Scientific Substantiation of Claims in the EU

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OUTLINE

- What EFSA does
- Scientific assessment of health claims
- Where to find information
EFSA

- was created to provide scientific advice
- regulatory issues outside scope
- covers the whole food and feed chain
- is independent from regulators
HOW DOES EFSA WORK?

- works with independent scientists supported by EFSA staff
- 10 scientific Panels
- numerous Working Groups
- rapporteurs
- tasks submitted by Commission, Parliament, Member States, self-tasks
GENERAL PRINCIPLES – SCIENTIFIC ASSESSMENT

- substantiated by generally accepted scientific evidence
- totality of the available scientific data
- scientific assessment of the highest possible standard

Whether a claim meets this standard is a scientific judgement
STEPS IN THE ASSESSMENT

- Applicant prepares the dossier (incl. systematic review of the evidence)
- Legal check at Member State level
- Scientific assessment at EFSA
  - Characterisation of the food?
  - Is the claimed effect beneficial?
  - Does the scientific evidence support the claim?
CHARACTERISATION

Claim for dairy products versus Claim for cow’s milk with 3.6 % fat

Or is the claim on calcium or protein?
CHARACTERISATION – WHY SO IMPORTANT

- to select the relevant studies
  - a systematic search of the literature requires a specific research question

- to know what you are looking at
  - only one specific question can be answered at a time

- to enable food control authorities to check
  - the food bearing the claim should be the same as the one for which it is authorised
BENEFICIAL EFFECT

- requirement of the legislation
- benefit for the target population
- related to a function of the body
- has to be measurable (i.e. precise and well defined)
  - how would one measure general well-being?
- methods for measurement should be reliable and validated
  - questionnaires?
NON-BENEFICIAL EFFECTS?

- Increasing numbers of gut bacteria (e.g. lactobacilli or bifidobacteria)
  - what is the benefit?
  - reduces the risk of diarrhoea???
    - if indeed so, this would be the claim

- changes in immune cells
  - if there is no effect on the incidence of infections, what is the meaning of an effect on immune cells?
SUBSTANTIATION

randomised, controlled human intervention studies

- minimise bias, minimise confounding
- can establish causality

human observational studies

- selection bias (important differences between groups), information bias (incorrect determination of exposure or outcome), and confounding present to some degree in all observational research
- reveal associations
- what about causality?
SUBSTANTIATION

- *in vitro, ex vivo and animal studies*
  - cannot predict the occurrence of an effect in humans
  - can be supportive
    - e.g. to investigate a possible mechanisms
  - insufficient on their own
SELECTION OF RELEVANT HUMAN STUDIES

- studies carried out with the food/constituent for claim
- appropriate outcome measure(s) for the claimed effect
- conditions for studies comparable to conditions of use for claim (e.g. dose tested vs. dose proposed)
- study groups representative of the target group or extrapolation to the target population possible
  - patients vs. healthy subjects
  - adults vs. children
COMMON PITFALLS (1)

- food studied not the same as for which claim is made
  - e.g. “just a bit different”, brand names w/o info on composition

- measurements used to assess the claimed effect not reliable or validated
  - e.g. non-validated questionnaires, BIA vs. DEXA in measurements of changes in body composition
COMMON PITFALLS (2)

- poor reporting or poor quality of the study
  - randomisation
  - concealed allocation
  - blinding
  - control used
  - sample size
  - drop-outs
  - statistical analysis

- Poor reporting ≠ poor quality
  - poses similar problems
FINALLY

- All relevant studies with sufficient quality are weighed with respect to their
  - strength
  - consistency
  - specificity
- additional consideration is given to
  - dose-response
  - biological plausibility
INFORMATION ON EFSA WEBSITE (1)

http://registerofquestions.efsa.europa.eu

Register of Questions
ON EFSA WEBSITE (2)


- Applications Helpdesk

Topics A-Z
Thank you