

Facts About "Functional Foods"

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Table of Contents

Executive Summary	5
Introduction	7
What Are Functional Foods?	7
FDA-Approved Health Claims	9
Safety Concerns and Other Reservations	15
safety issues	15
misplaced priorities	16
exaggerated claims and regulatory inconsistencies	17
Examples of Functional Foods with Very Strong Evidence of Health Benefits	20
whole oat products	21
psyllium	21
soy protein	21
foods containing plant stanol or sterol esters	22
sugarless chewing gum and sugarless candy	22
Other Foods with Possible Benefits	23
fatty fish	23
cranberry juice	24
garlic	25
green tea	25
tomatoes and tomato products	25
vegetables containing lutein	26
animal products containing conjugated linoleic acid	26
cruciferous vegetables	26
probiotics	27
other potentially functional foods	27
Putting Functional Foods in Perspective	28
Suggestions for further reading	31

Tables

Table 1. Health Claims for Food Labels Approved by the U.S. Food and Drug Administration	9
Table 2. Types of Claims that May Appear on the Labels of Foods and Dietary Supplements	14
Table 3. Strength of Evidence for Functional Foods Currently on the U.S. Market	18
Appendix	32

Executive Summary*

Foods that may have health benefits beyond the traditional nutrients that they contain are often called “functional foods.” The concept of functional foods has become popular in recent years, first in Japan and later in other countries, including the U.S.

In the U.S., the term “functional foods” has no official, universally accepted definition. Foods don’t have to pass any test or meet any standard in order to be described as “functional.”

In the U.S., the best way to find out whether a food has any scientifically established health benefits beyond basic nutrition is to look for a special type of statement called a “health claim” on the food label. Health claims must be pre-approved by the Food and Drug Administration (FDA) before they can be used. This differs from the procedure used for structure/function claims on the labels of foods or dietary supplements. Structure/function claims are expected to be truthful, but they do not require FDA pre-approval.

ACSH classifies the strength of the scientific evidence for the benefits of various functional foods currently on the market as follows:

Very strong: whole oat products (lowered cholesterol levels and reduced heart disease risk), foods containing psyllium (lowered cholesterol levels and reduced heart disease risk), whole soy foods and foods made with soy protein (lowered cholesterol levels and reduced heart disease risk), special fortified margarines made with plant stanol or sterol esters (lowered cholesterol levels and reduced heart disease risk), sugarless chewing gums and candies made with sugar alcohols (do not promote tooth decay). The FDA has approved health claims for all of these products.

Strong: Fatty fish containing omega-3 fatty acids (reduced risk of heart disease).

Moderate: Cranberry juice (reduced risk of urinary tract infection), organosulfur compounds in garlic (lowered cholesterol levels).

Weak to moderate: Green tea (reduced cancer risk), lycopene in

* Editor’s Note: The functional foods area is one of intense research activity; as new data accumulate, ACSH will evaluate it and update the information in this booklet accordingly.

Facts About “Functional Foods”

tomatoes and tomato products (reduced risk of some types of cancer, especially prostate cancer).

Weak: Dark-green leafy vegetables containing lutein (reduced risk of macular degeneration), meats and dairy products containing conjugated linoleic acid (various health benefits), cruciferous vegetables (reduced cancer risk), probiotics (beneficial effects on gastrointestinal function and immunity).

Safety concerns have been raised about some functional foods, especially foods containing added medicinal herbs. Concerns have also been raised about the possibility that the promotion of functional foods may mislead people into thinking that eating them is more important than choosing a balanced diet or taking other steps to prevent or treat health problems. Exaggerated claims for some functional foods and inconsistent regulations may contribute to consumer confusion.

Consumers need to be cautious and skeptical when evaluating claims made for functional food products. ACSH recommends that consumers who are interested in incorporating functional foods into a healthy lifestyle should first consider products that carry FDA-approved health claims. These foods have been convincingly demonstrated to be beneficial for their intended purposes when consumed as part of a generally well-balanced and healthful diet. Consumers who wish to try functional foods that do not carry FDA-approved health claims should realize that there is no substantial proof that these foods have the special benefits claimed for them.

