EFSA guidelines on the scientific requirements for health claims related to appetite and weight management

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Content

• EFSA’s role
• Health claims in the EU Regulation
• Health claims in relation to appetite and weight management
• EFSA’s guidance document on appetite and weight management – general and specific considerations
• Summary
The EFSA mission in nutrition:
To provide

- Scientific advice and scientific and technical support on human nutrition in relation to Community legislation

Regulation EC 178/2002, Article 22(5)(a)
EU Regulation 1924/2006
nutrition and health claim

CORRIGENDA


(Official Journal of the European Union L 404 of 30 December 2006)

Regulation (EC) No 1924/2006 should read as follows:

of 20 December 2006

on nutrition and health claims made on foods

ILSI Workshop, 27 November 2012
The need for the “Claims Regulation”

Consumer protection:
• To avoid false or misleading, claims must be \textit{scientifically substantiated}

Food industry:
• To improve \textit{free movement} of goods within the internal market by harmonizing rules
• To promote innovation
EU Regulation 1924/2006

Nutrition claims
- Content claims
- Comparative claims

Health claims
Function claims
- Based on generally accepted scientific data
- Based on newly developed scientific data

Reduction of disease risk claims + claims growth and development of children

What it contains
- Art. 13.1
- Art. 13.5
- Article 14

What it does
General principles for health claims

Claims must **not:**

- be false, ambiguous or misleading!
- give rise to doubt about the safety and/or the nutritional adequacy of other foods!
- encourage excess consumption!
- state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general!
Scientific criteria for the evaluation of health claims

Regulation (EC) No 1924/2006:

Health claims to be substantiated by:

- “generally accepted scientific evidence”
- “taking into account the totality of the available scientific data”
- “weighing the evidence”

• The Nutrition Panel makes a judgement on whether there is sufficient scientific evidence to support the claim
EFSA conclusions

• Cause and effect established: Sufficient conclusive evidence - generally accepted science

• Insufficient evidence to establish cause and effect (some evidence but not conclusive)
  – Emerging science
  – Conflicting results

• Cause and effect relationship not established: (very) limited scientific evidence
Health claims other than those referring to the reduction of disease risk and to children’s development and health

1. Health claims describing or referring to:

   (a) the role of a nutrient or other substance in growth, development and the functions of the body; or

   (b) psychological and behavioural functions; or

   (c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet,

which are indicated in the list provided for in paragraph 3 may be made without undergoing the procedures laid down in Articles 15 to 19, if they are:

   (i) based on generally accepted scientific evidence; and

   (ii) well understood by the average consumer.
EFSA Opinions (http://www.efsa.europa.eu/)
Health claims authorised/non-authorised by EC (http://ec.europa.eu/nuhclaims/)

EU Register of nutrition and health claims made on foods

The EU Register is for information only, showing:

- Permitted nutrition claims and their conditions of use
- Authorised health claims, their conditions of use and applicable restrictions, if any;
- Non-authorised health claims and the reasons for their non-authorisation;
- EU legal acts for the specific health claims;
- National measures mentioned in Art. 23(3) of Regulation EC 1924/2006.

The Commission will update the EU Register when required, namely upon adoption of EU decisions on applications for claims or on changes to conditions of use and restrictions.

Claims not in the EU Register

A number of submitted health claims do not appear in this EU Register:

- Health claims submitted as Article 13(1) 'function claims' but that do not qualify as such.
- Health claims not related to human health which cannot consequently be used on foods.
- Health claims for combinations of substances where health claims are already authorised for some of the individual substances.
- Some 'function claims', for which the assessment by EFSA or the consideration by the Commission is not finalised. These include health claims:
  - Under further assessment;
  - Referring to botanical substances;
  - Under further consideration by the Commission and EU countries.
- Some health claims subject to the individual authorisation procedure pending a decision.
Health claims
authorised/non-authorised by EC
(http://ec.europa.eu/nuhclaims/)

- Authorised claim related to satiety: None
- Non-authorised claims related to satiety: 36
  (= Art. 13(1))

