Evidence based nutrition and health claims on foods: a renaissance?

Although the general principles of nutrient requirements and functions are known, the nature of their dose relationship is poorly characterised, and it is unquestionably difficult to determine accurately marginal deficiencies and excess, that is, as it is commonly put, to determine nutritional status within the extremes of marked deficiency and incipient toxicity (Gibson 2005). There have not been enough resources available to support the necessary underpinning research. On the other hand in the past 20 years there has emerged within the food industry great interest in developing 'functional foods'. There is no commonly accepted definition for such a food. In some instances 'functionality' has been claimed on the basis of fortification with an essential micronutrient such as iron or a vitamin, whereas in other instances there is a distinctive innovation such as that deriving from the use of phytosterols or phytosterols. A recent European Union Concerted Action (FUFOSE) reviewed the nature of functional food science in Europe and made some proposals for its systematisation essentially within the context of Evidence Based Nutrition (Diplock *et al.* 1999). In this way concepts of functionality can be seen as a means of enthusing nutritional sciences.

A food, it was suggested in FUFOSE, could be regarded as 'functional' if it demonstrated an ability to affect beneficially one or more target functions in the body, beyond adequate nutritional effects, in a way that is relevant to either an improved state of health and well-being or reduction of risk of disease or both. The design and development of functional foods were seen as key scientific challenges that should be based on scientific knowledge, and it was envisaged that the development of such products would have the potential to improve health and to respond to societal demands and economic pressures affecting lifestyle, food safety and security, as well as accommodating product adaptation for preservation and reduced calorie content, reconciled by a continued need for an effective delivery of other essential

nutrients. As might be appreciated, this is seen very much in the context of the developed world and its socio-economic and demographic profile in which, for example, it is expected that in 30 years time 20–24% of the population will be over 65, compared with 14–17% at present. Even so, it is quite conceivable that foods with some demonstrable specific 'functionality' would have a role in other communities. Furthermore, there is no reason why the concepts outlined below should not be applied to natural or unprocessed foods and food components. The key element is being able to demonstrate that functionality (Diplock *et al.* 1999).

FUFOSE envisaged that this demonstration would depend on clear evidence of an association between consumption of a food, or food ingredient, and a specific response that either reflected directly an 'improved state of health and well-being' or a 'reduced risk of disease'. Clearly such relationships are not always easy to show, not least because of the time scale involved and of the numerous confounders that might influence the outcome during that time. FUFOSE therefore proposed a strategy based on the use of intermediate markers that represented intermediate or surrogate events and outcomes related to function or disease risk. It also appreciated that there was a need to develop and validate such markers.

However, FUFOSE did not consider fully how such markers could be used to establish a claim for a food's 'functionality' or effects. Some general claims are allowed within some existing national and international legislation, but it is by no means straightforward for specific products or food ingredients to have specific or general claims allowed, and the varying provision that is made available for 'generic' or well-established claims and for 'innovative' claims has been recently reviewed (Richardson *et al.* 2003). This review was part of a further EU Concerted Action: The Process for the Assessment of Scientific Support for Claims on Foods (Aggett *et al.* 2005). The purpose

of which was to produce a generic tool and principles for assessing the scientific support for health-related claims for foods and food components; to evaluate critically existing schemes which assess the scientific substantiation of claims; and 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.

This was an extensive exercise involving almost 200 participants from, amongst others, academia, industry, consumer and regulatory bodies. It produced a template of criteria which would provide a reasonable assurance that the data underpinning a health claim are adequate and that claims can be considered valid. The criteria are as follows:

1. The food or food component to which the claimed effect is attributed should be characterised.
2. Substantiation of the claim should be based on human data, primarily from intervention study is 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 group's 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 unclaimed benefit cannot be measured directly, studies should use markers.
4. Markers should be:
 - biologically valid in that they have a no relationship to the final outcome and their variability within the target population is known.

- methodologically valid with respect to their analytical characteristics.

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

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

The PASSCLAIM consensus report (Aggett *et al.* 2005) discusses these points in further detail, particularly the weighting of evidence, the nature of controls, dose response relationships and the nature of markers, but the report does not explain how studies should be designed and performed. It indicates the need for a sound evidence based approach to nutritional issues and questions if a claim is to be established. The justification of any claim is little different from establishing any new item of knowledge and one hopes very much that these criteria will be seen to have a broader relevance as a means of re-expressing benchmark approaches for the conduct of nutritional science in general.

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References

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