

David P. Richardson

The scientific substantiation of health claims with particular reference to the grading of evidence

Received: 8 June 2005
Accepted: 6 July 2005
Published online: 21 July 2005

Sirs, following adoption of the proposed EU legislation on nutrition and health claims, the new law anticipates that a list of approved claims will be compiled by Member States within a 12-month period, and that, within a three-year period, the European Food Safety Authority (EFSA) and the Commission will develop an 'EU Register' (Commission of the European Communities, 2003; Council of the European Union, 2005). These permitted claims will be based on well-established, generally accepted knowledge from evidence in the scientific literature – the so-called 'generic' claims – and for all other 'innovative' and 'product-specific' health claims, an authorisation procedure will be developed that is based on substantiation by generally accepted scientific data.

A process for the scientific substantiation of health claims has been developed (PASSCLAIM) to underpin the EU regulatory developments (Richardson et al. 2003). However, there is an urgent need to define 'generally accepted scientific data' to take into account the overall concepts of grades of evidence as well as the use of appropriate qualifying language to communicate claims in terms that consumers can understand and trust.

The current paper outlines a process by which a health claim

and reduction of disease risk claims could be made on a food category, a food or one of its components that is based on the totality of the available data, and by weighing the scientific evidence into three major grades: 'convincing', 'probable' and 'possible'.

This evidence-based approach takes account of both emerging science and consensus science, and it supports the development of appropriate wording of claims to reflect the evidence on which the claim is based. The objectives are to protect consumers from false and misleading claims, promote fair trade and encourage innovation in the food industry (Richardson 1996; Byrne 2003; Korver et al. 2004).

European Commission Concerted Action Project: PASSCLAIM

In April 2001, the International Life Sciences Institute (ILSI Europe) initiated the Concerted Action (CA), supported by the European Commission on a 'Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM)' (International Life Sciences Institute Europe 2001). The PASSCLAIM built on the CA on Functional Food Science in Europe (FUFOSE), which suggested that claims for 'enhanced function' and 'reduced risk of disease' should be based on sound scientific evidence, using appropriate validated biomarkers (Bellisle et al. 1998). The FUFOSE consensus documents were published in the *British Journal of Nutrition* (Diplock et al. 1999). The results of the PASSCLAIM CA and the criteria for the scientific substantiation of claims have been published in the *European Journal of Nutrition* (Asp et al. 2003, 2004; Aggett et al. 2005).

Although nutritional and med-

ical sciences recognise the contribution that diet and individual foods or food components may make towards the reduction of risk of disease, current EU law prevents the communications of those benefits to consumers, whereas the law on medicinal products is established on a very broad basis that includes foods making preventative, therapeutic or curative claims. The new EU regulatory proposals (Commission of the European Communities 2003), however, will reflect the 'health-promoting' properties of foods and food components in such a way as to facilitate such claims for risk reduction to be made outside the medical scope of the term 'prevention'. This new concept of health claims reflects the fact that foods with health claims are primarily aimed at healthy individuals, recognising that the disease is not present and that the cause of chronic disease tends to be multifactorial, including dietary, behavioural, environmental and genetic factors. It also recognises that the modification of certain dietary components alone cannot ensure that a disease will not develop, since it does not affect the other confounding factors. Nevertheless the food(s) or food component(s) may help substantially to reduce the likelihood of getting the disease.

The new EU draft proposals on nutrition and health claims will hopefully overcome the potential for divergent and inconsistent interpretations and enforcement of existing European local regulation, guidelines and codes.

A process for the scientific substantiation of health claims

One of the main objectives of PASSCLAIM was to identify common new ideas, definitions, best

practice and a methodology to underpin current and future regulatory developments (Richardson et al. 2003). A key criterion for the scientific substantiation of a claim is to take into account the totality of the available data and the weighing of the evidence (Aggett et al. 2005).

A health claim must be based on a systematic and objective compilation of all the available scientific evidence. The compilation must be done in a balanced and unbiased way, and individual studies should be evaluated for rigour of design, appropriateness of methods and procedures, reliability of measures of intakes and outcomes, and sufficient statistical power etc. (Truswell 2001). The conclusions should illustrate the weight of scientific evidence, and the strength and consistency of the evidence will underpin the use of the term 'generally accepted scientific data'.

This assessment of the totality of the evidence should be sufficient to permit the conclusion that a change in the dietary intake of the food or food component will result in a health benefit and/or health outcome, including a change in disease endpoint.

