

Rationale and scientific support for health claims on foods

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The role of diet and physical activity in health has been increasingly documented and pinpointed as a major target for health-promoting strategies. The supply, availability, marketing and price of food products have a strong impact on consumers' diets.¹ Therefore, national food and agricultural policies should be consistent with the protection and promotion of public health, and governments should be encouraged to examine food and agricultural policies for potential health effects on the food supply.² There is already a clear shift in many countries and regions regarding the scope of agricultural and food policies, from a farmers' to a consumers' perspective. The supply of nutritious foods with appropriate macronutrient composition, energy density and micronutrient content is a prerequisite for optimal nutrition and a main target for nutrition policies. In addition to optimising the nutrient content of foods, an increasing body of evidence regarding effects of food components – both nutrients and other substances – and food properties on physiological functions, provides a basis for additional benefits of foods on health, performance and well-being. This is the basis for the functional foods concept that was conceived in Japan in the late 1980s.³

The escalating cost of pharmacological treatment of diseases and risk factors related to lifestyle factors, such as diet and physical activity, is another increasingly important driving force for the development of nutritionally optimised foods. Several recent large-scale intervention studies (e.g. Tuomilehto *et al.*⁴ and Knowler *et al.*⁵) have demonstrated that diet and physical activity can be at least as effective as commonly used drugs against obesity, elevated blood pressure and blood lipids and type 2 diabetes. The principle of trying lifestyle changes including diet and physical activity before introducing lifelong pharmacological treatment of risk factors such as

elevated blood pressure and plasma cholesterol levels is gaining acceptance and becoming common practice in the medical community.

Functional foods are foods with health claims

Health claims on foods have received increased attention, both from the producers' perspective as a means of marketing foods with added value in terms of health, and from the consumers' point of view in terms of consumer education and improved health. However, there is also a risk of overemphasis of the importance of single foods for health. Different national and international bodies attempting to regulate this rapidly evolving market apply various approaches, not least to make claims compatible with and supportive of the general nutrition recommendations. There is a broad consensus that any regulatory framework should protect the consumer, promote fair trade and encourage innovation in the food industry.⁶

Functional foods are generally regarded as foods with scientifically substantiated beneficial effects on health, well-being and performance, in addition to providing the normal nutrients.⁷ Rather than formally defining functional foods, however, most national and international bodies have discussed and defined a number of health claims typically used for foods with added value in terms of health, well-being and performance. Guidelines were recently adopted by the Codex Alimentarius Commission.⁸ A claim means any representation that states, suggests or implies that a food has particular characteristics relating to its origin, nutritional properties, function, nature, production, processing, composition or any other quality. The two main types of claims are regarding: (i) what the food contains, i.e. nutrient content claims and comparative

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claims; and (ii) what the product does in terms of health, well-being and performance, i.e. health claims.⁹

Health claims can be: (i) *generic* (general) and relate to the importance for health of the dietary composition, to which the product can specifically contribute through its favourable nutritional composition; or (ii) *product-specific*, meaning that a certain effect on health, performance or well-being is obtained by consuming the particular food product.⁹

Codex guidelines⁹ specify three different types of health claims: (i) *nutrient function claims* describing a generally accepted role of a nutrient in growth, development and normal physiological functions of the body; (ii) *other function claims* – previously referred to as *enhanced function claims* as suggested in the Functional Foods Science in Europe (FUFOSE)⁷ project – referring to specific beneficial effects of food and food components on physiological and psychological functions other than nutrient function claims as described above; and (iii) *reduction of disease risk claims* referring to the reduction in one or several risk factors for diet-related chronic diseases, obtained by consuming certain foods or diets. Although the nomenclature shows some variation as seen in Table I, these principal types of health claims are now well established internationally.

In many countries claims about disease risk reduction, mentioning the disease in question, are regarded as incompatible with medical products legislation. However, such claims have been used in the USA since the implementation of the Nutrition Labelling and Education Act (NLEA) in 1993 and in Canada since 2003. Already in 1989 the Medical Products Agency in Sweden decided, under certain conditions, no longer to apply medical products legislation on foods ‘normally found on the dinner table’. This paved the way for the Food Industry’s Code of Practice introduced in collaboration with the authorities in 1990.¹⁰ A corresponding decision by the Commission of the European Communities in 2003 preceded the proposal for a regulation on nutrition and health claims for foods.^{9,11}

