



**ELECTRONIC SUBMISSION OF WRITTEN
COMMENTS TO:**

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Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Docket No. 2002P-0122 (formerly 02P-0122)

**Conventional Foods Being Marketed as “Functional Foods”;
Request for Comments**

COMMENTS BY:

**THE AMERICAN ASSOCIATION FOR HEALTH FREEDOM AND
THE ALLIANCE FOR NATURAL HEALTH**

DATE: 4 JANUARY 2007

INTRODUCTION

The American Association for Health Freedom (AAHF) and the Alliance for Natural Health (ANH) would like to thank the Food and Drug Administration (FDA) for giving us the opportunity to make this submission. Both organizations, which are formally affiliated, represent a wide range of natural health interests including consumers, food business operators and practitioners in the United States, Europe, and beyond.

AAHF and ANH agree that if additional oversight is to be considered, it must be proportionate, as there is a very real risk if excessive or unnecessary provisions are required to “register” or “authorize” health claims. Many of the smaller companies, which have typically been the pioneers in this field, will be prevented from including health claims of any type on their products. Such a restriction will negatively impact consumer choice and public health.

Additionally, since public health is dependent, among other factors, on the ready commercial availability of healthy foods, any restriction of such foods or health claims about these foods could be viewed as being contrary to the public health interest.

Consumers are becoming more and more health aware and are showing exponentially greater interest in taking responsibility for their own health through the consumption of higher quality foods and diets, functional foods, dietary supplements, and other alterations of lifestyle. The most debilitating and costly health conditions in today’s society are chronic diseases such as heart disease, cancer, obesity, diabetes and osteoporosis, all of which have been strongly associated with inappropriate diets and lifestyles. These diseases also provide the greatest burden on the healthcare system, especially in the western world. In response to consumer demand, the functional foods and dietary supplements industries have seen dramatic expansion over the last decade or so.

A view upheld in a number of submissions made by other interested parties engaged in this consultation process, is that existing provisions of food law are already sufficient, and that no further oversight is required. Current law prevents any company making claims which are misleading or untruthful, and this law is certainly enforced judging by the FDA’s record of prosecutions.

The AAHF and the ANH are aware that a ‘do nothing’ option may be counter-productive to consumer and public health interests in the longer term, given the continued expansion of the functional food (and dietary supplement) markets, and development of complex and apparently onerous regulatory regimes in Europe and also through the international Codex Alimentarius Commission. If the United States does not take a lead now, it might well find itself outvoted in future Codex discussions, leading ultimately to a potential collapse of America’s current functional foods and dietary supplements markets.

The types of provisions that are being contemplated by the FDA in its bid for greater oversight on health claims for functional foods could also lead to an unintended increase in legal uncertainty given the convergence of data requirements for authorization of health claims and licensed drugs. It is of paramount importance that any new regulatory approach seeks to minimize legal uncertainty while ensuring consumer and public health protection in such ways that any new measures do not have disproportionate impacts on smaller food business operators.

AAHF and the ANH are deeply concerned about the prospect of unnecessary over-regulation which could lead to a reduction in the number and diversity of health promoting foods and supplements on the market. However, we are also concerned that consumers should be adequately protected from any irresponsible or unscrupulous food business operators.

AAHF and the ANH welcome the FDA’s consultation on functional foods but urge the FDA to recognize the pitfalls associated with inappropriate regulation, including the possibility of legal redress should regulation be viewed as disproportionate on smaller companies incapable of managing a burdensome regulatory regime.

In this consultation exercise, the AAHF/ANH has sought to suggest a new legal framework that aims to help deal with the important issues of lack of legal clarity between various categories of foods (notably conventional foods, functional foods, dietary supplements and food additives) and licensed drugs. The proposed framework also helps to provide a regulatory platform that ensures adequate consumer and public health protection while at the same time avoiding measures that are disproportionate from the standpoint of smaller food business operators.

The bottom line: It is imperative to develop improved legal clarity through better definitions while adapting existing regulations on dietary supplements and food to cater for the expanding functional food market. It is critical to ensure that in this process consumer choice and information is not adversely affected.

More information about the AAHF and the ANH can be found at the end of this submission.

