Part 1
Regulatory status of functional foods

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About EAS

EAS was established more than 20 years ago as a centre of expertise in European and international food, nutrition and health policy.

Today, with offices in Singapore, Brussels, London, Moscow and Buenos Aires and networks in over 70 countries, we are leading experts in navigating the global challenges and opportunities in business.

Our core specialisation is the food and nutritional product area.
General outline of the training session

Regulatory status of functional foods
  Definition of functional foods and product classification
  Definition of claims and borderline issues

Regulatory approaches
  Claims based systems (e.g. EU – US)
  Trends and evolutions (e.g. Japan – South-Korea)

Scientific requirements
  Historic perspective (Fusfose / Passclaim / Codex)
  Examples from the EFSA assessments

Marketing implications
  What to consider when developing claims strategies
  Nutrient profiles
  The case of ASEAN

Safety aspects of functional foods
  Authorisation procedures - Novel foods
  Scientific requirements
  The case of China
Scope of the landscape

28 Member States

10 Member States
The Importance of Product Classification
Definition of Functional foods

Functional Food

A food that **beneficially affects one or more target functions in the body** beyond adequate nutritional effects in a way that is relevant to either an **improved state of health and well-being and/or reduction of risk of disease**.

Not a pill, a capsule or any form of dietary supplement.

Consumed as part of a normal food pattern.
Food vs Supplement

**Purpose**
- To provide nutrient
- Consumed as part of the diet
- To supplement a diet
- To provide nutrients and other substances with nutritional or physiological effects

**Composition**
- Added nutrients, permitted additives.
- Vitamins and minerals
- Botanical ingredients extract
- Other bioactive substances extracts

**Presentation form**
- Drink beverages, grains, loose powders, snack bars, noodles etc
- Capsules, tablets, liquid and powder

**Dosage**
- No defined dosage
- Defined dosage. E.g. 1 tablet per day
Foods with health claims
Foods with added nutrients
Natural and organic foods
Natural foods
Organic foods
Unrefined foods
Dietetic foods
Foods for pregnant women
Foods for infants and children
Foods for diabetics
Gluten-free foods
Lactose-free foods
Probiotic foods
Herbal teas
Foods for Special medical purposes
Dietary supplements
Herbal remedies
OTC pharmaceuticals
The importance of food products classification

Example: Mangosteen drink in 0.75 L bottle

Y  Foodstuff

?  Supplement the normal diet

?  Mangosteen extract: concentrated sources of other substances with a nutritional or physiological effect

?  1 glass per day (250ml): marketed in dose form […] and other similar forms of liquids designed to be taken in measured small unit quantities
The importance of food products classification

Example: Chewing gum with vitamin C

Foodstuff

Supplement the normal diet

Vitamin C: concentrated sources of nutrients

4 chewing gums per day: marketed in dose form […] designed to be taken in measured small unit quantities
The importance of food products classification

Example: Shot with taurine, guarana (caffeine), vitamins B

- **Y** Foodstuff
- **Y** Supplement the normal diet
- **Y** Vitamins, taurine, guarana: concentrated sources of nutrients or other substances with a nutritional or physiological effect

- **?** 1 shot of 50 ml per day: marketed in dose form [...] designed to be taken in measured small unit quantities
The importance of food products classification

The category of ‘functional food’ does not exist anywhere.

Regulations are build around product definitions.

Different rules apply for different categories:

Either the regulations cover all foods or specific categories.

- EU: Both foods and food supplements
- US: Different rules for food and dietary supplements
- China: Health Foods cover both food and supplements
- ASEAN: Only harmonisation of health supplements

Dietetic foods are mostly regulated separately.
Regulatory Approaches for claims

Variables

- Scope of the product type
- Scope of the health benefit
- List or authorisation process
- Qualifying language or not
- Target group
- Safety of intake
- Borderline issues

All to consider when developing a health claims strategy
Scope of the Health Benefit
Codex Alimentarius

Codex Alimentarius means ‘Food Law’ or ‘Food Code’

Codex Alimentarius is a United Nation ‘institution’, ‘parented’ jointly by the Food and Agriculture Organisation (FAO) and World Health Organisation (WHO)

It was founded in 1963

It today has over 185 Member governments as members

Over 240 finalised Standards
Over 40 adopted Codes of Practise
Evaluation of over 100 additives, 25 contaminants and 3300 Pesticide Residues
Recognised as authoritative body in trade disputes by WTO
Codex Alimentarius Definition of claims (Guidelines for nutrition and health claims (CAC/GL 23-1997))

**Nutrition claim** means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals.

- **Nutrient content claim** is a nutrition claim that describes the level of a nutrient contained in a food.
  
