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SUPPLEMENT

Functional foods in Europe: international developments in science and health claims

Summary report of an international symposium held 9–11 May 2007, Portomaso, Malta

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Introduction

The concept of functional foods derives from the realisation that specific components of the diet have the capacity to contribute benefits beyond those of basic nutrition. The last two decades have seen the development of this concept to the point where it has aroused significantly the interest of the food industry, consumers and the regulatory authorities. The future of functional foods will depend on continued advances in nutrition science and the development of innovative technologies by the food industry. It will also depend on consumer understanding and acceptance of the concept, of products derived from its application, and on the way in which access to the market place is mediated by the regulatory environment at national, regional and global levels. The present symposium, held in Malta from 9 to 11 May 2007 and organised by the International Life Sciences Institute European Branch (ILSI Europe) in collaboration with the Malta Standards Authority, University of Malta and ILSI South East Asia, provided a forum for dialogue between stakeholders from the food industry, academia, consumer groups and the regulatory authorities. It gave an opportunity to review the current status of health claims made on foods and their scientific substantiation, to explore consumer understanding, behaviour and communication in relation to the concepts, to assess the impact of regulation on health claims and innovations in functional foods, and to discuss the future challenges and opportunities for functional foods. The conference was timely in that it followed the formal adoption of the Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on Nutrition and Health Claims made on Foods [1] (hereafter referred to as the EU Regulation).

The overall chair of the symposium was Professor Nils-Georg Asp (Swedish Nutrition Foundation and Lund University, SE) and he was supported by Dr Detlef Müller (Procter and Gamble, DE), acting as overall co-chair. More than 300 experts from 45 countries participated.

The Symposium was opened by Hon. Louis Deguara, Minister of Health, the Elderly and Community Care, Malta. In doing so, he noted the need for a sound science base to underpin development of the functional foods sector and he stressed the value of collaboration between academia, the food industry, the government sector, consumer groups and the media in further exploring the potential for functional foods and their role in health promotion and disease-risk reduction.

Session I

Evolution in dietary patterns, health trends and functional foods

Professor Furio Brighenti (University of Parma, IT) chaired the session with the support of Jean-Michel Antoine (Groupe Danone, FR) as co-chair. This first session set the scene for the symposium by highlighting current health concerns in Europe—namely obesity and the diet-related chronic diseases, including heart disease, stroke, diabetes

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and cancer—and exploring the options for dietary interventions and the role for functional foods.

Professor Pirjo Pietinen (National Public Health Institute, FI) summarised the current status of health in Europe and the development in non-communicable diseases based on data from the World Health Organization (WHO). The burden of mortality in Europe is related to the chronic diseases of over-nutrition, with obesity and overweight increasing at an alarming rate and cardiovascular diseases being the principal cause of death. Raised blood pressure is the leading risk factor, while elevated blood cholesterol, high body mass index and excessive alcohol consumption are additional diet-related risk factors. There is a wide variation in life expectancy in Europe, which currently mirrors the prevalence of cardiovascular diseases, rather than obesity, and reflects the inequalities between the countries of Europe. Inequality, particularly in socio-economic status, within countries also has an impact on obesity and chronic disease, prevalence being higher in poorer communities. Probable dietary determinants of disease are a too high intake of fat (high energy density) and saturated fat and a too low intake of fruits and vegetables. There is particular concern about the rising prevalence of obesity and related type 2 diabetes in children, and there is a need to break the cycle of deprivation of low income, poor diet, lack of physical activity, psychiatric problems and reduced ability to care for children. Thus, WHO has developed the European Charter on Counteracting Obesity that outlines policy tools to address this issue through actions for all stakeholders. Finally, Professor Pietinen called for the support of the research community to provide a strong science base for action.

Although better diet and safe food have contributed to increased average life expectancy in Europe, there are some unfavourable trends in terms of food availability and eating habits. The potential for dietary intervention to contribute to further improvements in health was explored by Dr Nynke de Jong (National Institute for Public Health and the Environment—RIVM, NL). She described a conceptual framework and methodology to assess and weigh positive and negative health effects of population dietary interventions. A measure of disease impact, used by WHO and researchers alike, is the disability-adjusted life year (DALY). DALY is a summary measure of early death (years lost) and years lived with a disease burden. Using the DALY as a scoring system, it proved possible to calculate that the positive impact of dietary change such as reduced saturated fat consumption and increased fish intake can, by far, outweigh the negatives of well-established food safety concerns such as microbial contamination and food allergy. In addition, Dr de Jong recommended risk–benefit analysis of functional foods, showing, in the case of benefit, that it is possible to measure the benefits of functional foods, such as those containing cholesterol-lowering phytosterols, in well-designed post-marketing cohort studies.

