Consideration of possible legislation within existing regulatory frameworks[1–3]

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ABSTRACT Legislation on a particular food or on a particular claim to be used in connection with a food require a definition of the food and unequivocal requirements for the use of the claim. The definitions of prebiotics and probiotics presently place these terms between the categories for conventional foods and foods for special dietary uses. Because probiotics and prebiotics, as a group, do not fulfill the criteria for special dietary uses, they have to comply with the rules and laws for conventional foods even if the requirements for the use of the terms *prebiotic* and *probiotic* include effects on body functions. These effects on the health and wellness of the consumer and to stimulatory activity, eg, body defense mechanisms, can be used in claims that should underline the importance of the total dietary pattern. It is suggested that setting up rules for the use of the terms *prebiotic* and *probiotic* is preferable to creating new food standards. *Am J Clin Nutr* 2001; 73(suppl):471S–5S.

KEY WORDS Probiotic, prebiotic, labeling, claim, food law, safety

INTRODUCTION

Food legislation aims at protecting public health and the safety and interests of consumers without impeding innovation in the field of food production and trade. Such legislation should be transparent and based on scientific evaluation that is preferably unequivocal, and a balance should be found between horizontal approaches (where possible) and detailed product-category-specific rules.

In considering possible legislation for specified food groups of probiotics and prebiotics, and eventually synbiotics, 2 principal questions evolve: *1*) Is there a need for legislation in addition to existing laws and rules? and *2*) If the answer to the first question is "yes," what kind of law or rule will best cover the needs of consumers, manufacturers, and food control authorities?

A need for special laws or rules on prebiotics and probiotics may be assumed if evidence shows that prebiotics and probiotics are not sufficiently covered by existing laws and rules and, therefore, the interests of consumers, manufacturers, and control authorities are not considered. Naturally, the interests of these 3 groups differ, as shown in **Table 1**.

DEFINITIONS

A probiotic animal feed supplement was originally defined by Fuller (1) as "a live microbial feed supplement which beneficially affects the host animal by improving its intestinal microbial balance." The definition was later changed to include microbial food supplements for human use.

A prebiotic was defined by Gibson and Roberfroid (2) as "a non-digestible food ingredient that beneficially affects the host by selectively stimulating the growth and/or activity of one or a limited number of bacteria in the colon, and thus improves host health." Synbiotics combine the properties of both probiotics and prebiotics.

ARGUMENTS FOR AND AGAINST SPECIAL LEGISLATION FOR PROBIOTICS AND PREBIOTICS

There are certainly safety concerns for the consumer with regard to the selection of nonpathogenic bacteria strains and the selection and dosage of nondigestible substances, mainly carbohydrates, and their ability to be tolerated. If, on the other hand, the consumer is to understand the criteria for defining the nature and effects of probiotics and prebiotics, it is essential that the consumer be clearly and sufficiently informed through adequate food labeling and be protected against misleading statements on products that do not fulfill these criteria and in fact are fraudulent.

Manufacturers are responsible for the safety of their products and thus we hope we can assume that they will take good care of safety aspects. Manufacturers who have invested intensively in the research and development of new, well-defined products with identifiable effects or properties will be eager to advertise these products and their special properties, thus gaining an advantage in the market over competitors. Such manufacturers would be especially interested in preventing fraudulent products from boasting the same kind of claims as their original product.

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TABLE 1
Main points of interest in connection with food

Group	Interest
Consumers	Safety
	Composition and nutritional value
	Organoleptic quality
	Protection from fraud and misleading labeling
Manufacturers	Safety
	Claims
	Coherent and transparent legislation
Control authorities	Coherent and transparent legislation
	Control

Rules that define the production, nature, and composition of these products will help to prevent the misbranding of imitation products. Such criteria will also facilitate control by the appropriate authorities with regard to product composition and the claimed nature of food.

The question of whether prebiotics and probiotics are covered sufficiently by existing legislation cannot be answered in a general way because national laws on food differ widely. Therefore, the following discussion will center around the guidelines and standards of the Codex Alimentarius (3).

Bacterial cultures are treated in accordance with Codex standards, eg, fermented-milk products as intrinsic parts of these products, need not be labeled. However, in the Codex standard for infant formula, lactic acid–producing cultures are listed under pH-adjusting food additives. Probiotic microbial cultures, however, do not fulfill the definition of a food additive, as do nonprobiotic bacterial cultures, as given in the General Standard for the Labeling of Prepackaged Foods under section 2: "'Food Additive' means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has a nutritive value, the intentional addition of which to food for a technological…purpose…results, or may be reasonably expected to result (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include…substances added to food for maintaining or improving nutritional qualities" (4). Probiotic microbial cultures can be best regarded as ingredients that improve the nutritional quality of the food, which means that they must be listed in the ingredient list and can be referred to in the name of the food. The same considerations apply to nondigestible substances in food: they should appear in the ingredient list and must be listed as a percentage when special emphasis is placed on their presence or when "the description of the food has the same [emphasizing] effect" (4).

