Part 4
Marketing Implications

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Claims Strategies from a marketing perspective
How do companies deal with the claims requirements?

There are three types of companies using health claims

1. Companies that look for opportunities for highlighting beneficial effects of existing products
   - For natural products (e.g. milk, cheese, kiwi, nut, …)
   - For products because of their nutritional properties (e.g. low in fat)
   - For products with added vitamins/minerals

2. Companies that need communication of health benefits for consumer communication
   - E.g. for dietary supplements to inform consumers about the product’s indication
   - E.g. children products to inform consumers about the specific intended use

3. Companies that explore the use of a new food ingredient
Use of Nutrition and Health Claims is a Marketing Tool

Publicity for the healthiness of a food
Attract attention to specific features of the product’s composition
To identify specific target groups for whom the product is useful
To differentiate the product from competing products

Two consequences:

Decisions on whether and how to use health claims are taken by commercial people, not by scientists
Legislation is focused largely on protecting consumers against misleading information and not on stimulating research
Use of Nutrition and Health Claims is a Marketing Tool

Decisions on whether and how to use health claims are taken by commercial people, not by scientists

This basically means that the claim:

- must serve the product positioning in the market
- must be consumer friendly
- must be strong
- must differentiate the product from other products
- must be exclusive for the company
- must come on the market quickly
- must be such that it can be adapted to changing environment
- must fit within the limits of the budget
How do companies deal with these strict requirements?

Looking for the easy way

Use the strongest claims that are allowed and available
- Sometimes this may be a nutrition claim
- In most cases this is a claims for vitamins/minerals, included in a list
- In the US for dietary supplements, this is virtually any structure/function claim
- This means that doing research for a specific claim needs incentives

Use claims that are not considered as health claims
- General non-specific health benefits
- Claims relating to ingredients (e.g. contains milk, organic, natural, …)
- Claims for products that are not covered (e.g. foods for particular nutritional use)

Use exemptions in the law
- e.g. brand names and trade marks

Go to other less strict jurisdictions
How do companies deal with these strict requirements?

What is the added value of a claim?

- Contains calcium
- Is a source of calcium
- Is rich in calcium
- Calcium is necessary for bones
- Calcium contributes to strengthening of bones
- Calcium makes bones stronger
- Calcium increases bone density
- Calcium reduces the risk of osteoporosis
- Calcium Improves osteoporosis lesions
- Calcium for the dietary management of osteoporosis
- Calcium treats osteoporosis
- Calcium prevents osteoporosis
How do companies deal with these strict requirements?

What is the added value of a claim?

e.g. US qualified claims:

Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.

Green tea may reduce the risk of breast or prostate cancer although the FDA has concluded that there is very little scientific evidence for this claim.

One study suggests that consuming tomatoes does not reduce the risk of pancreatic cancer, but one weaker, more limited study suggests that consuming tomatoes may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that tomatoes reduce the risk of pancreatic cancer.
Calcium contributes to:
- normal blood clotting
- normal energy-yielding metabolism
- normal muscle function and neurotransmission
- normal function of digestive enzymes
- is needed for the maintenance of normal bones and teeth

How do companies deal with these strict requirements?

For most fields of health there are approved function claims.

Zinc contributes to:
- a normal function of the immune system
- maintenance of normal bone
- maintenance of normal vision
- normal acid-base metabolism
- normal cognitive function
- normal DNA synthesis and cell division
- normal fertility and reproduction
- normal metabolism of fatty acids
- normal metabolism of vitamin A
- the protection of cell constituents from oxidative damage
How do companies deal with these strict requirements?

For most fields of health there are approved function claims, such as Vitamin C to support the normal function of the immune system.
How do companies deal with these strict requirements?

Marketing language is often quite inventive

Examples:

- Sustaining your vitality while ageing / anti-ageing properties
- Promotes physical and mental well-being
- Vitalising / invigorating
- Promotes digestive health / digestive system
- Avoid inconveniences / ease discomfort / effects on immune system
- References to parts of the body with a specific function (e.g. activity of heart, liver, muscles, joints etc.)
How do companies deal with these strict requirements?

How to ensure that flexibility of the wording continues to have the same meaning as the approved claim?
See national guidance in the EU
How do companies deal with these strict requirements?

Alternative ways of communicating
How do companies deal with these strict requirements?

Alternative ways of communicating
How do companies deal with these strict requirements?

Repositioning products

Dietetic food

FSMP

“For the dietary management of [disease, disorder, medical condition]“

Medical devices

Medicinal product

Traditional Herbal Medicinal Product

Legislation is being changed for this reason in the EU
How do companies deal with these strict requirements?