Functional foods are only one aspect of diet, and diet is only one aspect of a comprehensive lifestyle approach to good health, which should include regular exercise, tobacco avoidance, maintenance of a healthy body weight, stress reduction, and other positive health practices. Functional foods can sometimes be part of an effective strategy to promote good health, but they should never be considered a substitute for other good health habits and they should never be used instead of medically prescribed therapy for any health problem.

Introduction

Can foods be beneficial to your health for reasons that go beyond basic nutrition? An increasing amount of scientific evidence says yes. Some foods or food ingredients may help to reduce the risk of certain diseases if they're eaten regularly as part of a generally healthful diet. Such foods are often referred to as "functional foods." An alternative term is "nutraceuticals."

Scientists, the food industry, and consumers have all expressed a growing interest in functional foods in recent years. At the same time, however, concerns have been raised about the safety of some of these products and about the promotion of functional foods on the basis of inadequate scientific evidence.

This report by the American Council on Science and Health (ACSH) discusses some of the issues and controversies surrounding functional foods and assesses the strength of the scientific evidence supporting the potential benefits of some of the most popular functional foods. The report is based on a scientific analysis prepared for ACSH by Clare M. Hasler, Ph.D., of the University of Illinois Functional Foods for Health Program.

What Are Functional Foods?

Although you've probably heard of "functional foods," chances are you don't have a clear idea of exactly what this term means.

You're in good company. Experts aren't sure what it means, either.

In the United States, the term "functional food" has no official, universally accepted definition. Different organizations define the

Origin of the Functional Food Concept

The functional food concept was first developed in Japan in the 1980's when, faced with escalating health care costs, the Ministry of Health and Welfare initiated a regulatory system to approve certain foods with documented health benefits in hopes of improving the health of the nation's aging population. These foods, which are eligible to bear a special seal, are now recognized as Foods for Specified Health Use (FOSHU). As of September 2001, 271 food products had been granted FOSHU status in Japan.

Facts About “Functional Foods”

term in different ways.

The American Dietetic Association (ADA) takes one of the most inclusive views. In a position statement issued in 1999, the ADA described functional foods as “any potentially healthful food or food ingredient that may provide a health benefit beyond the traditional nutrients it contains” and also made the following very important points:

- Functional foods may be whole, fortified, enriched, or enhanced foods.
- To have a beneficial effect on health, a functional food would have to be consumed as part of a varied diet on a regular basis, at effective levels.
- It’s likely that all foods are functional at some physiological level.

ACSH considers this to be a very reasonable explanation of the functional food concept as it is used in the United States today. Others, however, prefer narrower definitions. For example, the International Life Sciences Institute prefers to limit the term “functional foods” to foods that may provide a benefit because of the presence of a physiologically active component (thus excluding those that might be beneficial for other reasons, such as the absence of a harmful component). The Institute of Medicine of the National Academy of Sciences prefers to limit the term “functional foods” to those foods in which the concentrations of ingredients have been manipulated or modified, thus excluding unmodified foods with beneficial characteristics supplied by Mother Nature.

From your point of view as a consumer, however, these differences of opinion aren’t particularly important. What is important is that *the use of the term “functional” to refer to a food doesn’t prove anything*. Foods don’t have to pass any test or meet any standard in order to be described as “functional.” Since there is no official government-regulated definition, anyone can call any food “functional,” in much the same way that anyone can call any product “modern.”

To find out whether there is convincing evidence that a food has health benefits that go beyond basic nutrition, it isn’t enough to look for the word “functional” on the label or in an advertisement. You have to look for something else.

FDA-Approved Health Claims

The best way to find out whether a food has any scientifically established health benefits beyond basic nutrition is to look for a special type of statement called a “health claim” on the food label. A health claim is a statement about the relationship between a food or its components and any disease or health-related condition. Although foods don’t need to pass a test in order to be called “functional,” they do need to meet strict criteria in order to be allowed to carry health claims.

In the U.S., health claims intended for use on food labels must be pre-approved by the Food and Drug Administration (FDA) before they can be used. In order for a health claim to earn approval, there needs to be significant scientific agreement the claim is factual. FDA has developed criteria for “significant scientific agreement,” as illustrated in the Appendix of this report.

Table 1 lists currently approved health claims for foods and food ingredients. Some of these claims pertain to general diet-disease relationships; others are more narrowly focused on specific foods or food ingredients.