It is questionable whether the consumer will be able to deduce the prebiotic or probiotic nature of the food from the ingredient label alone when the term *prebiotic* or *probiotic* is not included. Both of these terms can and have been used in connection with products that do not comply with the proposed definitions and criteria that were discussed at this meeting as warranting their use.

Although the manufacturer's responsibility for the safety of the product can not be questioned, the lack of criteria for selecting bacterial strains, and, for example, nondigestible carbohydrates, poses a potential hazard, especially in combination with insufficiently controlled production procedures and without regard for possible interactions within the product. The various arguments for and against special regulatory measures for prebiotic and probiotic products are listed in **Table 2**. The number of arguments in favor of regulatory measures seems to outweigh the arguments against such measures, with "safety" and "not-misleading" being the strongest points.

CONSIDERATION OF POSSIBLE REGULATIONS ON PREBIOITCS AND PROBIOTICS.

The Codex Standard for the Labeling of Prepackaged Foods determines under section 3.1 that "…prepackaged food shall not be described or presented on any label or in any labeling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect" (4). If the prebiotic or probiotic nature of a food can be described clearly and provides unequivocal differentiation from other foodstuffs, these terms can be regarded as claims according to the definition given in the Codex General Guidelines on Claims under section 2: "For the purpose of these guidelines, a claim is any representation which states, suggests or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or other quality" (5).

There are examples in the Codex Alimentarius that conditions for the use of certain terms (claims) in separate guidelines. Criteria for use of the term *halal*, ie, food permitted under the Islamic law, were defined and adopted in 1997 (6). These criteria define lawful and unlawful food of animal and plant origin, drinks and food additives, requirements for the slaughtering of animals, and preparation, processing, packaging, transportation, storage, and labeling requirements. Criteria for use of the term *organically produced*, or similar terms according to national or regional customs, are being developed by the Codex Committee

TABLE 2
Arguments against and for a special legislation on prebiotics and probiotics

Against	For
Fermented foods with live microbes do not essentially differ from probiotics.	Probiotic foods differ from other fermented foods with live microbes.
The term *probiotic* need not be defined.	The term *probiotic* can be used inappropriately and mislead consumers.
The use of microbes in food is covered in existing rules and laws on food production.	Microbes are selected for their special properties, in addition to technologic considerations.
The labeling of microbes used is covered in product standards and general labeling directives.	The consumer should be informed about the probiotic properties of selected microbe strains.
Indigestible substances (ie, ingredients) are covered by existing laws on food and food labeling.	Criteria defining probiotic bacterial strains and products allow control by authorities.
	A prebiotic or probiotic claim offers an advantage in marketing.
	Indigestible substances (ie, ingredients) are selected for their effects on special colonic bacteria, not for technologic or nutritional purposes.
	Safety

on Food Labeling (7). Such terms have been defined for agricultural products of plant origin in EU directive 2092/91 (8) and for products of animal origin in EU directive 1804/1999 (9). These criteria cover labeling, production methods, control systems, and import controls, in addition to general production rules and listings of permitted substances for production.

However, there is a distinct difference between these existing rules or recommendations for use with the terms *halal* and *organically produced* and the proposed criteria for defining pre- and probiotic foods. Whereas the former are defined according to production methods, the latter would require proof of the beneficial health effects on the consumer, in addition to extensive criteria for the selection of bacterial strains and their desirable properties and for the selection of colonic foods and their selective stimulation of growth of desirable bacterial populations.

Although there should be a reasonable probability in reaching a consensus on the selection of bacterial strains (eg, counts, survival of gastrointestinal passage, growth conditions, nonpathogenicity, nontoxinogenicity, stability, and identity) and on prebiotic metabolic substrates (eg, digestibility, composition, dosage, and specificity of metabolization), there will likely be disagreement on what other effects need to be evident to warrant the denomination of a food as prebiotic or probiotic.

Is evidence of ingested bacteria in feces or desired quantitative changes in colonic bacteria sufficient for a bacterial strain to be labeled as *probiotic* or a nondigestible carbohydrate as *prebiotic*? If, in addition, a health-promoting effect is required and if this has been shown adequately by criteria to be established, will the suffix *prebiotic* or *probiotic* be sufficiently informative for the consumer to understand what benefits he or she can expect?

