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Abstract

Scientific research has identified potential health benefits of many food ingredients. These health-promoting (bioactive) food ingredients may be naturally present in a food, or may be added by manufacturers into foods that do not naturally contain such components. These bioactives have challenged traditional concepts of food fortification and consequently food regulations. Dairy foods and ingredients have significant potential as vehicles for the delivery of such bioactives and health-promoting physiological effects, if regulatory hurdles can be overcome. The regulatory landscape on the addition of bioactive ingredients (from dairy streams and non-dairy sources) into foods is rapidly evolving, and the industry will need to be aware of the 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 Aspects of Bioactive Dairy Ingredients

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Introduction

Scientific research has identified potential health benefits of many food ingredients. These health-promoting (bioactive) food ingredients may be naturally present in a food, or may be added by manufacturers into foods that do not naturally contain such components. These bioactives have challenged traditional concepts of food fortification and consequently food regulations. Dairy foods and ingredients have significant potential as vehicles for the delivery of such bioactives and health-promoting physiological effects, if regulatory hurdles can be overcome.

Food regulations and standards differ significantly between countries, and across larger jurisdictional organizations (e.g. Codex Alimentarius, USA Food and Drug Administration) but generally, before a “new” food can be placed on the market, specific authorization will need to be obtained from the relevant regulator. The process of authorization will depend on whether the food or ingredient is regarded as new, novel, traditional or non-traditional (i.e. does not have a significant history of consumption in that market).

The requirements for food labelling and the substantiation of health claims are currently being debated by regulatory authorities and food manufacturers world-wide. The regulatory landscape on the addition of bioactive ingredients into foods is rapidly evolving and this paper will provide an overview of the challenges facing food manufacturers. The information in this paper not only applies to dairy foods, but also applies to functional ingredients sourced from dairy processing streams for addition to non-dairy foods.

Dairy Foods

Milk is a major provider of important nutrients for humans, including calcium, protein and riboflavin, however, it is now recognised that dairy products and ingredients derived from milk and whey can provide functional food products with beneficial effects on human health, as well as nutritional benefits. Casein and whey proteins and their derivatives have been shown to possess biological activities, including peptides able to exert anti-hypertensive and other bioactive 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).

Probiotics comprise approximately 65% of the world functional food market. Probiotic products have been reported to improve and maintain intestinal microflora, protect against infections, alleviate lactose intolerance, reduce blood cholesterol levels and also stimulate the immune system (Holzapfel and Schillinger, 2002). 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. Dairy products such as cheese have 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).

Peptides can be released by enzymatic proteolysis of food proteins and may act as potential physiological modulators of metabolism during the intestinal digestion of the diet. The possible

physiological effects of peptides relate to nutrient uptake, immune defence, opioid and antihypertensive activities. Milk proteins, especially caseins, are an important source of these bioactive peptides. During recent years, major whey protein components, alpha-lactalbumin and beta-lactoglobulin have also been shown to contain bioactive sequences. Peptides showing opioid and angiotensin I-converting enzyme (ACE) inhibitory activity have been found in alpha-lactalbumin and beta-lactoglobulin. Opioid peptides, alpha-lactorphin and beta-lactorphin, have been liberated during in vitro proteolysis of bovine whey proteins, and pharmacological activity was observed at micromolar concentrations. Whey hydrolysates showed ACE-inhibitory activity after proteolysis with different digestive enzymes, and several active peptides were identified. The results demonstrated the existence of several biologically active whey-derived peptides and hydrolysates (Pihlanto-Leppala, 2000).

An issue of concern to the dairy industry relates to recent regulations on the labelling of foods with respect to the level 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 rule that requires the declaration of the amount of TFA present in foods, including dietary supplements, on the nutrition label from January 1, 2006. For the purpose of nutrition labelling, TFA 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. There are many issues that the FDA has yet to resolve: (1) defining nutrient content claims for "free" and "reduced" levels of trans fat, (2) placing limits on the amount of TFA in conjunction with saturated fat limits for nutrient content claims, health claims, and disclosure and disqualifying levels, (3) a daily value, and (4) a possible footnote or disclosure statement to enhance consumer understanding of cholesterol raising lipids. The FDA will be conducting consumer research to determine consumer understanding of various TFA labelling possibilities (Moss, 2006). Researchers (Lock et al. 2005) and the International Dairy Federation (IDF) are attempting to differentiate certain health-promoting dairy-derived trans fats (such as CLA) from the industrially-produced hydrogenated trans fats that have been reported to result in an increased risk of CHD.