Table 1. **Health Claims for Food Labels Approved by the U.S. Food and Drug Administration ***

Diet-Disease Relationship	Example of an Acceptable Wording
Calcium and osteoporosis	Regular exercise and a healthy diet with enough calcium help teens and young adult white and Asian women maintain good bone health and may reduce their risk of osteoporosis.

* The first eight claims listed here were mandated for FDA review by the Nutrition Labeling and Education Act of 1990. The remaining claims were approved by FDA following petitions submitted by the food industry, except for those pertaining to potassium, blood pressure, and stroke and whole grains, heart disease, and cancer, which were approved on the basis of authoritative statements by other federal scientific bodies (as authorized by the Food and Drug Administration Modernization Act of 1997).

Facts About “Functional Foods”

Table 1. **Health Claims for Food Labels Approved by the U.S. Food and Drug Administration (*continued*)**

Diet-Disease Relationship	Example of an Acceptable Wording
Sodium and hypertension	Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.
Dietary fat and cancer	Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.
Dietary saturated fat and cholesterol and coronary heart disease	While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.
Fiber-containing grain products, fruits, and vegetables and cancer	Low fat diets rich in fiber containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors.
Fruits, vegetables and grain products that contain fiber, particularly soluble fiber, and coronary heart disease	Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.
Fruits and vegetables and cancer	Low fat diets rich in fruits and vegetables may reduce the risk of some types of cancer, a disease associated with many factors.
Folate and neural tube birth defects	Healthful diets with adequate daily folate may reduce a woman’s risk of having a child with a brain or spinal cord birth defect.

Table 1. Health Claims for Food Labels Approved by the U.S. Food and Drug Administration (*continued*)

Diet-Disease Relationship	Example of an Acceptable Wording
Sugar alcohols and dental caries	Frequent eating of foods high in sugars and starches as between meal snacks can promote tooth decay. The sugar alcohol [name of product] used to sweeten this food may reduce the risk of dental caries.
Foods that contain fiber from whole oat products and coronary heart disease or heart disease.	Diets low in saturated fat and cholesterol that include soluble fiber from whole oats may reduce the risk
Foods that contain fiber from psyllium and coronary heart disease	Diets low in saturated fat and cholesterol that include soluble fiber from psyllium seed husk may reduce the risk of heart disease.
Soy protein and coronary heart disease	Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of [name of food] provides _____ grams of soy protein.
Plant sterol or stanol esters and coronary heart disease	Plant sterols: Foods containing at least 0.65 grams per serving of plant sterols, eaten twice a day with meals for a daily total intake of at least 1.3 grams, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies _____ grams of vegetable oil sterol esters. Plant stanols: Foods containing at least 1.7 grams per serving of plant stanol esters, eaten

Facts About “Functional Foods”

Table 1. **Health Claims for Food Labels Approved by the U.S. Food and Drug Administration (*continued*)**

Diet-Disease Relationship	Example of an Acceptable Wording
	twice a day with meals for a total daily intake of at least 3.4 grams, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies _____ grams of plant stanol esters.
Potassium, blood pressure and stroke	Diets containing foods that are good sources of potassium and low in sodium may reduce the risk of high blood pressure and stroke.
Whole grains, heart disease, and cancer	Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol may reduce the risk of heart disease and certain cancers.

If a company wants to put a new type of health claim on the label of a food product, it can obtain approval to do this in either of two ways: 1) petitioning FDA and submitting research results to support the petition, or 2) proposing the claim on the basis of an authoritative statement by other federal health authorities (such as the National Institutes of Health or the National Academy of Sciences).

Either way, getting a health claim onto a food label requires quite a lot of scientific evidence showing a beneficial effect. FDA doesn't approve petitions—and other federal agencies don't issue authoritative statements—unless there is plenty of solid science to back them up. For example, the petition for the health claim for soy protein and reduced risk of heart disease included evidence from more than 40 studies in human volunteers.

