Health Claims EU
state of play early April 2011

BCCC 2011 Annual Conference
Working Together
For a Healthy Future

Dr. Alexander Schoch
Outline

- Who is the Beneo Institute
- A look to health claims history & legislative structure
- Current state of play in the health claims arena
- How claims are substantiated – EU vs. US approach
- Next steps & outlook
BENEO – Part of a Global Organization

- Turnover 5.8 bn €, ~20,000 people
- Market leader in sugar & fruit preparations, bio-ethanol, starches, pizza’s

BENEO is a global organization created in 2007

- Turnover 350 mil €, 900 people
- BENEO includes 3 companies
  - Beneo-Orafti – Inulin, oligofructose
  - Beneo-Palatinit – Isomalt, Palatinose™
  - Beneo-Remy – Rice derivatives

BENEO includes 3 companies
- Beneo-Orafti – Inulin, oligofructose
- Beneo-Palatinit – Isomalt, Palatinose™
- Beneo-Remy – Rice derivatives

connecting nutrition and health
Creation of the BENEIO-Institute in Nov 2009
Outline

- Who is the Beneo Institute
- A look to health claims history & legislative structure
- Current state of play in the health claims arena
- How claims are substantiated – EU vs. US approach
- Next steps & outlook
EU Claims Regulation


of 20 December 2006

on nutrition and health claims made on foods

(OJ L 404, 30.12.2006, p. 9)

Amended by:


Corrected by:

| C1  | Corrigendum, OJ L 12, 18.1.2007, p. 3 (1924/2006) |
Milestones in the development of the NHCR

2001
• COM-proposal of a discussion paper

2003
• COM developed a Regulation Proposal

2005
• May: EP 1st reading
• Dec: Council Common Position

2006
• May: EP 2nd reading
• Dec: Regulation adopted

2007
• January 19: enter into force
• July 1st: applicable
Objectives of the NHCR

Consumer Protection
- To achieve a high level of consumer protection
- Not to mislead the consumer by false messages on health and nutrition

Economic Aspects
- To improve the free movement of goods within the internal market
- To increase legal security for economic operators
- To ensure fair competition
Things looked different in 2006:
An extract from Commissioner Kyprianou’s Press Release

Commissioner Kyprianou welcomes European Parliament vote on Health and Nutrition Claims

Brussels, 16 May 2006

Health claims – benefits must be proven

With regard to health claims, the Commission will draw up a positive list of well-established claims, such as “calcium is good for your bones”, which may be used on a label so long as they are proven to apply to the food in question. Member States will submit a list of claims already approved at national level and, within 3 years of the Regulation entering into force, the Commission will produce an EU positive list of health claims. Any claims submitted for the EU list after this period will have to be examined by EFSA and approved by the Commission and Member States through the Comitology procedure.

→ Common understanding in 2006: Grandfathering action for those claims already used in the market
A health claim is:

“any claim that stated, suggests or implies that a relationship exists between a food category, a food or one of its components and health”
1st pre-market approval for all claims
Structure of the NHCR (II)

2nd only for products meeting the “Nutrition Profile”

Claims

Nutrition Claims

Health Claims

If profile could not be met by food product (threshold exceeded) ...

STOP

Health claim not possible to communicate

Nutrition claim possible to communicate but disclose disqualifying profile
## ANNEX 1: specific nutrient profiles and conditions of use, which food or certain categories of food must comply with in order to bear nutrition or health claims

<table>
<thead>
<tr>
<th>Food category</th>
<th>Specific conditions*</th>
<th>Thresholds</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Sodium (mg/100g or 100ml)</td>
</tr>
<tr>
<td>Solid foods</td>
<td></td>
<td>300</td>
</tr>
<tr>
<td>Other foods</td>
<td>Solid foods, insofar as they do not qualify for one of the above mentioned food categories</td>
<td></td>
</tr>
</tbody>
</table>

* the minimum quantity required should be calculated on the basis of the ingredients entering into the recipe.
Outline

