

## Workshop Report

### Food & health forum meeting: evidence-based nutrition

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(Received 23 July 2010 – Revised 27 July 2010 – Accepted 29 July 2010 – First published online 23 September 2010)

#### Abstract

The present report summarises a meeting held by the Food & Health Forum at the Royal Society of Medicine, London, on 27 May 2010. The objective of the meeting was to review the problems associated with the use of evidence-based nutrition and to discuss what constitutes the efficacy for foods and food constituents and how the strength and consistency of the evidence can be assessed and adapted to circumstances in which health claims are to be used on food products. The meeting highlighted the limitations with the present evidence-based nutrition models with the prospect that this may have long-term consequences for nutrition science and ultimately the consumer who may not benefit from new science that could have an impact on health.

**Key words:** Evidence-based nutrition; Food labelling; Health claims

#### Introduction and objectives of the meeting

A regulation on nutrition and health claims made on foods was introduced in the European Union in 2007 (Regulation EC 1924/2006). This regulation provides the opportunity to develop and use nutrition and health claims on foods in Europe, including functional and reduction of disease risk claims<sup>(1)</sup>. Voluntary codes of practice on health claims for foods had been applied by some European countries while awaiting the regulation, and valuable experience was gained with scientific evaluation and use of health claims during that period. Building on this experience and an International Life Sciences Institute (ILSI)-Europe-initiated European Concerted Action, 'Functional Food Science in Europe' (FUFOSE)<sup>(2)</sup>, a further European Commission-supported action project, 'Process for the Assessment of Scientific Support for Claims on Foods' (PASSCLAIM)<sup>(3)</sup> was developed. PASSCLAIM defines a number of generally applicable criteria for the scientific support of claims, emphasising the need for direct evidence of benefits to humans, recognising the usefulness of markers of intermediate effects and emphasising that

the effects should be both statistically and biologically meaningful. Since its publication in 2005, PASSCLAIM has been useful in assisting those seeking to establish a health claim to prepare their supporting dossiers as well as in aiding the European Food Safety Authority (EFSA) to evaluate the scientific evidence for the claim. The PASSCLAIM criteria were developed to be, and are considered to be, a robust tool for evaluating the data submitted in support of health claims on a food ingredient or foods<sup>(4)</sup>. PASSCLAIM thus provides a strong template for international use in assessing the completeness and fitness for purpose of the evidence being submitted in support of a claim. It is thus a standard against which the quality of existing evidence can be transparently graded by risk assessors, risk managers and policy developers. The PASSCLAIM criteria and their use to support substantiation or justification of a claim are not necessarily the sole determinants of whether or not a claim should be allowed. Claims on foods have educational and public health purposes, the potential benefits of which may well be considered to outweigh any deficit in the quality of the evidence as

**Abbreviations:** EFSA, European Food Safety Authority; FUFOSE, Functional Food Science in Europe; PASSCLAIM, Process for the Assessment of Scientific Support for Claims on Foods.

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assessed by the PASSCLAIM criteria. In this context, it is noteworthy that there are in present use several public health nutritional and dietary health messages, which would not be substantiated against the PASSCLAIM criteria but which have, nonetheless, been enacted by policy-makers, taking into consideration other interests and stakeholders. This pragmatic approach is at variance with the concepts of evidence-based nutrition and with the way in which EFSA is evaluating the evidence it receives and subsequently advising the European Commission on the validity of claims. Additionally, it could be argued that the Commission, as Risk Manager, is not considering other relevant issues when it decides to allow or disallow specific health claims. Consequently, the nature and number of claims that are being rejected have raised questions about how the advice of those evaluating the submitted evidence in support of claims is being qualified when it is presented to risk managers and about the subsequent process of risk management.

