14:
- Reduction of disease risk claims, and
- Claims referring to children's development and health

Applications for health claims shall be reviewed by the European Food Safety Authority (EFSA)
- To ascertain that the health claim is substantiated by scientific evidence

A Register established and updated regularly
- to list authorised health claims and the relevant conditions for use, any restrictions
- rejected health claims and reasons for rejection
A recent Register includes the following approved claims for functional foods, or components

Reduction of risk factor of disease:
- Plant sterols, stanols; free or fatty acid esters
- Sugar-free chewing gums;
- Chewing gum with xylitol

Development and health of children:
- $\alpha$-linolenic acid (ALA) and linoleic acid (LA)
- Ca, Vit D, Iodine, Iron, Phosphorus, Protein
- Docosahexaenoic acid (DHA)
Another dimension is the establishment and application of nutrient profiling to nutrition and health claims (Article 4)

- to determine whether foods are eligible or not to bear claims, on the basis of their nutrient composition

To include exemptions, which food or certain categories of food must comply and the conditions for the use of nutrition or health claims for foods or categories of foods

To take into account various factors, including
- the quantities of certain nutrients and other substances in the food, e.g. fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium
Worldwide regulatory developments in health claims ….

….. United States of America FDA

Three ways which health claims may be used:
1. Health Claims that Meet Significant Scientific Agreement (SSA)
2. Health or Nutrient content claim based on authoritative statements
3. Qualified Health Claims
1. Health Claims that Meet Significant Scientific Agreement (SSA)

- based on an extensive review of the scientific literature, generally as a result of the submission of a health claim petition
- using the significant scientific agreement standard to determine that the nutrient/disease relationship is well established (disease risk reduction claims)
- An evidence-based review system in place
- Examples ....
Examples of approved Health Claims

- Dietary Fat and Cancer
- Dietary Non-cariogenic Carbohydrate Sweeteners and Dental Caries
- Fiber-Containing Grain Products, Fruits and Vegetables and Cancer /CHD
- Sodium and hypertension
- Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease (include barley beta-fibre; beta-glucan from oat and barley; psyllium husk)
- Soy Protein and Risk of CHD
- Plant Sterols/stanols and esters and Risk of CHD
2. Claims based on authoritative statements by federal scientific bodies

- FDA Modernization Act (FDAMA) of the Food, Drug, and Cosmetic Act 1997 permits the industry to use health claims or nutrient content claims if such claims are based on current, published, authoritative statements from certain federal scientific bodies.

- Recognized scientific bodies include the National Academy of Sciences (NAS), the National Institutes of Health (NIH) and the Centers for Disease Control & Prevention (CDC).
2. Claims based on authoritative statements by federal scientific bodies (2)

Examples …

- Choline nutrient content claim
- Fluoride and risk of dental caries
- Potassium and the Risk of High Blood Pressure and Stroke
- Saturated Fat, Cholesterol, and *Trans* Fat, and the Risk of Heart Disease
- Substitution of Saturated Fat with Unsaturated Fatty Acids and Risk of Heart Disease
- Whole Grain Foods and Risk of Heart Disease and Certain Cancers
3. Qualified Health Claims

- 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.
3. Qualified Health Claims (2)

- About Cancer Risk
  - Tomatoes, Tomato Sauce & some cancers
  - Calcium and Colon/Rectal Cancer
  - Selenium and cancer
  - Green tea and cancer
  - Antioxidant Vitamins & Cancer

Example of wording:
- 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

- Others related to cardiovascular disease risk, cognitive function, diabetes, hypertension
Way ahead ….
- Interest in functional foods will further increase, with greater consumer interest in health and wellness
  - Seeking for benefits beyond basic nutrients to reduce risk to chronic diseases
- Product R&D will intensify in keeping with consumer interest
- Current focus on scientific substantiation of functional foods will need to be kept up
  - to support regulatory systems and
  - gain consumer confidence
- Need to have more data of consumer perception
  - Ensure appropriate understanding and usage of claim messages
There are significant differences in:
- types of approved health claims and
- approaches to regulating health claims in Asian countries, Europe and USA

There are, however, also general similarities:
- all regulatory authorities require adequate scientific substantiation of health claims

In all cases, regulatory frameworks exist or are being established for review of applications from the food industry for making health claims on foods

Important to continue to have opportunities to network:
- such as this international symposium
- to share in all aspects of development
Thank you!