Substantiate what one claims; claim only what has been substantiated
Scientific Substantiation
Nutrition & Health Claims
European Union

National Conference on Processed Foods & Beverages for Health: Beyond Basic Nutrition
New Dehli, 30 April 2011

Dr Loek Pijls, Group Leader  Claim Development & Assessment
• Who are we / am I
• EU Regulation
• Types of claims
• Authorisation
• Terminology
• Scientific Substantiation: Principles
  – Food (constituent) characterisation
  – Health relevance
  – Effect exists
• EFSA Opinions so far
• Who are we / am I
• EU Regulation
• Types of claims
• Authorisation process
• Terminology
• Scientific Substantiation: Principles
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Support development of health claims, from start early research, to claims on products
• Who are we / am I
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(Official Journal of the European Union L 404 of 30 December 2006)

Regulation (EC) No 1924/2006 should read as follows:

of 20 December 2006
on nutrition and health claims made on foods

**General principles of claims**

**SHOULD**

1. Fit in healthy diet & public health messages
2. Be understandable for consumers
3. Scientifically substantiated

**CANNOT**

1. Be false, ambiguous or misleading
2. Raise doubts about competitors’ products
3. Encourage or support excessive consumption of any food
4. Suggest varied diet is not adequate
5. Exploit fear
EU Regulation

• Largely similar to Codex
• Harmonisation across EU
• Non-EU (Switzerland, Norway) follow
• Maximise & protect R&D investment (our company: 1.3 US $)
• 500 million consumers
27 Member States of the EU
• Who are we / am I
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Nutrient (Content) & Comparative Claims

What is *in* the food?

- High in calcium

Health (or functional) Claims

What does the food *do*?
Health Claim

Any

Text

Graph

Picture

that

States

Suggests

Implies

that a food has an effect beneficial for health
Types of Claims

Nutrition claims
- Nutrient content claims
- Comparative claims

Health claims
- Bodily functions
- Psychological & behavioural
  - Slimming, weight control & Satiety
- New public science
- New proprietary data
- Disease risk reduction claims
  - Claims on children’s development and health

Art. 13.1
Based on generally accepted scientific evidence

Art. 13.5
Based on newly developed scientific evidence

Art. 14

Input closed

Individual Submission any time
**EU terminology**

**Nutrition Claim**
- High in Calcium

**Health Claim**
- Functional (art 13)
  - Calcium builds strong bones
- Disease Risk Reduction / Children (art 14)
  - Calcium can reduce the risk of osteoporosis

**Medicinal Claim**
- Daily intake of calcium-rich food prevents bone fractures, or treats or cures osteoporosis
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Procedure claim approval

Nutrition claims

Must be listed in the Regulation’s nutrition claims annex

Health claims

Article 13 ‘Generally Accepted’

Article 13.5 ‘New evidence’

Article 14

MS list of A13 Claims

Dossier submission

EFSA

Opinion

EC

Approval/Rejection

Nutrition and health claims: the role of food composition data
"New function" health claims under Article 13.5

Claims under article 13/5 EC Regulation on nutrition and health claims are those based on newly-developed scientific evidence and/or for which protection of proprietary data is requested. For these health claims, authorisation is required on a case-by-case basis, following the submission of a scientific dossier to EFSA for assessment.

Valid applications are transmitted to EFSA by competent authorities in Member States. EFSA is then required to deliver its opinions within five months. If supplementary information is needed, EFSA has an additional month for the evaluation.

Article 13.5 applications submitted to EFSA are included in the Register of Questions, with indication of the food substance and claimed effect. The panel has received to date 42 applications, 9 have been withdrawn and so far 25 scientific opinions have been adopted.

For confidentiality reasons, and in accordance with the claim regulation, summaries of these Article 13.5 claims applications are not published.

NDA opinions on Article 13/5
Food Safety - From the Farm to the Fork

EUROPA > European Commission > DG Health and Consumers > Overview > Food and Feed Safety


European Union Register of nutrition and health claims made on food - Introduction

Health claims means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its components and health.