The coupling of technical criteria with functional criteria for the characterization of a food poses important questions on how to regulate for the necessary studies to prove the claimed function and on the labeling of foods with such a proven function.

Pro- and prebiotic foodstuffs with identifiable functions can be rightly considered as functional foods, another term that is not regulated in most countries. Functional foods are "…food and drink products that derive from naturally occurring substances, are consumed as part of the daily diet, and possess particular physiologic benefits when ingested" (10). This definition certainly provides no differentiation from the definition of ordinary food, most of which, if not all, provide some particular physiologic benefit, be it only satiety.

A working definition rather than a firm definition is provided in the 1999 Consensus Document on Scientific Concepts of Functional Foods in Europe (11): "A food can be regarded as 'functional' if it is satisfactorily demonstrated to affect beneficially one or more target functions in the body, beyond adequate nutritional effects, in a way that is relevant to either an improved state of health and well-being and/or reduction of risk of disease. Functional foods must remain foods and they must demonstrate their effects in amounts that can normally be expected to be consumed in the diet; they are not pills or capsules, but part of a normal food pattern." It is further explained that such a food can be functional by nature or as a consequence of modifications that change the composition or the bioavailability of its components, and that the defined functionality can be restricted to particular groups of the population. This is a much broader description than that applied, for example, in Japan.

Japan has regulated functional foods and defines them as foods to which beneficial, effective ingredients have been added to aid in the maintenance of a healthy body condition. Again, one could ask what the difference is between a beneficial ingredient and, for example, the definition of nutrient, as given in the Codex General Principles for the Addition of Essential Nutrients to Foods (12). The Codex General Principles for the Addition of Essential Nutrients to Foods defines a nutrient as any substance normally consumed as a constituent of food *1*) that provides energy; *2*) that is needed for the growth, development, and maintenance of healthy life; or *3*) a deficit of which will cause the occurrence of characteristic biochemical or physiologic changes. In many cases, the beneficial ingredients added to functional foods in Japan do not fulfill the criteria required to be defined as a nutrient. In some cases these ingredients are simply nutrients with good bioavailability, eg, calcium citrate malate and heme iron.

Functional foods in Japan compose 1 of 5 categories under Foods for Special Dietary Uses and are called Foods for Specified Health Use (FOSHU). These functional foods must undergo a permission procedure, which includes an evaluation of their medical nutritional basis, their safety, and the approval of their health claim. By August 1997, 40 of 79 registered FOSHU were deemed as possible prebiotics and 3 of 79 FOSHU were deemed as possible probiotics. For example, this would allow the claim "…act to increase intestinal bifidobacteria, and thus helps maintain a good intestinal environment along with well regulating gastrointestinal condition" to be attributed to chocolate made with xylo-oligosaccharides, and for a yogurt drink containing *Lactobacillus* GG to be attributed to the claim "reaches one's intestine in an active state so as to help increase bifidobacteria and lactobacilli, thus promoting maintenance of a good intestinal environment and to well regulate gastrointestinal condition." In addition, FOSHU must be labeled with daily intake recommendations and suggestions on how to lead a healthy life, in addition to all the items required for foods that are used for special dietary uses.

In principle, neither FOSHU nor prebiotic and probiotic foods, as defined above, fall under the definition of Foods for Special Dietary Uses according to section 2.1 of the Codex General Standard for the Labeling of and Claims for Prepackaged Foods for Special Dietary Uses (13). The definition is as follows: "Foods for Special Dietary Uses are those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such. The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist" (13).

However, pre- and probiotic foods might be considered as Foods for Special Dietary Uses if appropriate testing shows that they beneficially and specifically influence particular physical or physiologic conditions or diseases and disorders. Even if this was unequivocally proven, it would not, within the Codex system, automatically mean that claims on the suitability of a food (for special dietary uses) for use in the prevention, alleviation, treatment or cure of a disease, disorder, or particular physiologic condition are permisible. Such claims are allowed only if they are either "in accordance with the provisions of Codex standards or guidelines for foods for special dietary uses," which would mean that probiotics or prebiotics would have to be the subjects of a product standard or guideline, or if such claims are "permitted under the laws of the country in which the food is distributed" (13). Both probiotics and prebiotics are presently marketed as conventional foods and, therefore, the general rules for labeling

and claims, nutrition labeling, and nutrition claims apply. The Codex General Guideline on Claims (5) prohibits, in section 3.3, claims that cannot be substantiated and, in section 3.4, claims on the suitability of a food for use in the prevention, alleviation, treatment or cure of a disease, disorder, or particular physiologic condition, with the exception of the 2 instances mentioned above.

