

Current international approaches to food claims; Kwak, No-Seong; Jukes, David John
Nutrition Reviews 12-01-2000

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Volume: 58

Number: 12

ISSN: 00296643

Publication Date: 12-01-2000

Page: 370

Type: Periodical

Language: English

The market for functional foods is rapidly increasing. It is necessary to establish a legal framework for these foods. This has proved difficult in a number of countries. The control through health claims is generally accepted as the most appropriate measure. Activity in this area has been developing both at the national and international levels. However, the regulations and proposals from a number of national authorities and other nongovernmental sectors are varied and difficult to reconcile. This paper examines the range of health claim controls being used in the food area. They are considered in detail so as to establish a better understanding of the claims. In this paper, the claims have been classified into six categories: nutrient content claims, comparative claims, nutrient function claims, claims related to dietary guidelines or healthy diets, enhanced function claims, and reduction of disease risk claims. Of these, the latter four claims are considered to have significant implications for functional foods.

The Role of Claims in the Control of Functional Foods

Various factors have led to an increase in the number of functional foods now being placed on the market. These include the development of nutrition and food technology, increasing consumer interest in health, and increasing number of elderly. According to Hickling,¹ the global market for functional foods was estimated to be approximately \$17 billion in 2000. This consists of \$3 billion in the European market, \$9 billion in the U.S. market, and \$5 billion in the Japanese market. Young² more optimistically anticipated an even bigger market in the future (i.e., a global market of \$100 billion with Western Europe accounting for some \$30 billion).

Whether a new type of food, such as a functional food, is introduced into the market or the consumption of an ordinary food increases abnormally, a food should satisfy safety requirements. Safety controls have been developed for these situations that take into account the use of novel raw materials, the application of novel processes, or the novelty of its potential use or role in the diet.³ Once these safety requirements are satisfied, a fundamental issue arises in terms of functional food marketing: how

can functional foods be distinguished in the market from other ordinary foodstuffs?

The scope and position of functional foods from a regulatory viewpoint have been considered elsewhere.^{4,5} What has been demonstrated is that functional foods are not a separate category of food. Many ordinary foods can be regarded as functional foods (e.g., some fruits and vegetables). Functional foods also overlap with other categories of special foods (e.g., fortified foods and foods for special dietary uses). In other words, functional foods can be both foods of special categories and ordinary foods. This, therefore, requires a horizontal approach (i.e., applying across a range of different foods or a widely defined group of foods; e.g., regulations relating to labelling, materials in contact with food, or the general acceptance for use of food additives, etc.) to the regulation of functional foods. Because the most distinctive feature of functional foods is their claimed "health benefits," the labelling of the claims should be the criteria used to distinguish between functional foods and other ordinary foodstuffs. It is this issue that forms the basis of this paper.

This type of approach can be found in the Japanese regulatory system for functional foods.⁶ Although functional foods are classified as "Food for Special Health Uses" (FOSHU), the difference between FOSHU and ordinary foods is whether they can be labelled with a claim that indicates that people may achieve the intended health benefits) by consuming it. So long as it meets safety requirements, without the intention to label with a claim, any functional food can be sold as an ordinary food without the approval to be sold at FOSHU.

Although "functional food" is not a legal term in the United States, health claims largely relating to functional foods are allowed.⁷ The relationship between a food and the disease or health-related condition can be labelled if the U.S. Food and Drug Administration (FDA) has accepted a health claim regarding this relationship.

This approach to the control of functional foods through the control of claims is supported by industry.

The Confederation of the Food and Drink Industries of the European Union (CIAA) was of the opinion.⁸ that: "If claims concerning these health benefits are not allowed, the highlighting of the relationship between foodstuffs and their improved health promoting properties is too costly to continue to invest in this type of research. [Consequently,] the regulatory framework should leave sufficient room for innovation, but be strict enough to prevent false and misleading claims."

On the other hand, some consumer organizations may not be in favor of this approach. Consumers International (CI) expressed its opinion in a paper to the Codex Alimentarius Commission in which they stated that health claims should not be permitted because the potential to mislead and confuse consumers and thereby lose any trust in claims is great.⁹ New Zealand expressed a similar opinion and did not support the use of health claims on food labels.¹⁰ Despite this objection, the establishment of the recommendations for the use of health claims has already been discussed in Codex as a part of the guidelines for the use of nutrition claims. CI therefore subsequently changed their position and has stated the following:¹¹ "They were not in favour [sic] of health claims in general; however, as these

were found on the market, there was a need to consider this issue further from the point of view of consumer information and education in health and nutrition matters."