A 'Food & Health Forum Meeting' on evidence-based nutrition was held at The Royal Society of Medicine in London on 27 May 2010. The purpose of this meeting was to review the questions associated with evidence-based nutrition and to discuss what constitutes the efficacy for foods and food constituents and how the strength and consistency of the evidence can be assessed and adapted to the circumstances in which claims are to be used. Specific questions were addressed concerning how to:

1. Define the 'totality of the evidence'.
2. Discuss the strength and limitations of different sources of evidence.
3. Determine the appropriateness of the application of evidence-based medicine, which relies on randomised clinical trials to evaluate the efficacy and safety of drugs for individual patient care and for public health policy, to the assessment of dietary factors and health.
4. Develop a scientific framework to assess the amount and quality of the evidence and the overall levels of certainty about food and health relationships.
5. Identify the functional biomarkers within the normal healthy homeostatic ranges.
6. Utilise, develop and validate the physiological risk factors (biomarkers) and behavioural factors (including dietary risk factors) in evidence-based nutrition.
7. Apply evidence from preclinical and clinical studies and biomarkers developed for disease identification and progression to the normal healthy population.
8. Provide policymakers and regulators with a practical scientific framework for making decisions and recommendations about diet and health.

The present article summarises the presentations and discussions from the meeting.

## Summary of presentations

Professor Peter Aggett (School of Medicine and Health, Lancaster University, Lancaster, UK) opened the proceedings by outlining the above issues and describing the emergence of evidence-based nutrition in the context of FUFOSSE and the derived strategy of using this concept to enhance the standard and international competitiveness of the agri-food industry within the European Union. Professor Aggett explained the six PASSCLAIM criteria that can be used as a generic guidance tool for the evaluation of portfolios of evidence submitted for the scientific substantiation of claims<sup>(3)</sup>.

Presently, the primary source of information for claims comes from the evidence supplied from epidemiological intervention and observational studies in human subjects. Animal and *in vitro* data can be used as supportive evidence. In the case of drugs, the 'gold standard' for definitively substantiating a causal relationship is the randomised clinical trial. This trial design generates evidence which can be more effectively evaluated against standard criteria of causality than can other types of evidence such as observational studies. Nonetheless, in nutrition science, all forms of evidence, and the body of evidence as a whole, can be evaluated against the criteria of causality, and part of this exercise, as with any risk assessment, is to set the assessment in the context of the known uncertainties and variabilities of the studies and the populations involved. Usually, randomised clinical trials evaluate the efficacy of an intervention where the causal chain between the agent (food) and the outcome (blood pressure, body weight, blood lipids, etc.) is relatively short and simple so that straightforward inferences can be drawn in a relatively short period of time. FUFOSSE and PASSCLAIM illustrate how intermediate or surrogate markers can be developed and applied to studies to generate more immediate and less confounded outcomes in prospective and, in some cases, observational studies. Unfortunately, it is almost inevitable that causal chains in nutrition outcomes involve complex individual variability in the biological response, measurement of often subtle changes in markers, cultural influences on food habits, economic and geographic effects and motivation to make behavioural changes. The fact that a single food or food component may have more than one effect related to an enhanced function or reduced risk claim adds to the complexity of the question of what represents the 'totality and causality' of the evidence. PASSCLAIM comments on the use of intermediate markers of outcome and on the assessment of causality but does not give specific advice on weighing the impact of confounders, uncertainties and variabilities. This is very much a specific aspect of the risk assessment.

Professor Aggett highlighted some of the present issues regarding the evidential science about health claims, including the quality of data, the limitation of biochemical assays and consideration of all available physiological,

