European Food Safety Authority
EFSA CONFERENCE ON NUTRITION AND HEALTH CLAIM
Bologna 8-10 November, 2006

Session 3 - Scientific substantiation of claims

Claims as addressed in the PASSCLAIM project

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PASSCLAIM

Process for the Assessment of Scientific Support for Claims on Foods

Consensus on Criteria

A European Commission (EC) Concerted Action

Organised by the International Life Sciences Institute

ILSI Europe 2001-2005

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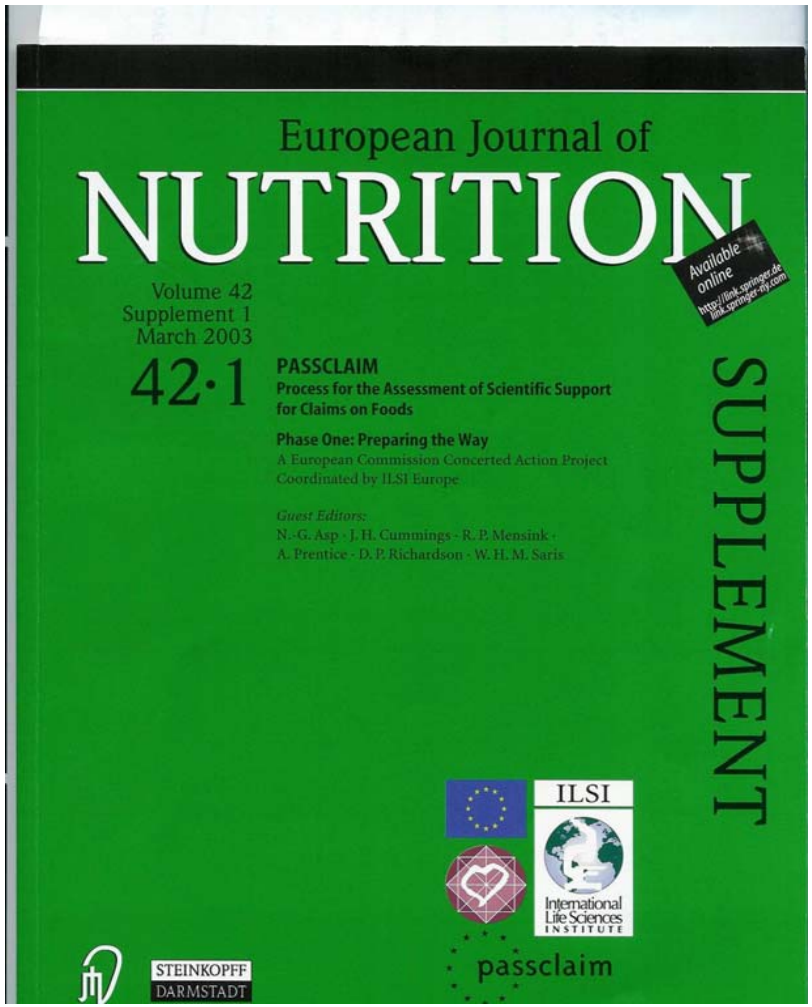
Three PASSCLAIM publications have appeared in the European Journal of Nutrition

* 2003;42(Suppl 1):1/1-1/119
* 2004;43(Suppl 2):II/1-II/183
* 2005;44(Suppl 1):1-31
  (The consensus document)



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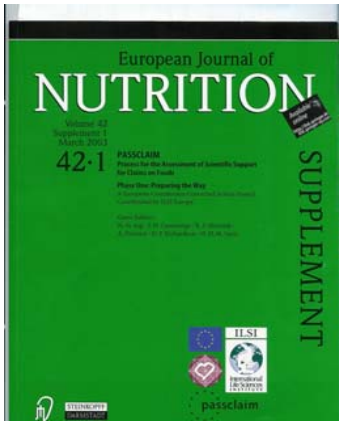
Individual Theme Group reports on

*Diet-related cardiovascular disease
*Bone health and osteoporosis
*Physical performance and fitness
*Synthesis and review of existing processes

*Body weight regulation, insulin sensitivity and diabetes risk
*Diet-related cancer
*Mental state and performance
*Gut health and immunity