ISSUES AND QUESTIONS FOR DISCUSSION

A. Food Ingredients

ISSUE 1: The CSPI [Center for Science in the Public Interest] petition requests that we require food companies to notify us regarding the use of “novel ingredients” prior to marketing foods containing such ingredients. The CSPI petition does not define the term “novel ingredients.” For the purpose of this hearing, we are using the term “functional food” to mean conventional foods that are being marketed as “functional foods,” and we are using the term “ingredients” to mean “functional food” ingredients that may have a purported health benefit and that may be the subject of a label statement about this purported health benefit, whether or not the ingredient is new to the food supply.

Question 1a. Is there a need for a regulatory definition and a distinct regulatory approach to the evaluation of the safety of ingredients added to “functional foods”? If yes, what would be included in this new definition and approach that is not adequately addressed under the existing definition of food additive or the provisions in the definition for GRAS substances, and what is the scientific and legal basis for your position? Under what legal authority could FDA create this new definition and distinct regulatory approach?

AAHF/ANH response: Yes. There is considerable value, especially as a means of reducing legal uncertainty, in establishing a definition to distinguish functional foods both from dietary supplements, which according to the definition in the Dietary Supplement Health & Education Act (DSHEA) of 1994, do not include products “represented for use as a conventional food or as a sole item of a meal or the diet”, as well as from the parent category, conventional foods, for which health claims are not generally made. It is also important to segregate functional foods from food additives, since such substances are ingredients added to conventional foods usually for technological reasons, rather than for the purpose of achieving health benefits. Defining functional foods uniquely as a sub-category of conventional foods will establish further credibility for this category of product in the eyes of the consumer, and a variable, tiered approach to nutrition and health claims (as proposed here) will help consumers to make more informed choices. The definition, we believe, will assist in reducing the present legal blur between conventional foods marketed as functional foods, dietary supplements and licensed drugs. However, establishing a definition for functional foods should not be regarded as synonymous with the requirement for stringent regulatory controls.

Question 1b. Should companies that market ingredients for addition to “functional foods” be required to notify us prior to introducing the ingredients into interstate commerce? If yes, what is the scientific and legal basis for your position?

AAHF/ANH response: Premarket notification is a reasonable requirement for any functional food but only on the basis that a health claim is made for the given food. Many conventional, whole foods, such as particular fruits and vegetables, contain ingredients which have “functional” effects (e.g., glucosinolates in broccoli, lycopene in tomato paste, beta glucans in oats, carotenoids in capsicums), but since these foods are not sold in specific quantities or serving sizes, it is not possible to estimate their likely functional effect. Accordingly, conventional foods are not marketed with any specific health claim or claims.

If a “functional food” (being identical in its composition to one that is marketed with a health claim), is to be marketed *without* a health claim, then it should not be regarded legally any differently from a conventional food, and, accordingly, there should be no requirement for any premarket notification.

The scientific and legal basis of our position is that if a structure/function, disease risk reduction or qualified health claim is to be used in the marketing of a functional food, notification is a reasonable requirement so that there is provision to prospectively assess the appropriateness, accuracy and, where relevant, the qualification of the claim, to help ensure that consumers are properly informed.

ISSUE 2: Generally, food additives have been used in conventional foods for their technical effects on the food, not for their effects on the body. Now, the interest in various uses of certain ingredients in conventional foods is due to the marketing of these conventional foods as “functional foods” with claims about health benefits.

Question 2a. What types of data and information would be appropriate to demonstrate that ingredients added to conventional foods being marketed as “functional foods” meet the safety standard of “reasonable certainty of no harm”? What is the scientific and legal basis for your position?

AAHF/ANH response: Although there are already workable provisions under the definition of GRAS substances which allow for substances that meet the safety standard of “reasonable certainty of no harm”, these requirements are not appropriate for more novel ingredients, introduced as dietary supplement or functional food components after 1 January 1958. The safety data requirements for GRAS approval by the FDA may be even more onerous than those required for food additives (Hathcock, J. Dietary Supplements: How They Are Used and Regulated. *Journal of Nutrition* 2001; 131: 1114S-1117S.) which, in our view, is not legally proportionate.