dietary and clinical information. He also suggested that serial observations and intervention trials are encouraged but very few are available and he questioned whether all postulated claims are physiologically reasonable and responsible. All these points demonstrate the complexity and scope of the 'evidence-base' for health claims and indicate that there may be scope for a more nuanced critique of the evidence portfolios to enable risk managers and regulators to generate qualified or conditional claims where there is a weighting or grading of the evidence as in the USA; e.g. convincing, probable, possible or insufficient: A,B,C,D. PASSCLAIM does not consider qualifying the evidence in the context of generating qualified health claims: it proposed a standard against which evidence could be gauged. The weighting of that evidence, and the subsequent qualification, if any, of a claim is a complex issue which is not easily systematised, and would need an informed judgement and decision. Thus, PASSCLAIM foresaw a need in the advisory and regulatory process for intelligent interpretation of the evidence and, perhaps, further independent informed scientific advice for the regulators on options for allowing, qualifying or rejecting claims. In this process, Professor Aggett suggested that risk managers might apply the precautionary principle in allowing and/or qualifying the claims on some foods or food components in the context of potential public health benefits which might be considered more imperative than awaiting further evidence. These are political decisions reflecting Winston Churchill's view that 'Scientists should be on tap; not on top'<sup>(5)</sup>.

Professor Hans Verhagen (National Institute for Public Health and the Environment, Bilthoven, The Netherlands) described the processes involved in the scientific evaluation of health claims and outlined EFSA's experience based on his recent paper<sup>(6)</sup>. European Union regulation 1924/2006 distinguishes between nutrition claims and health claims. Health claims can be subdivided into function claims based on generally accepted scientific data (Article 13.1), function claims based on newly developed scientific data (Article 13.5) and reduction of disease risk claims and claims targeted at children (Article 14)<sup>(7)</sup>. The general principles of the European Union Regulation 1924/2006 are that health claims should not be false or misleading and that they cannot claim to prevent or cure diseases. Within that framework, the claim has to be scientifically justified and there has to be a benefit from normal consumption of the food. All pertinent scientific data (in favour and not in favour) of the health claim are required by EFSA and their scientific assessment is provided to the European Commission.

In 2008, EFSA rejected seven of the first eight food health claims it evaluated. The first set of eight opinions on claims drew praise from consumer groups and general support from scientists but concern from the food industry<sup>(8,9)</sup>. EFSA have reported that the quality of literature cited for some claims is far from optimal either because the

references were incomplete, vague, inaccessible and proprietorial or that the scientific substantiation of the references was questionable. EFSA suggests that where there is a well-established consensus supported by scientific sources, there is no need to review the primary scientific studies. However, there is a need to review the primary studies for those claims for which there is no established consensus, based on authoritative scientific sources. All the data available to EFSA from which scientific conclusions can be drawn (supportive/non-supportive) are considered pertinent by EFSA and weighed for the evidence. There are three possible outcomes from EFSA's scrutiny of the evidence: a cause-and-effect relationship has been established; a cause-and-effect relationship has not been established; insufficient evidence has been given to enable a decision to be made. EFSA has published several hundreds of opinions on health claims, several of which have been positive, many negative and a few for which there is insufficient evidence.

According to Professor Verhagen, another issue to consider with health claims is consumer understanding and this element is not assessed by EFSA. He provided data showing that consumers in the USA were unable to distinguish between communications that reflected the different strengths of evidence used in the US system, and that they made little or no distinction between different types of claims, i.e. they could not distinguish clearly between nutrient content claims, structure–function claims and health claims. Members of the audience asked that if the consumer is unable to differentiate between claims, what is the point of the EFSA bureaucratic process and is the process stifling innovation in the food industry? Professor Verhagen suggested that as consumers understand nutrition and health claims differently from scientists and regulators, that innovation in industry can proceed via approved nutrition claims and approved general function claims. He concluded that the market and the shelves in the stores will not be empty; rather they will look different in the years to come. Clearly, there is a substantial need to undertake research in Europe into consumer understanding of health claims, including questions relating to the use of appropriate qualified health claims that are proportionate to the evidence and not misleading.