If you see a health claim on the label of a functional food (or any food, for that matter), you can be confident that there is strong scientific evidence that the food does what it claims to do. But there are two things that you should be careful about:

1. Make sure to read the health claim in its entirety. To obtain the benefits from a food, you need to use it in the manner called for in the health claim statement. For example, the health claim for soy protein states that diets must include 25 grams of soy protein daily in order to reduce the risk of heart disease. That number is there for a reason; smaller amounts of soy protein have not been shown to have a cholesterol-lowering effect.
2. Make sure that the claim you're reading actually is a health claim—that is, a claim concerning a diet-disease relationship. Foods are also allowed to carry statements regarding their effect on the structure or function of the body (e.g., “calcium builds strong bones”). Structure/function claims are expected to be truthful, but they do not require FDA pre-approval and therefore don't have the same stature as health claims. How can you tell the difference between a health claim and a structure/function claim? It's simple. If the claim mentions a disease or health problem other than a nutritional deficiency disease, it's a health claim. If it doesn't, it isn't. Table 2 (see page 14) gives more information on the types of claims that may appear on food labels.

There have been instances in the past—and perhaps there will be more in the future—in which unauthorized claims about diet and disease have appeared on food labels. If you suspect that the claim you're reading may not be authorized, here are some things that you can do to check it out:

1. Take a close look at the wording of the claim. Authorized claims almost always include caveats that explain how to use the product correctly and point out that it should be incorporated into a generally healthful diet. For example, all of the authorized claims for foods that may help to reduce heart disease risk state that the food should be used as part of a diet that's low in saturated fat and cholesterol.

Facts About “Functional Foods”

2. Take a close look at Table 1 of the booklet you’re now reading. It includes every health claim that has been authorized by the FDA as of March 2002. If the claim you’re looking at isn’t on the list, it’s either newer than that or it isn’t authorized.
3. See what the FDA has to say about the claim. You can find a great deal of useful information about all aspects of food labeling on the FDA’s Web site at www.fda.gov. The page on health claims and nutrient content claims at <http://www.cfsan.fda.gov/~dms/lab-hlth.html> is particularly useful.

Table 2. **Types of Claims that May Appear on the Labels of Foods and Dietary Supplements**

	Health Claim	Structure/ Function Claim	Nutrient Content Claim
What it is:	A statement about the relationship of a dietary factor to the risk of a disease or health condition	A statement about the relationship of a dietary factor to the structure or function of the body (without reference to any disease)*	A statement about the nutrients present in a food
Examples:	All of the claims listed in Table 1	“Calcium builds strong bones”; “Fiber maintains bowel regularity”	“Low calorie”; “Sugar free”; “Good source of vitamin C”

* In the case of dietary supplements, a structure/function claim must be accompanied by a disclaimer indicating that the statement has not been approved by FDA and that the product is not intended to diagnose, treat, cure, or prevent any disease; no such disclaimer is required for foods. In the case of conventional foods, the effects mentioned in structure/function claims must be achieved through the food’s nutritive value; no such restriction applies to dietary supplements.

Table 2. **Types of Claims that May Appear on the Labels of Foods and Dietary Supplements** (*continued*)

	Health Claim	Structure/ Function Claim	Nutrient Content Claim
What it takes to get it on the label:	Pre-approval by FDA based on a petition <i>or</i> an authoritative statement by a federal scientific body ⁺	No pre-approval required, but claims are expected to be truthful and not misleading	Claims must be consistent with regulations that have defined terms such as “low,” “free,” and “good source”; new types of claims not covered by existing regulations require FDA pre-approval

⁺ In addition, most types of health claims are allowed only on foods that provide a significant amount of at least one essential nutrient and do not contain high levels of potentially harmful components such as saturated fat. Exceptions have been made in some instances. For example, gums and candies made with sugar alcohols are allowed to carry a health claim about tooth decay even though they do not provide significant amounts of nutrients.

Safety Concerns and Other Reservations

Although there is good scientific evidence that certain functional foods or food ingredients can play a role in disease prevention and health promotion, concerns have been raised about several aspects of functional foods.

Safety Issues. The first and most important concern is safety. A functional food needs to be safe for practically everyone, under practically all conditions of use. Although a company that markets a functional food may intend for it to be consumed by a particular

Facts About “Functional Foods”

group of people (e.g., those with high cholesterol levels) and in a particular quantity (the amount specified in a health claim statement), people may use the food in other ways. They may eat the food at more than one meal. They may have second or third helpings. They may serve it to other family members or guests, including children, elderly people, pregnant or lactating women, or people who take medications. The food needs to be safe for all of these people to eat, even if they consume it in larger-than-usual amounts.

Putting ingredients that are not safe for all segments of the population into functional foods is unwise. Functional foods containing added herbal ingredients are an example of this problem.

