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Understanding and Working with European Union Legislation on Nutrition and Health Claims

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INTRODUCTION

The development of foods and food components that provide benefits beyond their traditional nutritional value has created tremendous academic, commercial, regulatory and public interest. Thus, health promotion, "optimal" nutrition, concepts of enhanced performance—both physically and mentally—and reductions of risk of disease through the consumption of nutraceuticals and functional foods, are all receiving more attention (Richardson, 1996).

Broadly, functional foods are those with a similar appearance to their traditional counterparts, while nutraceuticals are components that are consumed in the form of tablets or capsules. Although confusion still exists about how best to define these evolving areas of food and ingredients technology, the common thread is that any health claims will require scientific validation and substantiation. The nutraceutical and functional foods commercial sectors in Europe have grown significantly over the past 5～10 years, and the challenges ahead relate to the demonstration of safety and efficiency, the identification of specific active components, their absorption and metabolism, and to the effects of processing.

The Proposed European Regulatory Framework

Consumers should be able to make choices based on clear and accurate information and an important objective for the development of European legislation is to ensure that claims on foods can be properly justified and scientifically substantiated (Byrne, 2003). A final proposal for Regulations of the European Parliament and of the Council on nutrition and health claims made on foods is expected to permit the use of "health claims" and "reduction of disease risk claims" on foods outside the scope of medicinal law, and Article 6 sets out the general principles for substantiation (see Table 1) (Commission of the European Communities, 2003). Health claims will, therefore, only be approved for use on the labelling, presentation and advertising of foods in the community market after a scientific evaluation of the highest possible standard. Currently, the proposed legislation states that, in order to ensure harmonised scientific assessment of a health claim, the European Food Safety Authority (EFSA) should carry out the assessments. It is anticipated that for long-established and non-controversial science e.g. for health claims that describe the role of a nutrient or other substance in growth, development and normal physiological functions of the body, the assessment and approval prior to their use, will result in the compilation and adoption of an approved list within a 3 year period and that the EU will develop a "Register" of health claims. For all other health claims, an authorization procedure will be developed based on substantiation by generally accepted scientific data.

Many academic, scientific and regulatory organisations worldwide are considering ways to establish the scientific basis to support claims for functional components or the foods containing them. Any regulatory framework will

Table 1. Proposal for a Regulation of the European Parliament and of the Council on nutrition and health claims made on foods

Proposal for a
REGULATION OF
THE EUROPEAN PARLIAMENT AND
OF THE COUNCIL
on
nutrition and health claims made on foods
(Brussels, 16.7.2003 COM(2003) 424 final)
Article 6
Scientific Substantiation for Claims

1. Nutrition and health claims shall be based on and substantiated by generally accepted scientific data.
2. A food business operator making a nutrition or health claim shall justify the use of the claim.
3. The competent authorities of the Member States may request a food business operator or a person placing a product on the market to produce the scientific work and the data establishing compliance with this Regulation.

need to protect consumers from false and misleading claims and to satisfy the needs of industry for innovation in the production, development, marketing and promotion of foods. For functional foods to deliver their potential public health benefits, consumers must have a strong confidence level in the scientific and regulatory processes used to support health effects and claims.

European Commission Concerted Action Project: PASSCLAIM

In April 2001, the International Life Sciences Institute (ILSI Europe) initiated the Concerted Action (CA), supported by the European Commission on a "Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM)" (International Life Sciences Institute Europe, 2001). The PASSCLAIM built on the CA on Functional Food Science in Europe (FUFOSE), which suggested that claims for enhanced function and "reduced risk of disease" should be based on sound scientific evidence, using appropriate validated biomarkers (Bellisle *et al.* 1998). The FUFOSE consensus documents were published in the *British Journal of Nutrition* (Diplock *et al.* 1999). The objectives and applications of PASSCLAIM are shown in Table 2.