Professor Nils-Georg Asp (Swedish Nutrition Foundation and Lund University, SE) referred to functional foods as denoting positive nutrition. Functional foods may have optimised nutrient content, or may offer additional benefits in terms of health, well-being and physical or mental performance. Although there have been many attempts to define functional foods, for example under the ILSI Europe Functional Food Science in Europe (FUFOSE) project [2], there is no single, accepted definition; however, in general it is true that functional foods are those for which health claims are made. The EU Regulation defines nutrition claims and health claims, the latter including both claims for the function of nutrients and other substances as well as claims for disease risk reduction. Codex Alimentarius (Codex) Guidelines have slightly different, but overlapping, categories. In the development of lists of health claims, Professor Asp pointed out the difference between claims that can be used for a range of food products fulfilling certain compositional criteria, sometimes referred to as "generic claims", and product-specific or innovative claims that rely primarily on intervention studies with the product. He stressed the importance of communicating health claims in the context of the diet, and the need for consumer relevance as well as consumer understanding. Allowing health claims that are scientifically substantiated can stimulate product development and may assist in consumer education, as well as improve health, well-being and performance.

In the discussion session there was clarification that the EU Regulation regulates claims not foods. Hence, if the food composition and science provide appropriate support, any food, including a traditional food, can bear a claim. There was a comment about the cost of functional foods and it was pointed out that the investment to develop and produce such foods is high. However, the proportion of consumers that choose functional foods may be quite small; 2–5% in the case of foods containing phytosterols in the Netherlands, even though re-imbursement of costs is available from health insurers in that country. It was noted in relation to life expectancy that for older people to be moderately overweight is positively related to longevity.

Session II

Scientific substantiation of claims on foods

The session was chaired by Professor Gerhard Rechkemmer (Federal Research Center for Nutrition and Food, DE) and co-chaired by Dr Anne Franck (Raffinerie Tirlemontoise—ORAFTI, BE). The objective of this part of the

programme was to compare the different approaches taken around the world to formalise the scientific substantiation process and to learn the latest thinking from the European Food Safety Authority (EFSA), currently preparing its guidance for the submission of dossiers on health claims in the EU.

The Chair of the PASSCLAIM Consensus Group, Professor Peter Aggett (Lancashire School of Health and Postgraduate Medicine, UK), described the outcome of the EU Concerted Action, "The Process for the Assessment of Scientific Support for Claims on Food" (PASSCLAIM), which was co-ordinated by ILSI Europe in 2001–2005. The key output from the programme was a set of criteria for the scientific substantiation of claims [3]. These criteria relate to the characterisation of the food or food component, appropriate methodology for human studies, the use of markers, and to the evaluation and use of the totality of the data (both published and unpublished) in weighing the evidence. The PASSCLAIM criteria provide a guidance template to inform the evaluative and regulatory process; they do not establish the validity of the claim. The process of evaluation must be applied on a case-by-case basis with an intelligent interpretation of the evidence, its consistency and coherence, its plausibility and its biological relevance — including instances where there are gaps in knowledge. An intelligent approach is also needed for the re-evaluation of claims. Expanding on the original project, Professor Aggett explored the notion of causality and also the use and interpretation of markers, as well as the difficulty of interpreting the complex link between markers and the causal pathway. In many cases, single components might influence several outcomes while, in others, single outcomes might be influenced by several components.

Outlining the current thinking of the US Food and Drug Administration (FDA), Professor Joanne Lupton (Texas A&M University, USA) noted that, in the USA as in most countries, it is the health claims rather than the foods that are regulated. She pointed out that functional foods were currently regulated as conventional foods (not as supplements), but that the FDA was conducting a public consultation prior to considering legislation on functional foods. US health claims are essentially the equivalent of disease-risk reduction claims in Europe and require "significant scientific agreement" (SSA) prior to publication of their approval in the Federal Register. Qualified health claims are those that do not reach the level of SSA but are nevertheless used under enforcement discretion, which means that the FDA advises against enforcement action being taken against the claim. The process of evaluation of all these claims is the same, whether qualified or not or whether applied to conventional (or functional) foods or to supplements. The important features of the process for the scientific substantiation of health claims in the USA are firstly that the food or food component is defined and, secondly, that the specific statement or claim is evaluated. In reviewing the evidence, the FDA ensures that all relevant studies are identified, rather than relying on the petitioner's dossier. Human studies in non-diseased populations are the most relevant, and markers need to be those approved by the FDA or the National Institutes of Health (NIH). The totality of the evidence is rated for strength, extent and consistency, and a recommendation made. Beyond the regulation of health claims, the safety of functional foods and appropriate vehicles for health claims are topics worthy of further consideration.

