HEALTH CLAIMS AND FOODS

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Recent years have seen an increasing number of products sold under food law for which health claims are made. Many more such products (**functional foods**) are likely to appear in the coming years, aiming to reduce risks of various diseases, enhance well-being, etc. This prospect has led to concerns over the ability of the current regulatory framework to cope with such products.

This briefing note looks at recent developments in this area, and examines the issues that arise.

FOODS AND DISEASE

The idea that food can prevent disease is nothing new - for instance, the naval surgeon James Lind proved that citrus fruit could prevent scurvy as long ago as 1747. Since this time, many other **deficiency diseases** have been identified, and the minimum average daily intakes of nutrients (essential vitamins and minerals, energy, etc.) needed to stave them off have been defined. In most developed countries, the vast majority of the population can readily achieve such intakes by eating a normal balanced diet, although this has been assisted by the development of **fortified foods** (e.g. bread and breakfast cereals with added vitamins and / or minerals).

It is also well established that foods can have beneficial effects on health beyond merely supplying the body with nutrients. Evidence here comes from a wide variety of sources (epidemiological, clinical and laboratory) investigating the significant variations in disease rates and longevity among different populations throughout the world. Such studies have strongly implicated diet as a major factor behind many of the main 'killer diseases' (e.g. certain types of cancer, coronary heart disease [CHD], hypertension and diabetes) in western countries. Further epidemiological studies have since established that certain types of food can help to protect against such diseases. For instance:

- **fruit and vegetables** protect against various forms of cancer and also reduce the risk of CHD and stroke;
- **fish and fish oils** may help to prevent CHD and increase the chances of surviving heart attacks;
- **whole grain foods** protect against various cancers;
- **fibre** can reduce risk of CHD and colorectal cancer;
- **saturated** (e.g. in meat and dairy products) and **trans unsaturated** (e.g. in some hardened fats, biscuits, cakes, etc.) fats increase blood cholesterol and risk of CHD while **poly-unsaturated fats** (e.g. in soya bean or sunflower oil) reduce blood cholesterol. Mono-unsaturated fats (rapeseed, olive oils) are neutral.

BOX 1 FUNCTIONAL FOODS AND OTHER TERMS

Functional Food - a marketing term coined in Japan in the 1980s which is loosely used to describe any modified food or food ingredient that may provide a health benefit beyond the nutrients it contains.
Designer Food - processed foods that are supplemented with food ingredients naturally rich in disease-preventing substances (this may involve genetic modification of food).
Nutraceutical - any substance that may be considered a food or part of a food and that provides medical or health benefits, including the prevention and treatment of disease.
Pharmafood - food or nutrient that claims medical or health benefits, including the prevention and/or treatment of disease.
Source: American Dietetic Association (http://www.eatright.org).

Such findings underpin current dietary advice (e.g. to eat five portions of fruit or vegetables daily) and have prompted the development of a range of food products with reduced fat (e.g. milk, other dairy products), whole grain (bread, pasta, cereals, etc.), higher fibre, etc.

FUNCTIONAL FOODS

More recently, scientists have started to identify some of the specific dietary components involved and to understand more about the mechanisms by which they exert their effects within the body. Such advances span a wide range of disciplines (from food science through biochemistry to human genetics) and have led to the possibility of 'designing' foods to give specific health benefits. The various terms coined to describe such products (**Box 1**) are loosely defined, mean different things to different people and have no legal status in the UK. In practice, products (including soft drinks, dietary supplements, etc.) aiming to promote health by **preventing** disease are often called '**functional foods**', whereas terms such as 'nutraceuticals' and 'pharmafoods' (see Box 1) extend the concept to include the possible **treatment** of disease.

Main Functional Components

To date, hundreds of potentially promising (functional) food components have been identified. Some of the main classes under investigation are summarised in **Box 2**. They include a wide range of antioxidants, carotenoids and other chemicals found in plants (collectively known as phytochemicals), fatty acids (such as the omega-3 fatty acids found in fish oils), carbohydrates and soluble fibre, vitamins and minerals, proteins and their breakdown products (peptides and amino acids), etc. The strength of the evidence linking such components to disease prevention varies. In most cases, the factors were originally investigated because

BOX 2 SOME FUNCTIONAL COMPONENTS OF FOOD

Phytochemicals - a generic term used to describe chemicals from plants that are non-toxic (i.e. tolerated in daily gramme quantities) and which potentially protect against chronic disease (particularly cancer). It covers many different categories of potentially functional components, including:

- **Antioxidants** - such as carotenoids (notably β-carotene), vitamins (particularly vitamins E and C) and other antioxidants (e.g. glutathione, polyphenols) found in fruit, vegetables, herbs and spices. There is good evidence that these chemicals play a role in the body's defence against certain types of cancer and cardiovascular disease, and that foods containing them help to protect against such diseases (although it is less clear whether this protective effect occurs when antioxidants alone are taken as supplements).
- **Indoles**, **isothiocyanates, sulphurophane** - chemicals found in broccoli which may protect against DNA damage (and thus cancer). Evidence from animal studies shows that these compounds can reduce tumour size and may protect against hormone-related cancers (by decreasing the effectiveness of oestrogen-like hormones).
- **Carotenoids** - recent research has shown that lycopene (a carotenoid found in tomatoes, red peppers, pink grapefruits, etc.) may reduce the risk of prostate/cervical cancer. Other carotenoids such as lutein and zeaxanthin reduce the risk of age-related pigment problems.
- **Allylic sulphides** - substances found in garlic and onions, decrease proliferation of tumour cells (in animal experiments) and may reduce blood levels of cholesterol.
- **Isoflavonoids** - a class of chemicals found in soya products which have been shown to reduce blood cholesterol levels (and by implication, risk of CHD). It is also thought that genistein and other isoflavonoids may protect against hormone-related cancers and colon cancer.

Fats and fatty acids - much attention has focused on the omega-3 fatty acids found mainly in fish and fish oils and which are thought to help protect against CHD. Other fatty acids (notably stanol fatty acid esters) are claimed to reduce cholesterol absorption and thus to reduce the risk of CHD.

Carbohydrates/fibre - oligosaccharides (carbohydrates consisting of 3-10 single sugar units) and soluble forms of fibre (β-glucans) are thought to have a number of beneficial effects including improving gastrointestinal health (by stimulating the growth of *bifidobacteria*) and reducing absorption of cholesterol respectively.

Vitamins, minerals, etc. - many health benefits are claimed for vitamins and minerals beyond the prevention of deficiency diseases. In general, the best evidence concerns folic acid (to prevent neural tube defects) and calcium (to reduce the risk of osteoporosis). Other claims include protective effects against cancer and CHD for supplements containing vitamin (e.g. E and C) or mineral (selenium) antioxidants, and the role of vitamin B6 in preventing premenstrual syndrome.

Amino acids and peptides - currently under investigation are claims that oligopeptides (short chains of amino acids) present in fermented milk protein reduce blood pressure in people with mild hypertension and that soya proteins reduce cholesterol absorption.

Bacteria - various approaches aim to promote health via the microbiological flora in the gastro-intestinal tract. These include **probiotics** (foods with beneficial bacteria such as *Lactobacillus* or *Streptococcus)* as well as prebiotics (foods containing non-digestible ingredients such as oligosaccharides, designed to encourage the growth of *bifidobacteria* in the colon). Combinations of probiotics and prebiotics (synbiotics) may produce synergistic effects.

they were components of foods implicated in disease prevention by epidemiological studies. There is strong evidence that diets containing foods naturally rich in such components do protect against a wide range of chronic diseases. In general however, there is much less evidence concerning the protective effects of the individual components themselves.

Much of the research on isolated, purified dietary components such as those outlined in Box 2 has been conducted in animals, and there is a general lack of evidence from large-scale trials in humans. Where such trials have been conducted, some have provided strong evidence for disease prevention (e.g. using folic acid to prevent neural tube defects), but others have given more equivocal results. For instance, clinical trials investigating β-carotene supplements for the prevention of cancer have generally failed to show any evidence of harm or benefit, apart from when given to smokers, where several studies suggest the supplements **increase** the risk of lung cancer. Such studies illustrate that the mechanisms by which diet can protect against some diseases may involve complex combinations of dietary components rather than single factors.

Technical Approaches

In the past, improved knowledge of the health benefits associated with different elements of the diet was used as the basis of dietary advice (to eat less fat, more fruit and vegetables, etc.). These days however, such knowledge is increasingly also being used to produce functional foods, using a number of different technical approaches:

- **Product formulation** - this includes incorporation of functional ingredients into foods (e.g. fortification, re-formulation to increase levels of ingredients such as bran or fibre and adding novel ingredients such as probiotics, phytochemicals, etc.), as well as re-formulating foods to contain lower levels of potentially harmful components (e.g. reducing fat).
- **Novel processing** - e.g. enhancing the functionality of foods by fermentation (e.g. to produce oligo-peptides), by heat or enzyme processes (e.g. to produce modified starches), or by novel processing to increase the availability to the body of components already present in the food.
- **Modification** of raw materials - until recently, this involved using conventional breeding/selection techniques to enhance the properties of plants and animals. More recently, the advent of genetic engineering has led to the development of a wide range of genetically modified (GM) foods, and crops with enhanced functional components (altered fatty acid profiles, iso-flavone content, etc.) are a major priority of current research.