Scientific substantiation of claims essential

Scientific substantiation is of key importance for any type of claim: (i) to provide truthful information and to support consumer confidence in foods for which there are claims; (ii) to satisfy regulatory requirements; and (iii) to allow fair market competition. This is one of the areas of public health nutrition where evidence-based science is, and should be, used. The type of claim determines the type and extent of evidence required. For instance, a generic claim reflecting the well-established relationship between saturated fat intake/plasma total and low-density lipoprotein (LDL) cholesterol levels/risk of cardiovascular disease will be based on the same extensive documentation that underpins the general recommendation to limit saturated fat intake to 10% of the energy intake in most national and international nutrition recommendations (e.g. WHO¹). Claims about a specific effect of a proprietary food, on the other hand, would rely in the first instance on human nutrition studies with volunteers consuming that particular food product.^{9,12,13}

PASSCLAIM defines the criteria

A major European Commission (EC)-supported concerted action project, ‘Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM)’, was recently concluded. The project was organised by the International Life Science Institute (ILSI Europe) during 2001 - 2005 and engaged more than 160 scientists from academia, industry, research institutes, public interest groups and the regulatory environment. The main objective was to produce a generic tool for assessing the scientific support for health claims for foods.

PASSCLAIM defined a number of generally applicable criteria for the scientific support of claims, listed in Table II. These criteria emphasise the need for direct evidence of benefits to humans, recognise the usefulness of markers of intermediate effects and

Table I. Health claims classification according to FUFOSE,⁷ Council of Europe,¹² Codex Alimentarius Commission⁸ and the proposed EU regulation¹¹ (adapted from Aggett *et al.*¹³)

FUFOSE (1999)	Council of Europe (2001)	Codex Alimentarius (2004)	Proposed EU regulation (2003)
Nutrient function claims not considered	Nutrient function claims not considered	Nutrient function claims	Health claims related to the generally accepted role of nutrients and other substances
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Enhanced function claims	Enhanced function claims	Other function claims	
Disease risk reduction claims	Disease risk reduction claims	Disease risk reduction claims	Health claims related to disease risk reduction

Table II. The PASSCLAIM criteria for the scientific substantiation of claims¹³

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 influence of the food matrix and dietary context on the functional effect of the component
 - Monitoring of subjects' compliance concerning 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.

highlight that effects should be both statistically and biologically meaningful. A consensus report¹³ presents these criteria and gives an outline of the context within which they are to be assessed.

The context within which a claim is made should be considered in relation to existing legislation as well as dietary guidelines. Foods for which health claims are made should fit into a healthy diet. Requirements on the nutritional composition of the food product for which a claim is made, in addition to the active component(s), are a matter of discussion, not least within the European Community in terms of 'nutrition profiling'. In any case, products for which health claims are made should be possible to accommodate within a balanced diet according to current nutrition recommendations. Other important contextual points stressed in the PASSCLAIM project are that the regulations should in principle reflect the evolving science base taking into account new scientific developments as appropriate, rather than for instance excluding certain areas *a priori*. An important point outside the scope of PASSCLAIM is that a claim should reflect its scientific basis, and, at the same time, should be understandable, and not be misleading to the intended consumer.¹³

The way to develop valid scientific study designs and to identify, validate and use markers to explore the effects of diet on health was dealt with by a number of expert groups, each focused on a specific theme. Seven comprehensive reviews on diet-related cardiovascular disease, bone health and osteoporosis, physical performance and fitness,¹⁴ body weight regulation, insulin sensitivity and diabetes, diet-related cancer, mental state and performance, and gut and immunity¹⁵

formed the basis for development of the criteria. One study made a synthesis and review of existing processes.⁹

The criteria describe the standards by which the quality and relevance of the scientific evidence should be judged and thus the extent to which a claim based on them can be said to be scientifically valid. Therefore, the criteria have the potential to increase public confidence in the role of diet in maintaining and improving health and well-being.

A key issue is that substantiation of a claim should be based on human data, primarily from intervention studies (criterion 2, Table II). There are many forms of human studies, which can be broadly classified into intervention and observational. Intervention studies include the randomised controlled trial (RCT) looking at physiological or psychological effects. RCTs are often the final piece of evidence for a claim, after data have been gathered from observational and other types of study. It is desirable to have more than one RCT showing the effect to be claimed. Mechanisms for the effects are desirable but not essential to know.¹³

Concluding remarks

Health claims on foods provide opportunities for marketing of foods with added value in terms of health, well-being and performance. Provided that strict criteria for the scientific substantiation of such claims are applied, and that the scientific evidence is translated into clear and balanced statements understandable for the intended consumer and taking into account the importance of the whole diet, foods

with health claims would provide well-documented alternatives for increasingly health-conscious consumers, for the benefit of consumer health. Furthermore, possibilities to develop and market such foods have the potential to focus on and promote nutrition as a main quality parameter with resulting improvements of the nutritional composition of a broader range of food products for the benefit of consumers in general.

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