Dr. E-Siong Tee (ILSI Southeast Asia, MY) described ongoing efforts to harmonise scientific substantiation of claims across Southeast Asia. Between 2000 and 2006, ILSI Southeast Asia organised a series of workshops to inform all stakeholders of international developments in the science and regulation of functional foods and health claims and to provide them with a platform to discuss the scientific basis of the regulation of nutrition labelling and health claims in Southeast Asia. Considering the countries of the region and also Japan and China, there is a varied approach to the regulation of functional foods and claims, with Japan undoubtedly having the most comprehensive system—the so-called FOSHU (Foods for Specified Health Use), a system that requires pre-marketing approval of health claims on a food-by-food basis. Qualified health claims have been admissible since 2005, recognising the importance of informing consumers about emerging evidence. The ILSI workshops have also prepared guidance on the scientific substantiation of health claims drawing on the work of PASSCLAIM and Codex. Once again, well-designed human intervention studies and the use of appropriate markers are emphasised. Evaluation of the safety of foods carrying health claims is also part of the procedure for scientific substantiation, but only where the target group, level of intake or potential interaction with other nutrients so warrants, otherwise standard food safety procedures apply.

Dr. Pilar Rodriguez Iglesias (European Food Safety Authority—EFSA, IT) affirmed the mission of EFSA with respect to nutrition and the role of the Panel on Dietetic Products, Nutrition and Allergies (NDA panel). The mandate of the NDA panel under the EU Regulation on Nutrition and Health Claims made on Foods falls under two main headings: firstly, the setting of nutrient profiles, and secondly, the scientific substantiation of health claims. In relation to the latter role, the first task for EFSA is to provide guidance on the content and preparation of dossiers to be submitted under Article 14 of the Regulation (claims for a reduction in disease risk and claims related to children's development and health) [4]. The European Commission will also consult EFSA as it prepares a list of

claims based on generally accepted scientific evidence under Article 13 of the Regulation. EFSA will also need to evaluate dossiers submitted for new or proprietary claims that also fall under this Article. EFSA may be consulted on other matters under the EU Regulation where their independent scientific opinion is required.

Professor Rolph Grossklaus (Federal Institute for Risk Assessment—BfR, DE) spoke in his capacity as chair of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCFNSDU). As part of its key role in protecting the health of consumers and ensuring fair trade practices in the global food market, Codex adopted revised Guidelines for Use of Nutrition and Health Claims in 2004. Several proposed draft recommendations on the scientific substantiation of health claims have been considered and amended by the CCNFSDU in recent years but the work is not yet complete. The current work draws on the work of FUFOSE and PASSCLAIM and also on that of WHO and FDA. Given the important role of Codex in food safety, the draft recommendations place importance on circumstances where additional evaluation of safety or nutritional safety needs to be considered. High quality human intervention studies are the prime evidence needed to substantiate claims but there is recognition that, in some cases, only observational studies may be available and that emerging evidence is also important. Animal and in vitro studies will also be evaluated as part of the totality of the evidence. The strength of the evidence depends additionally on the consistency and reproducibility of results. It has been suggested that the recommendations should include re-evaluation of claims after a certain time period, as well as in cases where new data call the validity of claims into question.

During the discussion, a question was raised about new evidence that might question the veracity of an approved claim. In fact, options for re-evaluation are built into most schemes and, in the case of the Codex draft, a timed re-evaluation is recommended. It was suggested that it may be important to consider public health relevance as well as biological relevance and consumer relevance. However, a public health benefit may not imply a positive benefit for the individual consumer who is relying on the health claim to guide choice. The importance of risk–benefit analysis was noted, particularly in regard to emerging science. At a more basic level, it was debated whether, if the removal of a component leads to a benefit, this could result in a health claim. In the USA, the legislation does not allow for such claims, but elsewhere it would seem that such claims can be made if they can be substantiated. The challenges for small and medium sized enterprises (SMEs) may be considerable in meeting the requirements for scientific substantiation and so the audience was made aware of a network called FunctionalFoodNet [5] that could be helpful to SMEs.

Session III

Regulatory issues of functional foods

Regulatory matters related to functional foods were addressed by four speakers in a session chaired by Professor Peter Biacs (Hungarian Scientific Society for Food Industry, HU). The co-chair was Dr. Michele Kellerhals (Coca-Cola European Union, UK). Key features of the EU Regulation were outlined and a perspective was provided on certain aspects of implementation including those related to transitional measures, compiling the lists of health claims and nutrient profiling. In addition, the concept of risk–benefit assessment of functional foods was introduced.

It was the task of Basil Mathioudakis (European Commission, BE) to provide a perspective on the EU Regulation on Nutrition and Health Claims made on Foods that came into force in January 2007. The primary aim of the Regulation is to provide a high level of consumer protection, but it must be recognised that the inclusion of claims about a reduction in disease risk was a substantial regulatory step for the EU. With the exception of those substantiated on the basis of proprietary data, the Regulation makes approved claims open to use by all operators. Claims based on proprietary data are reserved for the exclusive use of the owner of the data for a period of 5 years unless, in the intervening period, they are independently substantiated on the basis of data from alternative sources. Mr. Mathioudakis emphasised that restrictions on the use of claims are not related to good or bad foods but are, in the case of nutrient profiles for example, to counterbalance strong promotional activity. There is considerable work for all stakeholders around implementation of the EU Regulation. This especially relates to nutrient profiles and to the list of claims under Article 13 as well as some interpretational issues, particularly concerning the categorisation of claims into nutrition claims, health (function) claims or disease risk reduction claims. In the case of the latter, grading of evidence, wording of claims and consumer understanding are all complex issues. Transitional arrangements, particularly those that concern claims about child development and health, remained to be clarified at the time of the symposium.