Present Classification of Claims

Diversity of International Proposals

Because the horizontal approach has been generally preferred to the vertical approach (i.e., applying only to an individual or specific food category; e.g., regulations applying only to sugar or only to fruit juices) for the control of foodstuffs, the role of labelling is important at the international level. As part of this, claims have been considered as one of the leading labelling issues. The Codex has tried to establish guidelines for claims and has had some success. Nutrition claims have been agreed upon. Health claims are still being discussed, however, and there appears at present to be little chance of a consensus on their scope.¹² Besides which, although agreed upon, the guidelines for nutrition claims still seem to be causing difficulty. For example, the delegation of Denmark in Codex proposed that one of the nutrition claims (nutrient function claims) should be incorporated into health claims.⁹

At a national level, the basic concepts of claims seem to be similar to those of the Codex. In a number of countries, including the United States,¹³ and Australia,¹⁴ nutrient function claims, claims related to dietary guidelines, and health claims are considered as major types of claims. However, the strategies used to apply these claims can be quite different in spite of the establishment of the Codex guidelines. Whereas nutrient function claims and claims related to dietary guideline are considered nutrition claims in the Codex, all of them are considered as health claims in the United Kingdom.¹⁵ The subclassification of health claims is also different. In Australia,¹⁴ and the United Kingdom,¹⁶ health claims consist of generic and specific or innovative health claims. On the other hand, in the Codex proposal health claims are divided into two subcategories depending on the character of benefits-enhanced function claims and reduction of disease risk claims.

These various classifications of claims at the national and international levels have helped contribute to the understanding of claims. However, each of the various classifications adopted or proposed (both by Codex and other countries) has their own strength and weakness. Some regulations and proposals help the understanding about the scope of the claims relating to disease, whereas others show the scope of the claims relating to enhanced function.

In spite of using similar terms, the proposed claims have somewhat different scopes. This diversity can cause confusion in the use of terminology and is one of the obstacles to be discussed. For example, the term "health claims" is used in the most classifications. However, its scope varies slightly or significantly in these classifications and is discussed below.

In this regard, consolidation of the claims as suggested by the regulations and proposals is necessary at this stage. This would reduce the number of terms in use, limiting potential confusion, and would lead to a better understanding of claims.

Nutrition Claims

Originally, the guidelines for the use of health claims and nutrition claims were simultaneously proposed in the Codex.¹⁷ However, in spite of extensive discussion at the 24th session of the Codex Committee on Food Labelling, whereas there was consensus on nutrition claims, there was no consensus on health claims. Thus, only those parts concerning nutrition claims were adopted by the Codex Alimentarius Commission at its 22nd session in 1997. The guidelines for health claims are still being discussed at step three in the Codex procedure.

According to the Codex general guidelines on claims,¹⁹ the term "claim" is defined as: "any representation which [sic] states, suggests or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality."

According to the guidelines on use of nutrition claims,¹⁸ a "nutrition claim" means: "any representation which [sic] states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals, except the following: (a) the mention of substances in the list of ingredients; (b) the mention of nutrients as a mandatory part of nutrition labelling; (c) quantitative or qualitative declaration of certain nutrients or ingredients on the label if required by national legislation."

Nutrition claims consist of the following different claims.

Nutrient claim and comparative claim. In the Codex, two claims are separately identified relating to the level of nutrients in foodstuffs.¹⁸ One is the "nutrient content claim" that describes "the level of a nutrient contained in a food (e.g. source of calcium; high in fibre [sic] and low in fat)." The other is a "comparative claim" that compares the nutrient levels and/or energy value of two or more foods (e.g. "reduced; less than; fewer; increased; more than").

On the other hand, in the United States and Australia these are considered as one type of claim. For example, in the United States "nutrient content claim" is defined as "a claim that, either expressly or by implication, characterizes the level of any nutrient required to be listed on the nutrition label. Such claims include 'high fiber,' 'low fat,' 'reduced cholesterol,' and 'light.'"¹³

However, this difference in the scope of the claims may not represent a substantial difference of approach. It can be regarded as only a matter of classification.