  Examples: “source of calcium”; “high in fibre and low in fat”.

- **Nutrient comparative claim** is a claim that compares the nutrient levels and/or energy value of two or more foods.
  
  Examples: “reduced”; “less than”; “fewer”; “increased”; “more than”.

- **Non-addition claim** means any claim that an ingredient has not been added to a food, either directly or indirectly. The ingredient is one whose presence or addition is permitted in the food and which consumers would normally expect to find in the food.
Scope of the Health Benefit

Codex Alimentarius Definition of claims (Guidelines for nutrition and health claims (CAC/GL 23-1997))

Health claim means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Health claims include the following:

- **Nutrient function claim** is a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body.
  
  Example: “Nutrient A (naming a physiological role of nutrient A in the body in the maintenance of health and promotion of normal growth and development). Food X is a source of/ high in nutrient A.”

- **Other function claim** is a claim that concerns specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health.

  Examples: “Substance A (naming the effect of substance A on improving or modifying a physiological function or biological activity associated with health). Food Y contains x grams of substance A.”
Codex Alimentarius Definition of claims (Guidelines for nutrition and health claims (CAC/GL 23-1997))

- **Reduction of disease risk claim** is a claim relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition. Risk reduction means significantly altering a major risk factor(s) for a disease or health-related condition. Diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect. The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims.

Example: “A healthful diet low in nutrient or substance A may reduce the risk of disease D. Food X is low in nutrient or substance A.”

Example: “A healthful diet rich in nutrient or substance A may reduce the risk of disease D. Food X is high in nutrient or substance A.”
Most jurisdictions with recent laws on claims do follow these definitions.

However, the most influential ones with established legislation do not.

  e.g. US, EU, Japan

Another influential factor is the borderline with medicinal claims (prevention, treatment, cure of diseases)
Avoiding Medicinal Claims
Scope

Nutritional effect

Physiological effect

Psychological effect

Dietary management

Reduction of disease risk effect

Patho-physiological effect
What about emerging science?

- Personalised nutrition / Nutrigenomics / Metabolomics
- Challenge models to stress homeostasis and measure ability to adapt

No strict boundary between health and disease
- slightly elevated blood pressure
- slightly reduced insulin response
- slightly abnormal lipids
- mild liver damage
- elevated mediators of Inflammation

Genotype and predisposition to risk
Health is multidimensional, changing, dynamic and time-dependent

Source: Renger Witkamp, Wageningen University
General principle

The intended use of the product determines the right legal framework

- Decision by the company
- Scrutiny by enforcement
  - To ensure that legislation is correctly applied
  - To preserve fair competition
- Essential element when developing claims strategies

Regulatory attitudes determine the risk

- Botanicals
- Other substances (e.g. melatonin, lactulose, monacolin K)
Managing this borderline in the EU

Frameworks are Mutually Exclusive

Food Legislation

General Food Law (Reg 178/2002)

“Food shall not include Medicinal Products”

Medicinal Product Legislation

Medicinal product Directive (Dir 2001/83):

“Where a product comes clearly under the definition of other product categories, in particular food, food supplements, […] this Directive should not apply”

Traditional Herbal Medicinal Product Directive (Dir 2004/04)

“This Directive allows non-medicinal herbal products, fulfilling the criteria of food legislation, to be regulated under food legislation in the Community”
Managing this borderline in the EU

Medicinal Law: Presentation criterion

Definition by virtue of Presentation

« any substance or combination of substances presented as having properties for treating or preventing disease in human beings »

Only refers to treating or preventing disease in human beings.

General principle of food law: the labelling, presentation and advertising must not attribute the property of preventing, treating or curing a human disease, or refer to such properties.

Clarity?

Health Claims Regulation: Reduction of Disease Risk Claims

Traditional Herbal Medicinal Legislation: Monograph indications
Managing this borderline in the EU

Medicinal Law: Function criterion

Definition by virtue of Function

« any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action […] »

“Restoring, correcting or modifying physiological functions” vs. “substances with a beneficial nutritional or physiological effect or other health advantage”.

