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## Regulatory issues and functional health claims for bioactive dairy compounds

### Abstract

Dairy foods and ingredients have a natural advantage over new/novel foods, from a regulatory viewpoint, because they are generally considered as “traditional” foods, that is, there is a long history of human consumption. However, the regulatory landscape on adding bioactive ingredients, whether from dairy streams or from non-dairy sources, into dairy foods is rapidly evolving, and the dairy industry will need to be aware of potential regulatory challenges, within the countries they wish to market their products.

### Keywords

Dairy, functional foods, regulation

### Disciplines

Arts and Humanities | Life Sciences | Medicine and Health Sciences | Social and Behavioral Sciences

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# **Regulatory Issues and Functional Health Claims for Bioactive Dairy Compounds**

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## **Introduction**

As research into the health benefits of food components has expanded, both food manufacturers and consumers have developed a greater understanding of the relationship between food and health. Bioactive or health promoting components may be naturally present in the food product or extracted from waste or food streams, for addition to foods not naturally containing them. Addition of such components may also be used for fortification of foods which naturally contain these components to compensate for losses that may occur during processing. The development of the functional food category or foods with health properties beyond the commonly accepted nutritional benefits is rapidly evolving in all markets.

Milk and its products have long been regarded as a good source of nutrition. Dairy products and dairy ingredients are also widely used in many other manufactured foods. Current research undertaken into milk composition reveals it is a significant source of bioactives. Traditional dairy products such as milk beverages and yoghurt are also becoming widely used as vehicles to deliver non-dairy bioactives, such as phytosterols or omega-3 fatty acids.

This increased ability to enhance the health benefits of food products challenges traditional views and laws on fortification. The desire for food manufacturers and marketers to utilise new knowledge on the health-giving qualities of their products to garner market advantage, by making explicit health claims challenges what is currently permitted by food regulatory codes.

Food regulations vary from country to country and the increased movement of food across borders and even within large jurisdictions like the European Community, means that a particular food, ingredient or bioactive may have to meet several sets of regulations, in spite of attempts to create a global code with Codex Alimentarius.

All new foods require authorisation by relevant regulators but the process each must go through depends on whether the ingredient or food has a traditional history of consumption in that

jurisdiction. Non traditional foods (those that do not have a long history of human consumption) or new foods may be subjected to additional and separate “novel” food regulatory processes.

Regulatory authorities are debating how to deal with health claims, particularly in marketing and labelling of foods. The levels and types of substantiation required for health claims to be made for foods and bioactive ingredients are also evolving. This chapter will provide an overview of the current major approaches taken by larger jurisdictional groups such as the USA, European Union and Japan to regulating health claims.

## **Dairy Foods**

Clinical, observational and mechanistic data have demonstrated that dairy products and several of their constituents have a variety of metabolic roles (Smilowitz et al, 2005). Furthermore, market trends indicate that milk-based beverages and other dairy products such as yoghurt and cheese are ideal vehicles for newly discovered bioactive food ingredients targeting lifestyle diseases.

Oral administration of probiotics has been reported to be effective in preventing/treating diarrhoea, reducing lactose intolerance and allergic diseases, treating irritable bowel syndrome and reducing blood cholesterol levels (Desmond et al, 2005; Salminen et al, 2005). The physiological effects of probiotics can occur through either the direct effect of the live microbial cells, known as the probiotic effect, or indirectly via the metabolites produced by these cells which is referred to as the biogenic effect. Cheese has also been shown to be an excellent delivery vehicle for probiotics and biogenic substances (Hayes et al. 2006) and for a variety of naturally-occurring health-promoting components such as conjugated linoleic acid (CLA) and omega-3 fatty acids (McIntosh et al. 2006). Probiotics comprise approximately 65% of the world functional food market.

As there had been no international consensus on methods to assess the efficacy and safety of probiotic bacteria, recent initiatives from the Food and Agriculture Organization of the United Nations (FAO), and the World Health Organization (WHO) have resulted in the development of

a legislative framework for probiotic bacteria which is based on scientific criteria (*in vitro* trials, safety considerations, *in vivo* studies for the substantiation of effects) for the evaluation of health claims (Pineiro and Stanton, 2007).

Drinking yogurt and low-fat milk and are the most commonly used vehicles for the delivery of bioactive food ingredients. Probiotic yogurt drinks are preferred for the delivery of plant sterols, while low-fat milk is commonly used to deliver omega-3 fatty acids. Drinks containing combinations of dairy and fruit juices, with added bioactive components, are also becoming common in the USA and European Union (EU) markets (Sharma, 2005).