Phase I of PASSCLAIM focused on three physiological areas or Individual Theme Groups (ITGs), namely diet-related cardiovascular disease (ITGA), bone health and osteoporosis (ITGB) and physical performance and fitness (ITGC). In each of these areas the current use of markers and the evidence base to support claims were critically assessed. In addition, a fourth group (ITGD) reviewed the current global situation in terms of existing laws, codes of practice and other schemes which were used to regulate health claims. These ITGA to ITGD papers were published in the European Journal of Nutrition in March 2003 (Asp *et al.,* 2003). In a second phase of PASS-CLAIM, four other ITGs are addressing the areas of insulin sensitivity and risk of diabetes (ITGE), diet-related cancer (ITGF), mental state and performance (ITGG) and gut health and immunity (ITGH) (Asp *et al.,* 2004). Based on this experience, it is anticipated that the process and the criteria for scientific support for health-related claims on foods and food components will help underpin the evolving European harmonised regulatory framework. The final PASSCLAIM plenary session will take place in Lisbon in December 2004.

Table 2. Objectives and applications of PASSCLAIM

Objectives

a. To produce a generic tool with principles for assessment of the scientific support for health-related claims for foods and food components

b. To evaluate critically the existing schemes which assess the scientific substantiation of claims

c. 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

Applications

1. PASSCLAIM will offer a practical scientific framework to prepare scientific dossiers supporting claims. This framework will ensure that all claims have a firm scientific base. European food manufacturing industry, including SMEs, will benefit because of the competitive edge that will be provided.
2. PASSCLAIM will enable the compilation of guidelines to prepare submissions for claims on foods. This will expedite and improve the efficiency of the regulatory review process.
3. Consumers will benefit from an improved approach to the scientific support for claims on foods. This integrated strategy will generate more consumer confidence in the science base related to claims on foods and will better address the concerns of consumers.

Guidelines and Codes of Practice on Health Claims in the EU

Several European countries have already developed guidelines and codes of practice on what to do with health claims and they evolved in the absence of an EU regulatory framework. They all, however, established a broad consensus that any new legislation should protect consumers from false and misleading claims, promote fair trade and encourage innovation in the food industry.

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

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

The UK Joint Health Claims Initiative (JHCI)

In the UK, a strong consensus has emerged that the present legal and enforcement frameworks governing health claims are both incomplete and inflexible, and that there is a need to review existing laws where the communication of the role of a healthy diet in reducing the risk of disease is prohibited. As a result, the UK Joint

Health Claims Initiative (JHCI), a tripartite group comprising regulatory authorities, the food industry and public interest organisations, has established a voluntary code of practice for the use of health claims (JHCI, 2001). The UK Code covers "generic", i.e. scientifically, well-established claims, and innovative, i.e. product-specific, health claims. The claimed benefit must be scientifically valid, with evidence supporting the efficacy of the food(s) or food component(s) in humans under typical conditions of use and exposure. This "evidence-based" approach consists of a systematic and objective compilation of all the scientific evidence relating to the health claim, including human intervention and observational studies, an evaluation of individual studies to determine the strengths and weaknesses of the data, a critical assessment of the data as a whole, and finally, a statement that there is significant scientific agreement that the body of evidence is sufficient to establish the validity of a health claim.

The reviews are carried out by an independent panel of leading scientists in the UK, and six generic claims have been approved. For example, on 8th February 2002 the JHCI published its advice that eating wholegrain foods such as wholegrain breads and breakfast cereals is an important factor in helping to maintain a healthy heart (Richardson, 2003). This UK generic health claim reflects the wholegrain health claim in the USA (Food and Drugs Administration, 1999) and the accumulation of evidence between 1996 and 2001 from several very large cohort studies in the USA, Finland and Norway, which show a consistent, protective effect of wholegrain and the reduced risk of coronary heart disease (Anderson *et al.* 2000). The research to date suggests that the health benefits of wholegrain foods are derived from more than just the fibre and that whole foods including whole grains, fruits and vegetables deliver "packages" of components that may work synergistically to promote health. A greater consumption of wholegrain foods has important public health implications and is an attractive and prudent food-based dietary strategy for targeting at the whole population. Eating a wholegrain cereal for breakfast each day is one of the easiest ways to include wholegrains in the diet, and some manufacturers have already pioneered the use of health claims on food labels. The JHCI has now given an authoritative endorsement that wholegrain foods are linked to a healthy heart. This UK experience has been utilised effectively in the process of developing a framework for health claims in the rest of Europe and in the approval of the wholegrain and heart health claim in Sweden (Swedish Nutrition Foundation, 2004). See Table 3.