Accordingly, it is pertinent to develop a new category for post-1958 ingredients for which the safety of the ingredients has been established or is known on the basis of historical use. The criteria required for this category should be less onerous than those currently required for GRAS ingredients. This category might be referred to by a name which distinguishes itself from the original GRAS category, or, alternatively, the original GRAS category should be amended to facilitate access of ingredients that scientific experts in the field have long known are generally safe.

However, since the safety of an ingredient is for some nutritional substances strongly related to the dosage delivered, it may be necessary in particular instances to amend these GRAS listings so they include “maximum amounts” which are deemed safe. Alternatively, such ingredients could be added to a new category (using the acronym GRASIU or similar) as proposed below. This might be relevant, for example, for particular fat soluble vitamins (e.g., retinol) or certain minerals (e.g., boron, vanadium, strontium, lithium) which have clear functional and beneficial effects at low dosages but may be harmful when used at very high dosages over long periods.

As phytochemical and nutrigenomic research progresses, there are increasing numbers of food-based ingredients being identified with beneficial functional effects on health. Data pertaining to both benefits, and, where appropriate, to risk, should be submitted by the food companies for evaluation by a task force associated with a relevant scientific body (see American Association for Health Freedom [AAHF]/ Alliance for Natural Health [ANH] comment to Question 2b) with significant representation from the non-governmental sector, with the aim of expanding the GRAS listings. In addition, this evaluation process should include evaluation of ingredients for inclusion on a list of beneficial ingredients, as per the “Generally Regarded as Efficacious” [GRAE] category proposed in the submission by the Institute of Food Technology (IFT).

To gain eligibility for a health claim, the functional food would need to contain a substance or combination of substances that were present on either the GRAS (existing and proposed novel GRAS categories) or the GRASIU categories (which include evaluation of safety) *and* the GRAE category (which includes evaluation of benefit).

Thus, it would be relevant to develop three new categories in addition to the existing GRAS and IFT-proposed GRAE categories that would include:

- 1) A category for post-1958 ingredients for addition to foods, which are established as being generally safe by qualified experts on the basis of proportionate criteria that are less onerous

than those presently used for GRAS ingredients and food additives. This category could be referred to as the Novel-GRAS category, or, changes to the criteria could be applied to the existing GRAS category to make it more applicable to novel ingredients.

- 2) Those ingredients generally regarded as safe *for their intended use* (e.g., the acronym GRASIU could be applied) – this category would be applicable for ingredients with a relatively acute dose-response curve which may be regarded by qualified experts as generally unsafe in high concentrations, or in combination with other ingredients in food or medicines (e.g., negative herb/food or herb/drug interactions), but, at the same time, are considered by the same experts to be both safe and beneficial in their defined intended use. Specific qualification of intended use would therefore need to be given on a case-by-case basis for such products. An example of a nutrient compatible with this proposed category would be strontium used as an ingredient to support bone health.
- 3) To include those ingredients which are not generally regarded as safe and which are likely to present a significant risk if widely available in conventional foods marketed as functional foods. This would effectively become a “negative list” of ingredients, and would probably be developed as a result of rejected applications. It is an adaptation of existing FFDCA 402(f)(1)(B): “is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury”.

Applications should be rejected (and placed on the “negative list”) *only* on the basis that the proposed task force maintains the burden of proof and can amply demonstrate that the ingredient is unsafe in its intended use. In some cases it might be necessary to downgrade an application from GRAS to GRASIU, depending on the available evidence.

Where there is ample evidence of a history of safe use, we propose that this be the sole requirement to establish safety, being the same criterion used for conventional foods and dietary supplements.

In considering data to establish both safety and benefit, it is imperative that the totality of evidence is utilized and this should include observational and epidemiological studies, as well as, where appropriate, medical records, for example derived from certified clinical nutritionists. Randomized controlled trials (RCTs) should not be given excess weighting as these invariably include confounding factors that are often not identified by the authors, which compromise their usefulness (e.g., they often pertain to isolated or very limited combinations of nutrients, diseased populations, there is insufficient follow-on, etc.).

It is more useful to utilize data from humans on the basis of relevance, than it is to make extrapolations from animal studies which induce greater levels of intrinsic uncertainty. This is a strong reason to support inclusion of data both from observational/epidemiological studies and from medical records derived from certified practitioners.