- Authorised health claims
- Rejected health claims

Available at http://ec.europa.eu/food/food/labellingnutrition/claims/community_register/health_claims_en.htm
EFSA evaluates the science, publishes Opinion

EU Commission authorises or rejects the claim

EC Decision applies once published in the Official Journal EU

EFSA opinion

EC draft decision

EU authorisation

3-6 months

Min 3 months

Permitted claim

3-6 months

Min 3 months

6 months

NON authorised claim

Removal, if on existing product

Unlikely but possible
The use of nutrition and health claims shall only be permitted if...a nutrient or other substance...has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence.

Assessment of highest possible standard

[EC 1924/2006, Article 5 (1)(a)]
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Not functional foods, but *foods with health claims*

1. All foods are *functional*
2. When we say FF, we mean *Foods with Health Claims*
3. No FF in EC, EFSA, EU HC Reg or PASSCLAIM
4. No *health effects of diet beyond nutrition effects*
5. Who wants *adequate* if *optimal* is better?
Maintain health = keep disease out

1. maintain health = prevent disease = reduce risk of disease

2. Disease risk reduction = maintaining health

1. If disease risk reduction is not maintaining health, then what is it?
2. If maintaining health is not reducing disease risk, then what is it?

3. Prevention = risk reduction, sometimes to 0, but usually not
The best vitamin to be a happy person is B1

Unknown

It is so Simple to be Happy, but so Difficult to be Simple

Mohandas Karamchand (Mahatma) Gandhi
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FUFOSE: Evidence-based markers for functional foods, to types of claims relevant to them

Consumption of functional food component

- Markers of exposure to food component
- Markers of target function / biological response
- Markers of intermediate endpoint

Enhanced target function

TYPE A CLAIMS (enhanced function)

Reduced risk of disease

TYPE B CLAIMS (reduced risk of disease)
PASSCLAIM to Health Claim

European Commission on

EFSA

European Food Safety Authority
The use of nutrition and health claims shall only be permitted if...a nutrient or other substance...has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence.

Assessment of highest possible standard

[EC 1924/2006, Article 5 (1)(a)]
In God we trust; everyone else, please bring data.
Cause and effect relationship

- Established
- Evidence insufficient to establish..
- Not established
Demonstrate what one claims; claim only what has been demonstrated

Characterised Constituent → Health effect

Causal relationship

Human studies
- Study design (randomised, double-blind, placebo-controlled)
- Quality (data collection, statistics, outcomes, subjects)

Interpret results

(Sufficiently) substantiated

Conclusion

Not (sufficiently) substantiated
EFSA assessment

1. Food (constituent) >> sufficiently characterized
2. Claimed effect >> beneficial to human health
3. Cause and effect relationship >> established

CLAIM SUBSTANTIATED
Demonstrate what ones claims; claim only what has been demonstrated

1. Characterise food (constituent)
2. Relevance human health
3. Causal relationship
4. Matching population & dose
• Who are we / am I
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Ensure that the scientific evidence that substantiates the claim also applies to the product that with the health claim.
Characterise food (constituent)

1. Source
2. Specifications: physical, chemical, microbiological
3. Variability batch-to-batch
4. Analytical methods
5. Quality assurance
6. Manufacturing process
7. Stability: storage, shelf-life
8. Bioavailability
Source and specification

- Simple for a single constituent, e.g. vitamin, mineral
- Complex for plants or (other) whole foods e.g. dairy
- Probiotic, prebiotic, antioxidant = health claim!
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Changes in “normal” ranges “biologically relevant”? 

- Yes, according to EFSA; also in US and Canada
- E.g.: *decrease blood cholesterol* to a lower end of normal range is biologically relevant
• **Maintain normal blood glucose concentration:** beneficial physiological effect

• But, studies in type 2 diabetes under therapy do **not** predict effect general population
Risk Factors

• No list of “accepted” risk factors

• EFSA
  – Risk factor is independent predictor of human disease
  – Relationship of the risk factor to development of the disease is biologically plausible

• Evaluated “case by case”
Relevance for human health

Function claim

Maintenance or improvement of a function, e.g.

- *gut health is too general,* it is unclear how to characterize this, but
- *transit time is specific and measurable by generally accepted methods.*

Reduction of disease risk

Reduce risk factor, e.g.

