Which foods may carry nutrition and health claims?
Update from EFSA

Leng HENG
Unit on Dietetic Products, Nutrition and Allergies (NDA)
EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel)

Legal framework

Key points on the scientific evaluation of health claims

Update on health claims evaluation status

Nutrient profiles
Which foods may carry claims?

EC Regulation 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods
Regulation (EC) No 1924/2006

✓ health claims only authorised for use in the Community after a scientific assessment of the highest possible standard

✓ in order to ensure harmonised 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

AUTHORISATION:
Commission/Member States, Eur. Parliament scrutiny
Classification of Claims

Nutrition claims

Art. 8
Nutritional properties of a food
Annex of nutrition claims

Health claims

“Function claims”

Art. 13.1
a) Growth /development /functions of body
b) Psychological /behavioural functions
c) Slimming /weight control & satiety

Generally accepted scientific evidence
List of claims (MS)
⇒ EC (01/09, ≈ 4637)
⇒ EFSA
⇒ Final list by EC/MS

Art. 13.5
Newly developed scientific data /proprietary data
Applications
⇒ MS
⇒ EFSA

Art. 14
- Reduction of disease Risk
- Children’s development & health
Applications
⇒ MS
⇒ EFSA

EFSA

MS
EFSA Tasks on Claims


Nutrient Profiles (Art.4): scientific advice and technical support (2008) √

Evaluation of scientific substantiation of health claims

- Art.14: Disease risk reduction
- Art.14: Children’s development & health claims
- Art.13.5 (=Art 18): based on newly developed science/proprietary data
- Art.13.1: List of “function claims” (4637)
Scientific criteria for substantiation of claims

- Regulation (EC) No 1924/2006 - Claims substantiated by:
  - “generally accepted scientific evidence”
  - “totality of the available scientific data”
  - “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

- EFSA’s scientific criteria for evaluation of Art. 13.5/14 health claims outlined in Guidance to applicants (2007)

- Commission Terms of Reference for EFSA’s evaluation of Art. 13.1 claims specified similar criteria (2008)
The evidence provided should demonstrate 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 (e.g. should not refer to general, non-specific health benefit)
- 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** are 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)
- EFSA’s scientific criteria similar to **FDA (2009), Codex Alimentarius (2009)**
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

- 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 population? *Extrapolation* to the target population?
- studies in animals/ *in vitro*: how do they support the claimed effect in humans?
Target population

- General population, subgroup of general healthy population (e.g. pregnant women, sport people, elderly)
- For EFSA evaluation, patients are not the target group for health claims
- However, studies in patients may be used to substantiate claims for the general population
  - case by case
  - Yes for gastrointestinal discomfort in Irritable Bowel Syndrome patients
  - No for joint function in osteoarthritis patients
EFSA conclusions on scientific 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 insufficient to establish a cause and effect relationship between the consumption of the food/constituent and the claimed effect
# EFSA Health Claims Evaluation Status (22 October 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 (Art. 14)</strong></td>
<td>218</td>
<td>39</td>
<td>49</td>
<td>8*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>opinions covering 56 applications</td>
<td></td>
</tr>
<tr>
<td><strong>Disease risk reduction (Art. 14)</strong></td>
<td>49</td>
<td>8</td>
<td>19</td>
<td>6**</td>
</tr>
<tr>
<td><strong>New science/proprietary (Art. 13.5)</strong></td>
<td>42</td>
<td>9</td>
<td>25</td>
<td>5***</td>
</tr>
<tr>
<td><strong>Conditions of use (Art. 19)</strong></td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total applications</strong></td>
<td>310</td>
<td>56</td>
<td>93</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>opinions covering 101 applications</td>
<td></td>
</tr>
<tr>
<td><strong>Art 13 list of health claims</strong></td>
<td>4637</td>
<td>310</td>
<td>1745</td>
<td>Remaining non botanicals</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(200 opinions)</td>
<td></td>
</tr>
</tbody>
</table>

* 4 in clock stop;  ** 2 in clock stop;  *** 0 in clock stop
Finalisation forecast for Art. 13(1) claims

- 44,000 claims from MS to EC (Jan 2008)
- 4637 claims from EC to EFSA (Jul/Nov/Dec 2008)
- EFSA is continuing evaluations for remaining claims
- Progressive adoption/publication of opinions
- Individual claims will be combined as appropriate to form coherent opinions

<table>
<thead>
<tr>
<th>Art 13 list of health claims - Finalisation</th>
<th>Number of IDs</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 2009 (1\textsuperscript{st} batch)</td>
<td>around 520</td>
</tr>
<tr>
<td>February 2010 (2\textsuperscript{nd} batch)</td>
<td>around 400</td>
</tr>
<tr>
<td>October 2010 (3\textsuperscript{rd} batch)</td>
<td>around 800</td>
</tr>
<tr>
<td>October 2010 – June 2011 (Adoption)</td>
<td>Remaining claims “non-Botanicals”</td>
</tr>
</tbody>
</table>
### Favourable health claim evaluations

<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, incl. omega-3</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>
</tr>
</tbody>
</table>
Main reasons

- Lack of suitable human studies to substantiate the claim for the intended population group
  - No human studies
  - Studies in patients only and not relevant to the intended population group
  - Studies relevant to the intended population group but of poor quality, unsuitable measurements, etc.