Although human data should be given the highest weighting, data from other sources, notably animal studies, *in vitro* cell studies, molecular studies and modeling (of mechanism) should be allowed as supporting evidence.

In the evaluation of benefits, where endpoints cannot or have not been established directly from clinical or observational studies, studies using accepted biomarkers should suffice as surrogates for relevant health endpoints.

Apart from safety and benefit data of specific ingredients, it may also be relevant to stipulate guidelines for acceptable levels of quality, although such quality controls should be fully compatible with the requirements for natural products which often comprise complex and variable components, as distinct from drugs or food additives. The main requirements should be the absence of known,

harmful concentrations of impurities and standardization against particular components or moieties within the ingredient.

Question 2b. *How could we partner with interested stakeholders regarding the development of appropriate recommendations or other information regarding the safety assessment of ingredients added to “functional foods”?*

AAHF/ANH response: We propose that a new task force be established as a satellite of a relevant scientific body (e.g., National Academy of Sciences or National Institutes of Health) that includes significant representation from the non-governmental sector (including independent scientists, industry representatives and consumers), for the purpose of evaluating, in a fully transparent manner, new applications for ingredients for use in functional foods.

This task force would have the capacity to “approve” or “authorize” qualified health and disease reduction claims through its associated scientific body.

The task force would evaluate applications for ingredients for inclusion in one or more of up to four different listings (detailed in comment to Question 2a):

- 1) GRAS (existing and proposed novel categories, as per present proposal)
- 2) GRAE (as per IFT proposal)
- 3) GRASIU (as per present proposal)
- 4) Negative list (as per present proposal)

It would then also consider authorization of specific, qualified health claims and disease risk reduction claims. It would not consider unauthorized structure/function claims (see comment to Question 2a).

The task force would not only need to operate in a fully transparent manner, it would need to function according to evaluation guidelines which would be agreed by government, industry, practitioner and consumer groups.

B. Food Labeling

ISSUE 3: The CSPI petition requests that we require food companies to notify us within 30 days of marketing a conventional food bearing a structure/function claim if such food contains a “novel ingredient,” and to include the disclaimer currently required on dietary supplements making structure/function claims on the label and in labeling of such foods.

Question 3. *If our statutory authority permits, should we require food companies to notify us within 30 days of marketing a conventional food bearing a structure/function claim and to include the disclaimer currently required on dietary supplements making structure/function claims in labeling of such foods? If yes, what is the scientific (e.g., consumer studies) basis for your position? Under what existing legal authority could FDA require notification of these claims? Under what legal authority could FDA require inclusion of such a disclaimer with these claims?*

AAHF/ANH response: Functional foods should be given legal status that is equitable with dietary supplements, so that where functional foods include a structure/function claim on the label, the food company marketing the product should notify the FDA within 30 days of the product going on sale.

We would envisage two categories of claim: 1) unauthorized structure/function claims (including disclaimer, as per DSHEA), and 2) authorized and qualified health or disease reduction claims, which do not include the same disclaimer as used for dietary supplement structure/function claims and which also require premarket notification, but which should be filed at least 120 days prior to a functional

food product going on sale. This longer time period would allow evaluation of the proposed claim by the aforementioned task force – and we stress that such evaluations should be open to public scrutiny.

The use of various types of (unauthorized and authorized) claim for functional foods would help to promote informed choice by consumers, as well as providing consumer confidence in functional food products, while also helping to stimulate innovation and encourage further research on functional foods which would have benefits to society.

On the condition that the requirements for successful authorization were not unnecessarily onerous, it would also allow the United States to lead the way in the scientific development of functional foods as well as regulatory approaches specific to this category. Such developments would help to encourage the consumption of healthy foods, and the regulatory framework so developed could ultimately act as a model elsewhere in the world, potentially through international Codex Alimentarius guidelines.

The need for a scientifically and legally rational, progressive model for functional foods is viewed as particularly important given the development of a European proposal for a “nutrition and health claims regulation” which has data requirements that look to be so extreme that only the very largest food companies will be able to meet them. If the US does not take the lead on this issue, it is highly likely that the international template will become that of the European Union, which will provide an excessive scientific and regulatory burden for many American companies. Data requirements should be set in a legally proportionate manner, and should be fully accessible to smaller companies in the food sector that are the major contributors to innovation.