“By exerting a pharmacological, immunological or metabolic action”: Introduced in order to make it possible to cover medicinal products such as gene therapy, radiopharmaceutical products and certain medicinal products for topical use.
Managing this borderline in the EU

ECJ Case Law

“ [...] it is for the national authorities to determine, subject to review by the courts, for each product, having regard to all of its characteristics, in particular its composition, its pharmacological properties as they may be ascertained in the current state of scientific knowledge, the way in which it is used, the extent to which it is sold, its familiarity to the consumer and the risks which its use might entail, whether or not it constitutes a medicinal product within the meaning of the definition set out in Article 1(2) of [the medicinal product Directive] ”.

Consequence:
as long as rules for Food Supplements are not harmonised, it is possible that a given product is considered as a medicinal product by one Member State and as a Food Supplement by another.
Managing this borderline in the EU

ECJ Case Law

Presentation criterion: Broad interpretation
Must cover all products, also those with no demonstrated efficacy

Function criterion: Narrow interpretation

“Physiological effect” is not specific to medicinal products but is also among the criteria used for the definition of food

In order to preserve the effectiveness of that criterion, it is not sufficient that product has properties beneficial to health in general, but it must strictly speaking have the function of treating or preventing disease

Medical purpose or therapeutic effect must be present

Cfr. article 26: medicinal licence to be refused if therapeutic efficacy is lacking or is insufficiently substantiated
Does it work?

Only to a certain extent

Co-existence is difficult in many Member States

Some plants and plant preparations are considered medicinal in some Member States

Despite health claims being accepted, the use of certain substances remains restricted in a number of Member States

  e.g. Melatonin, Monacolin K, Lactulose

This is increasingly becoming problematic

  (e.g. hydroxyanthracene derivatives, caffeine, …)
THPM Monograph indications | EFSA beneficial physiological effects
---|---
Symptoms of temporary *fatigue* and sensation of weakness | Reduction of *tiredness* and *fatigue* is
Symptomatic relief of *digestive disorders* such as dyspepsia [...], bloating and flatulence | Reduction of *gastro-intestinal discomfort* is
For relief of mild symptoms of *mental stress* | Resistance to *mental stress* might be
Used to aid *sleep* | Reduction of sleep onset latency and *improvement of sleep quality* might be
For relief of [...] heaviness of legs related to *minor venous circulatory disturbances* | Maintenance of *elasticity* and *strength of the venous walls* is
For the prophylaxis of *migraine headaches* after serious conditions have been excluded [...] | Relief from *stress-induced headache* is
For the relief of minor symptoms in the days before *menstruation* (premenstrual syndrome) | Reduction of *menstrual discomfort* is
For the relief of *menopausal complaints* such as hot flushes and profuse sweating | Reduction of *menopausal discomfort* is
For the treatment of habitual constipation or in conditions in which easy defaecation with *soft stool* is desirable | Changes in bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk, or *softer stools* may be
Managing this borderline in the US

Disease claims are not allowed on food

Disease:
Damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition.

Disease claim:
A claim to diagnose, cure, mitigate, treat, or prevent disease

10 criteria to judge is a claim is a disease claim or not
Managing this borderline in the US

Criterion 1:

A statement is a disease claim if it mentions a specific disease or class of diseases.

"protective against the development of cancer"
"reduces the pain and stiffness associated with arthritis"

A statement also is a disease claim if it implies that it has an effect on a specific disease or class of diseases by using descriptions of the disease state (implied disease claims)

"relieves crushing chest pain (angina)"
"improves joint mobility and reduces inflammation (rheumatoid arthritis)"
"relief of bronchospasm (asthma)"

Criterion 2:

A statement is a disease claim if it claims an effect on characteristic signs or symptoms of disease

The condition, to which the signs and symptoms refer, must be related to a disease

The signs and symptoms must be characteristic of the disease and permit the inference that the product is intended to affect that disease

The interpretation of this in other jurisdictions outside the US may depend on the claims framework.
Managing this borderline in the US

Criterion 2:

Examples

"inhibits platelet aggregation" or "reduces cholesterol" are associated with stroke and cardiovascular disease
  US: implied disease claim
  EU: Function claim / Reduction of Disease Risk Claim

"improves absentmindedness" might imply treatment of Alzheimer's disease and "relieves stress and frustration" might imply treatment of anxiety disorders
  US + EU: Also are characteristic of non-disease states

“maintaining normal cholesterol levels”
  US + EU: Function claim

words such as "restore", "support", "maintain", “raise”, "lower", "promote", "regulate" or "stimulate"
  US + EU: may create an implied disease claim if, in the context they are used, they imply an effect on disease
Managing this borderline in the US

Criterion 3:

A statement is a disease claim if it claims an effect on a condition associated with a natural state or process.

