Scientific requirements for substantiation of health claims

Albert Flynn
Chair
EFSA Scientific Panel on Dietetic Products, Nutrition & Allergies

European Food Safety Authority

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 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
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