In addition to being a major provider of important nutrients for humans, including calcium, protein and riboflavin, it is now recognised that ingredients derived from milk and whey can provide functional food products with other beneficial effects on human health. Casein and whey proteins and their derivatives have been shown to possess biological activities, including peptides able to exert anti-hypertensive (Pihlanto-Leppala, 2000; Lopez-Fandino, et al, 2006) and other biological effects, lactoferrin and lactoperoxidase able to exert anti-microbial effects, and growth factors used in sports health and for tissue repair applications including wound repair (Playne et al, 2003). The currently identified bioactive components in bovine milk or colostrum, their physiological activities and their concentration in bovine milk have recently been reviewed (Rowan et al, 2005; Huth et al, 2006).

Dairy foods with added dairy-derived or non-dairy functional ingredients, or non-dairy foods with added dairy ingredients may be considered by regulatory authorities to be “novel” or “non-traditional” foods i.e. foods that do not have a significant history of human consumption in that market. Such foods may raise human safety concerns and will need to undergo a risk-based assessment before being allowed into the food supply (Healy, 2003).

An issue of concern to the dairy industry relates to recent regulations on the labelling of foods with respect to their levels of trans fatty acids (TFA). With the scientific evidence associating trans fatty acid intake with an increased risk of coronary heart disease (CHD), the USA Food and Drug Administration (FDA) has issued a ruling that requires the declaration of the amount of

TFA present in foods, including dietary supplements, on the nutrition label. For the purpose of nutrition labelling, TFAs are defined as the sum of all unsaturated fatty acids that contain one or more isolated (i.e. non-conjugated) double bonds in a trans configuration. The FDA will also be conducting consumer research to determine consumer understanding of various TFA labelling possibilities (Moss, 2006). Denmark and New York City have imposed mandatory restrictions on these types of fats. The recent results from the TRANSFACT study (Chadigny et al, 2008) have shown differences (in women) between natural ruminant-derived trans fats and industrially-produced hydrogenated trans fats with respect to biomarkers of CHD. The different effects of natural, ruminant-derived trans fats and industrially produced trans fats on biomarkers / risk factors for CHD may result in further regulatory changes as new scientific knowledge is generated.

## **Health Claims**

Linking the consumption of functional foods or food ingredients with health claims should be based on sound scientific evidence, with the "gold standard" being replicated, randomized, placebo-controlled, intervention trials in human subjects. The assessment of scientific safety and efficacy of a food or ingredient by the relevant regulatory authority is likely to require data on the characterization and source of the ingredient, manufacturing processes, concentration in the food product, and related safety considerations. The evidence for confirmation of efficacy may include *in-vitro* data, *in-vivo* animal trials using levels of defined biomarkers as measures of a physiological effect, but more than one human intervention trial in different population groups is also likely to be essential. Evaluations will probably include a number of quality criteria such as the quality of the study design, conduct and analysis and decisions will need to be based on the totality of the evidence. Not all foods on the market that are claimed to be functional foods are supported by enough solid data to merit such claims (Hasler, 2002).

Legislation concerning health claims has progressed at a slow pace in many countries. After several years of debate, the European regulations on nutrition and health claims came into force in early 2007. This law sets out the conditions on the use of health claims, establishes a system

for scientific substantiation and should result in an European list of permitted claims by early 2010 (Richardson et al, 2007). Under these regulations, health claims fall into two categories: structure-function claims (e.g. calcium builds strong bones), and disease risk reduction claims (e.g. decrease in the risk of heart disease). The latter category will be required to have substantiated scientific evidence and must have special approval. Member states are compiling national lists of claims and will submit them to the European Commission. After consultation with the European Food Safety Authority (EFSA), the final Community list of permitted claims should be adopted by early 2010 (De Jong, 2007).

In Australia and New Zealand, the bi-national regulator – Food Standards Australia New Zealand (FSANZ) - is currently developing a new standard which will permit scientifically substantiated claims for foods that meet certain nutrient profiling criteria (FSANZ, 2008a). The proposed new standard will encompass two types of claims - nutrition content claims and health claims – and there will be two levels of health claims: general level health claims and high level health claims. The level of a claim will determine how the claim is regulated, including the evidence required for substantiation.

General level health claims refer to the presence of a nutrient or substance in a food and its effect on normal health function. High-level health claims are those that make reference to a serious disease or biomarker and these will need to be pre-approved by FSANZ. Five high-level claims have already been accepted for inclusion in the new standard, including two related to calcium, vitamin D and osteoporosis, and calcium and enhanced bone density. In the future, manufacturers will be able to make applications for approval of other high level health claims, which will need to be scientifically substantiated using a defined substantiation framework.

