EFSA’s evaluation of health claims: scientific substantiation

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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
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
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
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
• 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)

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