Some natural states or processes such as aging, menopause, and the menstrual cycle are not themselves diseases, but can be associated with abnormal conditions that are diseases.

If the condition is uncommon (i.e. occurring in less than 50% of subjects)

When the condition can cause significant or permanent harm that must be treated effectively to prevent that harm and where effective treatments are available.

Examples:

"mild memory loss associated with aging", "noncystic acne", "mild mood changes, cramps, and edema associated with the menstrual cycle"

  US: Function claim
  EU: Health claim or medicinal claim depending on the wording

"Alzheimer's disease or senile dementias in the elderly", "cystic acne", "severe depression associated with the menstrual cycle"

  US and EU: Disease claim

Companies try to fit such products under the cover of foods for special medical purposes / medical foods.
Managing this borderline in the US

Criterion 4:

A statement is an implied disease claim because of the product name, formulation, use of pictures, etc.

The product name should not contain the name, or a recognizable portion of the name, of a disease.

"CarpalHealth" or "CircuCure" are disease claims because they are implied disease claims for carpal tunnel syndrome and circulatory disorders.

"Soothing Sleep" could be considered a claim to treat insomnia, a disease, unless other context in the labeling makes clear that the claim relates to occasional sleeplessness.

The product name should not use terms such as "cure", "treat", "correct", "prevent" or other terms that suggest treatment or prevention of a disease (Context is very important).

Product formulation: Ingredients should not be listed if they have been regulated primarily as a drug and are well known for their use in preventing or treating a disease.

Product presentation: Pictures of healthy organs would are acceptable, while pictures of an abnormal tissue or organ would be an implied disease claim.

The heart symbol is so widely recognized as symbols for disease treatment and prevention that its use is ordinarily an implied disease claim.

Symbols such as EKG tracings are also implied disease claims because they are strongly associated with heart disease and the average consumer cannot distinguish a healthy from...
Managing this borderline in the US

Criterion 5:

A statement is a disease claim when it claims that a product belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease.

- Analgesics, antibiotics, antidepressants, antimicrobials, antiseptics, antivirals, or vaccines

Context should make clear

- Claiming a “laxative”, an “anti-inflammatory”, or a “diuretic” effect will not be a disease claim if there is context that makes clear that the intended effect of the product is on structure/function and not disease.

Criterion 6:

A statement is a disease claim when the product claims to be a substitute for a product that is a therapy for a disease.

A claim that a product is a substitute for a drug or other therapy for disease, or has fewer side effects than a therapy for disease, is an implied disease claim.

However, if a dietary supplement claims to be a substitute for a drug that is not intended to treat or prevent disease (i.e., a drug intended to affect the structure or function of the body), the claim comparing the drug and the dietary supplement would not be a disease claim.
Managing this borderline in the US

Criterion 7:
A statement is a disease claim if it claims to augments a therapy or drug intended to diagnose, mitigate, treat, cure, or prevent a disease.

A claim that a dietary supplement will augment a particular therapy or drug action that is intended to diagnose, mitigate, treat, cure, or prevent disease is a disease claim.

In general, mentioning the name of a specific therapy, drug, or drug action will associate the claim with the intended use of the therapy, drug, or drug action and be a disease claim.

A dietary supplement may state that it is useful in providing nutritional support, as long as that claim doesn't imply disease.

Criterion 8:
A statement is a disease claim when it claims to have a role in the body's response to a disease or to a vector of disease.

“Fights disease” or “enhances disease-fighting functions of the body” is a disease claim.

"Supports the body's ability to resist infection" and “Supports the body's antiviral capabilities”

US: Disease claim because the context of the claim is limited to the disease prevention and treatment capabilities.
EU: Function claim or Reduction of Disease Risk Claim

"Supports the immune system" is not specific enough to imply prevention of disease because the immune system has both structure/function and disease fighting roles.
US: Function claim
EU: Function claim, but too vague
Managing this borderline in the US

**Criterion 9:**

A statement is a disease claim if it claims to treat, prevent, or mitigate adverse events associated with a therapy for a disease.

