European Food Safety Authority

EFSA assessment of health claims

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Outline

- Key points related to the scientific evaluation of health claims
- Health claims evaluation status
- Article 13 claims list
- Outlook for article 13 health claims evaluation

Health Claims - science based evaluation

Regulation (EC) 1924/2006

- **Scientific substantiation** should be the main aspect to be taken into account for the use of nutrition and health claims and the **food business operators** using claims should justify them (Recital 17)

- A claim should be scientifically substantiated by taking into account the **totality of the available scientific data**, and by **weighing the evidence** (Recital 17)

- Nutrition and health claims shall be based on and substantiated by **generally accepted scientific evidence** (Article 6)

EFSA's role in evaluation

Regulation (EC) 1924/2006 (Recital 23)

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

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

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) adopts scientific opinions

EFSA guidance on health claims

Art. 14 and Art. 13.5 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 (public consultation, technical meeting with stakeholder, publication in 2007)

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

- Frequently Asked Questions (FAQ) related to the EFSA assessment of Article 14 and 13.5 health claims applications (public consultation, meeting with applicants, revised version published in September 2009)

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902433897.htm

Art. 13.1 claims

- Briefing document for Member States and European Commission on Article 13.1 health claims list (meeting with MS & Commission, revised version published 18 November 2009)

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211903064774.htm

Scientific criteria for Article 13 different from Art. 13.5 and 14?

- Similar claims have been submitted to EFSA under the various Articles
- Different criteria would result in inconsistencies in the scientific evaluation of claims
- Terms of references (TOR) provided by Commission forms the basis for criteria for Article 13.1 evaluation
- TOR are similar to the criteria used for the evaluation of claims applications (Art 13.5 and 14)

Evaluation of claims - 3 main questions addressed by EFSA

the extent to which:

1. the **food/constituent** is defined and characterised
2. the **claimed effect** is defined and is a beneficial physiological effect ('beneficial to human health')
3. a **cause and effect relationship** is established between the consumption of the food/constituent and the claimed effect (for the **target group** under the proposed **conditions of use**)

Evaluation of claims - other questions addressed by EFSA

if a cause-effect relationship is considered to be established, whether:

- the quantity of food/pattern of consumption required to obtain the claimed effect can be consumed within a balanced diet
- the proposed wording reflects the scientific evidence (consumer understanding not addressed by EFSA)
- the proposed wording complies with the criteria for the use of claims specified in the Regulation
- the proposed conditions of use are appropriate

Characterisation

- food (category), food constituent (e.g. nutrient, other substance, combinations)
- Is the food/constituent sufficiently defined and characterised?
- Is it sufficient to assure EFSA that the food/ constituent for which the claim is made is the same as that for which the evidence on efficacy is provided?

Characterisation of plants

- For plants, information provided should include the scientific name, part used, preparation procedure
- The Panel uses, in addition to information provided on the list, information from reference textbooks on standard preparations and conditions of use with respect to the claimed effect.

Pertinent studies for substantiation

- studies carried out with the food/constituent for claim?
- human studies - appropriate outcome measure(s) of the claimed effect?
- conditions for human studies vs conditions of use for claim (e.g. food/constituent quantity)?
- human studies - study group representative of the target group? Extrapolation to the target population?
- studies in animals/in vitro - how do they support the claimed effect in humans?

Patients vs general population

- For EFSA evaluation, **patients** are not the target group for health claims
- However, studies in **patients** may be used to substantiate claims for the **general population**
  - case by case
  - Yes for gastrointestinal discomfort in IBS patients
  - No for joint function in osteoarthritis patients

Human studies

human studies are central for EFSA for the substantiation of the claim

- human intervention studies
- Observational studies

Studies in animal or in vitro may provide supportive evidence

In weighing the evidence NDA considers all scientific pertinent data (hierarchy of evidence)

Not different from other standards like CODEX, FDA

EFSA conclusions

- Cause and effect established: Sufficient conclusive evidence - general accepted science
- Insufficient evidence to establish cause and effect (some evidence but not conclusive)
  - Emerging science
  - Conflicting results

- Cause and effect relationship not established: (very) limited scientific evidence

EFSA health claims evaluation status (9 December 2009)

European Food Safety Authority

Claim type	Received	Withdrawn	Adopted	In progress
Children (Art. 14)	215	25	47 opinions covering 54 applications	4*
Disease risk reduction (Art. 14)	45	4	15	3**
New science/ proprietary (Art. 13.5)	25	6	15	2***
Total -applications	285	35	77 covering 84 applications	9
Art 13 list of health claims	4185	119	846 + 94# (#adoption by written procedure until end 2009)	3126****

* 2 in clock stop
** 2 in clock stop
*** 0 in clock stop
****248 in clock stop

Article 13 list

Access database

- 9 (revised) access databases received between July and Dec 2008
- One combined database published in Jan 2009
- Since publication, a number of changes made to the list, e.g. reallocating misplaced claims, adding missing claims
- Updated access database will be published early next year, including timelines for remaining claims