FIGURE 1 THE FOSHU LOGO

BOX 3 CRITERIA FOR THE APPROVAL OF FOSHU

- Food should be expected to contribute to the improvement of the diet and the maintenance/enhancement of health.
- The health benefits of the food or its constituents should have a clear medical or nutritional basis.
- Manufacturers should be able to define appropriate daily intakes of the food based on medical/nutritional knowledge.
- The food should be safe to eat.
- The physicochemical composition of the food should be clearly defined using analytical techniques.
- FOSHU products should show no significant loss in nutritional qualities compared with similar conventional foods.
- Food should be of a form normally consumed in daily dietary patterns (rather than consumed only occasionally).
- Products should be foods, rather than pills or capsules.
- Foods should not contain components used exclusively as medicines.

Source: "FOSHU", Office of Health Policy on Newly Developed Foods, Environmental Health Bureau, MHW, Japan.

Available Products

Japan presently has the biggest market for functional foods, with some 108 different products (**Table 1**, over page) licensed for sale through a regulatory system known as FOSHU (Foods for Specialised Health Use). Manufacturers can obtain permission from the Ministry of Health and Welfare (MHW) to make agreed health claims for functional foods, provided that the products meet the criteria (concerning safety, substantiation of the health claim, etc.) outlined in **Box 3**. The MHW stipulate the exact form of words that can be used in the health claim made on the label, and all approved products must also display the FOSHU logo (**Figure 1**). Among the most common functional components (Table 1) are:

- carbohydrates and oligosaccharides (43 products, typically claiming to "*maintain a good gastrointestinal* [GI] *condition*" by encouraging the growth of *bifidobacteria*);
- fibre (28 products with added fibre which also claim to "*regulate and maintain a comfortable GI condition*");
- proteins ("*helps inhibit the absorption of cholesterol*") and peptides ("*helpful for people with mild hypertension*");
- other components including minerals (calcium and iron), probiotics ("*helps maintain a good intestinal environment*"), polyphenols (widely considered to have antioxidant properties but claims in FOSHU products are restricted to their non-cariogenic[1] properties), and various other substances (chitosan, alginate) which "*help inhibit absorption of cholesterol*".

Functional foods are far less well established outside of Japan, partly because regulations in Europe and the US prohibit many health claims of the type permitted under the FOSHU system (see later). The UK market is thus currently quite small, although various foods for which health claims are made have been marketed over the years (**Table 2**, over page). While not all of these are still on the market, the main product areas are bio-yoghurts (containing probiotics claimed to "*maintain the balance of the digestive system*"), energy drinks (claimed to "*revitalise*", "*help to fight dehydration*", etc.), high fibre and/or vitamin enriched breads and cereals and herbal drinks (see Table 2). However, there are indications that the UK market for such products will expand (see below) - for instance, a Finnish company recently announced its intention to launch a functional margarine (Benecol, which contains plant stanol fatty acid esters to reduce blood cholesterol levels) in the UK in 1999.

Future Trends

Although relatively few functional foods have found their way onto the UK market, there are a number of reasons for thinking that they will become increasingly important in the years to come. For instance, the basic science on the links between genes, diet and health continues apace, and as knowledge in this area increases, so will the potential for developing functional foods. Technological advances have also given manufacturers new tools (genetic modification, new food processes, etc.) to deliver such products. At the same time, factors such as escalating healthcare costs and an ageing population will put increasing pressure on governments to use diet as a means of preventing disease and promoting good health. Finally, the growing markets for dietary supplements, organic foods, etc. suggest increasing consumer interest in products aimed at promoting health through diet.