Table 3. Authorised claims for wholegrain and heart health

USFDA, 1997	Diets rich in wholegrain and other plant foods and low in total fat, saturated fat and cholesterol may reduce the risk of heart disease and some cancers.
UK, 2002	People with a healthy heart tend to eat more wholegrain foods as part of a healthy lifestyle.
Sweden, 2004	A healthy lifestyle and a well-balanced diet rich in wholegrain products reduces the risk for heart disease. Product X is rich in wholegrains (contains Y% of wholegrains).

A Process for the Scientific Substantiation of Health Claims

The objective of PASSCLAIM ITGD was to identify common new ideas, definitions, best practice and a methodology to underpin current and future regulatory developments (Richardson *et al.* 2003). The PASSCLAIM initiative, and now the proposed draft regulations, have defined two broad categories of claim: "Nutrition Claims," based on what the product *contains* and "Health Claims" relating to health, well-being and/or performance, including well-established nutrient function claims, enhanced function claims and disease risk reduction claims. These health claims relate to what the foods or food components do. When a health claim is used the criteria set out in Table 4 must be demonstrated, if appropriate. Depending on the nature of the health claim, the following

Table 4. Revised interim criteria for the scientific substantiation of health claims on foods and food components

1. Foods and food components for which claims are made should comply with existing legislation.
2. Health claims should be scientifically substantiated by taking into account the totality of evidence. A scientifically substantiated mechanism is valuable but not essential.
3. When a claim is made, it should be specified who may benefit from the effect, e.g. the entire population, a subgroup or an at-risk group.
4. Claims should be based primarily on human intervention studies that show demonstrable effects consistent with the claim. They should have a scientifically valid design compatible with the purpose of the study, including the following:
   - Study groups that are representative of the target group
   - Controls both for the intervention itself, and for the subject groups
   - An appropriate duration to demonstrate the intended effect
   - Characterisation of the target groups' background diet, which should be controlled for where necessary
   - The amount of the food or food components being evaluated should be consistent with its intended use and the expected consumption pattern
   - Ideally, an exposure-response relationship should be determined to identify optimum effective intake Dietary compliance, which should be monitored
   - The statistical power to test the hypothesis.
5. If the claimed enhancement of function or reduction of risk cannot be measured, studies should use markers of effect that have been scientifically validated.
6. Markers should be validated:
   Methodologically to include their:
   - Precision and accuracy
   - Specificity and sensitivity
   - Reproducibility and repeatability

   Biologically so that
   - They reflect closely the process leading to the claimed health benefit
   - Respond quickly in line with changing events
7. Within a study the marker should change in a biologically relevant way and be statistically significant for the target group consistent with the claims to be supported.

approach should be considered for scientific substantiation, where applicable:

The identification of all relevant studies

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

Human studies

In brief, studies on human subjects are accorded greater weight than animal and *in vitro* (preclinical) studies, and interventional (clinical) studies have greater weight than observational studies. However, the relationship between dietary components and health benefits can be demonstrated by a number of different types of studies

and designs, and methodological soundness overrides any hierarchy, given that validity depends not only on the appropriateness of the study type, but also on the quality of its design, execution and analysis. Although well designed, randomised controlled trials (RCTs) provide the most persuasive evidence of efficacy in human subjects, for many of the firmly accepted precepts of healthy eating, RCT findings are unlikely to be available. In fact, most of the health claims allowed by the USFDA have not had the benefit of RCTs, and cohort (prospective) studies stand out among types of observational epidemiology for their driving role in establishing the links between diet and disease.

FUFOSE (Bellisle *et al.* 1998) suggested that the primary source of evidence for "enhanced function" and "reduced risk of disease" in human subjects is only justifiable when based on appropriate, validated markers of exposure, enhanced function or reduction of risk of disease. Hence, the development of validated and predictive biomarkers is an essential research objective.

Totality of evidence

The determination of the weight of the evidence as a whole requires assessment of the persuasiveness of each relevant study. The overall assessment, however, should be the application of scientific judgement and critical interpretation of the data as a whole. This assessment of the totality of the evidence should be sufficient to permit the conclusion that a change in the dietary intake of the food or food component will result in a health benefit and/or health outcome, including a change in disease endpoint.