A view has been expressed that the ethical responsibility for marketing sound health messages for dairy products rests with the industry. Although there are regulatory processes in place to protect the consumer, these sometimes can be circumvented. Making a health claim requires a certain level of proof for it to be accepted, and the food industry should strive to meet these challenges. Consideration must also be given to potential negative effects, such as the denigration of the product category, by the use of unsubstantiated health claims which may



mislead the consumer (MacNeill, 2003). Consumers often express concern that health claims are just another sales tool, and the use of poorly substantiated claims could increase the current levels of consumer scepticism about all attempts to communicate the health benefits of food (Health Canada, 2000; Food Standards Agency, 2004).

A cautionary note with respect to making less than fully-substantiated claims for foods lies in the recent litigation brought by a group of overweight children against the McDonald's Corporation that sought compensation for obesity-related health problems. While many derided this lawsuit as representing the worst excesses of the tort liability system, others have drawn parallels to tobacco litigation. Food-related litigation raises the question of where accountability for the economic and public health consequences of food-related disorders properly rests (Mello et al, 2003).

It is anticipated that technological advances in the food industry, in conjunction with extensive clinical trials and governmental control, will eventually guarantee the credibility of health claims and ensure consumers' confidence in functional foods (Arvanitoyannis and Van Houwelingen-Koukaliaroglu, 2005).

### **Communication of Health Messages to Consumers**

The new EU legislation on nutrition and health claims emphasises that the wording of claims should be understandable and meaningful to the consumer and they will only be permitted if the average consumer can be expected to understand the beneficial effects expressed in the claims (Leathwood et al, 2007).

Recent trends in the USA and the EU indicate that regulators will require further research to test how consumers are likely to interpret and use any health claim. In a recent study of television food advertisements in the USA, 14.9% made a weight-related nutritional claim. The authors concluded that practitioners and policy makers should be aware of the prevalence of food advertisements and their potential impact on knowledge and behaviour and should consider working more closely with food manufacturers to encourage the creation and promotion of

weight-friendly foods. Furthermore, it was suggested that nutrition educators could help by teaching consumers critical thinking skills that may relate to food advertisements (Henderson and Kelly, 2005). Similar conclusions were reached in a study of food advertisements in a series of women's magazines (Hickman et al. 1993).

Consumer perceptions of nutrition- and health-related food claims attached to food products have been investigated in a large-scale, cross-national, internet-based survey. Participants were questioned in Germany (n = 1620), the UK (n = 1560), Italy (n = 1566) and the US (n = 1621). Nutrition and health claims relating to 6 health benefits (increased concentration, decreased overweight, fatigue, infection, stress and cardiovascular disease) and 5 claim types (marketing, content, structure-function, disease risk reduction and product) were studied. Considerable variations in consumer perception were found according to country of origin and benefit being claimed, but not in relation to claim type (Trijp and Lans, 2007)

It has been reported that young consumers are not interested in the effects of eating habits on health, whilst concern over consumption habits and health increases in older people. Young and middle aged male consumers only read the energy value and nutritional information on the food label, while female consumers read all the information on the labels of products which they purchased. Increase in educational level has also been reported to increase the preference for healthier foods (Isleten et al, 2007).

The use of health claims on the internet and the level of compliance of these claims with existing regulations in Australia and New Zealand has been studied recently (Dragicevich et al, 2006). This data showed that 14.5% of food product websites carried a health claim, and 40.7 and 37.0% of products previously identified as carrying claims on product labels or in magazines, respectively, had internet claims. Many of the claims (19.7%) were high-level or therapeutic claims not permitted by current food standards. The authors concluded that health claims were not being made more frequently on websites compared with product labels, but there was a greater prevalence of high-level and therapeutic claims made on the internet. In future, food standards enforcement will need to give greater priority to monitoring the use of health claims on the internet (Dragicevich et al, 2006). A similar study by the same group of magazine advertisements has also found that many of the claims were high level claims (29%) or

therapeutic claims (8%), which are not permitted by current food standards (Williams et al, 2007). In this study 17% of the advertisements with health claims were for dairy foods.

Food labels are an important tool to assist consumers in making healthy food choices. In addition to mandatory nutritional labelling information, manufacturers have a variety of options on food/supplement packages to communicate the nutrition/health benefits of their products (Agarwal et al. 2006).