Challenges around establishing the list of claims based on generally accepted scientific evidence under Article 13 of the EU Regulation were discussed by Noel Griffin (Food Standards Agency—FSA, UK). In some senses the task is difficult because most countries have no national list; nevertheless, there are many claims on the market and, in the case of the UK, these claims will form the basis for the list. The UK Voluntary Joint Health Claims Initiative evaluated a number of claims on several foods, as well as

statements on micronutrient function that can be considered for inclusion on the national list. A template has been provided for submission of claims to the FSA [6]. There is a large burden on regulators to succeed in this process and the UK believes continuing consultation with all stakeholders, both nationally and across the EU, is a key to a successful process. The national role should be to exclude spurious references and to ensure that there is adequate science for review (if needed) by EFSA. There is an opportunity for the EU Regulation to help inform and educate consumers as well as to provide protection.

Professor Gérard Pascal (National Institute for Agronomic Research—INRA, FR) addressed the important topic of risk–benefit analysis in evaluating functional foods. He described the evolution of the definition of risk from a narrow, strictly quantitative concept to a broader approach that embraces the concept of societal acceptance of risk. Also important is the ability to communicate that acceptable risk does not mean zero risk. The safety of functional foods must be equivalent to the safety of normal foods—that is, the functional food must be capable of providing its specific benefits without appreciable risk. For micronutrients and micro-components, classical toxicological testing can be applied. However, macro-components and whole foods have always posed a challenge to the toxicologist and, in this case, substantial equivalence and history of safe use are important criteria. Novel approaches for comparing beneficial and adverse effects on the same scale of measurement have been proposed and are being debated in several fora. In the future, other risks and benefits (economic, commercial, environmental, ethical, etc.) should be assessed from a scientific point of view. These assessments may be used by risk managers to define, after a discussion with all stakeholders, what is socially acceptable.

The last speaker in this session, Professor Albert Flynn (University College Cork—IE), dealt with the topic of the nutritional impact of functional foods and the role of nutrient profiling. He stressed that his observations were made in a personal capacity rather than in his role as chair of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). It is important in developing nutrient profiles that the specific objectives of the exercise (in this case ensuring that health claims do not mislead) are taken into account. The nutrient profile of an individual food does not have to match the nutrient profile of a balanced diet, and the level of usual intake needs to be taken into account. Professor Flynn explored the advantages and disadvantages of setting a profile that applies to all foods or setting profiles per category. Regarding the nutrients to be addressed, the EU Regulation is not prescriptive, so only nutrients that are pertinent need to be addressed. There are several different possible bases for a threshold approach or for scoring nutrient content as well as the option to apply these per 100 g, per portion or per 100 kcal. EFSA NDA will provide guidance to the European Commission on these scientific principles and also on the tricky operation of testing and feasibility of the proposed scheme. Given its potential complexity, it is comforting to know that the scheme does not need to be communicated as such to the consumer.

In the discussion session, a question was asked about whether it was still the current view that new claims under Article 13.5 of the EU Regulation could not be submitted until 2010, as indicated in the EFSA pre-submission guidance. Mr. Mathioudakis confirmed that there was a legal basis for this view because of the word "addition" in the text (i.e. the list must be in existence before it can be "added to"). Mr. Griffin stated that if a Member State received a dossier, it was bound to act in accordance with the Regulation and forward the dossier to EFSA. In answer to a question on probiotic claims, panel members indicated that criteria such as number of live cells would need to be met, as well as there being a need for evidence of a modification to the type or metabolic activity of the gut microflora. It was confirmed that front-of-pack labelling schemes that were making nutrition or health claims would need to be notified by Member States and comply with the EU Regulation. EFSA confirmed that it would be publishing population reference intake (PRI) values for macronutrients, but would not be working on related labelling values such as guideline daily amounts (GDAs) or reference labelling values (RLVs).

Session IV

Consumer perspective: behaviour, understanding and communication

The session on consumer perspectives was chaired by Professor Diána Bánáti (Central Food Research Institute—KEKI, HU) and co-chaired by Reg Fletcher (Kellogg, IE). Five speakers presented different aspects of the current state of knowledge on how the form in which information is presented to consumers influences their perception of functional foods, their understanding of the health messages conveyed and the dietary choices they make.

