European Food Safety Authority

Scientific requirements for health claims on bowel function, gastrointestinal discomfort, digestion/absorption of nutrients

Albert Flynn

Chair

EFSA Scientific Panel on Dietetic Products, Nutrition & Allergies

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

2 December 2010, Amsterdam

Overview

- General response to comments received on gut and immune function
- Scientific requirements for substantiation of claims on:
  - Bowel function
  - Gastrointestinal discomfort
  - Digestion/absorption of nutrients
  - Gastrointestinal development

Scientific requirements for substantiation of specific claims

- Scientific requirements for substantiation of specific health claims are established progressively - as claims are evaluated
  - NDA Panel decisions in published opinions
  - consolidated in guidance documents
  - stakeholder consultation in selected areas
- EFSA guidance:
  - which claimed effects are considered beneficial physiological effects?
  - which studies/outcome measures are accepted for substantiation?
  - guidance has limits
- Applicant responsibility:
  - provide justification

General response to comments received

- Many helpful comments received
- All comments relevant to this consultation considered
- NDA Panel will address as many as possible within the consultation
  - need for balance of resources between evaluation & guidance
- Some comments may need to be considered in the context of specific applications for health claims
- Some comments too detailed to address in guidance
  - experimental design and methods, statistical analysis
  - lists of appropriate outcome measures for claimed effects

Bowel function (1)

Beneficial physiological effects:

- reduced transit time
- more frequent bowel movements
- increased faecal bulk
- softer stools (consistency)

- changes in bowel function ‘within the normal range’
  - Improved frequency, transit time, consistency should not result in diarrhoea

Bowel function (2)

Beneficial physiological effects:

- reduce diarrhoea as beneficial physiological effect?
  - yes - see also claims related to GIT infection

Study group:

- 'functional constipation' acceptable as a study group for claims for the general population?
  - in principle yes
  - related to physiological status, mechanism of effect
  - patient treatment may interfere with study interpretation

Gastrointestinal discomfort (1)

Beneficial physiological effect:

- reducing gastrointestinal discomfort (adults)
- also beneficial physiological effect in young children?
  - in principle yes

Gastrointestinal discomfort (2)

IBS (adults) acceptable as study group for claims for the general population (adults)

- welcomed by most responses

IBS (children) acceptable as study group for claims for children?

- in principle yes
- Age of target group *vs* age of study group?

Gastrointestinal discomfort (3)

Appropriate outcome measures:

- subjective outcome measures accepted - caution to avoid bias
  - e.g. validated subjective global symptom severity questionnaire(s), frequency
  - distension/bloating, abdominal pain/cramp, borborygmi (rumbling), pain
  - appropriate selection of questions - valid for specific application?

Digestion/absorption of nutrients (1)

Beneficial physiological effect:

- improved digestion (e.g. lactose)
- target group - people with lactose maldigestion
- adverse consequences of maldigestion defined

- other nutrients?
  - what is target group?
  - what are consequences of lower digestion?

Digestion/absorption of nutrients (2)

Beneficial physiological effect:

- Improved absorption (e.g. iron)
- other nutrients?
  - where absorption is a limiting factor for the maintenance of adequate status of the nutrient
  - does it lead to increased retention?
  - target group?

Digestion/absorption of nutrients (3)

Beneficial physiological effect:

- reducing absorption as a beneficial physiological effect [e.g. cholesterol, glucose]?
  - consequences of reduced/delayed absorption?
  - may be beneficial in context of claims relating to lowering blood levels of glucose, cholesterol

Gastrointestinal development

Comment received: proposal for a claim on for infants/young children:

‘promoting normal development of digestion, intestinal barrier function, immune function’

- what is the beneficial physiological effect?
- age of target group for the claim?
- what is normal development?
- healthy breast fed infant as reference?