The FDA food labelling regulations aim to ensure that manufacturers aid consumers in making dietary choices by eliminating "hollow" health claims. Of particular concern are health claims made by one brand when the claim is inherent to the product category, but has not been featured previously in advertisements or on packaging. There is concern that consumers will use information provided by one brand about such an attribute to infer that the other brands in the product category do not possess the attribute and thus be misled. Results from three experiments show that this practice can mislead consumers and affect consumer inferences, use of the target attribute, and choice in favour of the brands displaying the attribute. Furthermore, it was shown that improved consumer education can be achieved without the deception associated with narrow (brand-specific) health claims by using broader (category-defined) claims (Burke et al. 1997).

A study of consumers (Urala et al, 2003) has been carried out to evaluate whether product-related health claims in foods are advantageous or disadvantageous. Claims were made for six functional components and two control products. In general, all claims were perceived as neutral or as advantageous. Increasing the strength of the claim did not automatically increase the perceived benefit. Gender, trust in different information sources and the frequency of use of so-called functional foods affected the perceived benefit. Women perceived the claims to be more beneficial than did men. Trustful respondents perceived the claims as more advantageous than did sceptical respondents, and the users of functional foods perceived health claims to be more advantageous than did non-users. In addition, personal motivation affected the perception of the claims. With less familiar functional components, the strength of the claim increased the perceived benefit, whereas with familiar components, claims mentioning the reduced risk or prevention of a disease did not increase the perceived advantage.

A further study by the same group (Urala and Lahteenmaki, 2004) quantified the attitudes behind consumers' willingness to use these products. Functional food-related statements formed seven factors describing consumers' attitudes towards functional foods. These factors were: perceived reward from using functional foods, confidence in functional foods, necessity for functional foods, functional foods as medicines, absence of nutritional risks in functional foods, functional foods as part of a healthy diet and the health effects of functional foods versus their taste. These attitude subscales differentiated between consumers in their reported willingness to use functional foods. The best predictor for willingness to use functional foods was the perceived reward.

One dilemma with health claims is that too much information can confuse consumers and too little information can mislead them. A controlled study has been used to examine the effectiveness of various front-sided health claims when used in combination with a full health claim on the back of a package. The results indicated that combining short health claims on the front of a package with full health claims on the back of the package leads consumers to more fully process and believe the claim (Wansink, 2003).

A similar approach has been used in a recent study comparing claims about reduced risk of osteoporosis made on milk or a calcium-fortified orange juice packaging. This study investigated whether splitting a claim (a brief claim at the front of a package directing consumers to the full health claim at the back), and/or endorsement of the claim (by a regulatory body), affected the acceptance of the claim, by the consumer. Split health claims produced more positive responses than not-split claims in several areas: they created a higher level of satisfaction with the labelling, they produced a higher level of trust, and they communicated better the health risk of the claim. Endorsement of the claim did not influence responses, possibly because of either the small print of the approval statement or the low awareness of the regulatory body among consumers, but belief in the claim was significantly higher on the milk product compared to the juice (Singer et al. 2006).

Consumers' main scepticism regarding functional foods resides in the veracity of health claims and in the often inadequate control of their claimed properties. It is very important that health

claims on food products can be understood by the consumer. However, there is no clear understanding of how consumers use health claims and their likely impact on consumer food behaviour or health. More research is needed, but a review of previous studies allows some common conclusions to be drawn. Health claims on foods are seen by consumers as useful, and when a product features a health claim they view it as healthier and state they are more likely to purchase it. Consumers are sceptical of health claims from food companies and strongly agree that they should be endorsed by government. Consumers do not make clear distinctions between nutrition content claims, structure-function claims and health claims. They generally do not like long and complex, scientifically worded claims on foods; they prefer split claims - with a short succinct statement of the claim on the front of pack and more detail provided elsewhere (Williams, 2005a). There is also some evidence that the use of health claims improves the quality of dietary choices and knowledge of diet-disease relationships (Williams, 2005b).

Dairy foods have long been promoted using health messages - dairy products have been promoted by governmental authorities wanting to improve public health and by dairy industry bodies promoting dairy foods. The health messages that have been used for the promotion of dairy foods include nutrient content messages (“a good source of calcium”), low-fat messages and health claims (“calcium reduces the risk of osteoporosis”). The changes in legislation permitting the use of (some) health claims beyond structure –function claims (“calcium helps promote bone health”) on food labels and in advertisements aimed at consumers will expand the repertoire of messages available to communicate the benefits of dairy foods. However, health claims will not replace nutrient content and low-fat messages, and all three types of health messages are likely to be widely used to promote dairy foods in the future (Lawrence, 2005).

