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

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

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

The current paper outlines a process by which a health claim and reduction of disease risk claims could be made on a food category, a food or one of its components that is based on the totality of the available data, and by weighing the scientific evidence into three major grades: ‘convincing’, ‘probable’ and ‘possible’.

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

European Commission Concerted Action Project: PASSCLAIM

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

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

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

A process for the scientific substantiation of health claims

One of the main objectives of PASSCLAIM was to identify common new ideas, definitions, best
practice and a methodology to underpin current and future regulatory developments (Richardson et al. 2003). A key criterion for the scientific substantiation of a claim is to take into account the totality of the available data and the weighing of the evidence (Aggett et al. 2005).

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

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

**Grades of evidence**

The preamble of the proposed EU legislation states that health claims should only be authorised by EFSA after scientific assessment of the highest possible standard. Whilst no one would disagree with the basic principles of scientific substantiation, there is major concern on the part of the scientific community and industry about how to accommodate emerging science. The World Health Organisation (WHO 2004) and the World Cancer Research Fund (WCRF 1997) use four grades of evidence: ‘convincing’, ‘probable’, ‘possible’ and ‘insufficient’. The EU has not yet considered the concept of grades of evidence, but it is crucial to support scientific initiatives to find an approach where the term ‘generally accepted scientific data’ includes not only generic or well-established linkages between a food or a food component and a health benefit but defines ‘generally accepted scientific data’ to take into account the overall concept of the grades of evidence and the balance of probabilities that an association between a food or a food component and a health benefit will be refined (not reversed) by subsequent scientific research (see Table 1). The academic community should have a key role in identifying suitable scientific criteria on which health claims can be based. For example, the provision of insufficient evidence to support a claim is clearly inappropriate and would be misleading to consumers. However, depending on the state of the science and history of use, there is a need to embrace a system that stimulates, not stifles, academic research, product innovation and communication of nutrition and health messages to the public (Richardson 2004).

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

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

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

a) An inventory of foods and components, diets and botanicals based on national and international sources of knowledge.

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

**Insufficient**

Categories 1 and 2 Insufficient substantiation; more data needed

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