Professor Chris Seal (School of Agriculture, Food and Rural Development, Newcastle University, Newcastle-upon-Tyne, UK) described the connection between the consumption of whole grains and cardiovascular health and presented the sources and weight of evidence supporting this connection. In North America, Sweden and the UK, there are presently health claims allowed for use on whole-grain foods with specific dietary recommendations for whole grain intake in North America and Denmark. The evidence to support these dietary recommendations and health claims has been based mostly on evidence from observational studies that show a strong link between whole grain consumption and reduced disease risk at

the population level. These data show strong inverse relationships, i.e. with increased consumption, risk of heart disease, type 2 diabetes and some cancers are reduced. The strongest relationships have been found for CVD, where the reduction in risk between the lowest and the highest whole grain consumers is estimated at between 20 and 40%<sup>(10)</sup>.

Nutrition scientists recognise two types of evidence confirming the links between diet/food/nutrients and health: (1) primary: original studies, based on observation or experimentation on subjects; (2) secondary: reviews of published research, drawing together the findings of two or more primary studies. A descending hierarchy of evidence for nutrition research includes consensus reports from national and international expert panels and authoritative statements, human intervention studies, observation/ecological studies, animal and *in vitro* studies and, lastly, evidence of tradition and history of use.

Professor Seal indicated that while observational data are powerful indicators of the relationship between whole grain intake and improved health, they do not demonstrate causal relationships. Causal relationships can only be demonstrated from dietary intervention studies. Three intervention studies using wholegrain foods were described in some detail by Professor Seal, which included The CHEWit Study<sup>(11)</sup>, The Grainmark Study<sup>(12)</sup> and The WHOLEheart Study<sup>(13)</sup>. The limitations in these studies included varying degrees of volunteer control, differing range of wholegrain foods used, different and varying advice given about eating whole grains and varying degree of purpose/motivation for volunteers. Two out of the three studies showed 'positive' effects of increased whole grain consumption, but Professor Seal questioned whether these differences could be explained? Were they 'real' metabolic differences or were the differences due to experimental design? According to Professor Seal, there are many problems associated with all food-based intervention studies, namely: changing the diet in free-living intervention studies is not easy, particularly in complex food-based systems; compliance is always an issue particularly in studies with longer durations (biomarkers may help resolve this problem); should studies use volunteers who are 'at risk' or who should be expected to change? Professor Seal suggested that there is no simple solution and questioned whether intervention studies should still be seen as the 'gold standard' and weighted more strongly than observational studies. He also questioned whether we can design intervention studies which are 'more effective' in demonstrating cause-and-effect relationships<sup>(14)</sup>.

Professor Seal was asked whether we could learn from the lessons about using observational studies for the use of pharmaceutical hormone replacement therapy where observational studies showed little or no risk, but true intervention studies showed risk. Professor Seal said that observational studies for foods indicated what happens over a lifetime of consumption, whereas food intervention

studies only change the diet over a short period of time and that this is different from the medical paradigm.

Professor Seal was asked whether the complexity of CVD brings into question the biomarkers being measured and whether there is a need for different markers and maybe more valid biomarkers. Professor Seal suggested that a 'joined-up' approach was needed by research authorities for public health to provide funding in the right areas.

Bridget Benelam (British Nutrition Foundation, London, UK) explained how satiation and satiety are part of a complex network of controls that affect energy intake. She also explained the present status of health claims relating to satiety. Any food or drink consumed has some effect on satiation and satiety, so it is important to understand whether particular foods, drinks or ingredients can have consistently differing and meaningful effects on satiety and subsequent energy intake at a feasible level of consumption. A number of food components, including protein, fibre and alcohol, have been found to have effects on satiety. However, the factor that appears to have the greatest effect on the satiating properties of foods is their energy density. Similar to internal appetite sensations, external cues to eat also play a role on affecting eating behaviour and energy intake – the interconnection between these phenomena is complex and it is important to consider both these internal and external influences when considering eating behaviour in free-living people. She explained that satiety health claims made under Article 13.1 can describe or refer to 'Slimming, weight control, an increased sensation of satiety or the reduction in available energy from the diet'. Satiety claims can also be made under Article 13.5 (claims based on newly developed scientific evidence). Fifty claims related to satiety have been submitted to EFSA for evaluation and most are in progress. To date, no health claims related to satiety have been given a positive EFSA opinion. Cause-and-effect relationships have not been established for many products. It is clear that a greater evidence base is needed for the approval of satiety claims based on the present system. The question of how claims about satiety are perceived by consumers was posed. She also cited Blundell<sup>(15)</sup>, who considers that there are many outstanding questions about health claims on satiety. These questions include:

1. Can a change in appetite be useful even without a change in energy intake?
2. If a reduction in energy intake is observed, at what point does this become useful?
3. Can a reduction in energy intake at a single meal translate into a reduction over a whole day, and if so, would this occur over subsequent days?
4. Will these changes result in weight management?

A member of the audience commented that only macronutrients have been considered as having an effect on satiety. The addition of fruit and vegetables in the diet

reduces energy density and therefore the micronutrient composition of the diet may also be important in terms of satiety.

Professor Ian Rowland (Department of Food and Nutritional Sciences, University of Reading, Reading, UK) outlined the evidence for the health benefits of pro- and prebiotics and considered the present opinions from EFSA. Despite considerable evidence for efficacy in a number of areas, probiotics currently have a poor profile, in particular because of negative opinions from EFSA. The negative opinions were mainly due to insufficient characterisation of the micro-organism(s) concerned. To date, probiotics research has concentrated on establishing clinical efficacy (often in patients). Professor Rowland suggested that future studies to satisfy EFSA health claim criteria need to concentrate on healthy/at-risk subjects – not patients, reducing risk of disease, underlying mechanisms involved in the beneficial effects and the characterisation of species and strain of microbe involved. However, present research, confirmed by meta-analyses and efficacy data, indicates that some probiotics do have beneficial effects (e.g. towards antibiotic-associated diarrhoea<sup>(16)</sup>, irritable bowel syndrome<sup>(17)</sup>, necrotising enterocolitis<sup>(18)</sup>, rotavirus infection) but this has not translated into approved health claims. According to Professor Rowland, this is, in part, a procedural problem in terms of lack of clarity about the criteria that need to be met in the supporting dossier, but there is also a need to develop more information.

The evidence for health benefits of prebiotics is less well developed than that of probiotics. There are reasonably sized intervention studies indicating that prebiotics can increase Ca absorption and bone mineral density in adolescents<sup>(19)</sup> and reduce infection in babies and infants<sup>(20)</sup>. Studies have been done mostly in healthy subjects. One of the main claims for prebiotics is that they beneficially modulate the intestinal microbiota by increasing the proportion of beneficial bacteria, usually bifidobacteria. While this is unquestionably the case, doubt has been cast on the significance of these changes in terms of human health. This means that increased bifidobacteria as a health claim needs further research support. More human interventions are also needed to establish the health benefits independent of, or beyond, any bifidogenic effect.

Professor Hans Biesalski (Department of Biological Chemistry and Nutrition, University of Hohenheim, Stuttgart, Germany) reviewed the present antioxidant controversy and considered studies needed to demonstrate their efficacy. According to Professor Biesalski, the recent poor profile of antioxidants has originated from studies where there was a high-dose supplementation. He proposed that the high-dose supplements are in the realm of pharmacology, not of nutrition. Pharmacology, unlike nutrition, is based on a disease-related benefit–risk philosophy. Professor Biesalski described the scientific basis for the use of antioxidants in clinical studies: epidemiological

studies usually show that a low intake of one or more antioxidants may promote a disease related to ‘oxidative stress’. The hypothesis therefore is that supplementation with one or more antioxidants should reduce the risk of the disease. However, epidemiological studies deal with intake data from complex nutrients and dosages that do not exceed the dose which might be achieved via nutrition. Epidemiological studies show that a low intake of one or more micronutrients is as a consequence of a poor or imbalanced diet. A poor intake of micronutrients including antioxidants is not healthy, neither in the long term nor in the short term, but in developed countries like the UK and Germany, it is claimed that an intake below recommendations does not exist and deficiency only occurs in rare cases. It is difficult to assess whether intake of micronutrients is suboptimal or deficient but malnutrition has a negative impact on the quality of life, especially in the elderly. An inadequate supply of micronutrients, including antioxidants, especially in childhood and early adulthood, promotes the occurrence of chronic diseases in later life. Studies are needed which evaluate the effect of micronutrients in populations with either low intake (short latency effects) or higher demand (long latency effects) of micronutrients.