Nutrient function claims. In the Codex, a "nutrient function claim" is classified as a nutrition claim and is defined as "a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body (e.g. calcium aids in the development of strong bones and teeth)."¹⁸ The scope of nutrients is limited to "only those essential nutrients for which a Nutrient Reference Value (NRV) has been established in the Codex guidelines on nutrition labelling or those nutrients which [sic]

are mentioned in officially recognised [sic] dietary guidelines of the national authority having jurisdiction."

In Australia, "nutrition messages" are defined as claims that "set out in general terms the nutritional consequences of the intake of the nutrient (e.g. this food is a good source of calcium, which helps build strong bones and teeth)."" Preston and Lawrence" of the Australia New Zealand Food Authority stated, "this definition is very similar to the Codex Alimentarius definition of a nutrient function claim."

Claims related to dietary guidelines or healthy diets. Whereas claims related to dietary guidelines or healthy diets are considered as a form of nutrient claim in the Codex, a claim based on dietary guidelines is considered as a health claim in the United Kingdom.¹⁵ In the United States, a message to provide "guidance about general food choices or achievement of a healthy lifestyle"¹³ is not generally considered as a health claim. It is a health claim, however, when it contains two elements of a health claim: a food substance and a disease or health-related condition (two elements principle of health claims). As an example, if "the National Cancer Institute recommends that you eat five servings daily of fruits and vegetables to increase your intake of fiber" is labelled on a certain foodstuff, it would be a health claim because this sentence refers to a specific nutrient, fiber, and a disease, cancer.

Classical nutrient deficiency claims. This claim is separately mentioned only in the United States and is not an official claim in the Codex. It is defined as a claim on diseases "resulting directly from a deficiency of a vitamin, mineral, or other essential nutrient" such as scurvy.¹³ In other countries, it may be considered as a claim on dietary guidelines.

Health Claims

The first Codex draft. After the adoption by the Codex of the guidelines on nutrition claims the recommendation on health claims has so far only been discussed at step three of the Codex procedure.¹² According to the proposed draft guidelines for use of health and nutrition claims,²⁰ the definition of a health claim was: "Any representation that states, suggests or implies that a relationship exists between a food or a nutrient or other substance contained in a food and a disease or health-related condition." As examples, three type of health claims were given: "Healthrelated effects on the body attributed directly to a food or nutrient or substance (e.g., X fish oil lowers serum triglycerides and increases clotting times...);" "disease prevention attributed to nutrient or substance contained in a food (e.g., X contains soluble fibre [sic] which reduces risk of heart disease);" "disease prevention or healthrelated effects related to diet (e.g., a low-fat diet will reduce risk of cancer. X is a low-fat food.)."

Approach in the United States. After considerable turmoil in the 1980s, the U.S. FDA has controlled health claims under the Nutrition Labelling and Education Act of 1990, in which a health claim is defined as:⁷ "Any claim made on the label or in labelling of a food, including a dietary supplement, that expressly or by implication... characterises [sic] the relationship of any substance to a disease or health-related condition."

A health claim should simultaneously relate to two basic elements: a food substance, which can be a specific food or a component of food; and a disease or health-related condition. In some respects this approach is similar to that proposed for the Codex. In the previous draft recommendation in Codex,²⁰ a health claim involved the relationship between "a food or a nutrient or other substance" contained in a food and "a disease or health-related condition."

Based on this principle, which requires two components for a health claim, four possible cases can be considered: an increased level of a substance and a health-related condition; an increased level of a substance and a disease; a decreased level of a substance and a health-related condition; a decreased level of a substance and a disease.

In the previous subclassification of the Codex, the first and the second type of health claims are the first two cases in which the increase or presence of a substance such as fish oil and soluble fiber contribute to the health-related effects and the reduction of disease risk. On the other hand, the third type of health claims is the latter two cases in which the decreased intake of a substance such as fat contributes to the reduction of disease risk. This sort of claim may have a great impact on the countries, such as the United Kingdom or the United States, where reduced fat intakes are encouraged for better health. This type of claim may be less relevant to functional foods, however, because these recommendations are usually based on the well-known nutrition problems related to nutrients rather than nonnutrients.

Structure/function claims in the United States. In the United States, another type of claim exists that is similar to the nutrient function claims in the Codex. A "structure/function claim" can be defined as a claim to describe "the effect of a food or a food substance on a structure or function of the body."¹³ The U.S. FDA specifically excluded this claim from the definition of health claims. Without a clear definition of this claim the difference between the two claims can be illustrated with some examples. The claim "builds strong bones" suggests that the scope of structure/function claims at least incorporates the nutrient function claims in the Codex.

