Background and objectives of PASSCLAIM

Much attention is being paid to health claims on foods, including enhanced function claims, reduction of disease risk claims and also nutrient function claims. Many food products on the market contain claims about health effects beyond the simple provision of nutrients. One important basis for claims is the increasing number of reports of the effects of dietary components on body functions. However, there was no scientific consensus as to how claims based on these reports should be evaluated at European level.

With this background, ILSI Europe initiated the Concerted Action ‘Process for the Assessment of Scientific Support for Claims on Foods’ (PASSCLAIM). PASSCLAIM has set principles for assessing the scientific support of health claims.

In 2003, the European Commission proposed its Regulation on nutrition and health claims made on foods, which states that scientific substantiation of claims should be the main aspect to be taken into account for the use of claims. This regulation already recognised PASSCLAIM as a considerable work that should be taken into account when assessing claims.

Criteria for the scientific substantiation of claims

1. The food or food component to which the claimed effect is attributed should be characterised.

2. Substantiation of a claim should be based on human data, primarily from intervention studies the design of which should include the following considerations:
   - Study groups that are representative of the target group
   - Appropriate controls.
   - An adequate duration of exposure and follow up to demonstrate the intended effect.
   - Characterisation of the study groups’ background diet and other relevant aspects of lifestyle.
   - An amount of the food or food component consistent with its intended pattern of consumption.
   - The effect of the food matrix and dietary context on the functional effect of the component.
   - Monitoring of compliance with intake of food or food component under test.
   - The statistical power to test the hypothesis.

3. When the true endpoint of a claimed benefit cannot be measured directly, studies should use markers.

4. Markers should be:
   - biologically valid in that they have a known relationship to the final outcome and their variability within the target population is known;
   - methodologically valid with respect to their analytical characteristics.

5. Within a study the target variable should change in a statistically significant way and the change should be biologically meaningful for the target group consistent with the claim to be supported.

6. A claim should be scientifically substantiated by taking into account the totality of the available data and by weighing of the evidence.

Achievements

• The criteria provide a scientific framework that will facilitate the assessment of scientific support for claims on foods.
• This, in turn, will enable the compilation of guidelines on the preparation of submissions for regulatory review and approval of claims on foods.
• By establishing a robust standard for the quality of scientific data submitted in support of health claims, the criteria provide a basis for the harmonisation of the regulatory review and approval of such claims.
• The compliance of data submissions with the criteria will provide consumers with the assurance that claims based on the data are well founded and justified.
• By establishing a standard for the data to be submitted in support of claims, the criteria will provide the agri-food industry with a stable frame within which new products to meet consumer needs and expectations for foods with benefits for health and well-being can be developed.
• Systematic use of the criteria will engender a more informed use of scientific data in support of claims.

For any questions about PASSCLAIM, please contact:
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A European Commission Concerted Action

This project has been carried out with financial support of the Commission of the European Communities, specific RTD programmes “Quality of Life and Management of Living Resources”,QLK1-2000-00086, Key Action 1 Food, Nutrition and Health, under coordination of the ILSI Europe Functional Food Task Force. EC-contract: Dr. Jürgen Lucas - Research DG, Food Quality (E.2).


Publications

The publications are downloadable from http://europe.ilsi.org/passclaim
To order free paper copies please contact publications@ilsieurope.be

Structure of the project

Criteria for the scientific substantiation of claims

Process

Through an iterative process of discussion in expert groups and workshops, sets of criteria which define requirements for assessing the quality of scientific data reporting the impact of foods and food components on health and well-being have been proposed and progressively refined.

Context

The context within which a claim or the case made in support should be assessed involves:
- considering existing legislation and dietary guidelines;
- the need for review in the light of evolving science; and
- the comprehensibility of the claim to consumers.

These aspects are not thought to be part of the scientific criteria reviewed by PASSCLAIM. They nevertheless provide the background against which the scientific validity of claims should be justified.

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