EFSA Criteria for screening of Article 13.1 claims

C0: Sufficient information

C1: Claims where clarification on scope is needed

C2: General well-being claims

C3: Claims which are too vague (claimed effect not specified/measurable)

C4: Foods which are not sufficiently characterised or conditions of use that are not sufficiently specified

C5: Combination of constituents not sufficiently defined

C6: Claims in languages other than English

Screening - Vague claims

Health relationship: Intestinal health

- *too unspecific*

Proposed wordings:

C 0: “Support gastrointestinal health" / "Supports better bowel performance" / "Supports regular bowel movements" / "For a regular bowel motion" / "Supports bowel transit" /

C 3: Helps to support the digestion; contributes to the function of intestinal tract

Screening - characterisation

- Only if it was very obvious from the list provided that food/constituent was not characterised, claims were sent back for more clarification on the characterisation (C4), e.g. ‘dairy products’, ‘soups’
- Out of over 4000 claims only 94 claims sent back for C4

NDA Panel considered during **scientific evaluation** whether the information provided was sufficient to characterise the food/constituent in relation to the claimed effect

Literature provided

- For 2118 claims with criterion 0 EFSA received around 39,500 references
- List of references for criterion 0 claims published on the EFSA website

http://www.efsa.europa.eu/panels/nda/claims/article13.htm.

- Quality of literature far from optimal
- Difficulties with translations of references provided in other languages than English
- Accessibility to some references

Difficulties with citations provided

- Unité INSERM 588-Bordeaux, 2003
- Own clinical trial carried out in Raisio, results analysed at the University of Kuopio in 2005.
- Study in progress by Brunero M. et al.
- Fernandez.
- P. Zoldaz, Wheeling Jesuit University / USA
- de vreese Möller 2003 38
- KOOLMAN J. and al. e, 1998. Weinheim 85
- Mader A, 1987. Deutsche Zeitschrift für Sportmedizin.
- Dr. Kameníková. 2000. Zdravotnické noviny [Dr. Kameníková, 2000. Medical papers]
- Andenne Omega3 – Menu. Not published intervention trial, realized from januari to june 2007, Andenne, Belgium
- Int J Food Microbiol. 2006 Nov 28
- Newsletter Food Ingredients & Sensorik, 2006
- Juarez Tomas MS, et al, n.a. Efecto de fuentes de carbono y nitr
- Loveridge (Chapter 13 Fatsoluble vitamins pp223).

Scientific substantiation?

Ezekiel 27.17. The Old Testament In: The Holy Bible. (For *"Panax ginseng" and "Cognitive performance")*

(Full text: Judah and Israel gave you their finest wheat, fancy figs, honey, olive oil, and spices in exchange for your merchandise.)

Tea association, 2003. Classical drink as trend: tea consumption stable at a high level. German tea industry satisfied with financial year. Press Release.

Caffeine. 2000. In: The American Heritage Dictionary of the English Language.

British Royal Air Force, 1966. Report der British Royal Air Force.

Beck, L, The complete idiot's guide to total nutrition for Canadians.

Wikipedia, Tribulus, http://en.wikipedia.org/wiki/Tribulus

Divergence between level of evidence for different claims?

- No need to review primary scientific studies for claims based on **well established consensus**, supported by authoritative scientific sources, e.g. many claimed functions of vitamins and minerals

- Need to review primary studies for those claims for which there is **no established consensus**, based on authoritative scientific sources

Textbooks

- EFSA did not reject reference textbooks and monographs – these were reviewed to see if they contained scientific data; if there were such data it was taken into consideration.

In other words:

- All data available to EFSA from which scientific conclusions can be drawn (supportive/not supportive) are considered pertinent by EFSA and weighed for the evidence

EFSA Art 13.1 health claims evaluation status

- c.a. 520 claims (covering ~ 200 food/constituents) evaluations adopted in July 2009 and published 1 October 2009

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902914361.htm

- Claims evaluated case by case - clustered into 94 opinions
- Uniform scientific criteria - consistency
- Opinions reflect the varying quality of the information submitted
  - about one third favourable, sufficient scientific evidence
  - half of the unfavourable evaluations had insufficient information on the food/constituent ('probiotic' bacteria, botanical substances)
- Reasons for EFSA's conclusions are outlined

EFSA Art 13.1 health claims evaluation status

- EFSA received back clarification from COM/MS on the over 2400 claims sent back in Jan.09 and June 09
  - Product specific claims and some other claims on hold (c.a. 260 claims)
  - Comparative claims to be evaluated by EFSA
  - Around 120 claims withdrawn
  - For c.a. 620 claims no clarification provided
  - Addendum to the list still to be submitted

Publication forecast for claims on the Article 13 list of health claims (10 Dec 2009)

- EFSA is continuing evaluations – taking into account clarification provided by MS/COM
- progressive adoption/publication of opinions

Art 13 list of health claims - publication	Number of IDs
October 2009	around 520
February 2010	around 400
July 2010	around 600
From July 2010 onwards	around 2250 + addendum

- Assessment of individual claims will be combined as appropriate to form coherent opinions