Professor Biesalski suggested that studies examining the biological effects of food or single nutrients should have a plausible rationale and that observational studies may fulfil these conditions. As a demonstration of plausibility, Professor Biesalski cited the example that mild vitamin A deficiency results in morphological changes of the respiratory epithelium without any clinical signs but with subsequent increased risk for respiratory tract infections. It is known from the National Health and Nutrition Examination Survey 1991 study that the relative risk for bronchitis increases significantly in the lowest quartile of intake for vitamin A<sup>(21)</sup>. Vitamins A and D regulate the immune function and it has been shown that the administration of cod liver oil (containing vitamins A and D) significantly reduces respiratory tract infection in children<sup>(22,23)</sup>. It should be possible to target nutritional intervention with micronutrients to special risk groups which have a higher demand based on plausibility data. However, the risk group needs to be clearly defined.

Professor Biesalski commented that epidemiological studies looking at short-term effects of low intake of micronutrients provide important data at typical intakes and indicate that acute diseases are related to suboptimal intake. Low intakes can be compensated via adequate nutrition. Long-term effects, when there is a higher demand, have similar consequences to short-term effects but dietary compensation for an increased demand is, in many cases, impossible. In both cases, it is important to define the target population.

Professor Renger Witkamp (Wageningen University and TNO Quality of Life, Wageningen, The Netherlands) presented information on the robustness of homeostasis

and early markers of disease and the challenges in nutrient and health research. The present predominantly pharmaceutical approach to evidence-based nutrition, largely based on clinical end points and biomarkers for disease, has only limited value in testing positive health effects of foods and food supplements. Developments in the different 'omics' technological fields (transcriptomics, metabolomics, etc.) and the integration into systems biology mean that it is now possible to model biomarker profiles and to translate these into dynamic processes. In an individual, homeostasis acts to maintain biological processes in balance which is reflected in clusters of functional biomarkers that are kept within a certain range. Early signs of homeostatic disturbance as observed during the onset of disease may be detected using a biomarker profile approach. In a static situation, processes such as a chronically increased inflammatory status, clusters of cardiovascular risk parameters and changes in metabolic fluxes may already be used as indicators of suboptimal health well before there is a sign of disease. A broader and probably more predictive indication of health status is obtained by measuring the robustness (resilience) of process homeostasis in an individual. To measure the robustness of homeostasis, methods known as challenge tests are introduced in nutrition and health research. These include variations of oral glucose and lipid tolerance tests, organ function tests, exercise or even psychological stress challenges. Although some of these tests, for example, the glucose tolerance test, are not new at all, the combination with new bio-analytical technologies (micro-array analysis and metabolomics) and calculation power makes them particularly useful to test health-improving effects of nutrients, foods and nutritional products. Challenge tests look promising for quantification of phenotypic changes and health effects of nutrition based on homeostatic adaptability but there are some remaining issues, including the nature of the challenge, the force of the stimulus and accepted designs and validation. Based on robustness of homeostasis and monitoring by process (e.g. cognitive testing, appetite and postprandial wellness), challenge tests provide valuable tools where fewer people and better measurements are used.