- Authorised claims related to body weight: 3
  (e.g. Glucomannan (konjac mannan); Meal replacement for weight control)
- Non-authorised claims related to body weight: 73
  (= 71 Art 13.(1), 1 Art 13(5), 1 Art 14(1)b):
  e.g. Ethanol-water extract of Caralluma fimbriata (Slimaluma®); Milk product, rich in fibre and protein; Dairy foods and healthy body weight
SCIENTIFIC OPINION

Guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations

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

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

The European Food Safety Authority (EFSA) asked the Panel on Dietetic Products, Nutrition and Allergies (NDA) to draft guidance on scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations. This guidance has been drawn from scientific opinions of the NDA Panel on such health claims. Thus, this guidance document represents the views of the NDA Panel based on the experience gained to date with the evaluation of health claims in these areas. It is not intended that the document will include an exhaustive list of beneficial effects and studies/outcome measures which are acceptable. Rather, it presents examples drawn from...
Guidance document – general considerations

• Health claims only to be permitted if the food/constituent has been shown to have a beneficial physiological effect

• Beneficial physiological effects are judged by the Panel from the scientific evidence provided

• Target population groups of health claims are intended as the general (healthy) population or specific subgroups

• The claimed effect should be sufficiently defined
Guidance document – questions addressed by the Panel

- **Conditions** in human studies vs conditions of use for claim (e.g. food/constituent, quantity)
- **Human studies**: appropriate outcome measures the claimed effect? – adequate design and quality of the studies? – scientifically sound?
- **Human studies**: study group representative of the target group? Extrapolation to the target population?
- **Animal studies/in vitro studies** – how do they support the claimed effect in humans (e.g. explain mechanism of action?)
Guidance on appetite ratings (1/2)

✓ The beneficial physiological effects of changing appetite/satiety/fulness/hunger/desire to eat depend on the context of the claim!

✓ Claims submitted in the context of reducing body weight:
  - evidence for a sustained effect on appetite ratings and on body weight with continuous consumption to the food must to be provided

✓ Claims submitted must use methods with appropriate validity and precision
Guidance on appetite ratings (2/2)

**Claims submitted:**

- Should provide evidence to allow exclusion of adaption through compensatory mechanisms.

- Biochemical markers may be used as supportive to the scientific evidence.

- Appetite ratings may be comparative claims – with a test food and a control food. *Both* have to be sufficiently characterised!
Guidance on weight management

Health relationships:

✓ Reduction of body fat/body weight
✓ Weight management after weight loss
✓ Reduction of abdominal fat
✓ Increase/maintenance of lean body mass
Guidance document - timeline

• Prepared in 2010 along with other claim guidance documents

• Draft released for public consultation from April 26-August 2011

TECHNICAL REPORT

Outcome of a public consultation on the Draft Opinion of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) on a draft guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations

European Food Safety Authority

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

The European Food Safety Authority (EFSA) carried out a public consultation to receive input from the scientific community and all interested parties on a draft guidance document on the scientific requirements for the substantiation of health claims related to appetite ratings, weight management, and blood glucose concentrations prepared by the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) and endorsed by the Panel for public consultation at its Plenary meeting on 23-25 March 2011. The draft guidance document is based on the experience gained with the evaluation of health claims, and is aimed at further assisting applicants in preparing and submitting their applications for the authorisation of health claims. The written public consultation for this document was open from 26 April 2011 to 31 August 2011. EFSA received comments from 49 interested parties including applicants for health claims, non-governmental organisations, industry organisations and academia. EFSA and its NDA Panel wish to thank all stakeholders for their very useful contributions. The current report summarises the outcome of the public consultation including
Summary points

The EFSA guidelines on the scientific requirements for health claims on appetite ratings and BW:

• Are drawn from the scientific opinions of the NDA Panel on such health claims

• Represent the views of the NDA Panel based on the experience gained to date

• Are not intended to include an exhaustive list of beneficial effects and studies/outcome measures which are acceptable
THANK YOU