If you went to the supermarket a few years ago, you could find a variety of soups, breakfast cereals, beverages, and other food products containing herbs traditionally used for medicinal purposes, such as St. John’s wort, echinacea, ginseng, or ginkgo biloba. (Many of these products are no longer on the market, but some, especially beverages, are still being sold.) Products of this sort can be risky because some herbs are not safe for everyone. Some people have allergic reactions to echinacea. Ginkgo biloba can promote dangerous bleeding in people who are taking anticoagulant drugs. St. John’s wort can impair the effectiveness of a variety of medications, including immunosuppressants, drugs used to treat HIV infection, and perhaps even birth control pills. People with allergies and those who are taking medications may realize that they shouldn’t take herbal supplements or drink herbal teas without consulting a physician, but they might inadvertently consume herb-laced foods.

Misplaced Priorities. Another important concern about functional foods is that their promotion may mislead people into thinking that eating them is more important than choosing a balanced diet or taking other steps to prevent or treat health problems. Consumers need to realize that functional foods are not a “magic bullet” or a panacea for poor health habits. Functional foods are only one aspect of diet, and diet is only one aspect of a comprehensive lifestyle approach to good health, which should include regular exercise, tobacco avoidance, maintenance of a healthy body weight, stress reduction, and other positive health practices. Functional foods can sometimes be part of an effective strategy to promote good health, but they should never be considered a substitute for other good

health habits and they should never be used instead of medically prescribed therapy for any health problem.

Exaggerated Claims and Regulatory Inconsistencies. Ideally, the promotion of functional foods should be based on strong scientific evidence. Claims should not be made until experts have reached a consensus that a particular product works and that people can consume it safely. All too often, however, functional foods are marketed on the basis of limited, preliminary scientific data. In some instances, products may even be marketed before their safety has been clearly established.

Inconsistencies among the regulations governing the promotion of foods and food ingredients may make matters worse. For example, as mentioned earlier, the criteria for health claims on food labels are much stricter than the criteria for structure/function claims, but people may have difficulty distinguishing one type of claim from the other. The regulations pertaining to food advertising (which is under the jurisdiction of the Federal Trade Commission) differ from those pertaining to food labeling (which is under FDA's jurisdiction). In addition, the regulations governing dietary supplements are different from those for conventional foods, and the dividing line between the two categories of products is sometimes blurred. Companies sometimes attempt to market functional foods as dietary supplements rather than taking the product through the complex, costly, and lengthy process of food health claim approval. (For example, the manufacturer of the margarine enriched with plant stanol esters initially planned to market the product as a dietary supplement, which would have enabled structure/function claims to be made on the label about the heart-health benefits of the product without going through the health claims authorization process. However, FDA blocked this effort, and the manufacturer then went through the steps necessary to get a health claim approved.)

Consumers need to be cautious and skeptical when evaluating claims made for functional food products. It's important to realize that the claims made for functional foods are sometimes exaggerated, that the regulations governing these products are inconsistent and confusing, and that the term "functional food" has no official meaning.

Facts About “Functional Foods”

Table 3. **Strength of Evidence for Functional Foods Currently on the Market**

Functional Food	Bioactive Component	Potential Health Benefit	Recommended Amount or Frequency of Intake	Strength of Evidence
Whole oat products	Beta-glucan	Lower cholesterol levels	3 g/day	Very strong
Psyllium	Soluble fiber	Lower cholesterol levels	1 g/day	Very strong
Whole soy foods and foods made with soy protein	Soy protein	Lower cholesterol levels	25 g/day	Very strong
Special fortified margarines or salad dressings	Plant stanol or sterol esters	Lower cholesterol levels	3.4 g/day for stanols; 1.3 g/day for sterols; must be consumed with meals	Very strong
Sugarless chewing gums and candies	Sugar alcohols	Does not promote tooth decay	Not applicable	Very strong
Fatty fish	Omega-3 fatty acids	Reduced risk of heart disease	Twice per week*	Strong

* Because of concerns about methylmercury contamination, the FDA has advised pregnant women and women of childbearing age who may become pregnant to limit their total fish intake to 12 ounces per week and to refrain from eating shark, swordfish, king mackerel, and tilefish.