Grades of evidence

The preamble of the proposed EU legislation states that health claims should only be authorised by EFSA after scientific assessment of the highest possible standard. Whilst no one would disagree with the basic principles of scientific substantiation, there is major concern on the part of the scientific community and industry about how to accommodate emerging science. The World Health Organisation (WHO 2004) and the World Cancer Research Fund (WCRF 1997) use four grades of evidence: 'convincing', 'probable', 'possible' and 'insufficient'. The EU has not yet considered the concept of grades

of evidence, but it is crucial to support scientific initiatives to find an approach where the term 'generally accepted scientific data' includes not only generic or well-established linkages between a food or a food component and a health benefit but defines 'generally accepted scientific data' to take into account the overall concept of the grades of evidence and the balance of probabilities that an association between a food or a food component and a health benefit will be refined (not reversed) by subsequent scientific research (see Table 1). The academic community should have a key role in identifying suitable scientific criteria on which health claims can be based. For example, the provision of insufficient evidence to support a claim is clearly inappropriate and would be misleading to consumers. However, depending on the state of the science and history of use, there is a need to embrace a system that stimulates, not stifles, academic research, product innovation and communication of nutrition and health messages to the public (Richardson 2004).

Netherlands proposal for a systematic approach for the development of a generic list of health claims in the European Union

In December 2004, The Netherlands Ministry of Health initiated

discussions on the establishment of an inventory of substantiated health claims to fulfil the obligations of Article 12 of the EU proposed legislation (The Netherlands Ministry of Health 2004). Member States, together with the EU Commission and EFSA, have been given the task to compile and adopt such a Community list.

The working procedure in The Netherlands is aimed at maximising cooperation and efforts in Member States whilst minimising duplication of actions. The basis of the proposed framework is:

- An inventory of foods and components, diets and botanicals based on national and international sources of knowledge.
- Judgement and classification of the foods and food components and their health relationships based on the strength and consistency of the scientific evidence in such a way as to underpin the definition of 'generally accepted scientific data'. The approach develops the PASS-CLAIM concept of a continuum of emerging and consensus science and it uses the WHO/WCRF terminology to create five categories based on the grade of evidence (see Fig. 1).

Insufficient

Categories 1 and 2 Insufficient substantiation; more data needed

Table 1 Qualifying language for the four grades of evidence in support of a health claim

Health claim	Grade of evidence	Qualifying language
Yes	Convincing	'Experts agree that scientific evidence supports...' <i>Modal verb 'will'</i>
Yes	Probable	'... Although there is scientific evidence supporting the claim, the evidence is not conclusive.' <i>Modal verb 'can'</i>
Yes	Possible	'Some scientific evidence suggests... However, the evidence is limited and not conclusive.' <i>Modal verb 'may'</i>
No	Insufficient	'There is little scientific evidence supporting this claim.'