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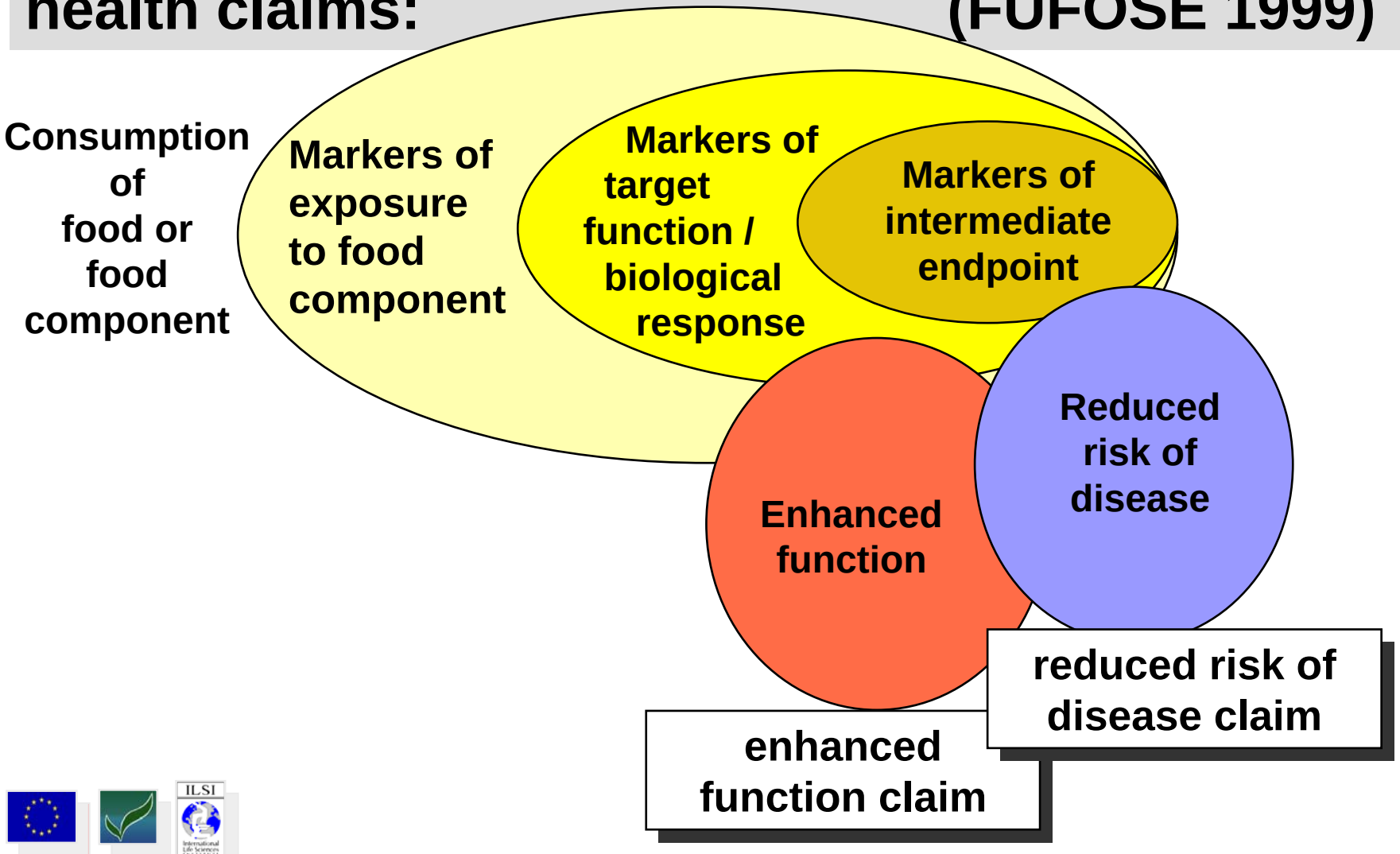
FUFOSE
Functional Food Science in Europe
Strategy for the Evidence Base

- Use of intermediate or surrogate markers as “outcomes”
- Validation and quality control of the markers (repeatability, reproducibility, specificity and selectivity etc)

Functional Food Science in Europe: Strategic use of the evidence base and markers to justify health claims: (FUFOSE 1999)



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Markers and the Causal Pathway

- Markers become less specific and more attenuated and subject to confounding variables the more remote they are from the endpoint
- Conversely they become more specific and quantitative the pathophysiologically nearer they are to the endpoint in question.

