Preparation of Scientific Dossier for Claim: Industry Challenges

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Topics of Discussion

1) Why Industries Need to Communicate Health Claims

2) What Authoritative Bodies Requires to Substantiate Health Claim
   - Codex Recommendations on Scientific Substantiation of Health Claim
   - How TH FDA Assess Scientific Substantiation for Health Claim of Probiotic

3) Industry Challenges
   - Preparing Dossiers to Substantiate Health Claim

4) Take Away Messages
Nutrition and Health Claims


**Nutrition Claim**
- Nutrient Content Claim
- Nutrient Comparative Claim

**Health Claim**
- Nutrient Function Claim
- Other Function Claim
- Disease Risk Reduction Claim
What will Nutrition Labeling and Health Claim Benefit Food Industries?

- Provide effective communication tools
- Provide springboard for sales and marketing promotion campaigns
- Enhance product profile
- Increase international trade opportunities
- Produce more nutritious products

Re: Guide to Nutrition Labeling and Claims: April 2006; Food Safety and Quality Division, Ministry of Health, Malaysia
Guidelines for the Use of Nutrition and Health Claims (CAC/GL 23-1997)

Annex: Recommendations of the Scientific Substantiation of Health Claims
These recommendations focus on

- Criteria for substantiating a health claim
- Systematic review of scientific evidence

Intended to assist competent national authorities in evaluating three types of health claims

- Nutrient Function Claim
- Other Function Claim
- Disease Risk Reduction Claim
Criteria for the Substantiation of Health Claims

Criteria applicable to the three types of health claims

1) Requires a well-designed human intervention studies

   Human observational studies
   Animal model studies

   Alone is not sufficient to substantiate a health claims

2) Review of the totality of the evidence

   Evidence to support the claimed effect
   Evidence that contradicts the claimed effect
   Evidence that is still inconclusive

3) Demonstration of a consistent association between the food or food component and health effect
Substantiation may take into account specific situation and alternate process

a) Nutrient Function Claims:
   - generally accepted authoritative statement
   - recommended by expert scientific bodies

b) Some Health Claims:
   - observational evidence such as epidemiological studies
   - consistent body of evidence from a number of well-designed studies
   - Evidence-based dietary guidelines and authoritative statements prepared/endorsed by competent authoritative body
Systematic Review of Scientific Evidences

a) Identify the proposed relationship between food and health effect

b) Identify valid measurements for food and health effect

c) Identify and categorize all the relevant scientific data

d) Assess the quality of and interpret each relevant scientific study

e) Evaluate the totality of the relevant scientific data
   - weigh the evidence across studies
   - determine what circumstances, a claimed relationship is substantiated
Substantiation Dossiers Needed for Health Claim of Probiotic Required by TH FDA

- TH FDA established a positive list of probiotic microorganisms
- In order to claim “Contain Probiotic”
  - If the microorganism is on the positive
    - submit the evidence if the viable microbe is at $10^6$ till the end of shelf-life
  - If the microorganism is **not** on the positive
In order to claim “Physiological Benefit of a Probiotic”

1) Either one of the following human intervention studies from at least two institutes shall also be submitted

   a) Well Design human intervention study or
   b) Other design of human intervention study with sufficient number of subjects with sufficient result for assessment

The result of study in a) and b) shall at least identify relating factors or parameters, namely food category, serving size, number of probiotic microorganism and duration needed to achieve beneficial effect. In case that endpoint is indefinable, due to a very long duration to realize health benefit, resource constraint or ethical issue, an appropriate marker may be accepted. However, the marker shall be biologically accurate and directly related with the end result, including deviation of the subjects.
In designing the study in a) and b), the following condition shall be taken

(1.1) Study groups shall represent the target group
(1.2) Appropriate control group
(1.3) An adequate duration of exposure and follow up to demonstrate the intended effect
(1.4) Characterization of the study group’s background diet and other aspects of relevance of lifestyle
(1.5) An amount of the food or food component consistent with its intended pattern of consumption
(1.6) The influence of the food matrix and dietary context on the functional effect of the component
(1.7) Monitoring of subjects’ compliance concerning intake of food or food component under test
(1.8) The statistic power to test the hypothesis
2) Health claim shall be scientifically proven, taking into account the completion of result and evidence to justify the following aspects.

(2.1) Result complies with other evidences or outcome from other method
(2.2) Accuracy of methodology in food technology
(2.3) Randomized sampling plan
(2.4) Dose-response relationship between food or food component and related health benefit
(2.5) Biological feasibility
(3) Condition for displaying health claim on product label
The claim shall in Thai language and eligible.

(3.1) Statement of “This product is not to relieve, prevent or cure the disease”
(3.2) Genus, species and strain of probiotic microorganism in the product
(3.3) Dose and duration of consumption to achieve the health benefit
(3.4) Claim statement, i.e. “Probiotic Microorganism”, “Probiotic” or other statement
(3.5) Recommendation for consumption and storage
(3.6) Information contact point
Industry Challenges
Dossiers Preparation to Substantiate Health Claims
Industry Challenges

1) Well Designed Human Intervention Studies

- Is the requirement of human study too stringent?
- A human intervention study requires approval of Institutional Review Board (IRB) on ethic perspective
  - It is difficult for specific group of consumer, i.e. infant and young children
- Discrepancies in regulatory requirement from country to country makes sharing of paper works not possible
Industry Challenges

**TH**: human intervention studies from at least two institutes shall also be submitted

a) Well Design human intervention study or

b) Other design of human intervention study with sufficient number of subjects with sufficient result for assessment

**ID**: randomized controlled trials (RCT) experimental research or observational studies if experimental research is not possible.

Under certain conditions, it is deemed necessary to conduct research in Indonesia.
Industry Challenges

2) Slow approval process resulting in restricted numbers of approved health claim in ASEAN Countries

TH - 29 Nutrient function claims
- Only one regulation that allows other type of health claim: Probiotic

ID - 12 Nutrient function claims
- 2 Other function claim
- 7 Disease risk reduction claim

MY - 23 Nutrient function claim
- 29 Other function claim

Positive list of nutrient function claim does not enable industries to differentiate their products from others

Off-pack communication on claim is commonly found in the market place
3) ASEAN Harmonization on the Guidelines for Scientific Substantiation

- To improve consumer understanding of key messages on food label
- To reduce trade barriers to the commercial distribution of foods in the ASEAN Region

➔ ILSI SEA: established “Guidelines for Scientific Substantiation of Nutrition and Health Claims for Food/Functional Foods

➔ ASEAN Framework: harmonization of nutrition labeling and claim is not priority of Prepared Food Stuff Product Working Group (PFPWG) under ASEAN Consultative Committee on Standard and Quality (ACCSQ)
Take Away Messages

- Nutrition labeling and claims are important messages for nutrition and health that can be communicated to consumer through product label and enable them to make an informed choice at the point of purchase.

- Nutrition labeling and claims also bring benefits to industrial trades activities and increase competitiveness in the market place.

- There are a number of challenges for industries dealing with regulatory framework around claims substantiation and this does not seem to be recognized by the food authorities.

- Discrepancies of regulatory requirement on health claim among ASEAN countries will be a critical barrier for free-flow of food product in this region. We may have to start identifying a platform to realize “Harmonization” of the regulation for scientific substantiation in this region.