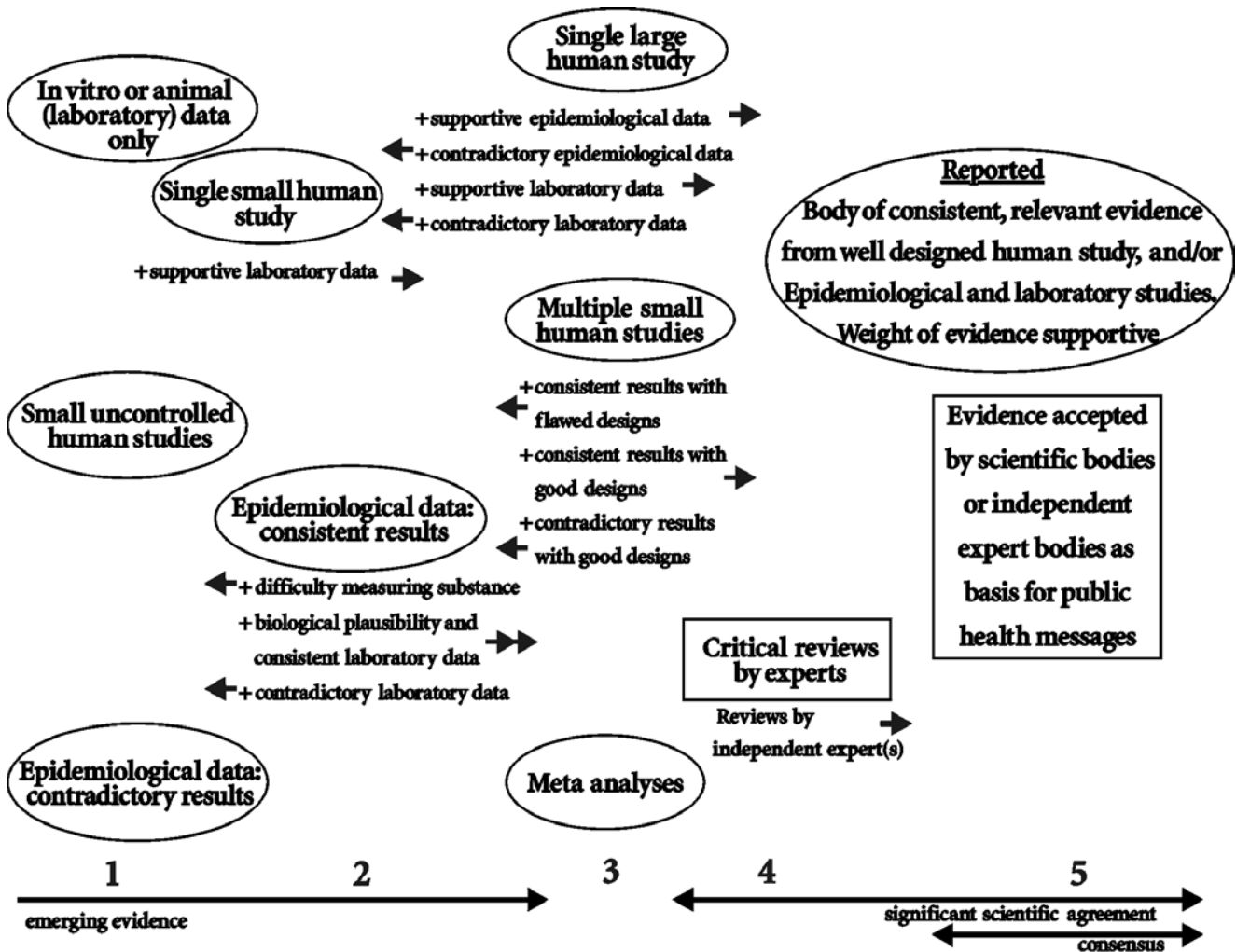


Fig. 1 Graphical representation for the grading of evidence in support of a health claim [Adapted from US Food and Drugs Administration (1999), Richardson et al. (2003) and The Netherlands Ministry of Health (2004)]

Probable/Likely (Possible)
Category 3 Positive outweighs the negative evidence; balance of probabilities justifies the diet/health relationship

Convincing
Category 4 Meta-analysis; peer-reviewed publications
Category 5 Text books, monographs, judgements by government-related organisations, scientific groups or expert organisations (e.g. WHO, EFSA, UK Scientific Advisory Committee on Nutrition (SACN) etc.)

The focus of the Dutch initiative

is to identify generally accepted relationships between foods and food components and health. The report reinforces the need to develop an acceptable procedure that takes into account the fact that scientific knowledge is constantly evolving and being refined. At this point, however, it becomes essential that this grading of the scientific substantiation be reflected in the terminology used in the communication of the health benefit on the product in order to allow consumers to be correctly informed and for them to be able to make informed choices. This

is even more critical when the same words can often have quite different meanings in the different languages of the European Union.

The wording and communication of claims

A key objective of the Commission is to ensure that health claims are relevant and understood by consumers. Consumer communication is complex and is unlikely to be a speciality of those involved in the evaluation of the scientific dossier submitted to substantiate a claim.

It is essential to give manufacturers flexibility in communicating messages regarding diet and health to reflect the intended consumer and the evolution of consumer knowledge. Hence it is important that any health claim that refers to general benefits of food and food components for good health or wellbeing must be formulated to reflect the specific evidence on which the claim is based and consumer understanding. The health benefits must not go beyond the scope of the evidence, confuse or mislead the consumer.

There needs to be not only a co-ordinated effort to promote the concept of appropriate grades of evidence from the scientific perspective but also in the development of suitable qualifying language to allow communication of claims in terms consumers can understand and trust. Although there are currently concerns that words such as 'may' and 'might' may be misleading based on some consumer research, it is worth considering the use and definition of such modal verbs (e. g. may, can, will) to reflect the strength of the evidence. The PASSCLAIM criterion that a health claim should be scientifically substantiated, taking into account the totality of the available data and by weighing of the evidence, provides the opportunity to establish different model qualifying language for the different grades of evidence. In the assessment of the diet/health relationships, the appropriate, illustrative language can be based on the analysis of the supporting scientific data (see Table 1).