[1] **Non-cariogenic - components that do not encourage tooth decay.**

TABLE 1 SUMMARY OF FOSHU PRODUCTS IN JAPAN

Category (No. of products)	Example of product	Example of health claim
Oligo-saccharide (43)	*Yoghurina* (yoghurt drink with xylo-oligosaccharides)	"helps increase intestinal bifidobacteria and maintain a good GI condition"
Fibre (28)	*Fibre-Mini* (carbonated drink with polydextrose)	"helps regulate the GI condition by conveniently providing the dietary fibre which tends to be insufficient in the normal diet"
Proteins + Peptides (10)	*Casein DP* (soft drink with casein peptides)	"helpful for people with mild hypertension to improve their diet patterns"
Minerals (8)	*Feminia* (soft drink with haeme iron)	"suitable for those who suffer from a mildly anaemic condition that may require an iron supplement"
Probiotics (9)	*Bifidus Plain* (yoghurt with bifidobacteria)	"helps increase intestinal bifidobacteria. It helps maintain a good intestinal environment and regulate GI condition"
Polyphenols + Glycoside (5)	*Natulove* (chocolate with polyphenols)	"low cariogenic chocolate with maltitol, palarinose, and green tea polyphenols - all non-cariogenic ingredients"
	Tochu 120 (soft drink with Eucommia leaves)	"contains glycoside from Eucommia leaves which is suitable for people with mild hypertension"
Chitosan, Alginate (4)	*Menard Chole-Toru Bar* (biscuit with chitosan)	"formulated with enough chitosan to help inhibit absorption of cholesterol. So it is useful for people with high blood cholesterol level or for those concerned about it "
	Cholecut (soft drink with sodium alginate)	"helps inhibit absorption of cholesterol.....it is helpful for people who have or are concerned about, high blood cholesterol level"
Diacyl-glycerol (1)	*Econa* (cooking oil)	"contains the ingredient diacyl-glycerol...it is difficult to increase blood neutral fat after a meal"

Note: GI - gastro-intestinal
Source: "FOSHU", Office of Health Policy on Newly Developed Foods, Environmental Health Bureau, MHW, Japan.

A recent review[2] of functional foods identified several categories of products likely to be developed:

- Enhanced variants of traditional foods - fortified foods, indirect fortification (e.g. adding minerals to fertilizers to increase levels in crops, feeding omega-3 oils to chickens to raise levels in eggs), GM foods with enhanced nutritional profiles, etc.
- Disease-specific foods - incorporating functional components (e.g. see Box 2) specifically designed to reduce risk of cancer, CHD, etc.
- Foods targeted at specific risk groups - sugar-free sweets for children, calcium and/or phyto-oestrogen fortified products for pre-menopausal women.
- Foods targeted at the elderly - e.g. products fortified with DHA[3] (claimed to retard senility).
- Products claiming to improve physical (e.g. high energy drinks) or mental (e.g. choline-containing products claiming improved memory) performance.

TABLE 2 SUMMARY OF FOODS MARKETED IN THE UK FOR WHICH HEALTH CLAIMS WERE MADE

Product category	Nature of typical claims
Milk and Bio-yoghurts	Bio-yoghurt claims typically refer to maintaining the balance of the digestive system.
Energy drinks	Isotonic, helps fight fatigue and dehydration, replaces lost energy, energising, etc.
Cereals + Bread	Claims relate to vitamin fortification and/or high fibre content.
Herbal drinks	Various claims involving words such as soothing, calming, stimulating, restorative, refreshing, uplifting, etc.
Meat + Fish	Most claims refer to the high content of omega 3 oils.
Fruit + Fibre drinks	Added fibre and/or vitamins.
Spreads / Oils	Various claims relating to fatty acid content, antioxidants, etc.
Snack bars	Main products are energy bars with claims referring to high carbohydrate content.
Night drinks	Claims referring to added vitamins which play a role in protecting your body from harmful effects.

Source: Ministry of Agriculture, Fisheries and Food (MAFF) Food Labelling and Standards Division

- 'Mood foods' - that alter psychological states (e.g. products including tryptophan and/or serotonin that satiate appetite and induce calm, as well as those with added stimulants such as ephedrine).

REGULATORY SYSTEMS

The Law

Functional foods present considerable challenges to regulatory systems because they blur the boundaries that such systems traditionally draw between medicines and foods. UK legislation defines medicines as products "*presented for the treatment or prevention of disease"* and/or which "*may be administered with a view to restoring, correcting or modifying the normal operation of a physiological function*". 'Foods' however, have no legal definition but are rather 'defined' as being products intended for human consumption that are not medicines.

This distinction between medicines and foods is important because EU Directives[4] and the Food Labeling Regulations 1996 (FLR) that implement them prohibit any form of **medicinal claim** (i.e. that a food can prevent, treat or cure a human disease) on food labels, advertising, etc. Medicinal claims are allowed only on products licensed under the Medicines Act 1968 which are, by definition, medicines and not foods. However, they make no specific provision for **health claims** (i.e. any statement, suggestion or implication in labeling or advertising that a food is beneficial to health) which are currently subject only to more general provisions (e.g. in the Food Safety Act or the Trades Descriptions Act) which make it an offence to falsely describe a food, or to mislead as to its nature, substance or quality.