Jens Lönneker (Rheingold GmbH, DE) presented findings from studies of how consumers' perception and behaviour is affected by information on aspects of food composition associated with health. Aspects reported included the presence or absence of preservatives, low glycaemic impact, low fat content, low calorie content and the presence of probiotics. Observations on consumers' receptiveness to sport-related communications and to retail environments were also reported. At a superficial level,

consumers respond positively to brands that eliminate food additives or that are formulated to meet concepts of health and well-being. However, such brands may generate underlying concerns associated with doubts about the hedonistic quality of the product and with loss of consumers' own control over their responses and dietary choices. In addition, consumers' perception of what it takes to achieve a state of health and well-being is often counterbalanced by their desire for pleasure and the excitement that comes with the taking of risks. Unease in the face of information overload and a desire for stability/familiarity at the point of sale also motivate consumers' purchasing choices in ways that may run counter to the pro-active use of health messages in connection with branded products. Ultimately, consumers' decisions are determined by a balance of influences relating to health and lifestyle, which may appear contradictory.

An industry perspective on the marketing of functional foods was presented by Dr. Edward Fern (Nestlé, CH). Dr. Fern's principal proposition was that, with the possible exception of foods for special health use (FOSHU) in Japan, functional foods are not perceived by consumers to be a coherent category of foods. Rather, they are seen as the moving edge of an evolving spectrum of food products in which traditional foods are under continual development with the aim of providing dietary choices leading to benefits beyond simple nutrition. In this context, the challenge in the development and marketing of functional products lies in the possibilities for adding functionality to traditional foods in such a way that they retain their appeal as a source of pleasure. The challenge must be approached simultaneously from the four aspects of food quality, nutrition science, regulatory oversight and consumer expectation. Science and regulatory oversight must work together to ensure the credibility of any claims for health benefits within a framework capable of communicating legitimate health messages to consumers. Nutrient profiling arguably has a role in underpinning that credibility. Outside the special confines of "FOSHU" foods, successful functional food products are likely to be those that are presented to consumers in a form that meets their expectations with respect to traditional food characteristics, and that communicate the additional health benefits consumers can expect to obtain in a context to which they can relate.

Professor Ulrich Oltersdorf (Federal Research Centre for Nutrition and Food—BFEL, DE) described the challenge of communicating knowledge generated by nutrition science to consumers in a form that has practical effect in influencing their dietary habits. Modification of dietary behaviour to produce successful health outcomes must be effective in modifying habitual, everyday behaviour rather than behaviour responding to discrete, episodic events. Such behaviour is controlled by two principal influences, one relating to metabolic input/outputs and the other to information input/outputs. Professor Oltersdorf's further discussion addressed the information input/output domain in which dietary behaviour is shaped by many factors ranging from sensations, through feelings and emotions, to habitual physical actions such as walking and eating. These many inputs are assimilated by a system that develops over an individual's lifetime and that is itself susceptible to societal and cultural influences. External messages relating to nutrition are received into an individual's acquired pattern of attitudes, beliefs and trusts and will be treated accordingly. Planned interventions have the potential to direct changes in nutritional behaviour but their effective design requires a systematic knowledge of the way individuals' behaviour responds to communication about nutrition. Research is required to develop a comprehensive model of nutrition behaviour in order that more effective nutrition communication can be formulated.

Further aspects of consumer understanding of nutrition communication, with a particular focus on information provided on food packs, were discussed by Professor Hans van Trijp (Wageningen University, NL). Claims on food packs provide a valuable source of information but the information always comes to consumers within a context that influences the effectiveness of the communication. When the claims are scientifically justified and the information is correctly understood and used by consumers, the interests of all stakeholders (policy makers, industry and consumers) are best served. Assessment of the effectiveness of on-pack communications presents methodological problems, but it is clear that the extent to which information is assimilated is influenced greatly by consumers' regional origins and societal and demographic characteristics. Consumer understanding is limited by the availability of nutritional knowledge and the facility to appreciate complex information, with the result that claims and information may be misinterpreted. The EU Regulation on Nutrition and Health Claims made on Foods requires claims to be understood by the average consumer, but there is as yet no consensus about how compliance with this requirement is to be assessed. The ILSI Europe Consumer Science Task Force has proposed a stepwise approach for gathering evidence to allow assessment of the comprehensibility of claims [7] but, within the EU, the responsibility for making the assessment will fall to the EFSA. Issues that remain to be addressed include the need to develop a pragmatic approach that recognises the need to balance scientific certainty against practical limitations in consumer science, the difficulties inherent in basing judgements about post-market effectiveness on information limited to the pre-market situation, and agreement of an appropriate standard of evidence.

