Updates on Nutrition Labelling and Claims Regulation in Europe

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Updates on Nutrition Labelling and Claims Regulation in Europe

• General considerations

• Weighing the evidence
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• Weighing the evidence
‘Taco Bell
Nineteen-year-old Alicia Vargas of Yuma, AZ, avoids getting pregnant with a delicious ContraceptiMelt’

Source: The Onion, March 12, 1997
http://www.theonion.com/content/node/29938/print/
What EFSA cannot do

• Be responsible for food safety legislation
• Take charge of food safety/quality controls, labelling or other such issues
• Act as a substitute for national authorities
NDA Panel & Working Groups

- Infant Formulae
- Novel Foods
- Dietary Reference Values
- Claims
- Upper Levels
- Food Allergy

NDA Panel
21 Members

Safety and suitability

Safety

Scientific advice

Evaluation of scientific substantiation

Supported by the EFSA Nutrition Unit
Article 5: *General conditions*: The use of nutrition and health claims shall only be permitted if the following conditions are fulfilled: (a) the presence, absence or reduced content in a food or category of food of a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect claimed as established by generally accepted scientific evidence.
What EFSA can do

• Recital 17: A claim should be scientifically substantiated by taking into account the totality of the available scientific evidence, and by weighing the evidence.

• Recital 23: Health claims should only be 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.

• Article 6: Nutrition and health claims shall be based on and substantiated by generally accepted scientific evidence.
What EFSA was expected to do

- Recital 26: Health claims other than those referring to the reduction of disease risk and to children’s development and health, **based on generally accepted scientific evidence**, should undergo a **different type of assessment** and authorisation. It is therefore necessary to adopt a Community list of such permitted claims after consulting the European Food Safety Authority.
## Health claims

<table>
<thead>
<tr>
<th>Article 13</th>
<th>Article 14</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Growth &amp; development &amp; functions of body</td>
<td>Based on newly developed scientific evidence or requesting protection of proprietary data</td>
</tr>
<tr>
<td>b) Psychological &amp; behavioural functions</td>
<td>Article 13.5</td>
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<tr>
<td>c) Slimming or weight control or reduction in sense of hunger or increase in sense of satiety or reduction of available energy</td>
<td>Reduction of disease risk (risk factor reduction) and claims referring to children’s development and health</td>
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*Based on generally accepted scientific evidence*
Advantages of Submission by Dossier

Allows:
1. Complete characterisation of the food which is the subject of the claim
2. Full description of the health relationship claimed and any underlying hypotheses
3. Clear indication of decision tree for collecting the pertinent studies
4. Case to be made for substantiation on the basis of the pertinent studies
5. Dialogue between Applicant and EFSA in order to clarify any issues arising
<table>
<thead>
<tr>
<th>ID</th>
<th>Food or Food constituent</th>
<th>Health Relationship</th>
<th>Proposed wording</th>
</tr>
</thead>
<tbody>
<tr>
<td>561</td>
<td>Xylitol-sweetened chewing gum</td>
<td>Ears</td>
<td>Xylitol is good for the health of ears.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Maintains good health of the ears.</td>
</tr>
</tbody>
</table>

**Conditions of use**
- Chewing gums with 65% xylitol. 2 pieces 3-5 times per day. The product may not contain sugars capable of fermentation and the requirements for other Finnish Dental Association recommendations must be fulfilled.
Ezekiel 27.17 The Old Testament In: The Holy Bible.

ID 3668: “Panax ginseng (common name: Asian, Korean ginseng)” and “cognitive performance”

Full text: Judah and Israel gave you their finest wheat, fancy figs, honey, olive oil, and spices in exchange for your merchandise.

Beck, L, The complete idiot’s guide to total nutrition for Canadians.


Food:

Before: “Vitamins, minerals, lysine and/or taurine”
After: “Combination of different vitamins and minerals, lysine and/or argine and/or taurine”

Before: “Carbohydrates from pasta”
After: “Pasta from different kinds of cereal grains, e.g. durum wheat, wheat, barley, oat and rye. Except autoclaved products”

Before: “Green tea extract (Camelia sinesis)”
After: “Green tea extract (Camelia senesis); People have always been plagued by high blood pressure, which is triggered by the loss of elasticity in the...”

Before: “Antioxidants”
After: “Antioxidants (Source of antioxidants from the list of health claims given a positive opinion by EFSA)”
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<th>Proposed wording</th>
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</table>
| 561 | Xylitol-sweetened chewing gum | Ears  
Clarification provided  
Ears Clarification: Inhibits the absorption of cholesterol.  
Heart Health and artery health | Xylitol is good for the health of ears.  
Maintains good health of the ears. |

**Conditions of use**
- Chewing gums with 65% xylitol. 2 pieces 3-5 times per day. The product may not contain sugars capable of fermentation and the requirements for other Finnish Dental Association recommendations must be fulfilled.
Article 13.1 is best suited to essential nutrient claims

1. All essential nutrients are sufficiently characterised.

2. Health relationships are generally straightforward and well known.

3. In general, all have clear biochemical and physiological (functional) roles which often can be linked to clinical symptoms of deficiency and it is relatively simple to establish causality.
Calcium and nerve function

• Well established science

• But where is the evidence?
Milk Fever
How do we weigh sick cows?
# Health claims

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<td>Based on generally accepted scientific evidence</td>
<td></td>
</tr>
<tr>
<td>Article 13.1</td>
<td></td>
</tr>
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</table>
Where did it all go wrong?

