Original Article

Implications for food regulations of novel food: Safety and labeling

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Novel or functional foods may provide health and nutritional benefits due to non-nutritice components such as fiber, flavonoids, and phenols. National, regional and international regulations are discussed as a means to control label claims, composition and uses.

Key words: functional foods, label claims, novel foods.

Novel foods, what are they?

Novel or functional foods have been difficult to define in a legal sense. The European Union (EU) has published regulations for novel foods, but the main thrust of these rules is to control newer foods derived from present biotechnology developments. Despite the difficulty of precise definitions, there appears to be a common public understanding of the concept that many foods may contain beneficial (or harmful) substances in addition to the common nutrients of digestible carbohydrates, proteins, fats, ethanol, and essential vitamins and minerals. Both from the public point of view, and as a result of science-based experimental test systems, the concept of novel or functional foods or components is that such foods or components can have a beneficial effect on bodily functions and structures. In some countries well-founded claims for such effects have been allowed, while in other countries no claims have been permitted.

There is no current legal definition for 'functional food' in most countries and foods of this type are regulated under existing food or related legislation in countries where functional claims are made. In many countries regulations exist for conventional foods, foods for special dietary use, dietary supplements, and medical foods for use under the supervision of a physician for management of specific diseases. In the EU there are regulations for 'novel foods' that in some cases could also be considered as functional foods. Each of these categories have regulations that govern which claims can be made, and either specific rules or guidelines for the types of data that are needed to establish the validity of any claims on the labels of foods, or in advertising. In most countries there are also clear legislative provisions for drugs, and certain claims for disease treatment can make a food product a drug in the legal sense and lead to severe regulatory consequences, even if that was not intended by the promoter making the claim for a food.[1,2]

At the international level there has been discussion about functional foods, novel foods, and labeling and claims for these types of foods and foods for special dietary use. The Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) Codex Alimentarius Commission has adopted a General Standard for the Labeling and Claims for Prepackaged Foods for Special Dietary Use, and General Guidelines on Claims, Nutrition Labeling, and Nutrition Claims, and all of these should be taken into consideration in determining if a claim can be made, and the nature of the claim.

As discussed here, there are rules in the EU, Australia and New Zealand that cover novel foods and foods derived from recombinant DNA techniques that are somewhat overlapping in the EU, while they are separate in Australia and New Zealand. At the Codex international-level foods derived from biotechnology are being actively discussed, and a number of FAO/WHO Expert Consultations have been held to better define basic concepts, examine the quality and safety aspects of these foods, including possible problems of allergenicity, and related topics. The FAO/WHO Expert Consultations have endorsed the approach used in the USA of 'substantial equivalence' for foods derived from biotechnology. This has meant up to now that, if the nutritional and other quality and safety aspects were substantially equivalent to similar foods that were not produced using recombinant DNA techniques, then specific labeling was not required. The Codex Committee on Food Labeling and the Codex Task Force on Foods Derived from Biotechnology are actively discussing international aspects of labeling and a general standard for foods derived from biotechnology, but no final recommendations have been made for adoption by the 165 member country members that comprise the Codex Alimentarius Commission.

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Novel or functional food claims

Foods are usually defined as articles for food and drink, while drugs are usually defined as articles intended for use in the diagnosis, cure, treatment, or prevention of disease. In the past there was no middle ground between foods and drugs, and health-related claims were not permitted on foods. However, developments in several countries and at the international level have tended to take into account newer features of foods and how they are produced and processed, research into the possible beneficial or protective effects of foods and their ingredients. Because of this, regulatory authorities and new legislation in some countries have opened up the possibility of properly substantiated health-related claims for foods and their ingredients.

This is an evolving area, in particular with the concept of 'novel foods' and 'functional foods', and it has been a difficult task to substantiate claims, and to maintain a good and constantly stronger scientific database to support claims. In the USA one of the first claims on a food product was on an all-bran cereal product stating that increased intake of wheat fiber could reduce the risk of colon cancer, and citing the US National Cancer Institute as the authority for this claim. Subsequent nutritional and dietary research has not fully supported this claim. Claims about increased intake of vitamin A and cancer protection have also been put in doubt due to a trial of smokers in Finland where results showed that higher intakes of Vitamin A actually increased the incidence of lung cancer. Therefore, in making claims about the functionality of foods or their ingredients, it is necessary to use caution because a disproved or doubtful claim can lead to regulatory problems or loss of market share for the product in question, and other products of the same company.[3–5]

