PASSCLAIM
Process for the Assessment of Scientific Support for Claims on Foods

A European Commission Concerted Action
Coordinated by ILSI-Europe
Duration of the Project: April 2001 - April 2005

Background

Food can provide us with much more than energy and nutrients for growth and metabolism. Good food enhances normal function and thereby improves quality of life. Food also plays an important role in preventing disease. Rather than having adequate nutrition, we should now aim for optimal nutrition.

This new concept of optimal nutrition has stimulated the food industry to produce functional foods – that is foods which benefit an individual beyond the normal provision of energy and nutrients.

Following on from the development of functional foods has come the need to be able to claim their ability to enhance physiological and psychological functions and to reduce disease risk.

Against this background the EU agreed in 1996 to fund a Concerted Action entitled "Functional Food Science in Europe (FUFOSE)" with the aim "to develop and establish a science based approach for the emerging concepts in functional food development". FUFOSE, in its final consensus document (Brit. J. Nutr. 1999 81 Suppl 1) concluded that the development of functional foods must be based on sound scientific knowledge of the target function of the body and show that the effects are relevant to improved health or reduction of disease risk. It identified the development of "validated markers for these target functions and the evaluation of sound scientific data from human studies for their possible modulation by foods and food components" as an important part of the validation process.

PASSCLAIM, an EU funded, ILSI Europe initiated Concerted Action commenced in April 2001 and built on these FUFOSE principles.

The principal objectives of PASSCLAIM are:

- To produce a generic tool with principles for assessing the scientific support for health-related claims for foods and food components
- To evaluate critically the existing schemes which assess the scientific substantiation of claims
- To select common criteria for how markers should be identified, validated and used in well-designed studies to explore the links between diet and health

Outline of the project

- A network of 53 academics, regulatory experts and representatives from public interest groups and industry across Europe has been set up.
- A Steering Committee oversees the work of the Concerted Action
- Eight Individual Theme Groups (ITGs) have been established, comprising members of the network, and are tasked with:
  - collating current and potential claims and describing scientific principles needed to support these claims
  - developing criteria to substantiate claims and basic science support
  - assessing the utility and validity of biomarkers to support claims.

The topics for the ITGs are

ITG A - Diet-related cardiovascular disease
ITG B - Bone health and osteoporosis
ITG C - Physical performance and fitness
ITG D - Review of existing processes
ITG E - Insulin sensitivity and diabetes risk
ITG F - Diet-related cancer
ITG G - Mental state and performance
ITG H - Gut health and immunity

- ITGs A-D have met on three occasions and produced four papers*
- On the basis of these papers, the Steering Committee has drawn up a Draft Set of Interim Criteria for the Scientific Substantiation of Claims on Foods
- The draft criteria were discussed by all members of the network, invited delegates from 20 countries and representatives from ILSI Japan, ILSI North America and ILSI Southeast Asia Region at the first Plenary Meeting in Berlin in September 2002

* These papers, together with the Report of the First Plenary Meeting will be published in the European Journal of Nutrition early in 2003
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<tr>
<th>Year</th>
<th>Event/Document</th>
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<tbody>
<tr>
<td>2002</td>
<td>ITG A, ITG B, ITG C, ITG D</td>
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<td>2003</td>
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<td>Draft Set of Wider Criteria</td>
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**PASSCLAIM: EU-wide network of academics and representatives from industry, consumer and public interest groups and legislators**
Outcome of First Plenary Meeting

A series of working groups and plenary sessions took place over three days in Berlin, attended by 80 delegates. The work of ITGs A-D was presented and discussed and aspects of the Draft Set of Interim Criteria for the Scientific Substantiation of Claims on Foods formed the basis for the 12 working groups.

A consensus was reached on a Revised Set of Interim Criteria for the Scientific Substantiation of Claims on Foods and these will form the basis for the discussion of ITGs E-H.

A number of issues of importance were flagged for future discussion

- The demarcation between functional foods and pharmaceuticals and their relevant claims is needed.
- Claims are proposed for enhanced function (Type A claim) and reduction of disease risk (Type B claim). However, there remained doubt in delegates’ minds as to the distinction between the two claims. Whilst Type A claims were for enhanced function, they almost invariably would imply prevention and, therefore, were really a health claim. If Type A did not lead to a Type B effect, then it was not necessarily useful. The consumer might expect this.
- The need to have an evidence based approach to the substantiation process was stressed.
- The standard of evidence required for generic as opposed to product-specific claims, should be specified.

Revised Interim Criteria for the Scientific Substantiation of Health Claims on Foods and Food Components

1. Foods and food components for which claims are made should comply with existing legislation.
2. Health claims should be scientifically substantiated by taking into account the totality of evidence. A scientifically substantiated mechanism is valuable but not essential.
3. When a claim is made, it should be specified who may benefit from the effect, e.g. the entire population, a subgroup or an at risk group.
4. Claims should be based primarily on human intervention studies that show demonstrable effects consistent with the claim. They should have a scientifically valid design compatible with the purpose of the study, including the following:
   a. study groups that are representative of the target group
   b. controls both for the intervention itself, and for the subject groups
   c. an appropriate duration to demonstrate the intended effect
   d. characterisation of the target groups' background diet, which should be controlled for where necessary
   e. the amount of the food or food components being evaluated should be consistent with its intended use and the expected consumption pattern
   f. ideally, an exposure-response relationship should be determined to identify optimum effective intake
   g. dietary compliance, which should be monitored
   h. the statistical power to test the hypothesis.
5. If the claimed enhancement of function or reduction of risk cannot be measured, studies should use markers of effect that have been scientifically validated.
6. Markers should be validated:
   Methodologically to include their
   • precision and accuracy
   • specificity and sensitivity
   • reproducibility and repeatability
   Biologically so that
   • they reflect closely the process leading to the claimed health benefit
   • respond quickly in line with changing events
7. Within a study the marker should change in a biologically relevant way and be statistically significant for the target group consistent with the claims to be supported.