Unlike other countries, dietary supplements are legally allowed to bear more varied types of claims than ordinary or functional foods in the United States—nutritional support statements as well as health claims. A nutritional support statement:²¹ "claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States; describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans; characterises [sic] the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function; [and] describes general well-being from consumption of a nutrient or dietary ingredient."

Nutritional support statements have a close relationship with structure/function claims, especially the second and third statements. Owing to their unclear scope, the U.S. FDA published proposed "regulations on statements made for dietary supplements concerning the effect of the product on the structure or function of the body."²² Following the consultation process, the U.S. FDA promulgated the final rule in January 2000.²³ Although the rule applies to dietary supplements and not ordinary or functional foods, it helps clarify the scope of structure/function claims for these as well.

According to the rule, claims that broadly refer to body systems or functions without implicitly or explicitly mentioning several objects including symptom, disease, and drug action are generally not regarded as disease claims. A general mention of the immune system or gut system is therefore recognized as a structure/function claim.

The criteria may, however, be too complex for consumers as well as professionals and there are several controversial issues that need to be addressed further. For example, it may be difficult to discriminate between "maintaining" normal function (e.g., "helps maintain a healthy cholesterol level")-an allowable structure/function claim-and "preventing or treating" abnormal function (e.g., "lowers cholesterol"-a disease claim.

The current Codex draft. At the 27th session of the Codex Committee on Food Labelling in 1999, an informal working group was set up to discuss this matter. The previous proposal about health claims was substantially changed into the proposal based on the opinion of France, the International Life Sciences Institute (ILSI), and the CIAA.²⁴⁻²⁶ In the proposed draft recommendations for the use of health claims,¹¹ the following two alternatives were proposed as definitions for health claims: "Any claim establishing a relation between a food or a constituent of that food and health, [whether it is good health or a condition related to health (or disease)];" and "any claim which [sic] suggests that a food or a constituent of that food has an impact on health."

Two type of claims were proposed as subcategories: "Enhanced function claims-these claims concern specific beneficial effects of the consumption of foods and their constituents on physiological [or psychological] functions or biological activities but do not include nutrient function claims. Such claims relate to a positive contribution to health or to a condition linked to health or to the improvement of a function or to modifying or preserving health; and reduction of disease risk claims-claims for reduction of disease risk related to the consumption of a food or food constituent in the context of the total daily diet that might help reduce the risk of a specific disease or condition."

The approach of the above draft is, to a significant extent, based on the opinion of ILSI Europe. Its adoption is especially meaningful for functional foods because ILSI Europe proposed those types of claims as claims for functional foods. The classification of the claims is based on the scientific classification of markers for target functions (Figure 1).²⁷ Markers are classified "according to whether they relate to: the exposure to the food component under study, such as a serum, faecal [sic], urinary or tissue marker; the target function or biological response, such as changes in body fluid levels of a metabolite, protein or enzyme; or an appropriate intermediate endpoint of an improved state of health and well-being and/or reduction of risk of disease, such as the measurement of a biological process that relates directly to the endpoint."

Based on the above classification, ILSI Europe proposed two types of claims:

Enhanced function claims: "These claims concern specific beneficial effects of nutrients and non-

nutrients on physiological, psychological functions or biological activities beyond their established role in growth, development and other normal functions of the body. This type of claim is also similar to a structure/function claim in the USA and makes no reference to a particular disease or pathological state. However, reference to a mild abnormal condition, as for example indigestion or insomnia, could possibly be permitted."

Reduction of disease risk claims: "These claims relate to the consumption of a food or food component that might help reduce the risk of a specific disease or condition because of specific nutrients or non-nutrients contained within it. These claims correspond to those referred to as 'health claims' in the USA."

Psychologic function is also considered under the umbrella of enhanced function claims; this is unusual and is not usually considered as the subject of claims.