### **Nutrient profiling**

Nutrient profiling of foods is defined as the science of categorizing foods based on their nutrient composition. For regulatory agencies, nutrient profiles can be the basis for disallowing nutrition or health claims and for regulating advertising to children. The EU and Australia/New Zealand have adopted nutrient profiling as the basis for regulating nutrition and health claims; whereas

the US approach has emphasized positive nutrients and the European approach has focused on the foods' content of fats, trans-fats, sugars and sodium. The Australian approach proposes a mixed scoring system of disqualifying nutrients (e.g. high salt, sugar, fat) balanced with positive scores for protein, fibre, fruit and vegetable content (FSANZ 2008b).

Several nutrient profiling approaches are being used in different countries. It has been reported that 23 nutrient profiling systems have been developed (Garsetti et al, 2007). One approach uses thresholds where an upper limit is set for negatively perceived nutrients. As positive/healthy nutrients are not taken into account, this system does not reflect the whole nutrient composition of a food, and as such would not recognise the importance of dairy foods in helping to meet nutritional requirements. Another approach is the use of scoring systems that allow the inclusion of both positive and negative nutrients, and these provide a more balanced view of the nutrient composition. However, a potential problem with this system is that if energy, total fat, saturated fat and sugars are all included in such a model, this can lead to multiple scoring of some nutrients such as fat. A further approach is based on nutrient density. Nutrient density is the ratio of the amount of a nutrient in a food to the energy provided by that food. This approach differentiates between energy dense, but nutritionally poor foods, and foods that are both energy dense and nutrient dense. Dairy foods are naturally nutrient dense, and their contribution to nutrient intake is well represented by this approach (IDF, 2007).

Nutrient profiling or scoring criteria can pose some challenges for dairy product manufacturers. Dairy products such as cheese and butter are naturally high in nutrients that would result in their disqualification from being able to make a health claim. For example, using the values for energy, saturated fat, sugar and sodium initially proposed by FSANZ, most cheeses could not carry a health claims in Australia or New Zealand because of their inherently high energy, saturated fat and sodium content. This is despite the fact that the National Health and Medical Research Council's (NHMRC) *Dietary Guidelines for Australian Adults* recommend that adult diets include milk, yoghurt and cheese (Lederman, 2007). Subsequent modifications to the profiling system have included a separate set of criteria for cheeses with a calcium content of more than 320mg/100g (FSANZ 2008b).

The development of competing nutrient profile systems by researchers, regulatory agencies, and

the food industry in the EU, the US and elsewhere, has been marked by different priorities, pressures and concerns. However, the development of nutrient profiles needs to follow specific science-driven rules. These include the selection of reference nutrients and reference amounts, the creation of an appropriate algorithm for calculating nutrient quality scores, and the validation of the chosen scheme against objective measures of a healthy diet (Drewnowski, 2007).

The application of nutrient profiling also aims to avoid a situation where nutrition or health claims mask the overall nutritional status of a food, which could mislead consumers when they are attempting to make decisions in the context of a balanced diet (Reuterswärd, 2007)

### **Regulation of functional foods and food supplements in Japan**

A policy of "Foods for Specified Health Uses" (FOSHU), by which health claims on some selected functional foods are legally permitted was established in 1993 by the Japanese Ministry of Health and Welfare. Since 1984, when the concept of "functional food" was first proposed there, the science of regulating and labelling functional foods in Japan has been progressing along a unique path of development. Their unique approach is seen in the development of functional foods by minimizing undesirable as well as maximizing desirable food factors, for example, hypoallergenic foods, developed from food materials by removing allergens (Arai, 2000).

The concept of 'functional foods' is well understood in Japan as a result of research initiated on the health benefits of foods in 1984. The Ministry of Education organized a national research and development project to evaluate the functionalities of various foods. Researchers from diverse scientific fields defined new functions of food, successfully incorporating previously recognized functions of nutrition, sensory/satisfaction and physiological effects of ingredients in foods.

Some food manufacturers and distributors unfortunately capitalized on such food functionalities to promote 'health foods' by violating the laws with claims for drug-like effects. In 1991, the Ministry of Health and Welfare's successor, the Ministry of Health, Labor and Welfare (MHLW), introduced a 'foods for specified health uses' (FOSHU) system, to control such

exaggerated and misleading claims. The other reason for such enforcement was an increase in the population of elderly people and lifestyle-related diseases, including obesity, diabetes mellitus, high blood pressure, cerebro- and cardiovascular diseases and cancer.

In 2001, a new regulatory system, 'foods with health claims' (FHC) with a 'foods with nutrient function claims' (FNFC) system and newly established FOSHU was introduced. The MHLW further changed the FOSHU, FNFC and other systems in 2005. Such changes included new sub-systems of FOSHU such as (1) Regular/Specific FOSHU (including disease risk reduction claims), (2) standardized FOSHU and (3) qualified FOSHU (Ohama et al, 2006).