### Discussion

There are clearly limitations with the present evidence-based nutrition models used to produce meaningful health claims that can be used by the food industry and consumers. Some of the reasons for the rejection of health claims include the lack of characterisation of the food or food constituent, lack of validated markers, poor study design and inappropriate extrapolation to give a conclusive cause and effect. An alternative approach would be to look at the probability of association between a food and an effect rather than looking for conclusive proof of cause and effect. This may be a more pragmatic way

forward in nutrition science and is consistent with the legislation. Presently, EFSA provides a 'yes or no' opinion for the approval of a health claim with the additional opportunity to suggest that insufficient evidence has been provided, but this may not be a suitably proportionate response in measuring the strength of the evidence. There may be scope for the generation of qualified or conditional claims, where there is a clear scientific framework for assessing the strength, consistency and biological plausibility of the evidence to support a particular claim, e.g. convincing, probable, possible or insufficient; strong, moderate or weak, or other suitable adjectives or graphical means of reflecting the evidence. PASSCLAIM does not consider qualifying the evidence in the context of generating qualified health claims. In this regard, there is concern that although the risk assessor's advice to the Commission considers the quality and strength of the evidence, the European Union is missing opportunities to allow qualified health claims which could be used to support public health nutrition and health improvement strategies.

It is essential that the regulation and its interpretation are fit for purpose. What is required is clear guidance to protect the consumer and to guard against dishonest food labelling. A member of the audience emphasised that health and safety and health improvement are different issues which should be approached differently. Qualified health claims would be a positive development in that they would assign some 'intellectual credit' both to consumers and to the food industry.

If conclusive proof of cause and effect is required, concerns have been raised that industry does not have the finances or resources to give EFSA what they require, with experts saying that the level of evidence is so high that it may not even be achievable scientifically, and that very few claims will ever be approved for food and drink products. Where epidemiological evidence is strong and the intervention evidence is not as good, a different approach to the hierarchy of evidence is required. The relative weighting of intervention *v.* other types of studies, including observational studies, should be realigned. EFSA appears to be placing particular emphasis on evidence from randomised clinical trials, whereas, as was appreciated by PASSCLAIM, other sources of information such as observational studies might suffice. Emerging and possibly superior technologies, including markers arising from nutrigenomics, proteomics and metabolomics, may provide the intermediate markers envisaged by FUFOSSE and PASSCLAIM, which would enable better determination of qualitative and quantitative nutritional needs of individuals and groups and facilitate future intervention studies. There are collaborative initiatives in biomedical sciences to develop markers which would facilitate more resource-efficient, yet effective, interventional studies: clearly nutrition and metabolism stand to gain and are gaining from such strategies.

In the meantime, the totality of the evidence, then the likelihood or probability of a benefit should be considered. Perhaps the use of the precautionary principle would also be a useful device.

Some concern was also expressed that EFSA's present approach will restrict innovation in the food industry. Although EFSA believes that it is possible for companies to use approved Article 13.1 claims to market products, the reality is that many food companies do not see this as giving them a competitive advantage and are concerned that if Articles 13.5 and 14 are the only routes to product differentiation, and that if only conclusive proof will be acceptable, that they will go out of business before they see a good return for their commercial investment. Businesses are seeking a commercial advantage via a health claim, without which they may not survive. Lack of motivation for food industry innovation reflects ultimately on research funding in other places, including universities, and this may have long-term consequences for nutrition science and ultimately the consumer who would not benefit from new science that could have an impact on health.

From a consumer protection point of view, the issue of consumer understanding is an important milestone in nutrition and health communication. Evidence had been presented that consumers are unable to differentiate between claims. There is clearly a pressing need for more research regarding consumer understanding of claims.

A long-term perspective is that the present legislation may lead to a medicalisation of foods with a disproportionality that the European Union would need to address. The purposes of nutrition and health claims need to be explored and restated. At one stage, creating harmonisation in the international market was deemed essential; other purposes include consumer information, public health improvement, health protection, the protection of the public from exploitation and product safety. These are regulatory and policy issues which should be advanced through member states, Members of the European Parliament and similar European Commission and Parliamentary avenues.

### Acknowledgements

The present meeting was supported by the Council for Responsible Nutrition. There were no conflicts of interest disclosed at the meeting or by any of the authors of the present report.

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