If the adverse effect is in itself a disease

"to maintain the intestinal flora in people on antibiotics"

- **US:** Disease claim because the claim implies that the product will prevent pathogenic bacterial overgrowth (a disease condition) associated with antibiotic use. The effect is itself a disease.
- **EU:** Function claim?

“Product X is useful because it counterbalances the effect of a drug in depleting a nutrient or interfering with the metabolism of a nutrient”

- **US:** Function claim
- **EU:** Medicinal claim?

**Criterion 10:**

A statement is a disease claim if it otherwise suggests an effect on a disease or diseases.

This provision of the regulation is intended to allow for implied disease claims that may not fit into the other nine criteria.
Borderlines within food

Borderlines also exist within food

Between categories of products
- Food supplements - Dietetic foods – Fortified foods – Foods carrying claims

Between claims
- Nutrition claims – Health claims – Reduction of Disease claims

“Regulatory shopping”

To make use of easier requirements
To avoid restrictions

Not only a consequence of legislation but also caused by legislation or its implementation

Aim of the Commission is to reduce the possibilities for shopping

Cfr. revision of the dietetic food and medical devices legislations
Medical Foods
Food for special medical purposes means:

Food specially processed or formulated and intended for the dietary management of patients, including infants, to be used under medical supervision;

Intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites,

or with other medically-determined nutrient requirements,

whose dietary management cannot be achieved by modification of the normal diet alone;

E.g.

Inborn errors of metabolism
Disease situations (gastro-intestinal, renal, liver, …)
Malnutrition (disease-related or gastro-intestinal)
Risk of malnutrition (e.g. elderly)
For the dietary management of [disease/disorder/medical condition]

“Legislative shopping”: repositioning of products as FSMPs to avoid restrictions in other legislation
  - Food supplements / other foods to avoid prohibited health claims
  - Foods for infants to avoid marketing and publicity restrictions
  - Certain foods to benefit from national reimbursement rules

Stretching of the definition: To cover products that go beyond the pure nutritional management
  - E.g. products intended for the dietary management of Alzheimer

Scientific justification: may or may not be supportive
  - Justification is responsibility of manufacturer
  - Products only need to be notified
Issues

FSMP status is often misused by products to avoid restrictions, e.g. on claims.

Many products have been notified, the status of which differs between the Member States.

Products are being developed for disease treatments and not dietary management.

EU: New delegated act: Nutrition and Health Claims will not be allowed.

US: FDA Compliance program – Warning letters.
# Differences between FSMPs and Claims in the EU

The following table outlines the key differences between FSMPs (Food for Special Medical Purposes) and Medical Foods, as well as Health Claims in the European Union (EU).

<table>
<thead>
<tr>
<th>FSMPs / Medical Foods</th>
<th>Health Claims</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Notification</strong></td>
<td>Pre-marketing authorisation</td>
</tr>
<tr>
<td><strong>Justification by the company</strong></td>
<td>Assessment by EFSA</td>
</tr>
<tr>
<td><strong>Intended for use in patients having particular nutritional requirements</strong></td>
<td>Conditions of use for the normal population having normal nutritional requirements</td>
</tr>
<tr>
<td><strong>Studies in patients required</strong></td>
<td>Studies in patients not accepted</td>
</tr>
<tr>
<td><strong>Must be labelled for the dietary management of a disease, disorder or medical condition</strong></td>
<td>Must not be labelled for the treatment or prevention of diseases (medicinal claims are prohibited for foods)</td>
</tr>
<tr>
<td><strong>Communication of disease-related information to health care professionals explicitly permitted by law</strong></td>
<td>Communication to health care professionals unclear</td>
</tr>
</tbody>
</table>
Regulatory approaches
Historic Perspective

Regulations on Nutrition and Health Claims

Fairly recent development in most countries
- US: 1990
- Japan: 1991 (FOSHU)
- EU: 2006
- ASEAN: under development

Learning process
- EU: multiple adjustments needed
- US: new standards developed over time
- Japan: extended over time (e.g. qualified and standardised FOSHU) over time + new law in 2015
- China: new law in 2016

Divergent systems worldwide
- Definitions
- Scope and Principles
- Scientific assessment
International experience

System

Pre-marketing Authorisation

Exhaustive list of permitted claims

General requirements + Notification

No pre-marketing requirements

Scientific principles

Conclusive

Significant Scientific Agreement

Authoritative Statements

Qualified Claims
International experience

Pre-marketing approval: **Product-based authorisation system**

**Strengths**
- Sense of full control
  - Only authorised products on the market
  - Verification of all aspects of the product: safety, composition, claims
- Authorities responsible for consumer protection