Research into phytochemicals, probiotics and prebiotic substances that do not have traditional nutritive value has shown a wide range of possible functions for foods. Phytochemicals such as indoles, thiocyanates, sulphur-containing compounds, allium compounds, isoflavones and phenols have been shown to have some possible beneficial or protective effects. Probiotics are microorganisms such as lactobacilli and bifidobacteria, which can modify the bacterial flora in the intestine and enhance certain immune functions, possibly promote absorption of certain essential minerals, and protect against some diseases of the intestine and colon. Prebiotics are oligosaccharides, which may be instrumental in modifying the risks on intestinal disorders, osteoporosis, cancer and heart disease. In each of these areas, considerable additional research is under way, and firmly establishing the beneficial effects of any of these substances has been shown to be difficult. In Table 1 a list is given of some examples of foods or food ingredients that have shown possible benefits.[6,7]

Other product classifications and their regulation

As mentioned here, in addition to foods sold as such, there are also foods for special dietary use for the general public, novel foods, dietary supplements, and medical foods, also called neutriceuticals. Each of these product classes has a more specific definition than do 'functional foods', and the regulation of their marketing is more structured in many countries.

The Codex describes foods for special dietary uses as 'foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such. The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist'. Although foods of this nature are obviously intended to be 'functional', the specific nature of such products and the restriction on their uses appear to clearly separate them from other types of possible 'novel foods' or 'functional foods'. The Codex description also implies that newly discovered beneficial effects of traditional foods would not be covered by the Codex description of foods for special dietary uses.

The EU regulation on novel foods and novel food ingredients (regulation EC no. 258/97)[8] applies to genetically modified products, foods and food ingredients isolated from microorganisms, fungi, algae, and plants or animals, except for foods and food ingredients obtained from plants or animals by traditional propagating or breeding practises and having a history of safe food use. Food additives, flavorings, and extraction solvents are exempted from the EU novel food regulation because they are regulated under other EU rules. The EU novel foods regulations are mainly concerned with food safety, are not specific about label claims, and have the thrust of having been prepared to regulate foods and food ingredients derived from biotechnology. Many of the novel foods regulated by EU rules have been developed to fit into the concept of functional foods, and are regulated under the EU novel food regulation at present. However, a lively level of discussion on the concept of functional foods is also under way in Europe and elsewhere and could lead to additional regulation, particularly with regard to health claims.

Dietary supplements such as vitamin and mineral capsules or tablets, and a wide array of other products such as herbal remedies, and even foods that are labeled as dietary supplements have become increasingly popular. In the USA there is specific legislation that exempts these products from many of the restrictions for foods or drugs contained in the US Food, Drug and Cosmetics Act.[9] Many of these dietary supplement products, and equivalent products sold over the counter in pharmacies in Europe, and perhaps elsewhere, have label claims that are considered by many food regulators as somewhat exuberant, and possibly false or misleading. In the USA, products of this type must bear a label statement that these products have not been approved by the US Food and Drug Administration (FDA) and that the product is not intended for use as a drug.

Medical foods or neutriceuticals are specially formulated products intended for use under the supervision of a physician for the specific dietary management of a disease or condition. These foods meet distinctive nutritional requirements that are based on recognized scientific principles and

Table 1. Examples of Functional Components[21]

Class/Components	Source†	Potential benefit
Carotenoids		
Alpha-carotene	Carrots	Neutralizes free radicals that may cause damage to cells
Beta-carotene	Various fruits, vegetables	Neutralizes free radicals
Lutein	Green vegetables	Contributes to maintenance of healthy vision
Lycopene	Tomatoes and tomato products (ketchup, sauces etc.)	May reduce risk of prostate cancer
Zeaxanthin	Eggs, citrus, corn	Contributes to maintenance of healthy vision
Collagen hydrolysate		
Collagen hydrolysate	Gelatine	May help improve some symptoms associated with osteoarthritis
Dietary fiber		
Insoluble fiber	Wheat bran	May reduce risk of breast and/or colon cancer
Beta glucan‡	Oats	Reduces risk of CVD
Soluble fiber‡	Psyllium	Reduces risk of CVD
Whole grains‡	Cereal grains	Reduces risk of CVD
Fatty acids		
Omega-3 fatty acids: DHA/EPA	Tuna; fish and marine oils	May reduce risk of CVD and improve mental, visual functions
CLA	Cheese, meat products	May improve body composition, may decrease risk of certain cancers
Flavonoids		
Anthocyanidins	Fruits	Neutralizes free radicals, may reduce risk of cancer
Catechins	Tea	Neutralize free radicals, may reduce risk of cancer
Flavanones	Citrus	Neutralize free radicals, may reduce risk of cancer
Flavones	Fruits/vegetables	Neutralizes free radicals, may reduce risk of cancer
Glucosinolates, indoles, isothiocyanates		
Sulphoraphane	Cruciferous vegetables (broccoli, kale), horseradish	Neutralizes free radicals, may reduce risk of cancer
Phenols		
Caffeic acid, ferulic acid	Fruits, vegetables, citrus	Anti-oxidant-like activities, may reduce risk of degenerative diseases; heart disease, eye disease
Plant Sterols		
Stanol ester	Corn, soy, wheat, wood oils	Lowers blood cholesterol levels by inhibiting cholesterol absorption
Prebiotic/Probiotics		
FOS	Jerusalem artichokes, shallots, onion powder	May improve gastrointestinal health
Lactobacillus	Yogurt, other dairy	May improve gastrointestinal health
Saponins		
Saponins	Soybeans, soy foods, soy protein-containing foods	May lose LDL cholesterol; contains anticancer enzymes
Soy protein		
Soy protein‡	Soybeans and soy-based foods	25 g per day may reduce risk of heart disease
Phytoestrogens		
Isoflavones: daidzein, genistein	Soybeans and soy-based foods	May reduce menopause symptoms, such as hot flashes
Lignans	Flax, rye, vegetables	May protect against heart disease and some cancers; lowers LDL cholesterol, total cholesterol and triglycerides
Sulphides/Thiols		
Diallyl sulphide	Onions, garlic, olives, leeks, scallions	Lowers LDL cholesterol, maintains healthy immune system
Allyl methyl trisulphide, dithiolthiones	Cruciferous vegetables	Lowers LDL cholesterol, maintains healthy immune system
Tannins		
Proanthocyanidins	Cranberries, cranberry products, cocoa, chocolate	May improve urinary tract health, may reduce risk of CVD