ISSUE 4: The IFT report recommends that companies wishing to make label claims regarding the effects of “functional foods” or ingredients convene panels of independent experts qualified to evaluate the efficacy of the functional food component under consideration. According to IFT’s recommendations, the findings of these Generally Recognized as Efficacious (GRAE) panels would be submitted to FDA under a process that is similar to the notification program that we proposed for GRAS substances. If the GRAE panel report found that the proposed label claim was supported by the available scientific evidence, the agency would have 90 days to object to the use of the notified GRAE label claim, and in the absence of such objection the label claim would be permitted at the end of the 90 days. The act limits FDA’s ability to accept this recommendation with regard to certain health claims and nutrient content claims (assuming that the recommendation applies to nutrient content claims, which is unclear because the IFT report does not specify). First, the act requires health claims and nutrient content claims for conventional foods to be submitted to FDA for review through a petition process (see section 403(r)(4)(A) of the act (21 U.S.C. 343(r)(4)(A))), unless the proposed claim is based on an authoritative statement. Second, even though claims based on an authoritative statement are submitted to FDA for review through a notification process, the act limits the “scientific bodies” that can be sources of such an authoritative statement to certain Government agencies and the National Academy of Sciences (now the National Academies) (see sections 403(r)(2)(G)(i) and (r)(3)(C)(i) of the act (21 U.S.C. 343(r)(2)(G)(i) and (r)(3)(C)(i))). The GRAE panels recommended in the IFT report do not qualify as scientific bodies for this purpose. FDA can and does consider the findings of outside groups that do not qualify as “scientific bodies” as part of the totality of publicly available scientific evidence evaluated in support of a health claim petition, however. In an advance notice of proposed rulemaking (ANPRM) on food labeling, including health claims (68 FR 66040 at 66044; November 25, 2003 (the 2003 ANPRM on food labeling)), we previously asked for public comment on a question about whether the evaluations of non-governmental groups should be given weight in evaluating the strength of the science supporting a health claim. In that ANPRM, we asked: “If the agency should give weight to the evaluations of these groups, how should this weight be determined?” That question is related to IFT’s recommendations regarding the agency’s acceptance of the findings of GRAE panels for “functional food” label claims. We are asking the question below, which is similar to the question we asked in the 2003 ANPRM on food labeling, because we would like additional input on this topic.

Question 4. *Within our statutory authority, how (if at all) should FDA utilize the findings of non-governmental groups, such as the IFT recommended GRAE panels, in support of health claims, nutrient content claims, and other labeling claims about the effects of a “functional food” or ingredient, such as structure/function claims? What is the scientific and legal basis for your position? Should FDA institute a premarket notification process for review of the scientific evidence for structure/function claims for “functional foods” and ingredients, as recommended by IFT? What is the scientific basis for your position? Under what existing legal authority could FDA institute a premarket notification process for review of the scientific evidence for “functional foods” and ingredients?*

AAHF/ANH response: If the panel assessing the risks and benefits of functional food ingredients is wholly independent of government, as proposed by the IFT, there may well be difficulties in establishing scientific consensus on important issues, and consumer confidence may suffer as a result. Furthermore, the panel would not be regarded as a “scientific body” by the FDA or other government organ, and its findings would not allow proper “authorization” of its findings.

However, there is good reason for the establishment of such independent panels so that their evidence can be submitted to the proposed task force for evaluation as part of the “totality of evidence” package.

We propose that the same notification system as used for structure/function claims of dietary supplements should be applied to functional foods which utilize structure/function claims on their labels (e.g., 30 days pre-market notification). To provide a more onerous data requirement for functional foods than for dietary supplements when the same claim is made would be legally disproportionate.

The legal authority under which the FDA would institute a premarket notification should in our view be the scientific body to which the proposed functional food evaluation task force is associated (e.g., National Academy of Sciences or National Institutes of Health).