EC COM (2003) 0424

• Being based on long-established and non-controversial science, health claims that describe the role of a nutrient or other substance in growth, development and normal physiological functions of the body shall undergo a different type of assessment....

EC 1924/2006

• Based on generally accepted scientific evidence....
# Health claims

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*Based on generally accepted scientific evidence*
Updates on Nutrition Labelling and Claims Regulation in Europe

• General considerations

• Weighing the evidence
Points to consider in determining whether a study is pertinent to the claim:

1. Human dietary studies are central for the substantiation of the claim.

2. Does the study address the food constituent which has been characterised in the application?

3. Does the study address endpoints of relevance to the health relationship as defined in the application?

4. Is the study in the target population as indicated in the application or could it be extrapolated to the target population?
Points to consider in determining whether a study is pertinent to the claim:

5. Is the dosage and/or food matrix relevant to the proposed condition of use as defined in the application?

6. Are supportive studies in animals or in vitro relevant for the claimed effect?

7. The human studies meeting all of the criteria outlined in 1-5 together with the relevant supportive studies identified in 6 should be regarded as the pertinent studies on which to base the substantiation.

8. If the opinion might be favourable from the references provided a check should be performed to confirm whether the references reflect the totality of the evidence in the literature.
Five conditions of causality

• Ability to manipulate the effect
• Specificity of cause and effect
• Consistent associations with outcome measures
• Dose response relationship
• Plausible biological mechanism
Concluding on a cause and effect relationship

- A cause and effect relationship has been established between the consumption of *the food* and *the beneficial physiological effect*.

- A cause and effect relationship has not been established between the consumption of *the food* and *the beneficial physiological effect*.

- The evidence provided is insufficient to establish a cause and effect relationship between the consumption of *the food* and *the beneficial physiological effect*. 
Conclusion on calcium and neurotransmission

• The Panel considers that a cause and effect relationship has been established between calcium and normal muscle function and neurotransmission. *However, the evidence provided does not establish that inadequate intake of calcium leading to impaired muscle function and neurotransmission occurs in the general EU population.*
### EFSA health claims evaluation status (31 July 2012)

<table>
<thead>
<tr>
<th>Claim type</th>
<th>Received</th>
<th>Withdrawn</th>
<th>Adopted</th>
<th>In progress</th>
<th>Under Validation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children (Article 14)</td>
<td>220</td>
<td>110</td>
<td>53 opinions covering 60 applications</td>
<td>0*</td>
<td>50</td>
</tr>
<tr>
<td>Disease risk reduction (Article 14)</td>
<td>58</td>
<td>23</td>
<td>32 opinions covering 33 applications</td>
<td>0**</td>
<td>2</td>
</tr>
<tr>
<td>New science/ proprietary (Article 13.5)</td>
<td>103</td>
<td>17</td>
<td>61 opinions covering 62 applications</td>
<td>18***</td>
<td>6</td>
</tr>
<tr>
<td>Conditions of use (Article 19)</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total applications</td>
<td>383</td>
<td>150</td>
<td>148 opinions covering 157 applications</td>
<td>18</td>
<td>58</td>
</tr>
<tr>
<td>Article 13.1 list of health claims</td>
<td>4728</td>
<td>331</td>
<td>2849 (2776 published)</td>
<td>0</td>
<td>1548 (on hold)</td>
</tr>
</tbody>
</table>

* 0 in clock stop  ** 0 in clock stop  *** 0 in clock stop
## Examples of positive health claims evaluations (> 200)

<table>
<thead>
<tr>
<th>Claim</th>
<th>Food/constituent</th>
</tr>
</thead>
<tbody>
<tr>
<td>LDL cholesterol and risk of heart disease</td>
<td>Phytosterols, oat β-glucan, replacing saturated fats by unsaturated fats</td>
</tr>
<tr>
<td>Dental plaque and risk of caries</td>
<td>Sugar-free chewing gum</td>
</tr>
<tr>
<td>Body weight</td>
<td>Meal replacements, VLCD</td>
</tr>
<tr>
<td>Bowel function</td>
<td>Cereal fibres (wheat, barley, oat, rye)</td>
</tr>
<tr>
<td>Blood glucose after meals</td>
<td>Pectins, guar gum, resistant starch, sugar replacers</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>potassium, reduced sodium</td>
</tr>
<tr>
<td>Lactose digestion</td>
<td>Yoghurt live bacterial cultures</td>
</tr>
<tr>
<td>Platelet aggregation</td>
<td>Water sol. tomato conc.</td>
</tr>
</tbody>
</table>