Biomarkers: Sub-classification

- If a marker represents an event and is directly involved in the process of interest (that is the causal pathway) then it should be considered as a factor.
- If the marker represents correlated or associated events it should be considered as an indicator.

Context for the Scientific Substantiation of Health Claims

- Foods subject to claims should comply with existing legislation and fit into a healthy diet

- Regulations should reflect new scientific developments

- A claim should
  - reflect its scientific basis
  - be understandable, and not be misleading for the intended consumer

Consensus Criteria for the Scientific Substantiation of Health Claims

1) The food or food component should be characterised

- to allow assessment of validity of scientific case

Consensus Criteria for the Scientific Substantiation of Health Claims

2) Human data (1)

- Substantiation should be primarily based on human data
  → Categories of evidence

- Primarily from intervention studies, the design of which should include:

Consensus Criteria for the Scientific Substantiation of Health Claims

2) Human data (2)

a) Study groups representative of the target group

b) Appropriate controls

c) Adequate duration of exposure to demonstrate effect

Consensus Criteria for the Scientific Substantiation of Health Claims

2) Human data (3)

d) Characterisation of the study group´s background diet and other relevant aspects of lifestyle

e) An amount consistent with intended pattern of consumption

f) Influence of food matrix and dietary context on functional effect

Consensus Criteria for the Scientific Substantiation of Health Claims

2) Human data (4)

g) Monitoring of dietary compliance

h) Statistical power to test the hypothesis

Consensus Criteria for the Scientific Substantiation of Health Claims

2) Human data (5).

Categories of evidence that may be used

Intervention studies - RCT gold standard, Clinical trials, physiological and psychological trials

Observational studies - Prospective (cohort), Cross-sectional (analytical), Case-control

Supporting - Animal, *In vitro* cell and molecular, Studies on genotype, Modelling (of mechanisms)

Consensus Criteria for the Scientific Substantiation of Health Claims

3) Use of markers (1)

When the true endpoint of claimed benefit cannot be measured directly,

- long-time period
- not feasible / ethical issues
- large scale study very demanding on resources

Consensus Criteria for the Scientific Substantiation of Health Claims

3) Use of markers (2)

Relate to:

- Exposure to the food component
- Target function or biological response
- Appropriate intermediate endpoint
- Combination of several relevant markers

Consensus Criteria for the Scientific Substantiation of Health Claims

4) Markers validation

Markers should be validated

- Biologically : relationship to outcome and known variability

- Methodologically: analytical characteristics

Consensus Criteria for the Scientific Substantiation of Health Claims

5) Statistical significance and biological meaningfulness

- Target variable should change in a statistically significant way

- Change should be biologically meaningful for the target group

Consensus Criteria for the Scientific Substantiation of Health Claims

6) Totality of data and weighing of evidence

- Different interpretations or conflicting evidence
- Different quality of studies
- Complementarity between individually incomplete studies
- Transparent selective consideration
- Published data should be reviewed and unpublished data, including confidential data must also be considered

Totality of data and weighing of evidence

Comment:

Grading of evidence, e.g. "convincing", "probable", "possible", was discussed as useful in scientific evaluations, but PASSCLAIM participants were generally against qualified health claims

ACHIEVED RESULTS

The criteria:

- Emphasize the need for direct evidence of benefit to humans
- Recognize the usefulness of markers, demonstrate limitations of existing markers and stress importance of valid markers
- Highlight necessity of magnitude and character of effects to be statistically & biologically meaningful
- Are a template for the evaluative process that needs informed scientific advice

EXPECTED IMPACT OF PASSCLAIM

- Constitute a scientifically robust tool for evaluating the quality of the data submitted in support of claims on foods.
- Assist those making claims and regulating claims.
- Improve the credibility of claims for consumers.
- Offer a practical scientific framework to prepare scientific dossiers supporting claims.

Use of PASSCLAIM criteria for generic claims applicable to a range of food products

- The same high standard of scientific evidence should apply to all types of health claims

- The nature of the evidence somewhat different:

  RCTs with the food product key elements for innovative/product-specific claims, but not required for all products eligible for generic claims

For PASSCLAIM publications, please visit:

http://europe.ilsi.org/passclaim

Thank you !

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