Professor Peter Biacs (Hungarian Scientific Society for Food Industry, HU) presented an assessment of the part

played by considerations of health in determining consumers' choices of foods. Although an appreciation of the role of diet in maintaining health is growing, it remains at a relatively low level at present. In a recent study in Hungary, the term "functional" in relation to food was found to be unknown to a large majority of consumers. Consumer surveys indicate that awareness of the role of nutrients in health and well-being varies across age groups. While older age groups recognise the role of calcium-rich foods in the maintenance of bone health, younger age groups are less aware of a possible positive role for antioxidant-rich foods in combating cardiovascular disease and cancer. An increased awareness of the value of diet to health can be achieved through a three-step approach in which foods are enriched with a nutritionally valuable component, the nutritional benefit of enrichment is established and, eventually, the role of a nutritionally enriched food in disease-risk reduction is demonstrated. An example of such an approach was presented in the context of marketing communication by the dairy industry in relation to the presence of calcium in dairy products, the role of calcium-rich foods in the maintenance of bone health and the possibility that the risk of osteoporosis may be reduced by regular consumption of milk and dairy products. Market research indicates a potential for future interest in functional foods by a wide group of consumers.

During discussion, interest focussed on the extent to which consumers are influenced in their dietary choices by the quality and the quantity of information presented on packs. The two aspects were seen as closely related. While superficially a larger quantity of information may lend greater credibility to the content of the information, at another level consumers are deterred by large amounts of information and so are likely to disregard it. Similarly, information that remains static over time ceases to be seen by consumers and so flexibility in the wording of claims may be important if the information they contain is to be refreshed and kept current in consumers' perception. Although "traffic-light" systems, GDAs and logos provide frameworks that can assist consumers in making sense of complex information, if there is no agreement on the thresholds and bandings they are based on, they become sources of confusion rather than of enlightenment. Despite care taken in the wording of health claims, evidence suggests that consumers do not distinguish between disease-risk reduction and disease prevention. As far as the underlying consumer science is concerned, assessment of the extent to which labelling information is used and understood is hampered by the limited methodologies available for this purpose. Also, there is a need to develop a more complete model of human nutrition behaviour so that the influence of communication on food choice can be better understood.

Session V

Roundtable discussion: different strokes, different visions: where lies the future of functional foods?

An opportunity for an overarching discussion about the future for functional foods was provided by a session in which a panel comprising Professor Joanne Lupton, Basil Mathioudakis, Dr. Edward Fern and Professor Nils-Georg Asp was invited to respond to debating points from the floor of the symposium. Alex Puissant (BE) acted as moderator for the session.

Overall, the panellists considered the prospects for the future of functional foods to be positive in a context where a developing science base provides the means to extend the range of familiar food items by addition to, or enhancement of, existing functionality. The present working definition of functionality is likely to provide continuing grounds for discussion since it presently relies on the concept of basic nutrition for its point of departure and, as nutrition science evolves, so will the concept of basic nutrition. However, the discussion may prove academic in the European context since the EU regulatory framework subsumes the issue into the more general one of food labelling and of claims made on all foods in relation to nutrition and health. The issue becomes one of the validity of the claim made about a food, rather than whether or not the food falls within the notional category of "functional". Where national and regional frameworks differ from that of the EU, the definition of functionality may remain an issue for scientific and legal discussion.

A question arose as to whether the burden of proof imposed by the EU Regulation for establishing the validity of a claim presents a barrier to entry into the market for SMEs and therefore disproportionately favours large business operators. Panellists felt that this was not the case, pointing to the fact that there are examples of innovative activity in the sector on the part of SMEs. Furthermore, all authorised claims, other than those dependent on protected proprietary data for their substantiation, will be available for use by SMEs. It was also pointed out that a counterbalancing disincentive exists for large enterprises in the form of risk to the image of established brands where claims might prove not to be supported or where product performance fell short of expectations. In addition, by establishing a Community procedure for the evaluation of claims and a register for those assessed to be valid, the Regulation provides an even playing field for all operators, reducing the possibility for large business operators to gain credibility for claims solely from their larger market presence.

There was discussion about the value of "traffic-light" systems as a means of conveying nutritional information in the face of evolving nutrition science. As knowledge

about the impact of intakes of macronutrients on health increases, the thresholds and bands forming the basis of any system may be adjusted up or down and the resultant changes to the labelling indicators will be confusing for consumers. A proposal for revised EU nutrition labelling rules is anticipated by the end of 2007. It remains to be seen how it will address the use of traffic-light or similar systems of nutrition signalling in Europe. Nevertheless, however, addressed in the short term, the issue will remain pertinent since continuing evolution of nutrition science is inevitable and, clearly, desirable.

Concern was expressed that the process of evaluation foreseen for the initial list of health claims ("Article 13 claims") during the introduction of the EU Regulation will be overwhelmed by the volume of information that will need to be assessed. In response, it was pointed out that the information will be provided in a structured format that will facilitate its assessment and that single datasets may provide the support for several claims, thus reducing the multiplicity of primary reviews that will need to be conducted. While acknowledging that significant resources will be required to evaluate the information, confidence was expressed on the part of the EU Commission that the procedure foreseen is sustainable.