Functional foods promise to deliver health and wellness to consumers in an environment where lifestyle diseases and an ageing population are threatening the wellness of society. Milk is a natural, multi-component, nutrient-rich beverage. Market trends indicate that milk-based beverages are ideal vehicles for newly discovered bioactive food ingredients targeting lifestyle diseases. Low-fat milk and drinking yogurt are the most commonly used vehicles for the delivery of bioactive food ingredients. Among the recent trends, low-fat milk is commonly used for delivery of omega-3 fatty acids, while probiotic yogurt drinks are preferred for the delivery of plant sterols. Drinks containing combinations of dairy and fruit juices with added bioactive components are also becoming common in the USA and European Union (EU) markets. Although a range of bioactive components is available for incorporation into dairy beverages, there are significant formulation challenges. Experience indicates that consumers will not buy food products that imply they are sick. Therefore, functional foods should be promoted as convenient, nutritious and tasty formulations with specific health benefits (Sharma, 2005).

Dairy foods with added 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. Such foods may raise human safety concerns and will likely need to undergo a risk-based assessment before being allowed into the food supply (Healy, 2003). Production of standard dairy products can also have its challenges in some parts of

the world with strict regulations in place regarding pesticides and antibiotics in milk (Heeschen and Suhren, 1993).

Health Claims

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 trials 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. In the future, regulators may also require research to test how consumers are likely to interpret and use any health claim.

Consumers' main scepticism regarding functional foods resides in the veracity of health claims and in the often inadequate control of their claimed properties. Legislation concerning this matter is progressing at a slow pace and currently only Japan, the UK, USA, Canada, the Netherlands and some Scandinavian countries have managed to make notable progress. 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-Koukaliaroglou, 2005).

Functional foods can be considered to be those whole, fortified, enriched or enhanced foods that provide health benefits beyond the provision of essential nutrients (e.g., vitamins and minerals), when they are consumed at efficacious levels as part of a varied diet on a regular basis. 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. However, not all foods on the market today that are claimed to be functional foods are supported by enough solid data to merit such claims (Hasler, 2002).

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).

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 seeks 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).

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 can sometimes 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).

Communication of Health Claims to Consumers

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

Dairy foods have long been promoted using health messages. People wanting to improve public health have promoted dairy foods, and people promoting dairy foods have used health messages. Health messages that have been used and are relevant for the promotion of dairy foods include nutrient content messages, low-fat messages and health claims. The changes in legislation permitting the use of (some) health claims 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).

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 approved 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).

An aim of the FDA food labelling regulations is to ensure that manufacturers aid consumers in making choices regarding their diets 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. Finally, it was shown that an incentive should remain for manufacturers to use broader claims whenever consumers are likely to be choosing between alternatives from broadly defined product categories (e.g. cooking oils versus peanut oils) (Burke et al. 1997).

A study of consumers (n = 958) has been carried out to evaluate whether product-related health claims in foods are either 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 (Urala et al. 2003).

A subsequent study by the same group 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 (n = 1158) in their reported willingness to use functional foods. The best predictor for willingness to use functional foods was the perceived reward (Urala and Lahteenmaki, 2004).

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 recently been used in a recent study comparing claims about reduced risk of osteoporosis on milk or a calcium-fortified orange juice. It 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), have affected the acceptance of the claim by the consumer. Participants recruited by a shopping mall intercept method were interviewed face-to-face using a questionnaire. 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 on the claim. Endorsement of the claim did not influence responses, possibly because of the small print of the approval statement or 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).

