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Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM) Phase Two: Moving forward

Introduction

Much attention is now being paid to claims for foods, especially those related to the increasingly documented effects of dietary components on body functions. The main thrust of the *Consensus Document on Scientific Concepts of Functional Foods in Europe*, produced as the final deliverable from the EU DG XII 'Functional Food Science in Europe' (FUFOSE) Concerted Action, was to suggest a scheme to link claims for functional foods to solid scientific evidence (see publication in British Journal of Nutrition, Volume 81, Supplement 1, 1999). FUFOSE suggested that any claim for 'enhanced function' and 'reduced risk of disease' is only justifiable when they are based on appropriate scientific studies. The key importance of validated markers of exposure, enhanced function or reduction of disease risk was highlighted (Fig. 1).

FUFOSE conclusions and principles are now taken to the next logical stage, i. e. application of the principles. The project 'Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM)' starts with, and builds upon, the principles defined within the FUFOSE project. The Concerted Action PASSCLAIM (QLK1-2000-00086) is supported by the European Commission, Quality of Life and Management of Living Resources Programme (QoL), Key Action 1 (KA1) on Food, Nutrition and Health, and is coordinated by the ILSI Europe Functional Food Task Force.

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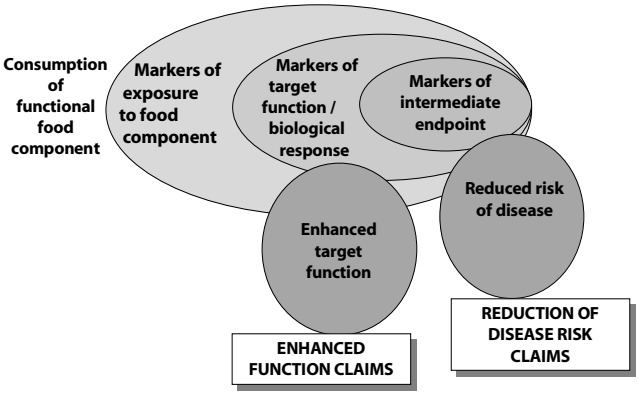

Fig. 1 Functional foods: a proposal for a scientific basis for claims

Objectives of the project

The main objective of PASSCLAIM is to produce a generic guidance tool to assess the scientific support for health-related claims for foods and food components. The project will select common criteria that can be used as a basis for the scientific substantiation of health claims, including a way to develop valid scientific study designs and to identify, validate and use markers to explore the effects of diet on health. In addition, the existing schemes that assess the scientific substantiation of claims were critically evaluated.

Process followed

In order to meet the project objectives (see Fig. 2), Individual Theme Groups (ITGs) were set up involving academic experts, regulatory experts and the food industry. Representatives of public interest groups were also approached. The goals were to:

- Collate potential types of claims in different areas

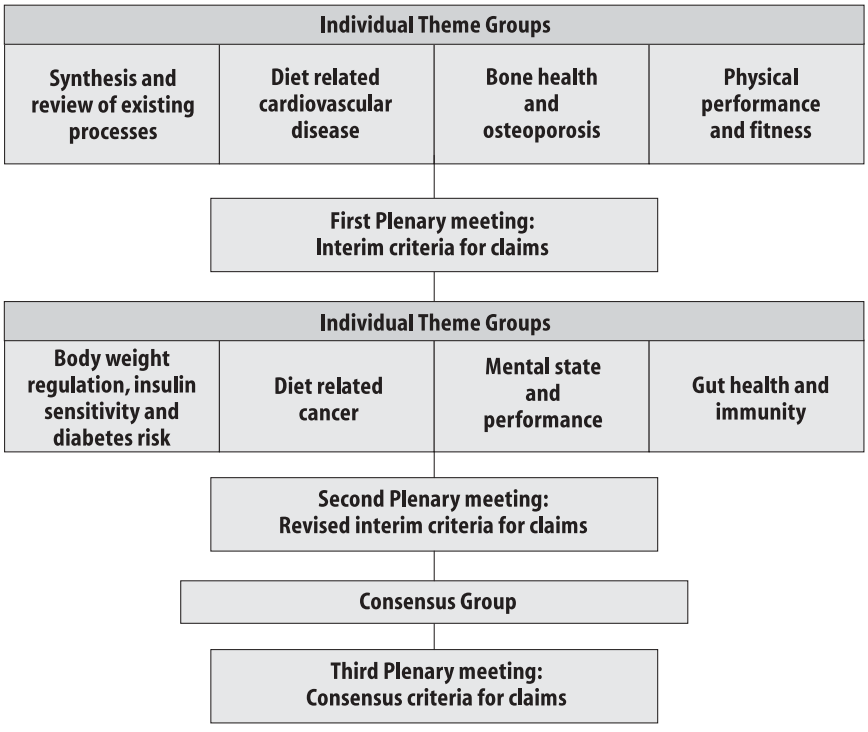

Fig. 2 Schematic representation of the PASSCLAIM project

(not an exhaustive list but suitable examples) from the perspective of the function related to physiological area;
- Describe the scientific requirements that would be needed to support these claims and evaluate the relevance of the scientific support;
- Assess the usability of markers (and their validation) for the scientific substantiation of the claims;
- Set the basis to develop a list of criteria to evaluate the substantiation of these identified claims: what needs to be done for the development and justification of enhanced function and reduction of disease risk claims.