ISSUE 5: Under *Nutrilab v. Schweiker* (713 F.2d 335 (7th Cir. 1983)), structure/function claims on the label or in labeling of conventional food make the product a drug if they promote the product for a structure/function effect (e.g., blocking the digestion of starch) that is unrelated to the product’s “food” attributes of taste, aroma, and nutritive value. FDA has interpreted this court decision to limit structure/function claims for conventional foods to claims about effects that derive from the taste, aroma, or nutritive value of the food or food ingredient that is the subject of the claim. FDA’s health claim regulations also require that the substance that is the subject of the claim contribute taste, aroma, nutritive value, or a technical effect recognized in FDA’s food additive regulations (21 CFR 101.14(b)(3)(i)). Because we recognize that food substances may confer health benefits through a number of processes, we have provided significant flexibility in determining whether a substance possesses nutritive value. Nutritive value is defined at 21 CFR 101.14(a)(3) as a value in sustaining human existence by such processes as promoting growth, replacing lost nutrients, or providing energy, and we have discussed this definition in many of our health claim reviews. Listings of health claims reviewed to date can be found at <http://www.cfsan.fda.gov/~dms/lab-ssa.html> (SSA claims) and <http://www.cfsan.fda.gov/~dms/qhc-sum.html> (QHCs). The IFT report criticizes the approach of requiring that the health benefit be derived from the food’s nutritive value as too restrictive to allow for claims on foods being marketed as “functional foods.” Instead, the IFT report recommends that FDA permit a labeling claim for a “functional food” if the claimed benefit is based either on nutritive value or on “the provision of a physical or physiological effect that has been scientifically documented or for which a substantial body of evidence exists for plausibility” (Ref. 1).

Question 5. *Given the agency's interpretation of the definition of nutritive value as reflected in 21 CFR 101.14(a)(3) and our decisions on the health claims reviewed to date, does or will the agency's interpretation of *Nutrilab v. Schweiker* to limit structure/function claims and health claims to those that are based on nutritive value (or other food attributes such as taste and aroma) adequately allow for claims in the labeling of "functional foods"? If no, how is the agency's approach inadequate? What is the scientific and legal basis for your position? If you favor a change in the agency's approach, do you recommend that FDA adopt the IFT report's recommendation on this issue, or some other alternative? What legal rationale would support your preferred change in approach?*

AAHF/ANH response: The FDA's existing legal basis for determining acceptability of structure/function claims is weak and subject to considerable legal uncertainty. The FDA and industry have arrived at the situation with regard to approval of structure/function claims only on the basis of the FDA's stated "flexible" approach towards the definition of "nutritive value" under the FDA's food additive regulations (21 CFR 101.14(b)(3)(i)).

However, the fact that the FDA has been involved in seizures and voluntary destruction of dietary supplements (e.g., to a value of \$515,000 in 2003; <http://www.cfsan.fda.gov/~dms/nuttfbg.html>) is an indication that there is insufficient clarity on criteria for acceptable structure/function claims.

Since formal recognition of the functional food category will likely lead to increased numbers of products in this category, it is of even greater importance to establish a more appropriate legal basis for structure/function claims that is specific to functional foods, and probably also to dietary supplements, as distinct from food additives (the latter not generally being added for reason of their nutritive or health promotion value).

Accordingly, the AAHF/ANH agree with the criticism given by the IFT, that the term "nutritive value" provides too restrictive a framework for functional foods and, in principle, we support the IFT's proposal that the claimed benefit should be based either on nutritive value or on the provision of a physical or physiological effect that has been scientifically documented or for which an *appropriate* (rather than "substantial") body of evidence exists for plausibility. This distinction between "substantial" and "appropriate" evidence is in our view critical to not acting disproportionately on emerging science.

The existing validity requirement for health claims [21 CFR 101.14(c)] still leads, in our opinion, to the prospect of considerable legal uncertainty. This requirement means that the FDA will authorize a health claim only when "it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement among those qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence".

Of concern for the functional food industry, in particular for innovative food companies (which rely on bringing products to the market based on emerging science), and the consumer, is the question of what precise interpretation is given to "significant scientific agreement"? (From the US Court of Appeals for the District of Columbia (1999) No 98-5043: *Durk Pearson and Sandy Shaw, American Preventive Medical Association and Citizens for Health vs. Donna E. Shalala, Secretary, U.S. Department of Health and Human Services*).