- Who is the Beneo Institute
- A look to health claims history & legislative structure
- Current state of play in the health claims arena
- How claims are substantiated – EU vs. US approach
- Next steps & outlook
Milestones – Health claim situation in Europe

- CIAA initiated work on 13.1-list
- July: CIAA submitted 776 HC via MS
- Jan: deadline for 13.1-list for MS
- Jan: deadline Community register
- March: COM sent TOR to EFSA and asked EFSA to provide scientific guidance for claims application
- Dec: COM guidance on implementation
- July: EFSA opinion Scientific and Technical Guidance for Art 14 HC applications
- March + Dec: EFSA pre-submission Guidance for applicants with Art 13 and 14; EFSA opinion of 07/2007 is relevant for 14 and 13(5)
- Nov 08: COM sent TOR on 13(1) to EFSA
- April: EC 353/2008 Implementation Rules for HC Applications
- Oct 09: EFSA 1st Batch
- Oct 10: EFSA 2nd Batch
- Oct 10: EFSA 3rd Batch
- Sep: COM Draft Guidance on implementation update
- Consolidation process:
  - 4696 claims EFSA received in total
  - 1748 claims evaluated (as of March 2011)
  - 1035 non-botanicals pending
  - 1549 botanicals on hold
  - Next batch expected for April 2011
  - Finalizing all "non-botanicals" by 09/2011

2006 2007 2008 2009 2010 2011
## EFSA opinions on Art 13(1) claims (total # 4637*) –
time table of publication (as of 2\textsuperscript{nd} March 2011)

<table>
<thead>
<tr>
<th>EFSA Opinions Art 13(1)</th>
<th># claims covered in (#) of opinions</th>
<th>Publication of EFSA opinions</th>
<th>Publication done/not done</th>
</tr>
</thead>
<tbody>
<tr>
<td>Batch 1</td>
<td>523 claims in 93 opinions</td>
<td>October 1, 2009</td>
<td>✔</td>
</tr>
<tr>
<td>Batch 2</td>
<td>417 claims in 31 opinions</td>
<td>February 25, 2010</td>
<td>✔</td>
</tr>
<tr>
<td>Batch 3</td>
<td>808 claims in 75 opinions</td>
<td>October 10, 2010</td>
<td>✔</td>
</tr>
<tr>
<td>Batch 4**</td>
<td>440 claims in 65 opinions</td>
<td>April 11, 2011</td>
<td>Pending</td>
</tr>
<tr>
<td>Batch 5**</td>
<td>? approx. 300 claims in ? Opinions</td>
<td>June 11, 2011</td>
<td>Pending</td>
</tr>
<tr>
<td>Batch 6**</td>
<td>? approx. 300 claims in ? Opinions</td>
<td>Sept 11, 2011</td>
<td>Pending</td>
</tr>
<tr>
<td>Botanicals</td>
<td>? approx 1550 claims in ? Opinions</td>
<td>„On hold“</td>
<td>Pending</td>
</tr>
</tbody>
</table>


Remark: Vitamin & minerals are not assessed by the same criteria as other ingredients. It is therefore justified to differentiate when judging the EFSA “success rate” of health claims.
State of play for confectionery, chocolate, cake, biscuit, chewing gum

### Confectionery

<table>
<thead>
<tr>
<th>Mandate Number</th>
<th>Question Number</th>
<th>Subject</th>
<th>Panel/Unit</th>
<th>Status</th>
<th>Output Number</th>
<th>Last Updated</th>
</tr>
</thead>
<tbody>
<tr>
<td>M-2008-1061</td>
<td>EFSA-Q-2008-1986</td>
<td>1197 - Foods in general, in particular confectionery, soft drinks, water-based, chocolate-type products, table-top sweeteners and certain foods for a particular nutritional use - foods which under typical conditions of use are neither cariogenic nor erosive, help maintain healthy teeth and are, therefore, tooth-friendly</td>
<td>NDA</td>
<td>In progress</td>
<td>13/04/2010 10:58</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mandate Number</th>
<th>Question Number</th>
<th>Subject</th>
<th>Panel/Unit</th>
<th>Status</th>
<th>Output Number</th>
<th>Last Updated</th>
</tr>
</thead>
<tbody>
<tr>
<td>M-2008-1081</td>
<td>EFSA-Q-2008-2021</td>
<td>1293 - Foods in general, particularly sugar-free chewing gum, candies, chocolate-type products and other confectionery; soft drinks and sports drinks, flavored water and table top sweeteners - Dental health</td>
<td>NDA</td>
<td>In progress</td>
<td>13/04/2010 10:58</td>
<td></td>
</tr>
</tbody>
</table>