- Food/substance not sufficiently described
  - Many probiotic bacteria
Substance: plant stanol esters/sterols

Proposed claim: reduce blood cholesterol (risk factor for heart disease)

Target group: people who want to lower LDL cholesterol

Specified daily amount: 2g

Evidence: 40 clinical trials in people with raised LDL cholesterol

EFSA conclusion:

• claim is substantiated
• Reasons outlined in detail in opinion
EFSA opinion on 13(5) claim (LGG MAX)

Substance: 4 species of “probiotics”
Proposed claim: Reduce gastrointestinal discomfort
Target group: general population
Specified daily amount
Evidence: 3 clinical trials in IBS patients + supporting studies

EFSA conclusion:
• Quality of studies not sufficient to establish that the claim is substantiated
• Reasons outlined in detail in opinion
<table>
<thead>
<tr>
<th>Proposed Claim</th>
<th>Scientific Substantiation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probiotic; beneficially affects the intestinal flora; supports a balanced beneficial gastro-intestinal microflora</td>
<td>Study on detection &amp; quantification of the B94 strain in human faecal samples from a consumption study in 5 healthy volunteers but not on the claimed effect; <em>In vitro</em> inhibition of <em>Helicobacter pylori</em>; animal studies investigating the effect of <em>Lactobacillus casei</em> and <em>B. lactis</em> B94 in a mouse model of <em>H. pylori</em> infection; a workshop poster; general reviews about “probiotic” research projects; combination studies with prebiotics</td>
</tr>
</tbody>
</table>
EFSA opinions on health claims

- Reflect the varying quality of the information submitted (poor quality of information for many claims)
- Reasons for EFSA’s conclusions are outlined
- Do not consider consumer understanding
- Wording adopted by Commission may need to take into account aspects other than agreement with the scientific evidence, e.g. consumer understanding
- Not binding
Conditions for the use of nutrition & health claims – Art.4

Nutrient profile: the nutrient composition of a food or diet.
Nutrient profiling is the classification of foods for specific purposes based on their nutrient composition

- To avoid that health claims mask the overall nutritional status of a food product and mislead the consumers when trying to make healthy choices
- To allow for product innovation
Nutrient Profiles

1) Application across the board and/or for categories of food

2) the choice and balance of nutrients

3) Reference quantity/basis (per energy, weight or volume of the foods; per portions)

4) approach to the calculation of profiles

5) feasibility & testing of a proposed system

25 g/100 ml
100 kcal/kJ
Reference amount

Across
the board
Combination
Food
category
Disqual.
ingredients
Disqual/
Qual.
Qualifying
ingredients
Added sugar
Non-milk sugar
Energy
Vit A
calcium
iron
protein
fiber
W-3 LC PUFA
Fruits & veg’s

EFSA: by 31 Jan 08 ⇒ EC (+ MS) to set the NP

As kindly provided by Hans Verhagen (2007)
Nutrient Profiles

- **EFSA NDA Scientific Opinion adopted: 31/01/2008**
  - Advice to Commission on scientific criteria for setting nutrient profiles
    - Potential of a food to adversely affect health outcome
    - Dietary role of different food groups
    - Consistent with national food-based dietary guidelines

- EFSA compiled in co-operation with Member States and industry a **tailor-made food composition database to test different nutrient profile scenarios**

- Commission (+ Member States) **will establish specific nutrient profiles, including exemptions**, and their conditions of use for foods that bear nutrition or health claims
Challenges for EFSA

- Large number of claims with limited time
- Claims will be evaluated on case by case . . . . . but aiming for consistency
- Technically complex
  - The process for establishing cause and effect has been a steep learning curve for all - EFSA must define scientific requirements for many claims for the first time
  - Needing extensive communication and consultation with industry, Commission and Member States
Specific guidance to applicants

- gut and immune function (public consultation)
  - Scientific meeting on Gut/Immune: 2 Dec 2010
- post-prandial blood glucose responses/blood glucose control
- weight management, energy intake and satiety
- protection against oxidative damage
- cardiovascular health
- bone, joint and oral health
- neurological and psychological functions
- physical performance
Thanks for your attention

leng.heng@efsa.europa.eu
www.efsa.europa.eu