Regular/Specific FOSHU (including reduction of disease risk) refers to foods intended for consumer products, where safety and efficacy regarding health claims have been proven by a series of safety/stability tests and clinical trials, and have been approved by the MHLW to make health claims for the specific product.

Standardized FOSHU was introduced in February 2005 and represents foods that contain certain effective ingredients that are proven to meet the standards and specifications for a specific health claim, ingredient and/or quality standard. Food that has an accumulation of scientific evidence (more than 100 cases of past approvals as FOSHU) can be approved as a Standardized FOSHU upon sole review of MHLW, without needing an individual review by the examination council.

Qualified FOSHU, also introduced in February 2005, refers to foods with certain effectiveness, but whose scientific data are less conclusive than those required for the existing FOSHU standard.

There are three requirements that are essential for the approval of a FOSHU application. These are (a) scientific evidence of the effectiveness of the product, proven by clinical studies, (b) additional safety studies or other evidence to prove that there are no side-effects following oral intake and (c) an exact determination of the specific effective component (Anon, 2007).



The regulatory range of FOSHU has been broadened to accept capsules and tablets, in addition to conventional foods. The MHLW regulatory system, 'Foods with Health Claims' (FHC), consists of the existing FOSHU system and the newly established 'Foods with Nutrient Function Claims' (FNFC).

FNFC refers to foods that are intended for consumption as supplements and are defined as "food products with supplemental nutritional components that are likely to be deficient in the elderly and other persons who deviate from normal eating habits due to an irregular lifestyle." Vitamins (A, B1, B2, B6, B12, C, D, E, Niacin, Folic Acid, Biotin and Pantothenic Acid) plus 5 minerals (Calcium, Iron, Zinc, Copper and Magnesium) have been placed in this group (Anon, 2007). Examples of claims regarding these substances include: 'Calcium is a nutrient which is necessary to form bones and teeth'; 'Vitamin D is a nutrient which promotes calcium absorption in the gut intestine and aids in the formation of bones'. The upper and lower levels of the daily consumption of these nutrients are also determined.

The claims of the Japanese FNFC are equivalent to the nutrient function claims standardized by the Codex Alimentarius. The enhanced function claim and the disease risk-reduction claims were proposed by both the Codex Alimentarius and an Economic Union project in 1999. The structure function claim, which is similar to the enhanced function claim, was enacted by the Dietary Supplement Health and Education Act in the USA in 1994. Most of the statements of the Japanese FOSHU system are close to the structure/function claims in the USA or the enhanced function claims of the Codex Alimentarius (Shimizu, 2003).

Food for Specified Uses (FOSU) or Food for Special Dietary Uses (FOSDU) is one of the categories of Food with Health Claims that is not regulated by the Food Hygiene Law, but rather by the Health Promotion Law. FOSU refers to foods that have been deemed appropriate for specified dietary purposes, such as infant nutrition, pregnant and lactating women, the maintenance of general health and recovery from illness. Individual consumer products are examined on a case-by-case basis and must be approved before being permitted to display that the food is appropriate for special dietary uses (Anon, 2007).

## **Codex Alimentarius**

The Codex Alimentarius (Latin for “food law” or “food code”) is a collection of internationally recognized standards, codes of practice, guidelines and other recommendations relating to foods, food production and food safety under the aegis of consumer protection. Officially, it is maintained by the Codex Alimentarius Commission, a body established jointly by the Food and Agriculture Organization of the United Nations (FAO), and the World Health Organization (WHO) in 1963 to protect the health of consumers and ensure fair practices in international food trade. Codex standards are used by many countries as benchmarks when developing local food regulations.

The Codex Alimentarius position is that health claims should be permitted provided that all of the following conditions are met:

- Health claims must be based on current relevant scientific substantiation and the level of proof must be sufficient to substantiate the type of effect claimed and the relationship to health as recognised by generally accepted scientific review of the data and the scientific substantiation should be reviewed as new knowledge becomes available. The health claim must consist of two parts:
  - (i) Information on the physiological role of the nutrient or on an accepted diet-health relationship; followed by
  - (ii) Information on the composition of the product relevant to the physiological role of the nutrient or the accepted diet-health relationship unless the relationship is based on a whole food or foods whereby the research does not link to specific constituents of the food.
- Any health claim must be accepted by, or be acceptable to, the competent authorities of the country where the product is sold.