Similar wording is to be found in the food laws of many countries. The Codex Guidelines for Use of Nutrition Claims (14) in its present form lists 3 kinds of nutrition claims: *1*) nutrient content claims, *2*) comparative claims, and *3*) nutrient function claims. Nutrient function claims are permitted only in relation to energy, protein, carbohydrate, fat (and components thereof), fiber, and sodium and vitamins and minerals for which Nutrient Reference Values have been established in the Codex Guidelines for Nutrition Labeling (14).

Thus, functional claims on the prebiotic properties of dietary fiber, ie, "edible plant and animal material not hydrolyzed by the endogenous enzymes of the human digestive tract" (14), would be acceptable provided they are based on scientific consensus and they do "not imply or include any statement…." (14). This consideration would be permissible under the condition that such functional claims are based on scientific consensus that is supported by the competent authorities and that such claims do not imply or include any statement to the effect that the nutrient would afford a cure or treatment or offer protection from disease (14).

There is an ongoing lively discussion on the terms *prevention of disease* and *health claims*. Health claims were deleted in 1996 from the Codex Guidelines for Use of Nutrition Claims because most member states could not accept the proposed definition: "Health claims means 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" (15). The argument was that such claims, despite efforts of careful wording, would mislead consumers in believing that increased consumption of a food, nutrient, or substance would have a direct consequence on related diseases. In 1999 the Codex Committee on Food Labeling attempted to construct a new definition of health claim and proposed 2 alternatives (16): "Health claim means 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)," or "Health claim means any claim which suggests that a food or a constituent of that food has an impact on health." Two types of health claims are distinguished, ie, enhanced function claims and reduction of disease risk claims. The Committee states that reduction of disease risk is not the same as disease prevention for circumventing the prohibited types of claims in section 3.4 of the Codex General Guidelines on Claims (5).

For foods that comply with defined nutrient concentrations and other requirements, certain health claims referring to the reduction of disease risk are permitted in the United States under the Nutrition Labeling and Education Act (17) after authorization by the US Food and Drug Administration or after notification of an intended health claim based on an authoritative statement of a scientific body (18). However, the proposed definition of *reduction of disease risk claims*, provided in a draft for a Codex Guideline on health claims, does not address health promotion, but instead addresses diseases and pathophysiologic conditions that can lead to disease. In section 8.5, the guideline used to define nutrition claims determines that "Foods should not be described as 'healthy' or be represented in a manner that implies that a food in and of itself will impart health," but permits in section 8.6 foods to be described as part of a "'healthy diet' provided that the label carries a statement relating the food to the pattern of eating described in the dietary guideline" (14).

What can be deducted in regard to prebiotic and probiotic foods from the present guidelines on claims? Claims addressing the positive effects of pre- and probiotic foods on the health of the consumer, eg, on the immunologic defense system, are permitted. Functional claims concerning the action of prebiotics and probiotics on the colonic bacterial population are permitted. More specific claims on the functional consequences thereof on pathophysiologic conditions are admissible but will require unequivocal proof for the product that is to bear the claim. All admissible functional claims should stress the importance of total dietary pattern.

CONCLUSIONS

The following conclusions are based mostly on the rules established in standards and guidelines on food and food labeling of the Codex Alimentarius as of 1999:

1) It is up to the experts in microbiology, nutritional sciences, and food technology to formulate unequivocal criteria for probiotic bacterial strains, prebiotic food substances, and products that contain either probiotic bacterial strains or prebiotic food substances. These criteria have been developed but have not yet been published.
2) Laboratory or clinical variables that are deemed necessary to characterize pre- and probiotic properties of a food need to be defined. Ample scientific literature exists on this topic.
3) Such criteria should be the basis for establishing requirements for the use of the terms *prebiotic* and *probiotic*. Requirements could be established by national or international authoritative bodies.
4) Clearly defined use of these terms on the basis of controllable criteria will increase the consumer credibility of the products and enable control by the authorities.
5) Testified prebiotic and probiotic products can be labeled with claims as to their function in establishing colonic bacterial balance of the consumer and resultant health promoting effects as part of a healthy diet.
6) Claims that directly relate consumption of probiotics or prebiotics to diseases are forbidden. Decisions as to the permissibility of reduction of disease risk claims are currently made on a national basis.
7) Application for approval of disease-related claims will require unequivocal experimental proof and would thus convert the product into a food for special dietary uses.

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