Phase One ITGs

Initially, four 'Phase One' ITGs were set up (see *Publication I* in European Journal of Nutrition, Volume 42, Supplement 1, March 2003).

Diet-related cardiovascular disease (A)

From the wealth of publications in one of the most researched areas of food and health, the group concluded that generally accepted biomarkers exist for LDL and HDL cholesterol, fasting triacylglycerol, homocystein, and blood pressure. Enhanced function and disease risk reduction claims could be made for diet-related changes in LDL and blood pressure. For HDL cholesterol, fasting triacyglycerol and plasma homocysteine biomarkers exist, but it is as yet not clear to what an extent changes in these biomarkers reflect "enhanced function" and reduction of disease risk. For haemostatic function and oxidative damage, there is a need to develop and validate biomarkers that are sensitive to dietary changes.

Bone health and osteoporosis (B)

Although bone health problems encompass many skeletal disorders, the group focussed on osteoporosis because this is a major public health issue in the EU. Bone mineral density (BMD) was identified as the only marker so far that can, for people of any age and sex, provide evidence of enhanced function. For people over 50 living in countries with a high risk of fracture, BMD was considered to be marker of fracture risk such that changes in BMD caused by a food component could provide evidence of a reduction in disease risk.

Physical performance and fitness (C)

The group reviewed claims relating to strength and power, endurance, energy supply and recovery, hydration status, flexibility, tissue growth and immune function. Many methods for measuring these parameters of fitness were examined as possible evidence for claims.

This included tests of muscle strength, energy metabolism, food intake, gastrointestinal function and immune function. The group had concluded that "for all physical performance and fitness domains, sets of biomarkers to substantiate claims are available and often identical with the true endpoints," and that "for most areas, reliability and validity are good". The position was less clear for immune function.

Synthesis and review of existing processes (D)

This group critically evaluated existing international approaches to the scientific substantiation of health claims, with a view to identifying common ideas, definitions, best practice and methodology to underpin current and future developments. The group summarised the regulatory approaches to health claims as set out by seven countries and two international organisations. A common thread in all these approaches is the requirement for solid scientific substantiation. The group focussed on the process of assessing claims, which included identification of all relevant studies, evaluation and interpretation of the totality of the evidence and the concept of "significant scientific agreement".

The information resulting from the Phase One ITGs provided the building blocks for a first draft set of interim criteria for the scientific substantiation of health claims on foods and food ingredients.

First Plenary Meeting

This first draft set of interim criteria was the starting point for discussions at the first Plenary Meeting and interim criteria were the main output from the meeting. The reports of "Phase One" ITGs (A to D) and a summary of the discussions at the Plenary Meeting including the interim criteria developed by the first Plenary Meeting were published as *Publication I*.

Phase Two ITGs

In the Second Phase of the project, the data as published in *Publication I* were used by four new "Phase Two" theme groups to explore the following areas (see *Publication II*, this issue):

- Body weight regulation, insulin sensitivity and risk of diabetes (E),
- Diet-related cancer (F),
- Mental state and performance (G)
- Gut health and immunity (H).

Second Plenary Meeting

The interim criteria resulting from the First Plenary Meeting were developed further at the Second Plenary Meeting, taking into consideration the outcome of the Phase Two ITGs. Their reports formed the starting point for discussions at the meeting. Revised interim criteria were obtained with a number of attached comments from all the participants in the Second Plenary Meeting. The present *Publication II* includes these Revised Interim Criteria and comments together with the reports of ITGs E to H.

Consensus Group

In the third phase of the PASSCLAIM project the Consensus Group will use the outcome of the ITGs, the comments from the Plenary Meetings and the revised interim criteria (*Publication I* and *II*) to propose a draft set of consensus criteria for the scientific substantiation of health claims on foods and food ingredients.

Third Plenary Meeting

This new draft set of consensus criteria will be reviewed by the Third Plenary Meeting and the final consensus criteria will be published in the PASSCLAIM Consensus Document, *Publication III*. This technique of reflective practice and continuous improvement will broaden and refine the set of criteria and ensure that a variety of possible methods for the scientific substantiation of claims are considered. This creates a broad basis for the final PASSCLAIM consensus document and will ensure its wide applicability.

Expected achievements and applications

- The final PASSCLAIM Consensus Document will assist those making claims, as well as those who regulate claims and it will also improve the credibility of claims for consumers.
- The present *Publication II* and the previous *Publication I* include state-of-the-art documents on application in key areas for development of functional foods.
- PASSCLAIM will offer a practical scientific framework to prepare scientific dossiers supporting claims. European food manufacturing industry, including SME's, will benefit because of the competitive edge that will be provided.
- PASSCLAIM will assist in the compilation of guidelines to prepare submissions for claims on foods, and thereby expedite and improve the efficiency of the regulatory review processes.

- Consumers will benefit from having more foods available with substantiated claims. This integrated strategy will address consumer concerns and generate more consumer confidence in science-based claims on foods.

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