[2] "The Future of Functional Foods", Food & Health Research, 1998.
[3] DHA - docosohexanoic acid.
[4] 79/112/EEC (Food Labeling Directive) and 89/398/EEC (PARNUTS Directive).

The FAC Draft Guidelines

This system leaves a number of 'grey areas' over what constitutes a medicinal claim, the level of evidence required to substantiate a claim, etc. In an attempt to clarify some of these, the Food Advisory Committee (FAC) published draft guidelines on health claims on foodstuffs in 1996 (see **Box 4**) which recommended that:

- health claims should not mention any disease since any such reference could be construed as a medicinal claim;
- general claims based on scientifically established and officially endorsed links between diet and health should be allowed (see Box 4 for examples);
- other (e.g. new) health claims should be allowed only where these can be substantiated by scientific studies in humans (see Box 4).

The JHCI Draft Code of Practice

The Food and Drink Federation (FDF), National Food Alliance (NFA) and LACOTS (Local Authority Coordinating Body on Food and Trading Standards), established the Joint Health Claims Initiative (JHCI) in June 1997 to progress the work started by FAC. This has recently culminated in a draft Code of Practice on Health Claims on Foods, which aims to clarify the existing regulatory position. The draft Code is voluntary and applies to health claims in labeling, advertising and promotion of all foods marketed to the general public (whether as foods, drinks or supplements). It distinguishes between two main types of claims:

- **Generic health claims** - based on well-established knowledge/evidence in the scientific literature or on recommendations made by national/international bodies such as COMA, US FDA and EU SCF[5]. One of the first tasks of the proposed Code Administration Body (CAB, see below) would be to draw up a 'menu' of approved generic health claims in conjunction with an independent expert authority. This would allow companies to make generic health claims for foods provided they comply with the criteria laid down by CAB (contain certain levels of a particular component, fall within the category of food to which the generic claim applies, etc.). No further substantiation of such claims would be required.
- **Innovative health claims** - defined as claims other than the generic claims outlined above. Companies wishing to make such claims must substantiate them in accordance with the criteria laid down in the draft Code (see **Box 5**). These strongly recommend (but cannot compel) companies to seek advice from CAB on such products **before** marketing them.

BOX 4 FAC DRAFT GUIDELINES ON HEALTH CLAIMS

The Food Advisory Committee reviewed the market for functional foods and the control of health claims and published draft guidelines for consultation in 1996. Overall, the Committee concluded that it had "*seen no convincing evidence for the need for pre-market approval of functional foods beyond the controls which already exist*", but noted that there was "*a need for advice to be available to companies and enforcement officers on health claims*". The draft guidelines outlined a number of principles underlying health claims.

Reference to disease - any reference to a specific disease is likely to be regarded by the consumer as implying that the food will have a medicinal effect. Non-specific references to disease may imply a more general medicinal effect. It would be best for retailers and manufacturers to avoid all mentions of diseases on food labels or in advertising.

Claims based on established links - positive messages which link foods and health may help purchasers improve their diet, provided they are based on officially endorsed (e.g. by the DH) links. Examples of acceptable nutrient function claims that command a general scientific consensus include:

- "*calcium aids in the development of strong bones and teeth*";
- "*protein helps build and repair body tissues*";
- "*iron is a factor in red blood cell formation*";
- "*vitamin E protects the fat in body tissue from oxidation*";
- "*folic acid contributes to the normal growth of the foetus*".

Other health claims - claims that are not based on official recommendations are not excluded, but must follow the principles outlined in the guidelines. Manufacturers and retailers must also be able to substantiate any such claims (see below).

Context - health claims should not encourage/condone excessive consumption of any food or disparage good dietary practice. In most cases claims need to be set in the context of the role of the food in the overall diet (e.g. "*if eaten as part of a low fat diet*"). Claims must also refer to the food as eaten, and must be fulfilled when normal quantities (reasonable sized portions or intakes) are consumed.

Substantiation - claims should be supported by a dossier of scientific evidence showing that the specific physiological effect claimed is beneficial to human health, and that the product is safe to eat. This should be based on studies in humans and should include epidemiological evidence from studies:

- carried out in a representative cross-section of a population similar to that of the UK;
- where the study group consume a reasonable portion of the food at a reasonable frequency (e.g. once a day);
- of sufficient duration to ensure that the beneficial effect lasts for a reasonable period of time (i.e. is not a short-term effect to which the body adjusts);
- which take into account potentially confounding factors such as smoking, other dietary components, etc.;
- which produce statistically significant results.