†Examples are not an all-inclusive list.

‡ Food and Drug Administration approved health claim established for component.

CLA, conjugated linoleic acid; CVD, cardiovascular disease; EPA, eicosapentaenoic acid; FOS, fructo-oligosaccharides; LDL, low-density lipoprotein.

are established by medical evaluation. As with foods for special dietary use, medical foods are also intended to be functional and have a direct and beneficial influence on a specific medical condition. In the USA, medical foods do not require premarket clearance by FDA and there have been some concerns about the quality and efficacy of some of the products that are being marketed as medical foods.

National regulatory systems and requirements and international considerations

Because 'novel foods' and 'functional foods' are not defined or set aside as a specific class of product in most countries, they are regulated under existing law as foods, novel foods, special dietary foods, medical foods, or as drugs, depending on how they are marketed, and the claims that are made for the products in their labeling, or in advertising.

In the USA many products that are being sold as traditional foods have label claims about their beneficial effects when consumed as a part of a varied and balanced diet. The 1990 Nutrition Labeling and Education Act (NLEA)[10] required additional labeling about the nutritional content of foods beyond that previously required or recommended under the Food, Drug and Cosmetic Act. The NLEA also allowed for properly substantiated nutrition and health claims on the labels of foods. With regard to health claims, FDA tended to require that marketers of foods with health claims obtain prior approval of the claim and present evidence of 'significant scientific agreement' among qualified experts showing that any claims were justified. In practise this process has not been very effective, but FDA regulation of claims under NLEA was restrictive enough to lead to new legislation called the Dietary Supplement Health and Education Act (DSHEA).[11,12]

The DSHEA further loosened control on products that are ingested and allowed claims for pills, capsules, tablets, or even food-like products that were labeled as dietary substances and included a label statement declaring that the products and claims were not approved by FDA, and that these products were not intended for use as a drug. While no pre-marketing approval is required from FDA, marketers of such products are required to notify FDA of such products and label claims, and to have evidence that any information provided is truthful and not misleading.

The FDA can regulate materials that advertise foods and dietary supplements if the advertising is used in association with the sale of a product and is considered 'labeling', while other advertising is regulated by the US Federal Trade Commission. In either case false or misleading claims are not allowed, but the enforcement of these regulations has not been particularly vigorous and products with questionable claims and possible safety problems continue to be marketed in the USA.[13–17]

In the EU countries foods are regulated under national food laws, and under EU regulations. In general the control of claims is more strict that in the USA, but differences exist between various EU member countries with regard to claims allowed under national law. These differences can lead to EU-wide marketing of products with hard-to-substantiate claims, because approval of a product in one or two countries can lead to EU-wide distribution of these products under existing EU rules.[18]

As an example of European control of claims, local level Trading Standards Officers in the UK have taken Nestle and other food marketers to court over certain label claims.[19,20] In June 2000 the Shropshire County Council successfully sued Nestle for marketing a shredded wheat product with label claims that eating this cereal would reduce the risk of coronary heart disease. Nestle was fined £7500 for making an illegal medical claim, and also had to pay £13 600 costs involved in holding the court proceedings. In the UK this court decision is considered as a test case, and will have significance to all food marketers about making future claims unless they have adequate scientific data to back up claims. In many cases it would appear necessary to liaise with regulatory authorities prior to marketing products, but this had practical difficulties when central government is not fully involved in regulating products, and at the same time allows local authorities to take legal action which has nationwide or EU-wide significance.[21]