Research is required in the different EU languages to explore and develop appropriate wordings and/or graphics to represent the level of certainty of the scientific evidence. If the levels of evidence are decided and defined more closely, the basis for scientific substantiation and the qualifying language would enable communica-

tions to be understood and trusted by consumers.

Consumer understanding of health claims

Consumer-related qualitative research undertaken by the UK Food Standards Agency (FSA) in 2002 concluded that health claims are of interest and relevance to consumers, but that their understanding of them is often partial and/or confused. Personal experience of a relevant health concern (i. e. if they or someone else close to them had issues with heart, bone or gut functioning) and the degree of confidence and trust in the source of the claim significantly influenced perception and understanding. Consumers seemed to be more confident about 'confident' verbs and adverbs rather than any predetermined or underlying scientific basis for a particular grouping of claims. There was particular confusion around the terms 'risk' and 'risk factor' with a substantial proportion of the sample of consumers believing there was no significant difference. Overall, the research indicated that the consumer's current perception of health claims is much less coherent, consistent and 'organised' than any scientific structure or qualifying language.

These observations from the FSA research reinforce the need to conduct consumer education and to evaluate understanding of a particular health claim depending on levels of knowledge. Academic research and market research carried out by the food industry on its intended consumers will be necessary to develop new, and refine existing, methodologies to demonstrate that consumers understand the claim in the context of the total diet and that they understand the relative level of science that exists to support the claim. For the purposes of this paper, the definition

of consumer understanding is that consumers are able to verbalise what the health claim is and what the product does (personal communication, ILSI Europe 2005).

Health claims should assist consumers to make informed choices. Claims are also intended to help consumers identify particular foods and food components and encourage greater consumption.

Nutrition and health claims can exert an effect on consumer behaviour to an extent that consumers:

- Are aware of the claim
- Understand the claim
- Make appropriate health inferences from the claim
- Consider the claim credible
- Attach attitudinal relevance to the claim i. e. the claims are appealing and motivating
- Translate the claim into action e. g. purchase intent

From the food industry perspective, claims are used to identify, market and promote products. Survey and questionnaire approaches to perception of health claims already make a substantial contribution to consumer understanding. However, there is a surprising lack of systematic research in the area on what health benefits appeal to consumers.

The importance of existing and new research methodologies will increase substantially when the new EU regulations on nutrition and health claims requires food companies to provide evidence that the health claims they use on foods and food components are understandable and not misleading to the average consumer.¹

¹ Article 5.2 states that the use of nutrition and health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects expressed in the claim. 'Average consumer' means the consumer who is reasonably well informed and circumspect (Article 2.8). Note also 'average individual' is defined by the Institute of Economic Affairs, March 2005 as someone alert to the circumstances in which he is living. www.iea.org.uk

Conclusion

Consumer confidence in claims is a critical issue from the point of view of the producer as well as the consumer. Setting out a common approach for the substantiation of claims is an important step in the use of health claims around the world so that consumers can be assured that claims made on foods and food supplements are well founded.

Developing the scientific criteria for the substantiation of health claims has already involved collaboration and debate amongst the different sectors, including scientists from academia and research institutes, industry, consumer groups and regulatory bodies. Further work will be necessary to harmonise terminology and to elaborate a process of substantiation that draws on best practice around the world and reflects emerging as well as consensus science.

There needs to be an objective process and a transparent assessment of scientific evidence to support a submission for a health claim related to a food or a food component. The substantiating evidence should be proportionate to the claim and take into account the totality of the available data.

The purpose of this paper is to contribute towards the development of a practical framework for the evaluation of scientific evidence and the compilation of a scientific dossier in support of a claim. It is important to have common approaches to establishing the science base for public health messages and for claims so that resources can be used effectively for the benefit of consumers and for the large and small companies who develop and market products.

Any process of substantiation of a health claim should (1) benefit consumers by providing information on healthful eating patterns that may help reduce the risk of diseases such as heart disease,

some cancers and osteoporosis; (2) provide consumers and healthcare professionals with a reference point and a measure of confidence that label claims are supported by sound scientific data; (3) provide the claimant with a return on their research investment as well as a measure of insurance when dealing with regulatory agencies; (4) stimulate new research to fill in the knowledge gaps revealed during the course of the scientific reviews.