Source: FAC, 1996. "Draft Guidelines on Health Claims on Foodstuffs", MAFF, London.

Because the Code merely seeks to clarify existing laws, the basic principles of the Food Labeling Regulations still apply. In particular, medicinal claims for foods are still prohibited, although the Code provides explicit guidance on the types of words, phrases and images that are (and are not) acceptable. Consumer perception is identified as the overriding principle in judging the acceptability of claims, and the Code gives a number of examples of things **to be avoided** because they might imply prevention, treatment or cure of disease:

- references to a specific disease;
- non-specific references to disease in general;
- pictorial/other references to changes in the body

[5] COMA - Committee on the Medical Aspects of Food and Nutrition Policy. US FDA - United States Food and Drug Administration. EU SCF - European Union Scientific Committee on Food.

caused by disease;
- references to relief of "*symptoms*";
- descriptions of particular symptoms which are perceived as signs of a disease (e.g. stress, anxiety, aches and pains, tension);
- targeting products at sections of the population suffering from disease or known to be at risk;
- use of (or reference to) associated promotions or literature which include reference to disease;
- use of medical terminology or images to increase the association of the product with medical use;
- use of certain words and phrases ("*restore, repair, eliminate, control, counteract, combat, clear, stop, alleviate, remove, heal, remedy, avoid, protect, relieve, regenerate, normalise, strengthen, check, end, fight, calm, detoxify, reduce, lower*") which if presented in a medical context might imply that the product can provide a medicinal benefit.

JHCI are expected to finalise the draft Code at a meeting in November 1998, whereupon copies will be sent to FAC and COMA (to advise Ministers) and to the European Commission. LACOTS (foods), the MCA (medicines) and the ASA[6] will continue to enforce the regulations. These are generally in line with the approaches taken by other EU countries, but are in stark contrast to the Japanese FOSHU system described previously. In the US, the FDA has long allowed only certain generic claims (e.g. stating that there was a link between dietary fat and cancer), but recently agreed its first food-specific claim, for foods containing oatmeal/bran. Products containing specified levels of fibre from these sources will now be able to claim that "*soluble fibre from oatmeal, as part of a low saturated fat, low cholesterol diet, may reduce the risk of heart disease*".

ISSUES

The debate about the regulation and enforcement of health claims on foods has now led to a consensus among food manufacturers, retailers, enforcement officers, regulators and consumers alike on the need to augment existing regulations. These are seen as being too strong in some areas (prohibiting some legitimate claims) and too weak in others (tolerating misleading or unsubstantiated ones). EU legislation (a general directive on food claims) in this area has been on the agenda since the early 1980s, but discussions proved fruitless (although the Commission recently signified its intention to consider the need for controls on health and nutrition claims). Efforts are thus focused on clarifying existing UK legislation through implementation of the guidelines or codes of practice outlined above.

BOX 5 JHCI DRAFT CODE - SUBSTANTIATION OF CLAIMS

Aims of substantiation - companies must be able to show:
- that the food (or its components) will cause a significant physiological benefit when consumed by the target population as part of their normal diet;
- that the effect can be achieved by consuming a reasonable amount of the food on a regular basis;
- that it is maintained over a reasonable period of time and is not a short-term effect to which the body responds;
- the minimum and maximum amount and the frequency of consumption required to achieve the effect;
- who can benefit from the effect (the whole population, at-risk groups, other sub-groups, etc.)
- how the effect occurs (although the exact biological mechanism is not necessary).

Source and nature of scientific evidence

The JHCI draft Code requires that the health claim is based on a systematic review of all the available scientific evidence (i.e. publicly available information in the scientific literature as well as any commercially confidential data). Conclusions should be based on all the evidence available (not just that which happens to support the claim), and should include evidence from studies in humans (not just evidence from animal or test-tube studies). The draft Code points out that clinical studies that directly assess human health are required for the testing of drugs and new medical interventions, and suggests that such studies should be required for foods for which health claims are made. However, since such studies are time-consuming and expensive, evidence of the effects of the foods on bio-markers (e.g. cholesterol levels) should be acceptable provided that there is an established link between the marker and the health claim made.

Source: JHCI 1998. "Code of Practice on Health Claims on Foods, Final Draft".

