European Food Safety Authority

EFSA's evaluation of health claims: scientific substantiation

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Background

Briefing document for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims (May, 2010)

Based on:

- Frequently Asked Questions (FAQ) related to the EFSA assessment of Article 14 and 13.5 health claims applications (2009)
- Briefing document for Member States and European Commission on the evaluation of Article 13.1 health claims (2009)

EFSA's role in evaluation of health claims

- Regulation (EC) No 1924/2006
  - health claims only 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
  - Resources - Panel experts, additional experts, EFSA staff

EFSA's scientific criteria for substantiation of claims

- Regulation (EC) No 1924/2006 - health claims substantiated by:
  - **generally accepted scientific evidence**
  - taking into account the **totality of the available scientific data**, and by **weighing the evidence**
- EFSA's scientific criteria for evaluation
  - similar for Art 13.1 (Terms of Reference from EC) and Art 13.5/14
  - similar to FDA (2009), Codex Alimentarius (2009)
- Whether the evidence is sufficient to represent **generally accepted scientific evidence** to substantiate the claim is a scientific judgement of NDA Panel
- Opinion - nature & quality of evidence but not grades of evidence

Scientific requirements for substantiation of specific claims

- Application of scientific criteria to specific health claims:
  - which claimed effects are beneficial physiological effects?
  - which studies/outcome measures are accepted for substantiation?

- Progressive - as claims are evaluated
  - Panel decisions in published opinions
- EFSA will consolidate these scientific requirements to provide additional guidance to applicants
- Stakeholder consultation in selected areas

Main issues addressed by NDA Panel

the extent to which:

1. the food/constituent is defined and characterised
2. the claimed effect is defined and is a beneficial physiological effect
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)

– scientific substantiation requires a favourable outcome to all three questions

Other issues addressed by NDA Panel

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
- the proposed wording complies with the criteria for the use of claims specified in the Regulation
- the proposed conditions of use are appropriate
- substantiation was dependent on data claimed as proprietary by the applicant

How does the NDA Panel decide whether a claim is substantiated?

- extent to which a cause and effect relationship is established between consumption of the food/constituent and claimed effect
  - for the target group under the proposed conditions of use
- all of the evidence from pertinent studies weighed - overall strength, consistency & biological plausibility
- human data central for substantiation - hierarchy of evidence
  - quality of individual human studies
  - studies in animals or *in vitro* may provide supportive evidence
- no pre-established formula (number/type of studies needed)

NDA Panel conclusions on substantiation

- A cause and effect relationship is established between the consumption of the food/constituent and the claimed effect

- A cause and effect relationship is not established between the consumption of the food/constituent and the claimed effect

OR

- The evidence provided is not sufficient to establish a cause and effect relationship between the consumption of the food/constituent and the claimed effect

Totality of the available scientific data

- all studies available to EFSA that are considered pertinent by the NDA panel
  - from which scientific conclusions can be drawn for substantiation of the claim
  - including studies that support the relationship, equivocal studies, & studies showing no effect/opposing effects
- Art. 13.5/14 - applicant responsible for providing totality of the available data
- Art 13.1- MS responsible for providing references to totality of the available data
- NDA Panel may use data not provided if considered pertinent 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?

Extrapolation between groups

- Extrapolation from studies in subjects with disease to general population
  - case by case, based on evidence provided
  - yes for gastrointestinal discomfort in IBS patients
  - no for joint function in osteoarthritis patients

Authoritative scientific sources

- claims with established scientific consensus for substantiation - authoritative scientific sources
  - Panel may rely on such sources without reviewing primary scientific studies
  - e.g. many of the functions of the essential nutrients
- claims without established scientific consensus
  - primary studies reviewed

Claimed effect beneficial?

- is the claimed effect a beneficial physiological effect?
  - specific requirement of Reg 1924/2006
  - case by case judgment by NDA Panel
  - may depend on context of the claim (e.g. target group, whether other conditions are fulfilled)

Disease risk factors

- Physiological factor associated with the risk of a disease that may serve as a predictor of development of that disease
- relationship of the risk factor to the development of the disease biologically plausible
  - Some well-established risk factors, e.g. elevated LDL-cholesterol and heart disease
  - Otherwise, case by case judgment by NDA Panel

Characterisation

- Is the food/constituent sufficiently defined and characterised?
- sufficient to establish that it is the same food/constituent as that for which the evidence on efficacy is provided?
- Sufficient for establishing conditions of use?
- If not sufficiently characterized, a cause and effect relationship between the food/constituent and the claimed effect cannot be established

Borderline issues

- Maintenance claims on well established risk factors:
  - maintenance of normal blood cholesterol levels, based on evidence of reduction of blood LDL-cholesterol
  - EFSA has evaluated this as a function claim
- Target population
  - EFSA considers that for a claim on a function associated with a disease, subjects with the disease are not the target for the claim (e.g. joint function & osteoarthritis)
  - applications for claims that specify target groups other than the general (healthy) population
    - ongoing discussions with COM/MS on admissibility

Compliance with criteria in Regulation

EFSA considers whether the claim:

- is specific (and not general, non-specific only)
- is a beneficial physiological effect
- is for a food/constituent that has an independent role in the claimed effect (not based on inclusion/substitution of other substances only)
- encourages excess consumption of a food

EFSA health claims evaluation status (May, 2010)

- Art 13.5/14: over 80 adopted, within legal deadlines
- Art 13.1: over 900 adopted
- Art 13.1 challenges
  - large number of claims (over 4,500) exceeded expectations
  - progressive evaluation and publication in series - complete by end of 2011
  - poor quality of information for many claims

Favourable health claim evaluations to date (~200)

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Food/constituent	Health relationship
Vitamins, minerals	Cardiovascular, brain, gut, immune, bone, dental, antioxidant, metabolism
Protein, carbohydrate	Muscle, bone, energy,
Fatty acids	Brain, cardiovascular, vision
Fibre(s)	Gut, cardiovascular
Other substances - phytosterols/stanols, chewing gum, meal replacements, tomato extract	Cardiovascular, dental, weight management