Among the most legally and scientifically rational methods of dealing with different strengths of evidence on which claims are made is the use of a graded evidence system, as proposed by the World Health Organization (using the terms convincing, probable, or possible). This and the FDA grading system is summarized in the table below:

Qualifying language for the four grades of evidence in support of a health claim (after Richardson, 2005*)

Health claim	WHO/WCRF grade of evidence	US FDA category of health claim	Qualifying language
Yes	Convincing	A	Experts agree that scientific evidence supports → <i>Modal verb “will”</i>
Yes	Probable	B	Although there is scientific evidence supporting the claim, the evidence is not conclusive → <i>Modal verb “can”</i>
Yes	Possible	C	Some scientific evidence suggests... however, the evidence is limited and not conclusive → <i>Modal verb “may”</i>
No	Insufficient	D	There is little scientific evidence supporting this claim

* Richardson DP, The scientific substantiation of health claims with particular reference to the grading of evidence and consumer understanding, *Food Science and Technology bulletin: Functional Foods*, 2005, 2 (4), 39-48).

Therefore, in our opinion, the IFT’s suggested definition will need to be further clarified to avoid continuing legal uncertainty. We propose an adjustment to the IFT’s proposal as follows:

“The provision of a physical or physiological effect that is expected from the consumption of the food according to its intended use and for which there is appropriate scientific evidence, the strength of which is ranked as [convincing *or* probable *or* possible].”

Such an approach which uses the WHO system of grading of evidence is also more likely to be acceptable for international trade purposes. However, although the AAHF/ANH supports the notion of graded evidence, it most certainly does not support the criteria and weighting of evidence as proposed by the International Life Sciences Institute (ILSI) (see *European Journal of Clinical Nutrition Supplements* 43(1) March 2003, 43(2) June 2004 and 44(1) June 2005), which we regard as excessive and disproportionate in terms of data requirements.

It would be of critical importance to develop a new framework for requirements of scientific evidence for health claims which better takes into account the totality of available evidence and apportions more appropriate weighting of evidence. It is the opinion of the AAHF and ANH that such a framework should value evidence from well-conducted observational and epidemiological studies in an equivalent manner to well-conducted clinical trials.

ISSUE 6: The IFT report recommends that research into “functional foods” be stimulated using incentives to the food industry, including market exclusivity for their bioactive food components and government research grants for the investigation of these components. There is currently no statutory provision for exclusivity of the use of a substance added to food (whether this be a food additive or a GRAS substance) or for the use of a health claim (whether a health claim has been authorized under NLEA or FDAMA or whether FDA has issued a letter of enforcement discretion for a QHC). In the 2003 ANPRM on food labeling, we previously asked “How can FDA more effectively develop public-sponsored research on substance/disease relationships?” (68 FR 66040 at 66043). We are asking the question below, which is similar to the question we asked in the 2003 ANPRM on food labeling, because we would like additional input on this topic.

Question 6. *Should FDA provide incentives to manufacturers to conduct further research on emerging substance/disease relationships? If yes, how? If yes, what is the scientific (e.g., consumer research) basis for your position? (For example, in the case of exclusivity, we are interested in consumer data concerning the use of a health claim on one product but not on other similar products*

by other manufacturers, and in how such data show that such claims are or are not misleading.) Under what existing legal authority could FDA provide such incentives?

AAHF/ANH response: From the perspective of two non-governmental organizations that work to protect and promote healthcare approaches based on the use of natural products and therapies, the AAHF and the ANH uphold that there should be no direct exclusivity for the use of a given naturally-occurring food substance added to food. Where an authorized claim is given, this may be for a very specific nutrient form or natural product extract, and such substances may be patented or the manufacturing or extraction process may be commercially protected in some other way. Such protection affords companies a form of *de facto* exclusivity for ingredients in which they have invested. However, we regard it as inappropriate to make exclusive the use of food-based nutrients or other natural components of food that are naturally occurring and are part of our global heritage and which give rise to beneficial effects in consumers.

It is of critical importance that research is prioritized on food component/nutrient/ disease relationships, especially given that this does not appear to be a priority for pharmaceutical corporations which appear to be more interested in the development, production and marketing of patented drugs.

We propose that a multi-disciplinary committee, comprised of academics, industry, consumer and government representatives, could be established to determine priority areas for research and projects could be tendered to in the usual way. This research would be particularly appealing to forward-thinking industry/academic partnerships.