Claims relating to functional foods in Japan. A number of claims are legally allowed for functional foods in Japan. Although the Japanese government has not officially established the scope of the claims, an examination of the claims that have been permitted for FOSHU products will help the understanding of their scope. The claims permitted in Japan can be divided into eight categories: "hypertension control (e.g., "this drink contains an infusion of tochu leaves. This food is suitable for [people with] high blood pressure."); cholesterol control (e.g., "chitosan suppresses cholesterol uptake, it is useful to improve the diet of those people who must be careful of high cholesterol."); prebiotics (oligosaccharides) (e.g., "fructo-oligosaccharide promotes the growth of bifidus bacteria in the gut and keeps your insides in good condition."); probiotics (e.g., "acidophilus bacteria and bifidus bacteria improve the environment in the intestines and help to regulate the intestines."); dietary fiber (e.g., "contains an appropriate quantity of dietary fibre [sic] (polydextrose) to keep your insides regulated."); minerals (e.g., casein phosphopeptide [CPP] "is a means to raise the absorption of calcium where there is a deficiency of calcium intake in the diet."); noncariogenic sweeteners (e.g., "dental caries worry-free gum"); and foods from which substances have been removed (e.g., "hypoallergenic rice").

Considering the wording of the claims, those relating to hypertension control and cholesterol control would be similar in that they are related to risk factors that may adversely affect good health. They can be classified into enhanced function claims in the proposal of ILSI Europe.

These types of claims would be allowable as structure/function claims for dietary supplements in the United States "if the context did not suggest treatment or prevention of a disease." However, some claims in Japan would be beyond the scope in the United States. For example, whereas the claims concerning reduction of the level of serum cholesterol are allowed in Japan,²⁹ the U.S. FDA considers those as disease claims.²³ Only "helps maintain a healthy cholesterol level" was considered as a structure/function claim.

Claims relating to prebiotics, probiotics, and dietary fiber can also be regarded as one category because they are related to the maintenance of a specific part or organ of the body. Although it is frequently

suggested that the claims for an improved state of health and well being as such should be considered as one independent category, they are included in the enhanced function claims in the proposal by ILSI Europe.²⁷

This type of claim is also considered an allowable structure/function claim for dietary supplements in the United States. For example, "helps maintain healthy intestinal flora" was not considered as a disease claim.^{22,23} The reason was that it refers "broadly to body systems or functions without sufficient reference to specific abnormalities or symptoms" and that it "did not mention a therapy for disease." "Supports immune system" was not considered as a disease claim either. The reason was that it generally refers to "an affect on a body immune system that has several functions, only one of which is resistance to disease."

Claims relating to foods from which substances have been removed would be considered as foods for special dietary uses in other countries because they are consumed by a specific group of the population and are significantly different from ordinary foods in composition.⁵

From the viewpoint of the United States, Japan seems to use structure/function claims for emerging health or functional foods, whereas claims relating to disease are major policy tools for foods in the United States.

The Approach in the United Kingdom and Australia. According to the Code of Practice on Health Claims in the United Kingdom,¹⁶ a health claim is defined as a direct, indirect, or implied claim "in food labelling, advertising, and promotion that consumption of a food carries a specific health benefit or avoids a specific health detriment. This includes nutrient function claims describing the physiological role of the nutrients in growth, development and normal functions of body but does not include nutrient content claims."

This is divided into two subcategories on the basis of whether it has been publicly accepted: a generic health claim, "a health claim based on well-established, generally accepted knowledge from evidence in the scientific literature and/or to [sic] recommendations from national or international public health bodies;" and an innovative health claim, "a health claim other than a generic health claim based on scientific evidence applied to existing or new foods..."

Regarding the scope of health claims, they are allowed to refer to the maintenance of good health in general or of a specific part or organ of the body and to refer to risk factors that may adversely affect good health. The former would be in line with the Japanese claims concerning prebiotics, probiotics, and dietary fiber. The latter would also be similar to the Japanese claims concerning hypertension and cholesterol control. On the other hand, any reference to a specific disease or to disease in general terms is not permitted.

In Australia, Preston and Lawrence,¹⁴ proposed two type of health claims based on whether an individual food can provide a health benefit: generic health claims, "a health claim which [sic] relates the

nutrient or nutrients in a product to risk reduction of a disease condition (e.g. this food is low in fat, and low-fat diets are associated with reduced risk for some cancers.);" and specific health claims, health claims that "link an individual food (albeit within the context of total diet) to a health-related outcome and to be subject to specific case-by-case assessment."

Although reference to disease is not allowed in the United Kingdom, the above classification of health claims in the United Kingdom and Australia would reflect the approaches in the United States and Japan, respectively. Health claims in the United States would be generic health claims in that a claim is considered based on "totality of publicly available scientific evidence" and every product can be labelled if the product satisfies certain requirements." This approach would provide more benefits to consumers because public scrutiny may prevent biased or politically influenced decisions concerning the claim and any one company cannot exclusively use certain health claims.