### Biscuits

<table>
<thead>
<tr>
<th>Mandate Number</th>
<th>Question Number</th>
<th>Subject</th>
<th>Panel/Unit</th>
<th>Status</th>
<th>Output Number</th>
<th>Last Updated</th>
</tr>
</thead>
<tbody>
<tr>
<td>M-2008-1061</td>
<td>EFSA-Q-2008-1979</td>
<td>1241 - Plain Biscuits (such as &quot;LU petit déjeuner&quot;). - The appearance, in the blood circulation, of exogenous glucose from biscuits consumed for breakfast is moderate and stable throughout the morning.</td>
<td>NDA</td>
<td>Withdrawn</td>
<td>06/07/2010 15:29</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mandate Number</th>
<th>Question Number</th>
<th>Subject</th>
<th>Panel/Unit</th>
<th>Status</th>
<th>Output Number</th>
<th>Last Updated</th>
</tr>
</thead>
<tbody>
<tr>
<td>M-2010-D298</td>
<td>EFSA-Q-2010-00656</td>
<td>1264. Biscuits - Art 13.5 Claim, Reg (EC) No 1924/2006, &quot;Biscuits for breakfast&quot;, and &quot;supply carbohydrates regularly and continuously absorbed and released throughout the morning”</td>
<td>NDA</td>
<td>In progress</td>
<td>18/02/2011 15:58</td>
<td></td>
</tr>
</tbody>
</table>
ON-2076 is expected to be published mid April 2011 and will cover several non-cariogenic & low-glycemic carbohydrates like the polyols isomalt & xylitol, as well as isomaltulose, tagatose & polydextrose.
EFSA NDA panel:

In weighing the evidence the Panel took into account that evidence from ten randomised controlled trials for a blood pressure-lowering effect of cocoa flavanols was inconsistent, that evidence from small and un-blinded studies with lower doses in favour of an effect was in conflict with evidence from adequately powered and well controlled studies with higher doses, and that evidence from blinded studies with lower doses was conflicting.

On the basis of the data presented, the Panel concludes that the evidence provided is insufficient to establish a cause and effect relationship between the consumption of cocoa flavanols and maintenance of normal blood pressure.
### Chewing Gum