Using claims that are out of the scope of the Regulation

<table>
<thead>
<tr>
<th>1</th>
<th>Nutrition claims</th>
<th>2</th>
<th>Health claims</th>
<th>3</th>
<th>Ingredients claims</th>
<th>4</th>
<th>Other Regulated Claims</th>
<th>5</th>
<th>Puffery borderline claims (slogans)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>‘Source of Calcium’</td>
<td>2</td>
<td>‘Calcium helps maintain strong teeth and bones’</td>
<td>3</td>
<td>‘100% Fruit’</td>
<td>4</td>
<td>‘Natural’</td>
<td>5</td>
<td>‘X gives you wings’</td>
</tr>
<tr>
<td>2</td>
<td>‘Healthy’</td>
<td>3</td>
<td>‘With fresh milk’</td>
<td>4</td>
<td>‘Organic’</td>
<td>5</td>
<td>‘Y makes your children happy’</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>‘Light’</td>
<td>4</td>
<td>‘Free from preservatives’</td>
<td>5</td>
<td>‘Suitable for vegetarians’</td>
<td>5</td>
<td>‘Z gives you a fizz’ (if fizzy)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Comparative claims</td>
<td>5</td>
<td>‘With barn eggs’</td>
<td>6</td>
<td>‘Hallal’</td>
<td>6</td>
<td>Famous pop-song titles</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>‘Food X helps decrease cholesterol, which contributes to reducing the risk of heart disease’</td>
<td>6</td>
<td>‘Gluten free’</td>
<td>7</td>
<td>‘Superfruit!’</td>
<td>8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Aspects to consider

Is a similar claim already approved?

Is the claim sufficiently different from an already approved one?

  e.g. DHA and EPA contribute to the maintenance of normal blood pressure

What is the market potential for the claimed benefit?

How much evidence is there already available?
Nutrient profiles
Nutrient profiles

Why?

Classification of foodstuffs depending on their nutritional composition in order to identify healthier food options

Focus is on those nutrients that are reputed to have a negative impact on health:

- Energy
- (Saturated) Fats
- Sugars
- Sodium / Salt

Fear that use will be extended

- Traffic Light labelling
- Marketing to children
- Taxation

…
Nutrient profiles
EU Discussions

02/06/08:
- First working document - Discussion
- Eurofir categories discussion (06/10/08)

21/10/08:
- Second working document

16/12/08:
- Third working document

13/02/08:
- Fourth working document - Preliminary draft proposal
- Interservice consultation
- Impact assessment
- Barroso letter

17/03/08:
- Fifth document - Unofficial not presented to the MS

BLOCKED AT POLITICAL LEVEL
<table>
<thead>
<tr>
<th>Food category</th>
<th>Sodium (mg/100g)</th>
<th>Sat. fat (g/100g)</th>
<th>Sugars (g/100g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non alcoholic beverage</td>
<td>300</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Vegetable oil / spreadable fat</td>
<td>500</td>
<td>30</td>
<td>10</td>
</tr>
<tr>
<td>Fruit, vegetable, nut products</td>
<td>400</td>
<td>5</td>
<td>15</td>
</tr>
<tr>
<td>Nuts, seed or kernel</td>
<td>400</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Meat based products</td>
<td>800</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>Fish and fish products</td>
<td>800</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Dairy product, except cheese</td>
<td>300</td>
<td>2.6</td>
<td>15</td>
</tr>
<tr>
<td>Cheese</td>
<td>900</td>
<td>20</td>
<td>15</td>
</tr>
<tr>
<td>Cereal and cereal products</td>
<td>400</td>
<td>5</td>
<td>15</td>
</tr>
<tr>
<td>Biscuits and fine bakery wares</td>
<td>500</td>
<td>8</td>
<td>25</td>
</tr>
<tr>
<td>Breakfast cereal</td>
<td>500</td>
<td>5</td>
<td>25</td>
</tr>
<tr>
<td>Ready meal, soup and sandwich</td>
<td>400</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>Soy products (3-10% soy protein)</td>
<td>300</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Soy products (&gt; 10% soy protein)</td>
<td>800</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>Other food</td>
<td>300</td>
<td>2</td>
<td>10</td>
</tr>
</tbody>
</table>
## Nutrient Profiles
**What was intended ...**