- The claimed benefit should arise from the consumption of a reasonable quantity of the food or food constituent in the context of a healthy diet.
- If the claimed benefit is attributed to a constituent in the food, for which a Nutrient Reference value is established, the food in question should be:
  - (i) A source of, or high in, the constituent in the case where increased consumption is recommended, or,
  - (ii) Low in, reduced in, or free of the constituent in the case where reduced consumption is recommended. Where applicable, the conditions for nutrient content claims and comparative claims will be used to determine the levels for “high”, “low”, “reduced”, and “free”.
- Health claims should have a clear regulatory framework for qualifying and/or disqualifying conditions for eligibility to use the specific claim, including the ability of competent national authorities to prohibit claims made for foods that contain nutrients or constituents in amounts that increase the risk of disease or an adverse health-related condition. The health claim should not be made if it encourages or condones excessive consumption of any food or disparages good dietary practice.
- If the claimed effect is attributed to a constituent of the food, there must be a validated method to quantify the food constituent that forms the basis of the claim.
- The following information should appear on the label or labelling of the food bearing health claims:
  - A statement of the quantity of any nutrient or other constituent of the food that is the subject of the claim.
  - The target group, if appropriate.

- How to use the food to obtain the claimed benefit and other lifestyle factors or other dietary sources, where appropriate.
- If appropriate, advice to vulnerable groups on how to use the food and to groups, if any, who need to avoid the food.
- Maximum safe intake of the food or constituent where necessary.
- How the food or food constituent fits within the context of the total diet.
- A statement on the importance of maintaining a healthy diet (CAC, 2004).

### **Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM)**

The European Commission concerted action PASSCLAIM aimed to produce a generic tool for assessing the scientific support for health-related claims for foods and food components (Prentice et al, 2003) as a result of the attention being paid to claims for foods, especially those related to the newly discovered effects of dietary components on body functions. The PASSCLAIM project, which ran from 2001 to 2005, built upon the principles defined in publications arising out of the EU DG XII Functional Food Science in Europe (FUFOSE) project.

The main thrust of the Consensus Document on Scientific Concepts of Functional Foods in Europe, produced as the final deliverable from the FUFOSE Concerted Action, was to suggest the outline of a scheme to link claims for functional foods to solid scientific evidence. FUFOSE suggested that claims for "enhanced function" and for "reduced risk of disease" are only justifiable when they are based on appropriate, validated markers of exposure, enhanced function or reduction of disease risk.

The objectives of PASSCLAIM were:

- To produce a generic tool with principles for assessing the scientific support for health-related claims for foods and food components which are eatable or drinkable.
- To critically evaluate the existing schemes which assess the scientific substantiation of claims, and
- 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.

The criteria for the scientific substantiation of health claims on foods defined by the PASSCLAIM project were as follows:

- The food or food component to which the claimed effect is attributed should be characterised.
- Substantiation of a claim should be based on human data, primarily from intervention studies.
- When the true endpoint of a claimed benefit cannot be measured directly, studies should use markers.
- Markers should be biologically valid (i.e. they should have a known relationship to the final outcome), and be methodologically valid with respect to their analytical characteristics.
- Within a study, the target variable should change in a statistically significant way.
- A claim should be scientifically substantiated by taking into account the totality of the available data and by weighing up of the evidence.

Potential health claims can be based not only on modifications of target body functions (for obesity: body fat deposition), but also on other relevant associated functions (for obesity: energy intake, energy expenditure and fat deposition) and should be evaluated using valid methodologies. According to the PASSCLAIM consensus document, the substantiation of health claims should take into account the totality of the available data; however, it should be based on human data, primarily from intervention studies with an appropriate design and a relevant endpoint (Riccardi and Giacco, 2005).

Regardless of the different approaches to the use of health claims on foods taken around the world, their common theme is that any health claim will require scientific validation and substantiation. There is also broad consensus that any regulatory framework should protect the consumer, promote fair trade and encourage innovation in the food industry. There is a need to have uniform understanding, terminology and description of types of nutrition and health claims. The two broad categories defined within PASSCLAIM were: (i) Nutrition Claims, i.e. what the product contains, and (ii) Health Claims, i.e. relating to health, well-being and/or performance, including well-established nutrient function claims, enhanced function claims and disease risk reduction claims (Richardson et al. 2003).

### **USA Food and Drug Administration (FDA)**

The USA Food and Drug Administration's regulatory authority over health claims was clarified in 1990 legislation known as the Nutrition Labelling and Education Act (NLEA). This law established mandatory nutrition labelling for most foods and placed restrictions on food label claims characterizing the levels or health benefits of nutrients in foods. NLEA set a high threshold for the scientific standard under which the FDA may authorize health claims; this standard is known as the significant scientific agreement (SSA) standard. An alternative to the FDA review of health claims was established in subsequent legislation (the FDA Modernization Act, 1997) which provided a USA government scientific body, other than the FDA, to establish that there is SSA for a substance/disease relationship.