Assessment of "generally accepted scientific data"

The use of a health claim should be subjected to rigorous substantiation on a case-by-case basis and depends on the strength and consistency of the body of evidence. The elements of substantiation are set out in the final proposal, COM 2003 429 final. The claims on the positive list must be based on, and substantiated by, "generally accepted scientific data" and the food business or person placing the product on the market may be asked by the competent authority to produce "all relevant elements" and data establishing compliance with the regulation.

Grades of evidence

The preamble of the proposed EU legislation states that health claims should only be authorised by EFSA after scientific assessment of the highest possible standard. Whilst no one would disagree with the basic principles of scientific substantiation, there is major concern on the part of the scientific community and industry on how to accommodate emerging science. The WHO and WCRF have established four grades of evidence: "convincing", "probable", "possible" and "insufficient". These definitions are defined for observational/epidemiological studies, but they need to be developed to cover the interpretation of other human studies and areas of supporting evidence, including animal and *in vitro* studies. The EU has not yet considered the concept of grades of evidence, but it is crucial to support scientific initiatives to find an approach where the term "generally accepted scientific data" includes not only generic or well-established linkages between a food or a food component and a health benefit but defines "generally accepted scientific data" to take into account the overall concept of the grades of evidence and the balance of probabilities that an association between a food or a food component and a health benefit will be refined (not reversed) by subsequent scientific research. The USA has already adopted an approach that recognises different grades of evidence. The academic community should have a key role in identifying suitable scientific criteria on which health claims can be based. For example, the provision of insufficient evidence to support a claim is clearly nonsense. However, depending on the state of the science and history of use, there is a need to embrace a system that stimulates, not stifles, academic research, product innovation and communication

of nutrition and health messages to the public.

There needs to be not only a coordinated effort to promote the concept of appropriate grades of evidence from the scientific perspective but also in the development of suitable qualifying language to allow communication of claims in terms consumers can understand and trust. Although there are concerns that words such as "may" and "might" may be misleading based on some consumer research now, it is worth considering the use and definition of such modal verbs to reflect the strength of the evidence, especially in the public interest and when there are no controls over statements/articles in the press and magazines. This more comprehensive approach to grades of evidence and qualifying language is less restrictive and more practical than disproportionate and restrictive measures that could undermine the efforts of all interested parties to promulgate sound nutrition practices for all ages.

Research is required in the different EU languages to explore and develop appropriate wordings depending on the level of certainty of the scientific evidence, e.g. may/might, can, will. If the levels of evidence are decided and defined more closely, the basis for scientific substantiation and the qualifying language would enable communications to be understood and trusted by consumers.

A Short Commentary on the Recent Regulatory Developments on Health Claims in the EU

The Commission of the European Communities has developed a proposal for regulation of nutrition and health claims on foods (EU Commission 2003).

Objectives

The main objectives of the proposal are:

- To achieve a high level of consumer protection by providing further voluntary information, beyond the mandatory information foreseen by EU legislation
- To improve the free movement of goods within the internal market
- To increase legal security for economic operators
- To ensure fair competition in the area of foods

Views are being sought from industry, consumer groups, regulatory authorities in the Member States and other interested parties.

Reduction of risk of disease

The industry has generally welcomed the new provision in the proposed legislation to distinguish between "prevention of disease" claims and "reduction of disease risk factor(s)". However, the terminology will need further clarification. Most chronic diseases are "multifactorial" and include genetic and lifestyle components such as smoking, diet, physical activity etc., all of which can impact significantly on health outcomes. The term "factor" is usually applied in this sense and should not be confused with the development and use of biomarkers, which are physiological indicators of health and well-being. The development of validated and predictive biomarkers is an essential research objective and they can be used as a primary source of evidence for "enhanced function" and "reduced risk of disease" claims. Potential biomarkers can be reduced or increased and hence the suggestion of "reduction of disease risk factors" will need careful interpretation.

Prohibited claims

A key area of concern is the Commission's proposals to prohibit certain claims. The overall prohibition of general, non-specific benefits of a food or food component (including a nutrient) for health and well-being is far too restrictive. It is essential that each claim is considered on a case-by-case basis on its own merits and on the

substantiating evidence supporting the claim. If, for example, a food or food component can "help support the body's natural defences" or "boosts the immune system" and the evidence supports those claims, then the claims should be permitted. Similarly, the proposal to prohibit psychological and behavioural claims does not reflect the significant research efforts on the effects of foods and food components on cognitive performance, hunger, appetite and satiety as well as effects on activation or sedation. Much of the research on functional food science and behaviour and psychological functions was funded by the EU Concerted Action Programme (FUFOSE) and reported by Bellisle *et al.* (1998). The preface to this research work was aimed at supporting the establishment of a science-based approach to functional foods.