<table>
<thead>
<tr>
<th>Food category</th>
<th>Nutrition or Health Claim</th>
<th>Nutrition Claim with derogation</th>
<th>No claim possible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beverages</td>
<td>Mineral water / Ice teas</td>
<td>Soft drink / Soy drink</td>
<td>-</td>
</tr>
<tr>
<td>Vegetable oils / Spreadable fats</td>
<td>Olive oil rapeseed oil</td>
<td>Coconut oil, palm oil / Butter</td>
<td>Salted butter</td>
</tr>
<tr>
<td>Fruits, vegetables, nuts</td>
<td>With low or no added salt sugars or fat</td>
<td>Compote with added sugars</td>
<td>Pastries, fruit dessert with cream</td>
</tr>
<tr>
<td>Meat (products)</td>
<td>Meat / Lean ham</td>
<td>Cured ham</td>
<td>Pâtés</td>
</tr>
<tr>
<td>Seafood (products)</td>
<td>Fish</td>
<td>Smoked fish</td>
<td>With added fat, salt</td>
</tr>
<tr>
<td>Dairy products</td>
<td>Whole milk / Yoghurt</td>
<td>Cream</td>
<td>Dessert products</td>
</tr>
<tr>
<td>Cheeses</td>
<td>Low fat cheese</td>
<td>Fresh cheeses</td>
<td>Hard cheeses</td>
</tr>
<tr>
<td>Cereal and cereal products</td>
<td>Rice, Pasta / Low salt bread</td>
<td>Brown bread</td>
<td>Cakes / Biscuits</td>
</tr>
<tr>
<td>Breakfast cereals</td>
<td>Low sugar breakfast cereals, porridge</td>
<td>Coated with sugars, or with honey</td>
<td>Breakfast cereal with chocolate</td>
</tr>
<tr>
<td>Ready meals, soups and sandwiches</td>
<td>Paella / Ready meal fish and pasta</td>
<td>Salad tuna with vegetables / Pizza</td>
<td>Sandwich, Cheddar cheese and pickle, white bread / Pork pie</td>
</tr>
<tr>
<td>Other foods</td>
<td>Spoonable soy</td>
<td>Confectionary</td>
<td>Chocolate</td>
</tr>
</tbody>
</table>
National developments
Example: Netherlands draft “blue tick mark” logo

Annex

This Annex belongs to Article 1, under b.

The two forms of the Blue Tick Mark are as depicted below:

<table>
<thead>
<tr>
<th>BEWUSTE KEUZE</th>
<th>CONSCIOUS CHOICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Binnen deze productgroep</td>
<td>Within this product group</td>
</tr>
<tr>
<td>GEZONDERE KEUZE</td>
<td>Healthier choice</td>
</tr>
<tr>
<td>Binnen deze productgroep</td>
<td>Within this product group</td>
</tr>
</tbody>
</table>
Nutrient profiles are already applied

In qualifying criteria for health claims in the US

e.g. Soy Protein and Risk of Coronary Heart Disease
   Low saturated fat,
   Low cholesterol, and
   Low fat

By claims that are being refused

e.g. Glucose contributes to normal energy-yielding metabolism during exercise

The use of such a health claim would convey a conflicting and confusing message to consumers, because it would encourage consumption of sugars for which, on the basis of generally accepted scientific advice, national and international authorities inform the consumer that their intake should be reduced.
How to market foods with claims in ASEAN
The case of ASEAN

Population 625 million
Youth 60%

10 countries

3rd largest market in the world (population)
ASEAN History

67
ASEAN formed by 5 founding Members: Indonesia, Malaysia, the Philippines, Singapore and Thailand. Objective: for political security in the region.

92
Signed ASEAN Free Trade Agreement. Reduce tariff and non-tariff barrier in intra-ASEAN trade.

90s
Brunei Darussalam, Cambodia, Myanmar, Lao PDR and Viet Nam (CLMV) joined in 1990s. Interest in economic integration.

07
Agree to form ASEAN Economic Community (AEC). Sign AEC Blueprint, Commit for full integration by 2015.
Priority sectors for ASEAN Economic integration

Agro-based products  Wood-based products

Automotive  Air travel

Electronic  e-ASEAN

Fisheries  Healthcare

Rubber based products  Tourism

Textile  Logistics

Cosmetic
Medical device
Pharmaceutical
Traditional Medicine and Health
Supplement
Current regulations on Health Supplements

<table>
<thead>
<tr>
<th>Countries</th>
<th>HS Regulations (?)</th>
<th>Relevant Regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brunei Darussalam</td>
<td>Y</td>
<td>Pharmaceuticals</td>
</tr>
<tr>
<td>Cambodia</td>
<td>N</td>
<td>(Pharmaceuticals)</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Y</td>
<td>Pharmaceuticals</td>
</tr>
<tr>
<td>Lao PDR</td>
<td>N</td>
<td>(Pharmaceuticals)</td>
</tr>
<tr>
<td>Malaysia</td>
<td>Y</td>
<td>Pharmaceuticals</td>
</tr>
<tr>
<td>Myanmar</td>
<td>N</td>
<td>(Pharmaceuticals)</td>
</tr>
<tr>
<td>Philippines</td>
<td>Y</td>
<td>Food</td>
</tr>
<tr>
<td>Singapore</td>
<td>Y</td>
<td>Pharmaceuticals</td>
</tr>
<tr>
<td>Thailand</td>
<td>Y</td>
<td>Food</td>
</tr>
<tr>
<td>Viet Nam</td>
<td>Y</td>
<td>Food</td>
</tr>
</tbody>
</table>
ASEAN TMHS Scientific Committee (ATSC)

Technical requirements reviewed by ATSC

- Safety substantiation requirements
- Claims and claim substantiation requirements
- Products at interface
- Negative list of active ingredients
- Restricted list of additives/excipients
- Limits of heavy metal
- Limits of microbial contamination
- Limits of pesticides residues
- Minimizing TSE risks
- Maximum levels of vitamins and minerals
- Stability and shelf life study requirement
ASEAN agreement on traditional medicines & health supplements

What will happen after signing of the agreement?