One of the most important questions to consider is how the health benefits can be communicated effectively to consumers. To ensure the consumer's right to reliable information, the process for the verification of health claims is a critical issue of importance for regulators, the food industry, the advertising industry, nutritionists and consumer representatives.

■ **Acknowledgement** The production of this paper was supported by the Council for Responsible Nutrition, UK.

References

1. Aggett PH, Antoine J-M, Asp N-G, Bellisle F, Contor L, Cummings JH, Howlett J, Müller DJG, Persin C, Pijls LTJ, Rechkemmer G, Tuijelaars S, Verhagen H (2005) PASSCLAIM – Process for the assessment of scientific support for claims on foods. Consensus on criteria. *Eur J Nutr* 44(Suppl 1):1/5–1/30
2. Asp N-G, Cummings JH, Howlett J, Rafter J, Riccardi, G, Westenhoefer, J (2004) PASSCLAIM – Process for the assessment of scientific support for claims on foods. Phase II: moving forward. *Eur J Nutr* 43(Suppl 2):1–183
3. Asp N-G, Cummings JH, Mensink RP, et al. (2003) PASSCLAIM – Process for the assessment of scientific support for claims on foods. Phase I: Preparing the way. *Eur J Nutr* 42(Suppl 1):1–119
4. Bellisle F, Diplock AT, Hornstra G, et al. (1998) Functional food science in Europe. *Br J Nutr* 80:1–193
5. Byrne D (2003) Health, nutrition and labelling. *Food Sci and Technol* 17: 26–28
6. Commission of the European Communities (2003) Proposal for a Regulation of the European Parliament and of the Council on Nutrition and Health Claims made on Foods. Brussels, 16th July 2003, COM (2003) 424 final
7. Council of the European Union. Proposal for a Regulation of the European Parliament and of the Council on Nutrition and Health Claims made on Foods. Outcome of proceedings (2005) 9807/05, 7th June 2005, Brussels
8. Diplock AT, Aggett PJ, Ashwell M, et al. (1999) Scientific concepts of functional foods in Europe: consensus document. *Br J Nutr* 81:51–519
9. Food Standards Agency (2002) Health Claims on Food Packaging: Consumer-related Qualitative Research Final Report, September 2002. London: FSA
10. International Life Sciences Institute (ILSI) Europe (2001) A European Commission Concerted Action Programme supported by the European Commission DG Research, Thematic Programme 1 Quality of Life and Management of Living Resources, Key Action 1 – Health, Food and Nutrition ILSI Europe, 83 Avenue E Mounier, Box 6, B-1200 Brussels
11. International Life Sciences Institute (ILSI) Europe (2005), Expert Group on Consumer Understanding of Claims (personal communication). ILSI Europe, 83 Avenue E Mounier, Box 6, B-1200 Brussels
12. Korver O, Kuhn MC, Richardson DP (2004) Functional Foods Dossier: Building Solid Health Claims. How to Prepare the Scientific Dossier for Health Claims of European Functional Foods. Practical Industrial Guide: 1–185, The Netherlands, Wageningen: FoodLink Forum
13. Richardson DP (1996) Functional foods – shades of grey: an industry perspective. *Nutr Rev* 54(11):S174–S185
14. Richardson DP, Affertsholt T, Asp N-G, et al. (2003) PASSCLAIM – synthesis and review of existing processes. *Eur J Nutr* 42(1):96–111
15. Richardson DP (2004) Food regulations and health claims—an industry perspective from Europe. Proceedings of the Australian Academy of Technological Sciences and Engineering Symposium. 15th/16th November 2004, Adelaide (in press)
16. The Netherlands Ministry of Health (2004) Netherlands Proposal for a Systematic Approach for a Generic List of Health Claims, VWA (Dutch Food Authority) Nutrition Centre
17. Truswell AS (2001) Levels and kinds of evidence for public health nutrition. *Lancet* 357:1061–1062

18. US Food and Drug Administration, Centre for Food Safety and Applied Nutrition, Office of Special Nutritionals (1999) Guidance for Industry. Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements. Washington D. C.: USFDA
19. World Cancer Research Fund/American Institute for Cancer Research (1997) Food, Nutrition and the Prevention of Cancer: a Global Perspective. Washington D. C.
20. World Health Organisation (2004) Diet, Nutrition and the Prevention of Chronic Diseases: Report of a Joint FAO/WHO Expert Consultation. Geneva: WHO Technical Report Series 916

D. P. Richardson
DPR Nutrition Limited
34 Grimwade Avenue
Croydon (Surrey) CR0 5DG, UK