European Food Safety Authority

EFSA´s work concerning health claims

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Role of EFSA in the Scientific Substantiation of Health Claims

EC Regulation 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods

- Health claims should only be authorised for use in the Community after a scientific assessment of the highest possible standard.

- In order to ensure harmonised scientific assessment of these claims, the European Food Safety Authority should carry out such assessments.

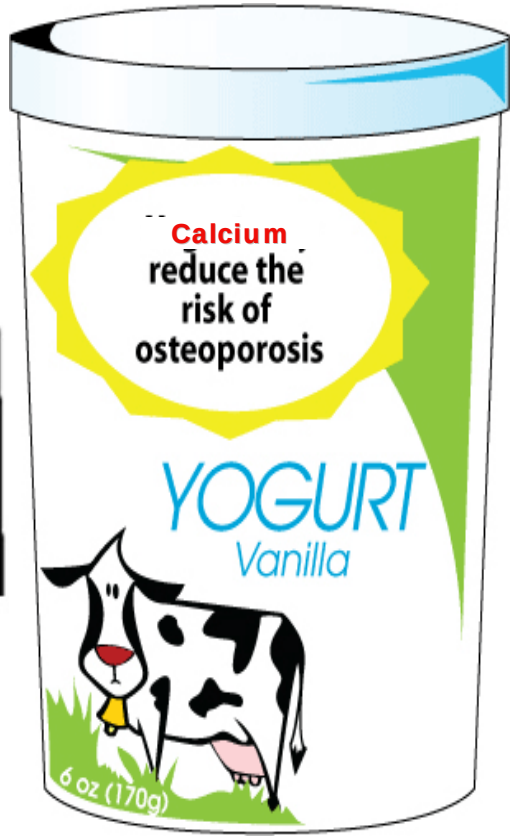
Classification of Claims Reg (EC) No1924/2006

- **Nutrition claims**
  - Nutrient content: ‘high fibre’, ‘low fat’, ‘reduced salt’, ‘light’
- **Health claims**
  - Function claims
    - ‘calcium is needed for normal bone structure’
      - based on generally accepted scientific evidence (Art. 13.1)
      - based on newly developed scientific data/proprietary data (Art. 13.5/18)
  - Reduction of disease risk claims (Art. 14)
    - ‘substance A reduces blood cholesterol which may reduce the risk of heart disease’
  - Claims for development and health of children (Art. 14)
    - scope now defined by EC, transition arrangements in place

Health Claims - Art. 14

= referring to reduction of disease risk

= or to children's development & health



EFSA guidance on health claims

Opinion of the EFSA NDA Panel on:

Scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim

- adopted 6 July 2007
- applies to Art. 14 and Art. 13.5/18 claims

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178623592448.htm

Principles

- Applicant is responsible for providing all information and data required to substantiate the claim
- Not all information specified applies for each claim - justify if some specified information not included
- Claims will be evaluated on case by case . . . . . but aiming for consistency

Criteria for substantiation

Regulation - health claims should be substantiated by

- ‘generally accepted scientific evidence’
- ‘taking into account the totality of the available scientific data’
- ‘weighing the evidence’

Scientific criteria:

- Characterisation of food/substance
- Beneficial to human health
- Causality of the relationship
- Food quantity required for claimed effect
- Representativeness of data for target population
- **Also** - wording should reflect the scientific evidence
  - conditions/restrictions of use should be appropriate

Characterisation

- Is it sufficient to assure EFSA that the substance for which the claim is made is the same as that for which the evidence on efficacy is provided?
  - it should also be sufficient to allow the Regulator to determine that the substance for which the claim is made is the same as that which was authorized

Beneficial

- Is the claimed effect beneficial for human health?
  - Validity of end-point used
  - Size of effect
  - Benefit in EU population groups

Causality

- Is a cause and effect relationship established between the consumption of the food/constituent and the claimed effect in humans?
- characteristics of the food-health relationship
  - strength
  - consistency
  - specificity
  - dose-response
  - biological plausibility

Food quantity

- Is the quantity of food/constituent proposed for the claimed effect adequate ?
- Could the quantity of the food/constituent and pattern of consumption required to obtain the claimed effect reasonably be consumed as part of a balanced diet?

Representativeness

- Is the specific study group(s) in which the evidence was obtained representative of the target population for which the claim is intended?
  - Patients vs healthy subjects?
  - Obese vs normal weight?
  - Adults vs children?
  - Case by case judgement

Consumer understanding

‘claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim’

- consumer understanding not assessed by EFSA

However

- wording of claim should reflect the scientific evidence
- claims considered from a scientific point of view to be vague, confusing or misleading will not receive a favourable opinion from EFSA

EFSA health claims evaluation status (12 November 2008)

Claim type	Received	Withdrawn	Adopted	In progress
Children (Art. 14)	207	9	22	23
Disease risk reduction (Art. 14)	26	1	6	3
New science/ proprietary (Art. 13.5)	9	2	2	5
Total	242	12	30	31

EFSA health claims received by MS Finland (15 November 2008)

Claim type	Received	Withdrawn	Adopted	In progress
Children (Art. 14)	0	0	0	0
Disease risk reduction (Art. 14)	3	1	2	0
New science/ proprietary (Art. 13.5)	3	1	1	1
Total	6	2	3	1

Article 13.1 claims

Member States lists to EC by 31 January 2008

- lists of claims
- conditions applying to them
- references to the relevant scientific justification

- 44,000 claims submitted by Member States
- EC sent draft consolidated list of claims to EFSA (31 July 2008) – 2,870 main entries and ca 7,000 similar health relationships
- EC to send revised consolidated list of claims
- EFSA evaluation
- Community list (by 31 January 2010)
  - EC adopts Community list of permitted claims + conditions of use

Modus Operandi – Art. 13 claims

- EFSA to pre-screen Article 13 list according to defined criteria and send back to the EC those claims for which further clarification/information is needed
- EFSA to evaluate remaining claims by July 2009
- For new claims added to the October list a timeline for completion still needs to be agreed

Criteria for initial screening of Article 13 claims

- Claims where clarification on scope is needed
- General well-being claims
- Claims which are too vague (claimed effect not specified/measurable
- Foods which are not sufficiently characterised or conditions of use are not sufficiently specified
- Combination constituents that are not sufficiently defined
- Claims in other languages than English

Consumer understanding

European Food Safety Authority

Regulation:

'claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim'

However

- ✓ consumer understanding not assessed by EFSA
- ✓ wording of claim should reflect the scientific evidence
- ✓ claims considered from a scientific point of view to be vague, confusing or misleading will not receive a favorable opinion from EFSA

Article 13 claims ToR

EFSA to evaluate whether

- Adequate characteristics of the food pertinent to the beneficial effect is provided
- Effect is beneficial to human health
- Beneficial effect of food on the function is substantiated (EFSA to comment on the nature and quality of the evidence provided)
- Specific importance of the food for the claimed effect
- Effect on the function is significant in relation to the quantity to be consumed
- Study group is representative for the target population
- Wording
- Conditions and restrictions of use

Article 13 Sub-working groups

Sub-working groups on various health relationship to prepare first draft, to be reviewed by Standing WG on claims and to be adopted by NDA Panel

- Gut and Immune System
- Cardiovascular Health
- Bone, dental health, connective tissue
- Weight management, sateity, physical performance
- Mental health, CNS, vision
- Miscellaneous
- Characterisation of Botanicals

Challenges related to Art. 13 claims list received

- Amount of work to be accomplished by EFSA is higher than originally anticipated
- Some un-clarity due to the nature of the list
- Quality of citations

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Thank you for your attention