The ASEAN Traditional Medicines and Health Supplements Committee (ATMHSC) will be established

- Coordinating, reviewing, monitoring for the implementation of the agreement
- Reviewing and updating the annexes of the agreements (technical requirements)

A scientific committee may also be established to provide technical advice/recommendation

- Members may be from the current ATSC
Definition

A Health Supplement means any product that is used to supplement a diet and to maintain, enhance and improve the healthy function of human body and contains one or more, or a combination of the following:

a) Vitamins, minerals, amino acids, fatty acids, enzymes, probiotics and other bioactive substances.

b) Substances derived from natural sources, including animal, mineral and botanical materials in the forms of extracts, isolates, concentrates, metabolite

c) Synthetic sources of ingredients mentioned in (a) and (b) may only be used where the safety of these has been proven.

It is presented in dosage forms (to be administered) in small unit doses such as capsules, tablets, powder, liquids and it shall not include any sterile preparations (i.e. injectable, eyedrops)
ASEAN guidelines on claims and claims substantiation studies requirements

Task lead by the Indonesia/Philippines/HS trade association

Discussed at Scientific Committee

Aim: to develop guidelines, which provide information on the acceptable type of claims and substantiation requirements
<table>
<thead>
<tr>
<th>Type of claims</th>
<th>Scope</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>General or Nutritional</td>
<td>For Nutritional Support &amp; General Health Maintenance</td>
<td>• Supplements nutrition</td>
</tr>
<tr>
<td></td>
<td>Benefits derived from supplementation beyond a person’s daily dietary intake</td>
<td>• Supports healthy growth and development</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Nourishes the body</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Helps to maintain good health</td>
</tr>
<tr>
<td>Functional</td>
<td>Relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health in the context of the total diet on normal functions or biological activities of the body</td>
<td>• Aids in digestion to relieve indigestion</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Supports health in ageing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Supports health in menopause</td>
</tr>
<tr>
<td></td>
<td>Maintains or enhances structure or function of the body, excluding disease related claims</td>
<td>• Supports health and to relieve/ reduce/ lessen/ ease* minor body discomforts in some physiological processes (e.g. ageing, menopause, pregnancy)</td>
</tr>
<tr>
<td>Disease risk reduction</td>
<td>Significantly altering or reducing a risk factor of a disease or health related condition</td>
<td>• helps to reduce risk of osteoporosis by strengthening bone</td>
</tr>
</tbody>
</table>
ASEAN guidelines on claims and claims substantiation studies requirements

The principles of Health Supplement claims substantiation are:

Proportional degree of supporting evidence corresponding to the type of HS claims

Totality of scientific evidence that demonstrates the beneficial effect
HS claims substantiation

Totality of evidence to support HS benefit claim

Disease Risk Reduction

Human intervention study on ingredient / product
- Human observational studies on ingredient/product
- Animal Studies
- Published scientific review

Functional

General or Nutritional

Authoritative reference texts
- Reputable/ international organizations or recognized regulatory authorities
- Documented history of use (e.g. classical texts, scholar or expert’s reports)

“To supply your calcium need”

“Calcium contributes to strong bone and reducing risk of osteoporosis”

“Calcium contributes to strong bones”
Functional Food Claims In ASEAN

National rules apply. No harmonization in ASEAN.

Brunei Darussalam: Very restrictive. Only nutrient content claims allowed, and not even for vitamins and minerals. No health claims allowed.

Indonesia: Nutrient content/comparative claims, nutrient function claims and disease risk reduction claims are allowed. Products need to be registered.

Malaysia: Nutrient content/comparative claims, nutrient function claims and other function claims are allowed, when included in a list. Disease risk reduction claims are not allowed.

Singapore: Nutrient content/comparative claims, nutrient function claims that are on the permitted list are allowed, as well as 5 specific diet related health claims (similar to disease risk reduction claims – US style). Also the phytosterol claims has been allowed.

Thailand: Nutrient content/comparative and nutrient function claim, included in a positive list, are permitted. All with accepted probiotic claims exist. No approvals yet for reduction of disease risk claims.

Viet Nam: nutrient content/comparative claims, nutrient function claims and disease risk reduction claims are permitted.

No specific rules in Cambodia, Lao PDR, Myanmar, Philippines.