Scientific Assessment of Health Claims: Role of EFSA

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Chair,

EFSA Scientific Panel on Dietetic Products, Nutrition & Allergies

Outline

- EFSA’s role in evaluating health claims
- Scientific criteria for substantiation of claims
- Status of claims evaluations
Classification of health claims (Reg. 1924/06)

- Function claims
  - ‘general function claims’ (Art. 13.1)
    - ‘calcium is needed for normal bone structure’

Applications

- Function claims
  - based on newly developed scientific data/proprietary data (Art. 13.5)

- Reduction of disease risk claims (Art. 14)
  - ‘substance A reduces blood cholesterol. Raised blood cholesterol is a risk factor for heart disease’

- Claims for development and health of children (Art. 14)
  - Claims exclusively for children, evidence only in children
• 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
Main issues addressed by NDA Panel

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 (e.g. 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 data
- Art 13.1- MS responsible for giving references to 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?
EFSA’s proposed wordings of claims?

- Does the proposed wording
  - reflect the scientific evidence?
  - comply with the criteria laid down in the Regulation (e.g. should not refer only to general, non-specific health benefits)

- EFSA may propose appropriate wording (scientific)

- EFSA does not consider consumer understanding

- Wording adopted by Commission during authorization takes into account consumer understanding
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
## EFSA health claims evaluation status (24 May 2010)

<table>
<thead>
<tr>
<th>Claim type</th>
<th>Received</th>
<th>Withdrawn</th>
<th>Adopted</th>
<th>In progress</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Children</strong> <em>(Art. 14)</em></td>
<td>219</td>
<td>32</td>
<td>48</td>
<td>2</td>
</tr>
<tr>
<td><strong>Disease risk reduction</strong> <em>(Art. 14)</em></td>
<td>48</td>
<td>7</td>
<td>15</td>
<td>7</td>
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<tr>
<td><strong>New science/proprietary</strong> <em>(Art. 13.5)</em></td>
<td>36</td>
<td>8</td>
<td>22</td>
<td>5</td>
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<tr>
<td><strong>Total - applications</strong></td>
<td>303</td>
<td>47</td>
<td>85</td>
<td>14</td>
</tr>
<tr>
<td><strong>Art 13 list of health claims</strong></td>
<td>4637</td>
<td>298</td>
<td>937</td>
<td>3402</td>
</tr>
</tbody>
</table>
• Art 13.5/14: over 80 adopted, within legal deadlines
• Art 13.1: over 900 adopted
• Art 13.1 challenges
  • large number of claims exceeded expectations
  • progressive evaluation and publication in series - complete by end of 2011
  • poor quality of information for many claims
<table>
<thead>
<tr>
<th>Food/constituent</th>
<th>Health relationship</th>
</tr>
</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, meals, tomato extract</td>
<td>Cardiovascular, dental, weight</td>
</tr>
</tbody>
</table>
Briefing document for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims (May, 2010)

Technical Meeting with stakeholders - recent developments related to health claims

1 June, Parma