<table>
<thead>
<tr>
<th>Mandate Number</th>
<th>Question Number</th>
<th>Subject</th>
<th>Panel/Unit</th>
<th>Status</th>
<th>Output Number</th>
<th>Last Updated</th>
<th>Select</th>
</tr>
</thead>
<tbody>
<tr>
<td>M-2010-0275</td>
<td>EFSA-Q-2010-00563</td>
<td>Safety of a &quot;novel chewing gum base (Rev-7)&quot; as food ingredient</td>
<td>NDA</td>
<td>Finished</td>
<td>3217</td>
<td>25/03/2011 10:38</td>
<td></td>
</tr>
<tr>
<td>M-2008-1061</td>
<td>EFSA-Q-2008-1993</td>
<td>1154 - Sugar-free chewing gum with Fruacol - Increases resistance of enamel to acid attacks and rate of remineralisation</td>
<td>NDA</td>
<td>Finished</td>
<td>3227</td>
<td>09/02/2011 18:38</td>
<td></td>
</tr>
<tr>
<td>M-2008-1061</td>
<td>EFSA-Q-2008-1993</td>
<td>1153 - Sugar-free chewing gum with Carboxide - Improved plaque acid neutralisation</td>
<td>NDA</td>
<td>Finished</td>
<td>3227</td>
<td>09/02/2011 18:38</td>
<td></td>
</tr>
<tr>
<td>M-2010-0004</td>
<td>EFSA-Q-2010-00120</td>
<td>1527_UK - Art. 14 Claim, Reg.(EC) No 1934/2006 Sugar-free chewing gum, and, neutralises plaque acids which reduces the risk of dental caries.</td>
<td>NDA</td>
<td>Finished</td>
<td>3217</td>
<td>10/02/2010 16:21</td>
<td></td>
</tr>
<tr>
<td>M-2010-0004</td>
<td>EFSA-Q-2010-00120</td>
<td>1527_UK - Art. 14 Claim, Reg.(EC) No 1934/2006 Sugar-free chewing gum, and, remineralises tooth enamel which reduces the risk of dental caries.</td>
<td>NDA</td>
<td>Finished</td>
<td>3217</td>
<td>10/02/2010 16:21</td>
<td></td>
</tr>
<tr>
<td>M-2008-0004</td>
<td>EFSA-Q-2008-1516</td>
<td>3004 - Sugar-free chewing gum - Plaque formation</td>
<td>NDA</td>
<td>In progress</td>
<td></td>
<td>05/01/2010 15:36</td>
<td></td>
</tr>
<tr>
<td>M-2008-1061</td>
<td>EFSA-Q-2008-1590</td>
<td>1151 - Sugar-free chewing gum - Localised tooth mineralisation (non-systemic)</td>
<td>NDA</td>
<td>Finished</td>
<td>3217</td>
<td>11/02/2009 11:42</td>
<td></td>
</tr>
<tr>
<td>M-2008-1061</td>
<td>EFSA-Q-2008-1596</td>
<td>1149 - Sugar-free chewing gum - Dental health/Oral health, Gum and mouth protection/symptom management</td>
<td>NDA</td>
<td>Finished</td>
<td>3217</td>
<td>11/02/2009 11:42</td>
<td></td>
</tr>
<tr>
<td>M-2008-1061</td>
<td>EFSA-Q-2008-1599</td>
<td>1150 - Sugar-free chewing gum - Plaque acid neutralisation</td>
<td>NDA</td>
<td>Finished</td>
<td>3217</td>
<td>11/02/2009 11:42</td>
<td></td>
</tr>
<tr>
<td>M-2008-1061</td>
<td>EFSA-Q-2008-1591</td>
<td>1152 - Sugar-free chewing gum containing polyols - Beneficial for weight management.</td>
<td>NDA</td>
<td>Finished</td>
<td>3217</td>
<td>11/02/2009 11:42</td>
<td></td>
</tr>
<tr>
<td>M-2008-1061</td>
<td>EFSA-Q-2008-1779</td>
<td>1240 - Sugar-free chewing gum - Dry Mouth (Reduces/Improves Dry Mouth)</td>
<td>NDA</td>
<td>Finished</td>
<td>3217</td>
<td>11/02/2009 11:42</td>
<td></td>
</tr>
<tr>
<td>M-2008-1061</td>
<td>EFSA-Q-2008-2046</td>
<td>1309 - Sugar-free chewing gum containing Polyolol - Gamma da mastina con zucchero e poliolsa (E412,K414,15) e tripoliolsa (E451) - Comprende la formazione del tartaro. Salute della gengiva</td>
<td>NDA</td>
<td>In progress</td>
<td></td>
<td>09/04/2010 15:41</td>
<td></td>
</tr>
<tr>
<td>M-2008-1061</td>
<td>EFSA-Q-2008-2046</td>
<td>2836 - Sugar-free chewing gum with Xylitol - Plaque formation (Xylitol is not metabolised by bacteria that can lead to plaque growth)</td>
<td>NDA</td>
<td>In progress</td>
<td></td>
<td>10/03/2010 10:53</td>
<td></td>
</tr>
<tr>
<td>M-2008-1061</td>
<td>EFSA-Q-2008-2046</td>
<td>1755 - Buffering salts (calcium carbonate + magnesium oxide) - Gut health</td>
<td>NDA</td>
<td>In progress</td>
<td></td>
<td>13/04/2010 10:53</td>
<td></td>
</tr>
<tr>
<td>M-2008-1061</td>
<td>EFSA-Q-2008-2046</td>
<td>1253 - Foods in general, particularly sugar-free chewing gum, candies, chocolate-type products and other confectionery: soft drinks and sports drinks, flavored water and table top sweeteners - Dental health</td>
<td>NDA</td>
<td>In progress</td>
<td></td>
<td>13/04/2010 10:53</td>
<td></td>
</tr>
<tr>
<td>M-2008-1061</td>
<td>EFSA-Q-2008-2046</td>
<td>1181 - Xylitol-sweetened chewing gum - Mouth, teeth</td>
<td>NDA</td>
<td>In progress</td>
<td></td>
<td>13/04/2010 10:53</td>
<td></td>
</tr>
</tbody>
</table>
# Positive Art. 13(1) - chewing gum & dental claims