In the EU novel food regulation, companies wishing to market a product that is considered a novel food must present information to authorities in a Member State where a product will first be marketed to demonstrate product safety, and also present information on proposed labeling. Information provided should include product specifications, effects of production processes, history of any organism used as a source of the novel food, anticipated intake or extent of use, information of previous human exposure to the product, and nutrition, toxicological and microbiological information. As noted here, the main concern is the safety of the novel food, but some consideration of labeling is also possible.[22–24]

Food and related rules that govern claims for functional foods also are in effect in Japan, other European countries, Australia and New Zealand, and there are differences between procedures and products allowed in each of these countries. Developing countries also have some legislation in place. Marketers of functional food products in these markets must carefully assess existing rules that apply because of the differences that exist in each of these markets.

In Japan regulations for Foods for Special Health Uses (FOSHU) have been in force for over 2 years. The Japanese rules require that a manufacturer or marketer of a FOSHU product present a dossier to the Japanese government with pertinent information on the ingredients, processing, labeling, quality, safety, and health effects of each FOSHU product. If the government authorities are satisfied that the dossier supports quality and safety requirements, and substantiates the health effects to be put on the label or used in advertising, approval of the FOSHU product can be given. Over 200 FOSHU-approved products are currently on the market in Japan, and appear to be freely accepted by Japanese consumers. Similar procedures are also in place in China.

In Australia and New Zealand, the Australia New Zealand Food Authority (ANZFA) has published rules under Part 1.5 for Foods Requiring Pre-market Clearance. Food Standard 1.5.1 covers novel foods, while Food Standard 1.5.2 covers foods produced using gene technology.[25]

Australia New Zealand Food Authority Standard 1.5.1 describes non-traditional foods as foods with no history of significant human consumption in Australia or New Zealand, and 'novel foods' as non-traditional foods with safety concerns. It requires pre-market approval of novel foods on the basis of a dossier that includes information on the composition of a product, on any undesirable substances that may be present, on any known adverse effects from consumption of the product, on traditional preparation or cooking, and on patterns and levels of consumption.

Australia New Zealand Food Authority Standard 1.5.2 covers food produced using gene technology and limits the technology to foods for which recombinant DNA techniques have been used. For such foods specific labeling is required that states that the food or certain ingredients have been genetically modified. It can be seen from the previous paragraphs on current ANZFA rules that the concepts defined in the EU rules on 'novel foods' have been divided into two separate ANZFA standards, with somewhat different procedures and results.

At the international level, the Codex Alimentarius Commission has not held extensive discussions on functional foods. Work has been done on basic labeling rules, on nutrition claims and nutrition labeling, and claims for foods for special dietary use. In general these Codex standards and guidelines state that packaged food should not be described or presented on any label or labeling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.[26–28]

Supporting data for novel food or functional food claims and future perspectives

Based on the discussion here, it is clear that marketers of foods that fit the profile of novel foods or functional foods must be prepared to have in their possession adequate scientific data to substantiate any claims that they wish to make on products. This will involve several steps in building an adequate level of data, and must be done with the realization that data to establish the safety and efficacy of foods and food ingredients is considerably more difficult than is the case with food additives, pesticide residues, or chemical contaminants that are used in or can occur in food production and processing. In previous discussions on functional foods three sequential steps have been suggested: (i) basic research and experimentation: identification and understanding of the mechanisms of interaction between the food or ingredient and modification of gene expression or cellular biochemical function in order to demonstrate potential functional effects; (ii) development of models and methodologies including possible biomarkers to demonstrate through studies on human nutrition possible functional effects and the consequences thereof to justify specific functional or physiological claims; and (iii) design and carrying out of appropriate human nutrition studies, which may have to be done on a large scale, to demonstrate functional effects and benefits to health including reduction to disease where pertinent to justify structure/function or health claims.

Consumer studies in the USA have shown that 95% of consumers believe that certain foods can provide health promotion of disease prevention benefits beyond basic nutritional benefits. Consumers are willing to accept the concept of functional foods and want to know more about them. It is likely that consumers in Europe and other parts of the world have similar attitudes and desires. Therefore, the future for novel foods or functional foods appears to be very positive. However, marketers of novel or functional foods or ingredients that can increase the functionality of foods must conduct careful and adequate basic studies and human trials to justify the claims that may be made for functional food products.

Given the differences in regulation of foods, special dietary foods, novel foods, foods for special dietary use, and medical foods in different countries and regions, potential marketers of these foods must be prepared to fully understand the regulatory requirements that apply in each marketing area, and be ready to meet these requirements both before marketing a product, and after a product has been placed on the market through adequate post-marketing surveillance. The potential for novel or functional foods is great. Those meeting the challenges of successful development of scientific data so that products can be marketed should meet with great success.

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