The wording of a claim

The wording of the claim will also be subject to prior approval by the European Food Safety Authority (EFSA). This proposed procedure could be particularly restrictive and cumbersome. In the UK, the JHCI has retained flexibility for the actual wording of the claim using the following text:

"The wording of the claim has been carefully formulated to reflect the evidence on which the claim has been approved. Wording may be altered, in consultation with the JHCI, as long as the claim does not imply health benefits beyond the scope of the evidence, change the meaning of the claim or confuse customers."

A key objective of the Commission is to ensure that health claims are relevant and understood by consumers. Consumer communication is complex and is unlikely to be a speciality of those involved in the evaluation of the scientific dossier submitted to substantiate a claim. The suggested requirement in the draft regulation to submit the precise form(s) of words in the language of every Member State along with an application to the EFSA is unreasonable, particularly if the product is not necessarily marketed in all Member States.

It is essential to give manufacturers flexibility in communicating messages regarding diet and health to reflect the intended consumer and the evolution of consumer knowledge.

Nutrition profiles

The EU proposal states that a "Nutrition or health claim should not be made if it is inconsistent with generally accepted nutrition and health principles or it encourages or condones excessive consumption of any food or disparages good dietary practice". From the text of Article 4, "Conditions for the use of nutrition and health claims", it is clear that nutrition profiling is likely to apply. The focus is on levels of fat, saturated fat, trans fatty acids, salt/sodium and sugars whose excessive intakes in the overall diet are not recommended, whereas beneficial components such as poly- and monounsaturated fats, available carbohydrates other than sugars, vitamins, minerals, protein and fibre will also be considered when drawing up nutritional profiles.

Already, Member States such as the UK and Sweden are working on nutritional criteria at national level. To avoid potential barriers to trade, the nutrition profiles will have to be harmonised at Community level. An 18-month timescale will apply for the development of nutrition profiles and the European Commission will work with EFSA and all interested parties.

The proposed law makes provision for exemptions and derogations based on the importance of particular foods, food categories or nutrients and effects on health (e.g. iron, folic acid) and on scientific knowledge. However, nutrition profiling is complex and there are many anomalies that could hinder rather than help consumer understanding of what constitutes a varied and balanced diet.

Mutual recognition and fast-track procedures for health claims

Several government agencies and voluntary bodies in the EU Member States are now approving health claims (e.g. UK JHCI, Sweden, France, Netherlands, Finland). In the UK, all of the JHCI claims are "generic" or "well-established" claims already approved in the USA. There is no need to reinvent the wheel for areas of consensus science, and hence there needs to be a concerted effort to promote the concept of mutual recognition, acceptance of simplified dossiers providing the basic scientific justification, and fast-track procedures. Many health claims in the USA are based on "authoritative statements" from national and international scientific organisations (e.g. WHO, WCRF) and these dietary guidelines should be rapidly endorsed by the international regulatory and/or voluntary bodies and a 2-STEP procedure for appropriate nutrition and health claims to be included in the EU Register.

CONCLUSION

Health claims refer to what the food or food component does that has a benefit to health. The process of substantiation of a health claim will (1) benefit consumers by providing information on healthful eating patterns that may help reduce the risk of diseases such as heart disease, some cancers and osteoporosis; (2) provide consumers and healthcare professionals with a reference point and a measure of confidence that label claims are supported by sound scientific data; (3) provide the claimant with a return on their research investment as well as a measure of insurance when dealing with regulatory agencies; (4) stimulate new research to fill in the knowledge gaps revealed during the course of the scientific reviews.

In Europe, the approach to health claims has been very systematic. FUFOSE and PASSCLAIM have contributed towards the establishment of a science-based approach to concepts in functional food science and have identified those areas in human physiology and nutrition where the scientific effort should be made. One of the most important questions to consider is how the health benefits can be communicated effectively to consumers. To ensure the consumer's right to reliable information, the process for the verification of health claims is a critical issue of importance for regulators, the food industry, the advertising industry, nutritionists and consumer representatives.

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