<table>
<thead>
<tr>
<th>Food</th>
<th>Opinion</th>
<th>Claims Wording (ID#)</th>
<th>Conditions of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sugar-free chewing gum</td>
<td>1271</td>
<td>„….helps neutralize plaque acids“&lt;br&gt;(ID 1150)</td>
<td>• Target is general population (except children under 3 years of age due to choking risk)</td>
</tr>
<tr>
<td></td>
<td>1271</td>
<td>„….helps maintain tooth mineralisation“&lt;br&gt;(ID 1151)</td>
<td>• Info for consumer that beneficial effect is obtained with use for at least 20 min after eating or drinking</td>
</tr>
<tr>
<td></td>
<td>1271</td>
<td>„….may reduce oral dryness“&lt;br&gt;(ID 1240)</td>
<td>• Should be used when the mouth feels dry</td>
</tr>
<tr>
<td>Fluoride</td>
<td>1212</td>
<td>„….helps maintain tooth mineralisation“&lt;br&gt;(ID 275, 276, 338, 4238)</td>
<td>• A food should be at least a source of fluoride as per Annex to Reg. 1924/2006</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Such amounts can easily be consumed as part of a balanced diet</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Target is the general population</td>
</tr>
</tbody>
</table>
Outline

- Who is the Beneo Institute
- A look to health claims history & legislative structure
- Current state of play in the health claims arena
- How claims are substantiated – EU vs. US approach
- Next steps & outlook
Possible reasons for the huge number of “not-positive“ EFSA opinions

The way the NHCR was implemented:

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
- Whether the evidence is sufficient to represent generally accepted scientific evidence to substantiate the claim is a scientific judgement of NDA Panel
- EFSA NDA Panel criteria not different from other standards like US FDA, Health Canada
United States: Level of scientific substantiation & regulatory steps for claims

<table>
<thead>
<tr>
<th>Type of Claim</th>
<th>Level of scientific substantiation</th>
<th>Required approval if any</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nutrient Content Claims</td>
<td>Criteria are defined CFR</td>
<td>Criteria are defined CFR</td>
</tr>
<tr>
<td>Structure/function (S/F) Claims</td>
<td>Scientific evidence</td>
<td>No pre-market approval required</td>
</tr>
<tr>
<td>Qualified Health Claims (QHCs)</td>
<td>Credible scientific evidence</td>
<td>Letter of enforcement discretion under interim guidelines</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Language to qualify scientific evidence is required</td>
</tr>
<tr>
<td>Health Claims (HC)</td>
<td>Significant Scientific Agreement (SSA)</td>
<td>Pre-market approval by FDA</td>
</tr>
</tbody>
</table>
Quality & Strength of Scientific Evidence for Claims
Addressing Disease Risk Reduction

Continuum of Scientific Evidence

Scientific Consensus

Significant Scientific Agreement

Emerging Evidence

“Health Claims”

“Qualified Health Claims”

Science is rarely (and if ever) conclusive, but also emerging evidence can be revealed truthfully

Science is rarely (and if ever) conclusive, but also emerging evidence can be revealed truthfully
List of ALL (16) health claims in the US

