European Food Safety Authority

Scientific requirements for substantiation of health claims

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EFSA Scientific Meeting on Health Claims related to Gut and Immune Function

2 December 2010, Amsterdam

General introduction - overview

- EFSA's role in evaluation of health claims
- Scientific criteria for substantiation of claims
- How does the NDA Panel decide whether a claim is substantiated?
- Pertinent studies for substantiation
- Extrapolation between groups
- Beneficial physiological effect
- Claims for reduction of disease risk
- Disease risk factors

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

Scientific criteria for substantiation of health 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**
- Whether the evidence is sufficient to represent **generally accepted scientific evidence** to substantiate the claim is a scientific judgement of NDA Panel

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
  - design and quality of individual human studies
  - studies in animals or *in vitro* may provide supportive evidence
- no pre-established formula (number/type of studies needed)
  - case by case

Pertinent studies for substantiation

- studies have appropriate design and quality?
- studies carried out with the food/constituent for claim?
- appropriate outcome measure(s) of the claimed effect?
  - what is generally accepted by experts in the field?
- conditions for human studies vs conditions of use for claim (e.g. quantity of the food/constituent)?
- study group representative of the target group?

Extrapolation between groups

Extrapolation from study groups to target groups:

- from subjects with disease to general population
- from one population group to another population group
  - case by case
  - yes for gastrointestinal discomfort in IBS patients
  - extrapolation to the target group biologically justifiable?
    - related to physiological status, mechanism of claimed effect
    - patient treatment may interfere with study interpretation
    - justification to be provided by applicant

Health claims for essential nutrients

- Proposed functions of essential nutrients:
  - if established scientific consensus for substantiation (authoritative scientific sources)
    - Panel may rely on authoritative scientific sources for substantiation without reviewing primary studies
  - if no established scientific consensus for substantiation
    - Panel reviews primary studies
- Proposed functions of other substances
    - Panel reviews primary studies

Beneficial physiological effect

- is the claimed effect a beneficial physiological effect?
  - specific requirement of Regulation 1924/2006
  - case by case judgment by NDA Panel
  - must comply with criteria in Regulation 1924/2006
  - may depend on context of the claim
    - target group?
    - whether other conditions are fulfilled?

Claims on reduction of disease risk

Regulation (EC) No 1924/2006

- refer to reduction of a **risk factor** in the development of a disease
- beneficial physiological effect is reduction of a **risk factor**
  - not reduction of **risk** of disease

- 'Plant sterols and plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease'

EU Register of Nutrition and Health Claims

Disease risk factor

- 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 coronary heart disease
  - Otherwise, case by case judgment by NDA Panel

Medicinal claims

- **claims on the prevention, treatment or cure of a human disease should not be allowed for foodstuffs as these constitute medicinal claims**
  - Directive 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs

Target population

The NDA Panel considers that:

- the target population for health claims is the general (healthy) population or specific subgroups thereof, e.g. children, elderly people, athletes
- for a claim on a function associated with a disease, subjects with the disease are not the target for the claim (e.g. bowel function and IBS)
- applications for claims that specify target groups other than the general (healthy) population
  - ongoing discussions with COM/MS on admissibility