- *Arterial stiffness is not a risk factor of cardiovascular disease but*
- *LDL cholesterol is a risk factor of coronary heart disease*
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</tbody>
</table>
Say what we mean, 
mean what we say

Marker: something that marks (something else)

It is not about the marker, but about the marked
Challenges

• When is extrapolation valid?
• When is effect beneficial to health?
• True risk factors?
• Relevant for health, but not preventing, treating or curing disease
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Does intake of the food (constituent) actually cause the claimed effect?
Does intake of the food (constituent) actually cause the beneficial health effect?

Core: studies in humans, primarily intervention:
1. Subjects representative target group
2. Appropriate control group
3. Long enough
4. Intake realistic
5. Outcomes reflect directly the claimed effect, or are biologically and methodologically valid markers
6. Effect statistically significant
7. Size of the effect biologically meaningful
8. Claimed effect plausible
9. Consistency; no rule for # studies, but > 1
10. TOTALITY of evidence
Intervention & Observational studies

• **Both** observe and compare aspects of health across groups with different intakes of a food (constituent)

• Only difference:
  – intervention: researcher allocates intake
  – Observational: researcher does not
Hierarchy of Study Design

- Human Intervention Studies
  - Randomized controlled
  - Controlled
  - No control
- Human Observational Studies
  - Cohort
  - Case-control
  - Cross-sectional
- Human Studies on Mechanisms
- Case studies
- Non-human Data
Claim for ..., studies on ...

- Single active constituent
- Mix
- Humans
- Children
- Healthy people
- Certain dose

*If no such match, then data, at best, supportive*
• Good data, and good assessment
• Next 47 sec: creative example of assessment / interpretation…
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Opinion of the Panel on dietetic products, nutrition and allergies (NDA) on a request from the Commission related to scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim

Question number: EFSA-Q-2007-066

Adopted: 6 July 2007
SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to wheat bran fibre and increase in faecal bulk (ID 3066), reduction in intestinal transit time (ID 828, 839, 3067, 4699) and contribution to the maintenance or achievement of a normal body weight (ID 829) pursuant to Article 13(1) of Regulation (EC) No 1924/2006\(^1\)

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)\(^2, 3\)

European Food Safety Authority (EFSA), Parma, Italy
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EFSA Opinions Art. 13.1
Oct 09, Feb & Oct 10, Apr 11

- EFSA provides scientific opinion
- EC and member states authorise or reject

Oct.09: 74% Negative, 26% Positive
Feb.10: 97% Negative, 3% Positive
Oct.10: 87% Negative, 13% Positive
Apr.11: 87% Negative, 13% Positive

1549
14 Positive:

- DHA: visual
- ALA, Fe, Vit B1: brain, cognitive, neurological
- Ca, Vit D, P, protein: for bone
- Essential fatty acids (ALA, LA): growth & development
- I: growth
- Vit B1: energy-yielding metabolism
10 Positive:

- Plant sterols, stanols, oat beta-glucan: reduced blood cholesterol
- Ca + Vit D: reduced loss of bone
- Sugar-free chewing gum: reduced tooth demineralization, neutralization plaque acids
3 Positive:

- Tomato extract concentrate: platelet aggregation
- Toothkind drinks: reduce tooth demineralization
Prunes/plums
Maintenance normal bowel function
Lutein
Maintenance of vision
170 substances for antioxidant effect
142 substances for joint, bone & muscle health
Mainly well-established nutrient functions:

**Vitamin A**  Normal function of immune system; maintenance of normal vision

**Vits B₁, B₁₂, niacin, pantothenic acid**  Normal energy-yielding metabolism

**Vitamin C**  Protection of DNA, proteins and lipids from oxidative damage

**Calcium & vitamin D**  Maintenance of normal bones at all ages

**Folate**  Normal blood function; normal maternal tissue growth during pregnancy

**Iron**  Normal formation of red blood cells and haemoglobin; oxygen transport
• Plant sterols lower blood cholesterol; blood cholesterol lowering may reduce the risk of coronary heart disease
• Meal replacements and weight control; reduction in body weight
Albert Einstein

Make things as simple as possible, but not simpler than that.
Substantiate what one claims; claim only what has been substantiated.
The art of asking questions is the source of every progress