On the other hand, claims concerning functional foods in Japan would be specific or innovative claims in that an individual claim should go through the case-by-case assessment of the Ministry of Health and Welfare. Besides, by comparison with that in the United States, the decision concerning the claim is not sufficiently open to public scrutiny.? This approach would be preferred by some leading companies developing functional foods because they can keep their own scientific evidence and easily discriminate their own products from their competitors'.

Conclusion

As discussed earlier, the classifications of claims in proposals and regulations are substantially different. This is understandable because the particular national situation must be considered in developing regulations. As an example, the claims allowed for functional foods in Japan are defined as enhanced function claims in the Codex proposals. On the other hand, the health claims in the United States are mostly reduction of disease risk claims.

The scope of enhanced function claims is not as clear as that of reduction of disease risk claims. The scope of reduction of disease risk claims is relatively simple, mainly considering the reference to a disease. Conversely, the scope of enhanced function claims is wider and more complex. Although the analysis of the claims for functional foods permitted in Japan may help to better understanding, more discussion seems necessary.

The claims discussed above can be classified into two categories, claims concerning quantity of nutrients and claims concerning statements about health benefits. Nutrient content and comparative claims are only related to simple description (such as the existence and level of nutrients) and can be termed "quantitative claims." On the other hand, the other three claims-nutrient function claims, claims related to dietary guidelines or healthy diets, and health claims-may contain a description of a health contribution. This could include the physiologic role of the nutrient and a relationship that exists between a food or a nutrient or other substance contained in a food and a disease or health-related

condition. These can be termed "qualitative claims."

All the claims can be used as tools to disseminate the health effects of functional foods. Quantitative claims would be useful to inform consumers of the high content of essential nutrients. However, the impact of quantitative claims is largely dependent on consumer knowledge. In addition, claims are only permitted for a limited number of nutrients. Conversely, qualitative claims can affect consumer choice by the direct assertion of the health contribution with various general and technical terms. Qualitative claims would therefore have more significant implications than quantitative claims in terms of functional foods.

From the regulatory viewpoint, a major issue concerning quantitative claims is the nutrients to be included and the terms, such as "source" and "reduced," to be controlled. The consumer familiarity with these nutrient terms may reduce the possibility of misinterpreting claims.

On the other hand, the control of qualitative claims must be more complex than quantitative claims because various scientific terminology and facts are used in making a claim and the construction of the claims are therefore more technical and may be more easily misinterpreted by consumers. Certain nutrient function claims, not referring to a certain disease but implying it, might mislead consumers more deliberately than reduction of disease risk claims that explicitly refer to a certain disease. Terminology unfamiliar to consumers would easily lead to misunderstandings and the same sentence may have different meanings in different situations. In addition, the complex issue of consumer response to these claims may not be clear enough at present.

Taking into account the above national or international classifications of claims, we therefore conclude that claims can be classified in detail as follows:

Nutrient content claims: claims related to the level of a nutrient contained in a food (e.g., high in fiber and low in fat).

Comparative claims: claims related to the nutrient levels and/or energy value of two or more foods (e.g., reduced fat).

Nutrient function claims: claims relating to the physiologic role of the nutrient in growth, development, and normal functions of the body (e.g., the function of calcium in the development of strong bones and teeth). Claims related to dietary guidelines or healthy diets. Enhanced function claims: specific beneficial effects of nutrients and nonnutrients on physiologic functions, psychologic functions, or biologic activities except nutrient function claims. They can be subdivided as follows:

1. Risk factor: claims relating to risk factors that may adversely affect good health, except nutrient functions (e.g., the maintenance of the level of serum cholesterol).

- 2 Bioavailability: claims relating to the bioavailability of nutrients such as minerals.

3. The state of a specific part or organ of the body: claims relating to the maintenance of a specific part or organ of the body (e.g., the regulation of intestinal flora).

4. Psychologic function: claims relating to the psychologic impact (e.g., caffeine can improve cognitive performance).

Reduction of disease risk claims: claims relating to the reduction of the risk of a specific disease or condition (i.e., health benefits resulting from the increased intake of a substance, health benefits resulting from the decreased intake of a substance).

The most important criterion in the classification of qualitative claims may be the relationship with disease. In practice, the confusion of consumers by the claims implying the benefits for a disease would be the most crucial concern of national authorities in terms of functional foods. Therefore, the definition of disease may have an important implication in terms of the claim classification.

Illustrations/Photos: Figure 1.

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