- Calcium and Osteoporosis
- Sodium and Hypertension
- Dietary Fat and Cancer
- Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease
- Fiber-Containing Grain Products, Fruits, and Vegetables and Cancer
- Fruits, Vegetables and Grain Products that contain Fiber, particularly Soluble Fiber, and Risk of Coronary Heart Disease
- Fruits and Vegetables and Cancer
- Folate and Neural Tube Defects
- Dietary Noncariogenic Carbohydrate Sweeteners and Dental Caries
- Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease
- Soy Protein and Risk of Coronary Heart Disease
- Plant Sterol/stanol esters and Risk of Coronary Heart Disease
- Whole Grain Foods and Risk of Heart Disease and Certain Cancers
- Potassium and the Risk of High Blood Pressure and Stroke
- Fluoridated Water and Reduced Risk of Dental Caries
- Saturated Fat, Cholesterol, and Trans Fat, and Reduced Risk of Heart Disease
EU vs. US claims evaluation standards

**Regulatory Framework**

In the US:
- "nutrient content claims"
- "structure/function claims"
- "qualified health claims" (a)  
  "health claims" SSA requ. (b)

(a) “Enforcement discretion”  
(b) “Approval” by FDA on SSA

No FDA pre-approval,  
“truthful not misleading”

In Europe:
- "nutrient content claims"
- "health claims" (Article 13)  
  (but SSA required)
- "reduction of disease risk" claims (Article 14)

Individual approval by EFSA
Structure function (S/F) claims – FDA definitions

FDA says on their homepage:

“Structure/function claims appear on the labels of conventional foods and dietary supplements.

They describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans, for example, "calcium builds strong bones" (…) In addition, they may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function, for example "fiber maintains bowel regularity" or "antioxidants maintain cell integrity" (…)

The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims (…)

S/F claims are not pre-approved by FDA but must be truthful and not misleading (…)”

Reference: homepage FDA:
http://www.fda.gov/Food/LabelingNutrition/LabelClaims/StructureFunctionClaims/default.htm
Beneo Institute Position:

The scientific evidence of a claim should be credible.

Credible is not identical to “generally accepted” – a goal that can hardly be achieved in nutrition science.

If a claim is substantiated by credible evidence, the consumer should have the option to be able to profit and benefit from it!
Outline

- Who is the Beneo Institute
- A look to health claims history & legislative structure
- Current state of play in the health claims arena
- How claims are substantiated – EU vs. US approach
- Next steps & outlook
Positive opinions of EFSA - what will be the next steps at Commission?

EFSA: finished all non-botanicals
- EFSA publications:
  - April 2011
  - June 2011
  - Sept. 2011

COM/MS claims WG discussions
- Conditions of use to be agreed upon & draft legislation
- Until approx. end of 2011 or longer

Standing Cttee approves
- Earliest: approx. early 2012 (most probably later in 2012)

Comitology at Parliament
- Earliest approx. spring 2012

COM publish in OJ
- Earliest approx. early summer 2012

End of 6 month transition period
- Earliest approx. end 2012
“not-positive” opinions of EFSA: in some cases additional data may be submitted

<table>
<thead>
<tr>
<th>EFSA Conclusion Category</th>
<th>Cause &amp; effect relationship*</th>
<th>Level of scientific evaluation</th>
<th>GASE status</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category I</td>
<td>established</td>
<td>conclusive</td>
<td>GASE</td>
<td></td>
</tr>
<tr>
<td>Category II</td>
<td>insufficient</td>
<td>some evidence, but non-conclusive – so not based on GASE</td>
<td>Not GASE</td>
<td>?</td>
</tr>
<tr>
<td>Category III</td>
<td>not established</td>
<td>limited/no scientific evidence</td>
<td>Not GASE</td>
<td></td>
</tr>
</tbody>
</table>

May qualify for a follow up 13(5) submission = extended transition

Negative opinion because
- Food not sufficiently characterized
- Claim not sufficiently characterized
- Cause and effect relationship not established

In some cases it may qualify for a follow up 13(5) submission = extended transition
Possible further proceedings for the claims, as presented by COM to MS in February 2010

Positives – need adoption & publish in OJ

COM homepage list: re-assessment of some claims

COM homepage - rejected -
How the COM proposal for re-assessment of some claims could work

Legal marketing as long as “add-on” 13(5)/(4) process take time

MS “screening” of 13(5) application no deadline (!)