**Weaknesses**
- Costly & Time consuming
- Extensive administration needed
- Bureaucratic
- Burden for innovation
- False feeling of control
  - Increase in unlawful products
  - Frustration with manufacturers
  - Difficult to effectively enforce

Experience from China

Is applied mostly to pharmaceutical products
International experience

Pre-marketing approval: **Claims-based authorisation system**

**Strengths**
- Sense of full control
  - Only authorised claims on the market
- Authorities responsible for consumer protection

**Weaknesses**
- Costly
- Time consuming (1-2 years)
- Administrative resources needed
- Bureaucratic
- Generic authorisations: Unfriendly for innovation
- Budgets shift away from research
- False feeling of control
  - Increase in unlawful products
  - Frustration with manufacturers
  - Difficult to effectively enforce
- Claims context may be misleading

Experience
- From Europe
International experience

List Approach: Ingredient-based claims generic approval process

Strengths
- Sense of control
- Legal certainty
- Easy to use for SMEs
- Less resources
  - No authorisation of all products

Weaknesses
- Difficult to capture all claims
- Flexibility of wording needed
- Context of claim can still be misleading
- Difficult to establish conditions of use that cover all products
- Not stimulating for innovation
- Little incentive to submit claims
- Initial assessment still needs criteria and resources
- Needs process to update the list which could still be bureaucratic
- All claims identical
- Difficult for combination products

Experience
From Europe

EU
International experience

Pre-marketing approval

Cost / Time consuming

Example: EU
- Pre-marketing authorisation for all claims
  - Over 44,000 applications
  - No clear criteria: resubmission for 50% of claims
  - 2 years delay in establishment of the list
  - 50% of claims still undecided (on hold)

  Average time for an application
  - 1-2 years (2 times longer than expected)

Example: Canada
- Pre-marketing authorisation of Natural Health Products
  - 72,000 applications: 8 years of backlog
  - Target for timing: 180 days
International experience

Pre-marketing approval

Generic Approvals
- Limits duplication of work
- Less applications
- Outcome easy for SMEs

But
- Limitations for combination products
- No incentive for applicants
- No differentiation between products
- Reformulation of products with approved ingredients

Product-specific approvals
- Control of individual products
- Full control of product composition
- Incentive because of exclusivity

But
- Requires resources for assessment of similar individual products
- Difficult for SMEs

Innovation

Shift of investments from research to marketing
International experience

Pre-marketing approval

Conclusive evidence approach

- RCT based
- Cause and Effect establishment

But

- Studies in healthy people
- Maintenance of health difficult to measure
- Difficult for complex foods
- No chance for investments in emerging scientific findings
- Tradition of use

Qualitative evidence approach

- Proportionate assessment of the totality of the evidence
- Enables early communication on emerging health benefits

But

- Need for appropriate communication
  - E.g. disclaimer

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Shift of investments from research to marketing

Innovation
International experience

Notification + Self responsibility of operators

Strengths

- Enables a dynamic and competitive market
- Enables quick innovation, product development based on new data
- Wide and affordable consumer choice
- Proportionate benefits for the maintenance of health
- Saves resources
- Enables enforcement to focus on priority areas
  - Irresponsible use of health claims
  - Safety concerns

Weaknesses

- Agreement on the criteria
  - Totality of the Evidence
  - Expert opinion
- Commitment from industry
  - Close collaboration is needed
  - Self-regulation codes
- Needs focused enforcement
  - Support by advertising boards and self-regulating codes

[Map of the United States]
International experience

Pre-marketing approval: Criticism voiced
- Shift of investments from research to marketing
- Unpredictability of the process and its outcome
- Undermining of the peer review process
- Trend towards research remaining unpublished

Notification: Criticism voiced
- Less investments is serious research
- Many unsubstantiated claims on the market
- Difficult enforcement
- Less consumer protection
Conclusions

When developing Health Claims strategies

Product classification is an element that needs to be considered from the start

Different rules may apply depending on the type of product
Some claims may or may not be permissible depending on the status of the product

The concept of functional foods does not exist in a regulatory sense
The type of claim determines the procedure to be followed
In some countries products need to be registered as such

Rules are different throughout the world
Identifying the claimed benefit is crucial to decide if it fits with the regulatory requirements and to determine how it should be substantiated