There was discussion about the infrastructure necessary to advance the development of functional foods proactively. Development of EU funding proposals in support of research into food functionality is foreseen as a possibility, for example within the European Technology Platform "Food for Life", which was launched in July 2005 as part of the European Food Industry's input into the EU Seventh Framework Programme (FP7). Subject to compliance with the provisions of the EU Regulation on Novel Foods and Food Ingredients [8], the EU regulatory environment controlling nutrition and health claims does not place limitations on the nature of the sources of functional components that may be used and, in this sense, can be regarded as supportive. The view was expressed that the establishment of dietary reference intakes (DRIs) for a wider range of nutrients would enable the commercial exploitation of a greater number of functional components. It was pointed out that many functional components are not nutrients in the conventional sense and that DRIs would not be applicable. However, it was suggested that, in the light of developing functional food science, evolving perceptions might indeed make it appropriate to consider them as such. The development of appropriate markers for a wider range of functional end-points was also cited as something that would facilitate advancement in the field.

While there was recognition that the EU Regulation does much to minimise the risk to consumers in relation to false and misleading claims, the question was raised about whether it could do more to encourage improvement in the health quality of foods. In response, it was pointed out that the Regulation does seek to remove disincentives, for example by providing protection for proprietary data generated in support of claims. However, the driver of the market is ultimately the consumer and the greater part of the incentive to develop food functionality must come from consumer demand.

It was suggested that, by maintaining a prohibition on claims for disease prevention, the EU Regulation unduly restricts the development of functional foods. In response, it was said that the present regulatory environment reflects the current societal perception of the distinction between foods and medicines. A change in EU law would in principle be possible, but it would require a consensus amongst all stakeholders that food has a legitimate role as medicine. At the present time such a consensus is not apparent.

The relationship between functional foods and dietary supplements was discussed. One consequence of not recognising functional foods as a separate category in food law is to include them in the same category as dietary supplements for the purpose of control. Yet the circumstances of use of the two, including the greater possibility of health risk from product over-use in the case of supplements, could be very different. Likewise, the functional performance of an active component could be different in the presence or absence of a food matrix. In EU law, the two categories will be treated equally from the perspective of nutrition and health claims and this may be regarded as a strength since it will ensure that the validity of any claims will be judged on a consistent basis. This will benefit both consumers and the credibility of the claims themselves.

The question of health risks from functional foods is a separate issue from that of the regulation of nutrition and health claims. In the EU, as in most other regulated systems, general food law requires that all foods are safe in use. However, it was felt that there are special considerations for functional foods, where arguments in support of their use are predominantly based on expectations of improvement in the health of those who consume them on an individual basis, without any countervailing assessment of their impact on public health overall. Against this background, it was agreed that there are strong arguments for conducting risk–benefit analyses in connection with the use of functional foods. On the part of the Commission, it was said that the responsibility for conducting any post-market surveillance within Europe would fall to the authorities of the Member States.

The difficulty of establishing consumer understanding of health claims, in advance of gaining market approval, was discussed. The difficulty arises not only because data from a real market situation are not available at that point in time, but also because consumer awareness of how dietary inputs might influence a particular aspect of health is

lacking when products designed for the purpose are not present in the marketplace. There are strong arguments for allowing claims onto the market place as a means of educating consumers about the benefits that functional foods may bring. It was agreed that the requirements of the EU Regulation concerning consumer understanding would need to be interpreted flexibly if the Regulation is not to function in an unduly obstructive fashion. It might, for example, be appropriate to interpret the "average consumer" as being representative of the target group for a functional food, where awareness of the relevant health issue is initially likely to be higher, rather than representative of the population overall, where initial awareness is likely to be low. It was also agreed that the introduction of particular health claims into the market place needs to be supported by parallel programmes designed to educate consumers on the issues concerned if a favourable impact on consumers' nutrition behaviour is to be maximised, always provided that consumers are not encouraged to use dietary means as alternatives to the proper medical management of health problems where this is appropriate.

In their closing remarks the panellists agreed that:

- The EU Regulation represents a positive contribution to the future development of functional foods in Europe
- Continued research in the field of food functionality will be important in sustaining the current upward trend in development
- Education will be important in raising consumers' awareness of the potential benefits to be gained
- Nutrition and health claims have a part to play in the process of education

Session VI

Future of functional foods: challenges and opportunities

The final session of the symposium addressed future challenges and opportunities for functional foods. It was chaired by Professor Albert Flynn (University College Cork, IE) and co-chaired by Dr. Hans Zevenbergen (Unilever, NL). The session provided an opportunity for expert speakers to map out how the future of functional foods might be affected by evolving consumer perceptions, the application of personalised nutrition and emerging technologies. The possibilities for financial support from the European Community for future research into functional food science were also described.