C. Overall Framework for Foods Being Marketed as “Functional Foods”

Issue 7: The FFDCFA does not recognize “functional foods” as a distinct category of food, either by definition or through establishing specific requirements for “functional foods.” The IFT report recommends that we establish, by regulation, a definition of, and labeling requirements for, “functional foods.” The IFT report asserts that these regulations are necessary because consumer interest in the relationship between diet and health has increased the demand for these foods. According to the IFT report, this increased consumer demand is causing the food industry to add more and larger amounts of substances to food and this competitive pressure has shifted the focus of food fortification from carefully orchestrated and closely monitored interventions for addressing specific dietary deficiencies to a focus on meeting market demands.

Question 7. Can the conventional foods being marketed (now or in the future) as “functional food” be adequately addressed through the current regulations for food additives, GRAS substances, and labeling claims? If no, how are these regulations insufficient to address these products, and what is the scientific and legal basis for your position?

AAHF/ANH response: Just as the existing definition of “nutritive value” is presently being stretched to encompass structure/function claims that are used today in the market place, the Federal Food, Drug & Cosmetic Act (FFDCFA), amended in 1997 through the FDA Modernization Act, does not recognize “functional foods” as a distinct sub-category of food. This is at least in part because functional food is a relatively new category of food and there has not yet been any legislative proposal to amend the Act to include specific regulation pertaining to this category. Furthermore, there has been some resistance by certain industry sectors (e.g., pharmaceuticals) to not promote categories of food which have specific health benefits.

Owing to the grey area that exists between functional foods with label claims and licensed drugs, also with distinct medicinal label claims, it is important in the longer-term to provide a regulatory framework that reduces legal uncertainty for functional food companies, so that they are able to work using clearly delineated criteria to avoid FDA drug classification of their products.

The Nutrition and Labeling Education Act (NLEA) modified the drug definition in the FDCA by establishing that a food for which a claim is made according to the specifications in the NLEA (i.e. in FDCA 403(r)(3)(B)), cannot be regulated as a drug solely because of that claim. However, with the likely expansion of the functional food market and emergence of increasing amounts of science in the “functional medicine” field, legal uncertainty is likely to become an increasing problem and may act as a constraint to otherwise progressive functional food companies.

In the meantime, it is quite feasible to continue to allow conventional foods, marketed as “functional foods”, with label claims, to be marketed using the existing legal infrastructure such as that pertaining to conventional foods, food additives, GRAS substances and food labeling, although this will only allow the level of claims currently afforded to dietary supplements.

It is envisaged, as per this proposal by the AAHF/ANH, that further development of the regulatory framework pertaining to functional foods (and, ideally subsequently also to dietary supplements), will allow high levels of claim to be made (e.g., authorized, qualified health claims and disease risk reduction claims).

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ABOUT THE AAHF AND THE ANH

The American Association for Health Freedom (AAHF) - www.healthfreedom.net

AAHF is the politically active voice at the federal and state level for the right of the consumer to choose and the practitioner to practice. We ensure health freedom by lobbying Congress and state legislatures and crafting legislation; acting as a government watchdog and filing comments on proposed rulings; educating the public, press, and decision-makers on integrative medicine; initiating legal activities (e.g., lawsuits, amicus briefs, petitions), and joining and forming significant coalitions.

AAHF was founded in 1992 in direct response to the problems faced by practitioners and consumers in the United States. Medical freedoms were and continue to be threatened by the government agencies, the allopathic medical community, insurance companies, and state medical boards around the country. It is clear that health freedom need a strong advocate on Capitol Hill, in the state legislatures, in the courts, and with the media. AAHF is that health freedom champion.

The Alliance for Natural Health (ANH) - www.anhcampaign.org

The ANH is a UK-based, EU-focused, international, legal-scientific, non-governmental organisation that is working on behalf of consumers, medical doctors, complementary health practitioners and food manufacturers and distributors, to protect and promote natural healthcare, using the principles of good science and good law.

The ANH's principal objective is to help develop an appropriate legal-scientific framework and environment for the development of sustainable approaches to healthcare. Within this setting, consumers and health professionals should be able to make informed choices about a wide range of health options, and in particular those that relate to diet, lifestyle and non-drug-based or natural therapies, so that they may experience their benefits to the full while not exposing themselves to unnecessary risks.