After 2 month “state of play info” to COM

1st batch to 6th batch 2009-11

ongoing for batch 1-6

“adoption”

earliest assumption mid 2012

earliest assumption end 2012

FBO → MS → COM → EFSA

13(5)/(4) route

pos. opin. → COM/MS process → OJ publ.

neg. opin. → “insufficient”

COM list acc. to Art. 20

List with claims eligible for clarification will be published on COM homepage

3 month for FBO to provide clarification via 13(5)

MS must also “notify” COM for which 13(1) claims the 13(5) dossiers were received during this time

2007 13(1)

Non-botanical 13.1 claims

6 month to phase out

3 month for FBO to provide clarification via 13(5)
THANK YOU
<table>
<thead>
<tr>
<th>EFSA Conclusion Category</th>
<th>Cause &amp; effect relationship*</th>
<th>Level of scientific evaluation</th>
<th>GASE status</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category I</td>
<td>established</td>
<td>conclusive</td>
<td>GASE</td>
<td>😊</td>
</tr>
<tr>
<td>Category II</td>
<td>insufficient</td>
<td>some evidence, but non-conclusive – so not based on GASE</td>
<td>Not GASE</td>
<td>😕 ?</td>
</tr>
<tr>
<td>Category III</td>
<td>not established</td>
<td>limited/no scientific evidence</td>
<td>Not GASE</td>
<td>😞</td>
</tr>
</tbody>
</table>

* Between the consumption of the food/constituent and the claimed effect; assessment includes clear characterization & established beneficial effect for human health

The EFSA approach in assessing health claims is different from any approach taken so far. Health claims that have been legally on the market before 2006 under a functioning & effective national jurisdiction/enforcement (e.g. by FSA/ASA in UK, AFFSA in France, AUTOCONTROL in Spain or the Food Control Authorities in Germany) are put in limbo & are already in conflict with EFSA opinions e.g.:

- Dietary fiber claims relating to a “promotion of a normal bowel function” have been documented in Estonia, Finland, Germany and Sweden as acceptable, but were rejected by EFSA as dietary fiber being “not sufficiently characterized” …
- Claims for “pre- and probiotics” / “bifidogenic effect”, are documented in France, Germany and the Netherlands, while EFSA does not regard an increase in the bifidoflora as beneficial to “human health” …

Reflecting what happened the last 4 years - if no correction will be made by the EC legislator & Member States - it has to be feared that:

(A)”normal” foods products that cover the basic nutritional requirements, will not be qualified for any health message

(B)”medicinal” food products will increase that e.g. are significantly lowering your blood cholesterol or helping to maintain a healthy blood flow.
EFSA applied a “drug” or medicinal approach to assess claims. This obviously leads to a gap in communication toward the consumer.

• “Active” substances that are added to a food “on top” to achieve a specific effect (e.g. changing e.g. a well established medical marker (e.g. cholesterol)) are eligible to be evaluated by EFSA.

• “Passive” ingredients that have a typical physiological profile that is transported into the final product by replacing other ingredients and that are changing the physiological properties of the final product in this way, are not eligible according to EFSA.

• Pharmacology and nutrition are separate disciplines, separate disciplines have different objectives and specific "highest possible standards“

• “Generally Accepted Scientific Evidence (GASE)” usually occurs when almost all research around a topic is finished and scientific consensus is reached. This means lead times of decades and ..

• … as such denying consumers freedom to make an informed choice, to access and benefit from credible science

Therefore, the European legislator should find ways to favor the **disclosure over the suppression** of claims.
The BENEÖ-Institute – a network of minds

GLOBAL SCIENCE NETWORK
SÜDZUCKER CENTRE FOR RESEARCH & DEVELOPMENT

Nutrition Science  Nutrition Communication  Regulatory Affairs

connecting nutrition and health