

N.-G. Asp
L. Contor

Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM): overall introduction

Introduction

The primary role of diet is to provide sufficient nutrients to meet the metabolic requirements of an individual and to give the consumer a feeling of satisfaction and well-being through hedonistic attributes (such as taste). In addition, by modulating specific physiological targets, diet can have an additional function: beneficial physiological and psychological effects beyond the widely accepted nutritional effects. In fact, diet can not only help to achieve optimal health and development, but it does also play an important role in reducing the risk of disease.

Much attention is now being paid to claims for foods, especially those related to the newly discovered effects of dietary components on body functions. The main thrust of the recent 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 the outline of a scheme to link claims for functional foods to solid scientific evidence. FUFOSE suggested that Claims for “enhanced function” and “reduced risk of disease” are only justifiable when they are based on appropriate, validated markers of exposure, target function or an intermediate endpoint (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 publications arising out of the FUFOSE project.

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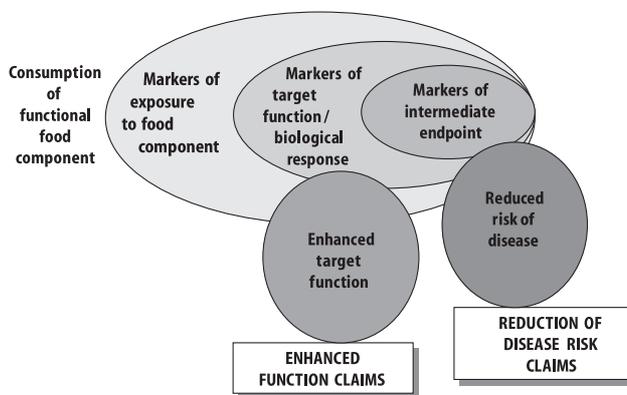


Fig. 1 Functional foods: proposal for a scientific basis for claims

Objectives of the project

The 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.

In order to meet the project objectives, a European network has been set up involving academic experts in different aspects of the physiological functions relating to health claims, representatives of public interest groups, regulatory experts and the food industry.

Initially, four “Phase One” Individual Theme Groups (ITGs) were set up (see Fig. 2). ITGs A, B and C focussed on three physiological areas, namely diet-related cardiovascular disease (A), bone health and osteoporosis (B) and physical performance and fitness (C).

ITG A, B and C held three meetings to critically assess the criteria currently used for the assessment of the sci-

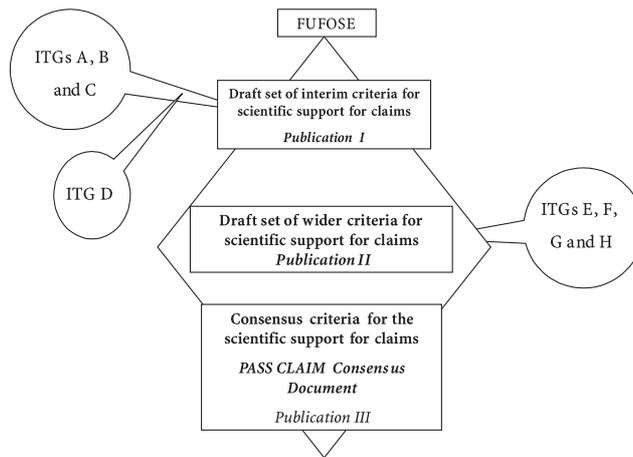


Fig. 2 Schematic representation of the project

entific support for claims related to their themes. More specifically they aimed to

- Collate potential types of claims (not an exhaustive list but suitable examples) from the perspective of the function related to the physiological area, to describe the general principles which would be needed to support these claims and to evaluate the rationale of the scientific support;
- Develop the background data that would be used to justify these identified claims: what needs to be done for the development and justification of enhanced function and reduction of disease risk claims and how these claims should be supported in terms of basic science;
- Assess the usability of the markers (and their validation) used for the scientific substantiation of the claims.

ITG (D) reviewed the current global situation in terms of schemes to regulate claims and other similar systems and concepts which are universally applied. The report from ITG (D) was made available to ITGs A, B and C while they drafted their reports.

This publication (Publication I), contains the reports of “Phase One” ITGs (A to D) and a summary of the discussions held at the First Plenary Meeting including a set of interim criteria agreed upon at this meeting.

The set of interim criteria as published in the current publication will now be used by four new “Phase Two” theme groups, concerned with insulin sensitivity and risk of diabetes (E), diet-related cancer (F), mental state and performance (G) and gut health and immunity (H).

Like the “Phase One” ITGs, the “Phase Two” ITGs will elaborate, in key areas for the development of enhanced function or reduction of disease risk claims, a “blueprint” for what needs to be done in terms of scientific research and how claims should be justified. The “Phase Two” theme groups will review and test how the draft set of interim criteria can be used in the different physio-

logical areas. They will then position their criteria with the draft set of interim criteria and produce a draft set of wider new criteria as necessary.

A draft set of wider criteria will then be obtained from the Second Plenary Meeting and will be published in Publication II together with the reports of ITGs E to H. This technique of reflective practice and continuous improvement will broaden and refine the set of criteria and will ensure that many possible methods for the scientific substantiation of claims are considered. This will enable the final PASSCLAIM Consensus Document to contain consensus criteria derived from a very broad basis and will ensure its wide applicability.

The Consensus Group will then use the outcome of the ITG and Plenary Meetings (Publication I and II) to propose draft consensus criteria for the scientific substantiation of claims. These will be agreed by the Third Plenary Meeting and published in the PASSCLAIM Consensus Document, Publication III. The consensus criteria will be widely disseminated among the scientific, industrial, regulatory and consumer communities.

Expected achievements

- The PASSCLAIM Consensus Document will contain consensus criteria to assess the scientific support for claims on foods, and will be widely disseminated among scientists, industry, consumer groups and regulators.
- The PASSCLAIM Consensus Document will assist those making claims and those who regulate claims, and will also improve the credibility of claims for consumers.

Applications

- PASSCLAIM will offer a practical scientific framework to prepare scientific dossiers supporting claims. This framework will ensure that all claims have a firm scientific base. The European food manufacturing industry, including SME’s, will benefit because of the competitive edge that will be provided.
- PASSCLAIM will enable the compilation of guidelines to prepare submissions for claims on foods. This will expedite and improve the efficiency of the regulatory review processes.
- Consumers will benefit from an improved approach to the scientific support for claims on foods. This integrated strategy will generate more consumer confidence in the science base related to claims on foods and will better address the concerns of consumers.

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ILSI Europe

Coordinator: Dr. Laura Contor
Scientific supervisor: Dr. Daphne Pannemans
Project manager: Ir. Sandra Tuijelaars

EC Responsible: Dr. Jürgen Lucas,
European Commission,
DG Research, Unit E.2 Health,
Food and Environment

Nils Georg Asp
Professor of Applied Nutrition
Swedish Nutrition Foundation
Chair of the Steering Committee

Laura Contor
Deputy Director
ILSI Europe
Project Coordinator