Foods for Specified Health Uses (FOSHU)

In 1993, the Ministry of Health and Welfare in Japan established a policy of "Foods for Specified Health Uses" (FOSHU) by which health claims of some selected functional foods are legally permitted. Since the time (1984) when the concept of "functional food" was proposed, it appears that the science in Japan has been progressing, among others, along a unique path of development. The uniqueness is seen in the development of functional foods by minimizing undesirable as well as maximizing desirable food factors, for example, hypoallergenic foods, developed from their materials by removing allergens (Arai, 2000).

Terms such as 'nutraceuticals' and 'dietary or food supplements' are not well recognised in Japan compared to many other countries. However, the concept of 'functional foods' is well known as a result of research studies 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 the 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 claiming drug-like effects and violating laws. In 1991, the Ministry of Health and Welfare (MHW) now as the Ministry of Health, Labor and Welfare (MHLW) introduced a 'foods for specified health uses' (FOSHU) system, for the control of such exaggerated and misleading claims. The other reason for such enforcement was due to an increase in the population of elderly people and lifestyle-related diseases that include 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. In addition, the MHLW changed the existing FOSHU, FNFC and other systems in 2005. Such changes include the new Subsystems of FOSHU such as (1) standardized FOSHU, (2) qualified FOSHU and (3) disease risk reduction claims for FOSHU (Ohama et al. 2006).

The regulatory range of FOSHU was broadened in 2001 to accept capsules and tablets in addition to conventional foods. The MHLW enacted a new regulatory system, 'Foods with Health Claims', in April 2001, which consists of the existing FOSHU system and the newly established 'Foods with Nutrient Function Claims' (FNFC). Under the FNFC, twelve vitamins (vitamins A, B-1, B-2, B-6, B-12, C, E, D, biotin, pantothenic acid, folic acid, and niacin) and two minerals (Ca and Fe) were standardized. 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 labelling of functional foods should be based on scientific evidence and be in harmony with international standards. The nutrient-function claim was adopted in the guidelines for nutrition claims by the Codex Alimentarius in 1997. 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).

Codex Alimentarius

The Codex Alimentarius (Latin = “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.

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 claimed effect 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.

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). Much attention is now being paid to claims for foods, especially those related to the newly discovered effects of dietary components on body functions. The main thrust of the recent Consensus Document on Scientific Concepts of Functional Foods in Europe, produced as the final deliverable from the EU DG XII Functional Food Science in Europe (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 "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 PASSCLAIM project built upon the principles defined within the publications arising out of the FUFOSE project and ran from 2001 to 2005.

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 have been defined by the PASSCLAIM project and are 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 storage) and should be evaluated by 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 end-point (Riccardi and Giacco, 2005).

Several approaches to the use of health claims on foods have been made around the world, and the 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. Two broad categories have been defined within PASSCLAIM: Nutrition Claims, i.e. what the product contains, and 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 the use of 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. Subsequent legislation known as the FDA Modernization Act (FDAMA) provided an alternative to FDA review of a health claim where a USA government scientific body other than FDA, concluded 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 has 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).

The USA Congress through the Nutrition Labeling and Education Act of 1990 authorized the use of health claims on food labels. These claims describe the relationship between a substance and a disease or health-related condition. In addition, Congress directed the U.S. FDA to apply a significant scientific agreement standard in approving these claims. Since 1990, the FDA has approved several health claims, but has also denied claims that did not meet this standard. The purpose of The Nutrient Disease Relationships: Closing the Scientific Knowledge Gap symposium was to provide researchers with perspectives to keep in mind when designing studies that examine the relationship between a nutrient and a disease or health-related condition, to help close the scientific knowledge gap for nutrient-disease relationships of scientific, consumer, and public health interest (Saldanha and Johnson, 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) - 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).

Concluding Remarks

The current intense commercial activity to develop new functional ingredients from dairy products will continue, and become more sophisticated as knowledge of human physiology and nutrition

advances, particularly in relation to gastrointestinal microbiology and immunology (Playne et al. 2003).