Allowable Health Claims

Claims that refer to the **maintenance of healthy or normal** body functions, processes, organs, etc. or to health in general are likely to be acceptable, since they should not be perceived as implying disease prevention, treatment or cure. Thus a claim that a product "*helps maintain normal cholesterol levels*" is acceptable (provided it is true!), whereas claiming it "*helps reduce (or lower) cholesterol levels*" is not. If a product has been proven to reduce the risk of a disease, it is also acceptable to make a claim that refers to the part of the body that may benefit from this reduced risk, but **not** to refer to the disease itself. Thus, a claim that "*healthy cholesterol levels are known to play a part in maintaining a healthy heart*" is acceptable, but one stating that "*healthy cholesterol levels lower the risk of heart disease*" would be unacceptable.

Decisions on generic and innovative health claims and their substantiation will be made by the proposed CAB, which is envisaged as consisting of:
- A Council with representatives of consumer, enforcement and industry interests.
- An independent Secretariat.
- An independent expert authority, which will consist of a panel of experts convened by CAB.

Where necessary (e.g. on matters concerning the legality of health claims) CAB may also seek the advice of bodies such as the MCA or LACOTS. At present, it is not clear

[6] **Medicines Control Agency (MCA), Advertising Standards Agency (ASA).**

exactly how CAB will interface with the new Food Standards Agency (FSA), although one possibility would be for the FSA to provide the independent Secretariat to CAB. Overall, the JHCI Draft Code of Practice will provide much-needed clarification of existing legislation relating to health claims. But the process has also served to highlight a number of potential problems, discussed in more detail below.

Medicinal Claims

If the number of (functional) foods available on the market for which health claims are made increases, and the science behind the claims improves, regulators may come under mounting pressure to allow ('medicinal') claims that refer to disease prevention, treatment or even cure. As noted previously, such claims are prohibited under current UK/EU legislation and would also fall foul of proposed international[7] regulations.

This prohibition is absolute - it takes no account of whether or not the claim is true. For instance, as things currently stand a manufacturer is not permitted to claim that a foodstuff with added vitamin C can "*help prevent scurvy*" even though such a claim is demonstrably true. Some see this situation as illogical, arguing that the regulatory focus should be on whether or not a claim can be substantiated, rather than on whether it may be interpreted as 'medicinal'. Such an approach would require a change in the primary legislation (to remove the prohibition on medicinal claims), with the *quid pro quo* being that companies wishing to make claims for foods would have to provide much stronger scientific evidence to substantiate them (see below).

However, any move to change the law to allow 'medicinal' claims for foods would be controversial. Consumer and other groups see existing health claims as open to abuse and misinterpretation, and would oppose allowing more explicit claims on the grounds that it would make things even more confusing and complicated for consumers. They further assert that the current legislation has proved useful over the years as a way of protecting the public against spurious claims made for products such as tonics, patent medicines, etc.

Substantiation

The link between the strength of the claims made and the strength of the evidence required to substantiate them is likely to be a recurring theme in the debate over the next few years. JHCI's draft Code (see Box 5) states that the "*outcome measure in clinical/human studies should be the improvement in some indicator of well-being or the lessening of some disease*". This places the standard of evidence required to substantiate health claims on foods on a par with that needed for new drugs and medical interventions. However, given the expensive and time-consuming nature of such studies, the draft Code noted that it is acceptable to measure the effects of foods on some intermediate physiological state or process (a bio-marker) "*until such time as full human studies are the norm*".

This raises questions as to when 'full human studies' will become the norm and the type of factors that will influence this. The expectation in the draft Code appears to be that there will be an incremental raising of the standards of evidence required for substantiating health claims on food, but it is not clear how this going to be achieved. In practice, companies are unlikely to invest in large-scale clinical trials assessing 'medicinal' effects (e.g. whether a product reduces the risk of heart disease) until such time as they can explicitly use such information in their claims (e.g. "*helps reduce the risk of heart disease*"). As things currently stand, a company would be much more likely to conduct smaller-scale research on a relevant bio-marker (e.g. cholesterol levels) to support a claim along the lines of "*helps maintain a healthy heart*".

Borderline Products

Although most products are readily identifiable as medicines, foods, cosmetics, etc., LACOTS and the MCA are increasingly encountering borderline products that are more difficult to categorise. Such products range from dietary supplements and inappropriately marketed health food snacks (one of which strongly implied that it prevented cancer) to products such as 'performance enhancing' drinks and even oxygen in tablet form (for which a variety of health-related claims were made). At present, close liaison between LACOTS and the MCA is required to ensure that such products are dealt with by the appropriate agency. Each of these bodies has also published guidance on the distinction between products needing a medicines licence (MCA's Medicines Act Leaflet No 8) and those sold under food law (LACOTS' Guidance on Medicinal Claims).