Possible future societal perspectives on functional foods were presented by Claude Fischler (National Centre for Scientific Research—CNRS, FR). Although at present functional foods have an indeterminate and rather variable identity in popular perception, Dr. Fischler pointed out that, historically, there has long been an association between health and the diet in general. The development of a discrete, popular identity for functional foods in the future will likely require consumers to confront three fundamental concerns that shape their attitude to food. First, consumers have a tendency to prefer naturalness in their foods and will form negative associations in response to triggers that have unnatural connotations. Second, to an extent that varies with their cultural background, they find the concept of food incompatible with the concept of medicine. Third, they are risk-averse and are likely to perceive "active" components as associated with risk. In addition, food has become trivialised. The main challenge for the future in finding a favourable identity for functional foods may first be to re-establish the perceived value of food in general by improving its quality with regard to both taste and nutritional value. However, in circumstances where obesity is increasingly seen as the major issue for health, any attempt by the food industry to create a perception of added value in the market for food may raise issues of trust in the minds of consumers that will make the task difficult for the industry to achieve.

Professor Mike Gibney (University College Dublin, IE) addressed the future role of functional foods in an era of personalised nutrition. Possibilities for dietary interventions exist because genetic variation, in the form of polymorphisms, results in discrete groups of individuals with particular traits that may influence their susceptibility to disease and that can be identified by DNA analysis. In principle, identification of such polymorphisms can serve as the basis for targeted dietary advice aimed at reducing disease risk or optimising health and well-being. Implementation of such advice has been termed "personalised nutrition". In practice, with a few exceptions, the precision with which such advice can be targeted is limited because the identification of polymorphisms likely to respond to intervention, and the individuals who possess them, is itself of limited precision. Where advice can be precisely targeted, the complexity of the dietary combinations necessary to meet population requirements is prohibitive. In order to satisfy consumer demand for variety, total diet formulations would have to be so numerous as to be impracticable on a commercial scale; alternatively, they would have to be so limited as to be unpalatable to consumers on a regular basis. While functional foods may have the potential to offer solutions to meet individuals' needs for personalised nutrition, the complexities of implementing personalised nutrition would appear to make realisation of the potential impracticable for the foreseeable future.

Peter Brown (Kraft Foods, USA) described the likely impact of emerging technologies on food from the perspective of the possibilities, the needs and the risks and

benefits. The impacts of nano-, digital and biomolecular technologies were considered with some indicative examples of the ways each might be used. Examples included the use of nanotechnology in the decontamination of water from groundwater sources, the application of digital technology to the use of information in food distribution, storage and preparation, and the use of biomolecular technology in cell-based, receptor-mediated functional assays to improve the taste quality of foods. While these technologies have the potential to contribute to the increased safety, convenience, quality and nutritional value of the food supply, and to the application of personalised nutrition in the pursuance of health, they must be adequately managed to ensure human and environmental safety and the privacy of the individual. If they are to be commercially viable in their application to food, they must be implemented in ways that are acceptable to consumers. This means that their application must be transparent to consumers, enabling them to make informed, personal choices.

Financial support for research into functional foods under the EU Commission's Seventh Framework Programme (FP7) was the subject of a presentation by Isabelle de Froidmont-Görtz (European Commission, BE). The European Community is committed to support health-oriented nutrition research. Research in functional food science has been a continuing recipient of funding from the EU Framework Programmes from 1989 onwards. Support amounted to €2 million under the Second Framework Programme, rising to €60 million under the Sixth Framework Programme. It is a candidate for support under the activity "From Fork to Farm: Food, health and well-being" of the Food, Agriculture, Fisheries and Biotechnology (FAFB) Theme within FP7. The FAFB Theme has been allocated a total budget of €1.935 billion over the lifetime of FP7, which runs from 2007 to 2013. There are two activity areas of relevance:

- 2.2.1 Consumer perception and attitudes towards food, understanding societal trends, cultural aspects of food, determinants of food choice
- 2.2.2 Nutrition, diet-related diseases, nutrigenomics, interaction between nutrition, physiological and psychological functions, food development (dietetic, functional, personalised foods)

Functional Food Science is also a candidate for support from FP7 under the European Research Area networking activity (ERA-NET).

Closing remarks and end of symposium

The overall co-chair, Dr Müller, briefly summarised some key messages from the presentations, concluding:

- Functional foods are a reality
- Functional food science is established and progressing rapidly
- Food manufacturers know how to translate the science into real products
- Regulatory frameworks are in place, but need to be implemented with due regard to practical realities
- There needs to be a better understanding of what motivates consumer choice if messages about healthy food choices are to be communicated in ways that result in changes in nutrition behaviour

In bringing the symposium to a close, the overall chair, Professor Asp, re-stated the view that the EU Regulation now in place provides a platform for the development of foods providing healthier choices for consumers that will further drive the ongoing reformulation of existing food products and the development of innovative products in the interest of consumer health and well-being, as well as in the interest of business opportunities. He proposed that further research is needed to explore diet/health relationships, to identify and validate surrogate markers of effect and, finally, to substantiate the health effects of diets, foods, food products and food components.

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