Courts have since extended the scope of health claims to include qualified health claims (QHC) that are health claims not substantiated on evidence that meets the level of SSA standard, but include a qualifying statement intended to convey to the consumer the level of evidence for the claim. FDA has responded by developing an evidence-based ranking system for scientific data to determine the level of evidence substantiating a health claim, and established a system with four different levels of substantiation (Rowlands and Hoadley, 2006). However, it appears consumers are confused by the system of qualified health claims. They find it difficult to understand the meaning of the different types of qualified claims and may even interpret the qualification levels

to refer to the overall safety of the product rather than an evaluation of the strength of the scientific substantiation (IFIC, 2005).

### **Generally Recognized As Safe (GRAS) Status**

The FDA in the USA had set the bar too high for health claims and was forced by the courts to implement a more reasonable standard, but the response, Qualified Health Claims, has failed to gain the confidence of the public because of the confusing wording of the claims demanded by FDA. The Dietary Supplement Health and Education Act (DSHEA) was the product of a compromise with a lower threshold for demonstration of safety (reasonable expectation of no harm) that would be met by consumer self-policing and assumption of some risk. FDA has thwarted this effort by raising the bar for New Dietary Ingredient Notifications (NDIN) to what appears to be the higher threshold for the safety of food ingredients (reasonable certainty of no harm). The FDA apparently sees these two safety thresholds as a distinction without a difference. As a result, increasing numbers of dietary supplement manufacturers, unwilling to gamble the future of their products to a system that provides little hope for the FDA's response of "no objection", have committed the additional resources necessary to obtain Generally Recognized As Safe (GRAS) status for their supplements.

The pressure on FDA and Congress for change is again building with increased dissatisfaction among consumers as the result of confusing labels. A second force for change will be a need to uncouple the FDA mandated substance-disease relationship and return to the substance-claim relationship to allow for progress in nutrigenomics and metabolomics, which will result in an increasing number of substance-biomarker claims (Burdock et al. 2006).

### **Conclusion**

Scientific discoveries and increasing interest in the potential health benefits of foods and food components have resulted in a range of content-, structure function- and health-claims. The clinical and epidemiological evidence on the way each particular dietary component fosters growth and development, healthy functioning and disease prevention is expanding. However,

defining a single ideal diet is complicated by the many factors that may influence biological processes.

The diversity of findings in the literature may reflect the multi-factorial nature of these processes. New and emerging genomic and proteomic approaches and technologies offer the prospect of identifying molecular targets for dietary components, thereby possibly determining the mechanisms by which specific individual dietary constituents modify the genetic and epigenetic events that influence the quality of life. Expanded knowledge on unique cellular characteristics with molecular targets for nutrients thus may be able to be used to develop strategies to optimize nutrition and minimize disease risk (Milner, 2002).

This increasing emphasis on food and its component ingredients to reduce disease risk and promote health requires the development of accurate biomarkers for predicting outcomes of food-based interventions. Improved knowledge of human genomics and the ability to use microarray technology to screen for biomarkers at the gene level may provide the opportunity for individuals to be diagnosed for and informed of their own particular disease risk profile.

It remains to be seen whether or not these technologies will provide sufficient understanding of food-gene interactions to permit more certain health claims rather than better therapeutic treatments (Roberts, 2002). The application of such personalised nutrition, from the earliest stage of life, including *in utero*, will present significant challenges for the substantiation of health claims in the post-genome era (McGinty and Man, 2007).

Manufacturers will face increasing demands to provide high quality scientific data before approvals for health claims are granted. They will also need to consider the economics of the time and expense of scientific substantiation / clinical data to support claims, even if these result in higher consumer confidence in the resulting claims.

Consumer research shows that dairy foods like yoghurt are viewed as desirable and credible carriers of functional ingredients, particularly over indulgent foods such as chocolate (Kleef et al, 2005). Dairy foods are also less likely to face the disqualifying criteria for health claims of



addition of a healthy ingredient into a less-than-healthy food vehicle, or the high threshold values for less than healthy nutrients (e.g. high sugar content) now being included in codes by some regulatory bodies.

Dairy foods and ingredients have a natural advantage over new/novel foods, from a regulatory viewpoint, because they are generally considered as “traditional” foods, that is, there is a long history of human consumption. However, the regulatory landscape on adding bioactive ingredients, whether from dairy streams or from non-dairy sources, into dairy foods is rapidly evolving, and the dairy industry will need to be aware of potential regulatory challenges, within the countries they wish to market their products.

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