Any increase in the number (or level of sophistication) of functional foods on the market is likely to cause more problems in this area, further muddying the distinction between medicines and foods. One option here would be to recognise functional foods as a separate legal category. A potential advantage of such an approach would be that it would represent a 'halfway house' between medicines and foods, where the levels of evidence required for substantiation of health claims could be lower than for medicines, but where the wording of substantiated claims could be more explicit

[7] Draft recommendations currently being considered by the Codex Alimentarius Commission (CAC) state that a "*claim that a food....has an effect on an adverse health-related condition in the body should not be permitted*".

than currently allowed under food law. However, consumer groups would oppose such a move on the grounds that it would confuse consumers further, and it might also prove difficult to define legally what is meant by functional foods.

Paying for the CAB

A final regulatory issue is how the proposed new CAB is to be paid for. The main question here is whether and to what extent CAB might be financed by Government. An alternative source of funding would be to charge a fee to companies submitting products for evaluation of claims to recover at least some of the costs, although this might be difficult to enforce, given the voluntary nature of the Code. ACNFP currently charge for assessing applications for novel foods, but this is a recent development coinciding with the introduction of the Novel Foods Regulations (under which the ACNFP became the UK Competent Authority).

Potential Nutritional Concerns

Expert advisory (e.g. COMA, ACNFP) and consumer groups have voiced reservations over the possible nutritional consequences of the kinds of functional foods currently being developed. These fall into two main areas. Firstly, there are concerns that some of the products might confuse consumer perception of what constitutes a healthy diet. For instance, a product such as a high-fibre yoghurt might help people increase their fibre intakes in line with current dietary advice. But the overall effect could be undermined if consumers increased consumption of conventional yoghurts in the mistaken belief that these were also a rich source of fibre.

Secondly, there are concerns over possible cumulative effects of small changes in the composition of an increasing number of foods. Small changes to the fatty acid composition of individual foods may in themselves be of little nutritional significance. But the cumulative effects of a diet containing several such products might have nutritional consequences - for instance through changing the balance of individual unsaturated fatty acids. The main concern considered at a recent joint ACNFP/COMA meeting is that there is currently no assessment of these wider nutritional issues.

Functional Foods and Public Health

The recent Government Green Paper '*Our Healthier Nation*' set targets in four main areas, two of which involve diseases with a major dietary component:

- heart disease, stroke and related illnesses (target - reduce deaths among people under 65 from these causes by at least a further 33% by 2010);
- cancer (target - reduce deaths among people under 65 from cancer by at least a further 20% by 2010).

Diet makes a significant contribution to these diseases and is thus one of the main tools by which such targets might be met. For instance, a recent COMA report *Nutritional Aspects of the Development of Cancer* estimated that diet contributed to as many as one in three cancers, and recommended:

- a fall in the average consumption of red and processed meat (those with intakes around the current average [8-10 portions/week] should consider a reduction, while those with high intakes [12-14 portions/week] should reduce consumption);
- increased intakes of a wide variety of fruit and vegetables;
- increased intakes of dietary fibre from a variety of food sources;
- maintenance of a healthy body weight throughout adult life.

While there is a reasonable scientific consensus on what people should and should not be eating to minimise their risk of cancer, heart disease, etc., it is less apparent how best to achieve such changes. At present, the focus is on educational and other initiatives advising people to increase their consumption of fruit and vegetables (e.g. 5 or more portions a day), eat more cereals, pulses, roots, vegetables, potatoes, tubers and plantains (e.g. 7 or more portions a day), etc. There is evidence that such campaigns do work, albeit slowly. For instance, figures from MAFF's National Food Survey show a small, long-term upward trend in fresh fruit consumption (e.g. the latest figures show a 2% rise in the first quarter of 1998 compared to the same period in the previous year).

A more pragmatic approach is to advise people to switch to 'healthier' versions of foods they already consume, and experience (e.g. sales of semi-skimmed milk now outstrip sales of full-fat milk) suggests that this approach can have a much bigger and more immediate impact on people's shopping patterns (though not on their overall nutrient intake). Some thus see a comparable future role for functional foods, helping to improve people's diet with the minimum of disruption to their established habits. However, the extent to which functional foods do prove to be a useful public health tool will depend on the type of products developed, the claims made for them, the quality of the science substantiating these claims and consumer/regulatory attitudes towards such products.