Collectively, epidemiological, pre-clinical and clinical studies are providing quite compelling evidence that numerous essential and non-essential dietary components are capable of influencing growth, development, performance and disease prevention. Scientific discoveries and widespread interest in the potential medicinal benefits of foods and food components have fostered a variety of content-, structure function- and health-claims. Unfortunately, defining the ideal diet is complicated by the numerous and diverse components that may influence biological processes. Inconsistencies in the literature may reflect the multi-factorial nature of these processes and the specificity that individual dietary constituents have in modifying genetic and epigenetic events. New and emerging genomic and proteomic approaches and technologies offer exciting opportunities for identifying molecular targets for dietary components and thus determining the mechanisms by which they may influence the quality of life. It is plausible that bridging knowledge about unique cellular characteristics with molecular targets for nutrients can be used to develop strategies to optimize nutrition and minimize disease risk (Milner, 2002).

The development of useful and accurate biomarkers for predicting outcomes of food-based interventions is becoming more important, given the emphasis being placed on ingredients in foods contributing to disease risk reduction and optimal health promotion. With the human genome now identified, opportunities abound to 'barcode' individuals with their risk profiles. The increase in DNA sequence information together with the development of new technologies such as genomics, proteomics and bioinformatics, has resulted in a much greater capacity to determine individual risk profiles. Screening for biomarkers at the gene or protein expression level using microarray technology has the potential to identify new biomarkers for disease diagnosis. Whether these techniques will enable a better understanding of food-gene interactions to permit health claims rather than better therapeutic treatment (at high economic cost) remains to be demonstrated (Roberts, 2002).

While nutrient content claims and general level claims (e.g. calcium and healthy bones) are allowable in many countries, higher level claims or specific claims relating to disease conditions are generally not currently allowable by most regulatory bodies worldwide. In contrast to the scientific substantiation of health claims required by countries such as the USA and Canada, regulations in China (for example) rely more on long-established and accepted practice and experience developed in traditional Chinese medicine but have specific requirements with respect to food safety and public health. A newly agreed to Food Labelling Directive is attempting to harmonise food labelling issues and health claims across Europe which will result in more stringent levels of scientific substantiation. However, at the time of writing, the new European nutrition and health claims regulations have hit an unexpected procedural barrier prior to their expected adoption in September 2006. It is currently unclear whether this barrier will result in a re-visiting of the debate over nutrient profiling.

In the immediate future, there will very likely be increasing demands on manufacturers in providing high quality scientific data before approvals for health claims are granted and this may result in higher consumer confidence in the claims that will appear on food products. However, manufacturers will also need to consider the time and expense in scientific substantiation / clinical data to support the claims being sought. In Japan, for example, of the 171 new FOSHU product approvals in the past 2 years, most were formulated with previously approved functional ingredients.

The requirements for food labelling and the substantiation of health claims are currently being debated by regulatory authorities and food manufacturers world-wide. An advantage that dairy foods and ingredients have over new/novel foods is that they are generally considered as “traditional” foods, that is, there is a long history of human consumption, which potentially would allow an easier path through regulatory approval. Consumer research has also shown that dairy foods such as yoghurt are viewed as much more credible and appealing carriers of functional ingredients than indulgent foods such as chocolate (van Kleef et al, 2005). It should be noted that some regulatory bodies are now including disqualifying criteria for health claims e.g. in the case of addition of a healthy ingredient into a less-than-healthy food vehicle (e.g. one with a very high sugar content). In Australia and New Zealand new regulations are being developed to allow the use of approved health claims. The new system may be finalised by mid 2007, but it is possible that disqualifying nutrient levels may make it difficult for some dairy foods (eg, high fat cheeses) to be able to carry health claims. Furthermore, if dairy ingredients are isolated and concentrated and manufacturers are considering adding such dairy ingredients into other food vehicles, the process for regulatory approval will still require demonstration of safety and efficacy.

The regulatory landscape on the addition of bioactive ingredients (from dairy streams and non-dairy sources) into foods is rapidly evolving, and the industry will need to be aware of the potential regulatory challenges within the countries they wish to market their products.

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