Table 3. **Strength of Evidence for Functional Foods Currently on the Market (*continued*)**

Functional Food	Bioactive Component	Potential Health Benefit	Recommended Amount or Frequency of Intake	Strength of Evidence
Cranberry juice	Proanthocyanidins	Reduced urinary tract infections		Moderate
Garlic	Organosulfur compounds	Lower cholesterol levels		Moderate
Green tea	Catechins	Reduced risk of some types of cancer		Weak to moderate
Tomatoes and tomato products	Lycopene	Reduced risk of some types of cancer, especially prostate cancer		Weak to moderate
Dark-green leafy vegetables	Lutein	Reduced risk of age-related macular degeneration		Weak
Meats and dairy products	Conjugated linoleic acid	Reduced risk of breast cancer;		Weak

Facts About “Functional Foods”

Table 3. **Strength of Evidence for Functional Foods Currently on the Market** (*continued*)

Functional Food	Bioactive Component	Potential Health Benefit	Recommended Amount or Frequency of Intake	Strength of Evidence
		increased muscle mass; various other possible effects		
Cruciferous vegetables	Isothiocyanates, indoles	Reduced risk of some types of cancer		Weak
Fermented dairy	Probiotics	Support gastrointestinal tract health; boost immunity		Weak

Examples of Functional Foods with Very Strong Evidence of Health Benefits

The functional foods listed in this section have all been tested in clinical trials (studies in which volunteers are given a test substance or an inactive placebo under controlled conditions), and all carry FDA-approved health claims. The evidence supporting their health benefits is very strong (see Table 3). As is true with all functional foods, however, they should be used only as part of a well-balanced, healthful diet. In particular, the foods listed here that have been associated with reduced heart disease risk should not be regarded as a substitute for a low-fat, low-cholesterol diet or for

prescribed cholesterol-lowering medication. They should be used only as an adjunct to other measures designed to achieve healthy cholesterol levels, not as a substitute for them.

Whole Oat Products. A substantial amount of scientific evidence indicates that foods made from whole oats, such as rolled oats, oat bran, and oat flour, can help to lower blood cholesterol levels and therefore reduce the risk of heart disease if consumed regularly in sufficient amounts. The active component of oats is a type of soluble fiber called beta-glucan. Since 1997, the FDA has allowed a health claim to appear on food labels linking consumption of whole oat products to reduced risk of heart disease.

Psyllium. Like oat products, foods containing soluble fiber from psyllium seed husk can help to lower blood cholesterol levels and therefore reduce the risk of heart disease if consumed regularly in sufficient amounts. Psyllium is best known as the active ingredient in some fiber laxatives. It can also be included in foods such as breakfast cereals. A health claim for psyllium and heart disease was authorized in 1998.

Soy Protein. Foods made from soy have been a part of many Asian cuisines for centuries, and they are popular among U.S. vegetarians as well. Soy foods were once considered a niche product and were available primarily in health food stores, but they are now sold in mainstream supermarkets as well. Scientific studies have shown that consumption of soy protein can help to reduce cholesterol levels. However, it takes a substantial amount of soy protein to achieve this effect: about 25 grams daily.

Foods that contain soy protein include tofu, soymilk, tempeh, soy nuts, soy nut butter, soy-based meat substitutes (such as soy “sausages,” “burgers,” and “crumbles”), and baked goods made with soy flour. Many soy foods contain between 6 and 20 grams of soy protein per serving. For example, four ounces of firm tofu contain 13 grams, one soy “sausage” link contains 6 grams, one soy “burger” contains 10-12 grams, and a quarter cup of roasted soy nuts contains 19 grams. Thus, people would need to eat more than one serving of soy foods a day, on a regular basis, in order to obtain a health benefit.

The soy health claim applies *only* to whole soy foods and foods

Facts About “Functional Foods”

made with soy protein. These are the only kinds of soy products that have been proven beneficial to heart health. Isolated soy components, such as the isoflavones daidzein and genistein, have not been proven beneficial to lower cholesterol and might even have adverse health effects if consumed in excessive amounts. The soy health claim also does not apply to soybean oil, which does not contain protein.

Foods Containing Plant Stanol or Sterol Esters. Sterols and stanols are substances that are found naturally in small amounts in vegetable oils and other plant products. These substances can help to lower blood cholesterol levels by blocking the absorption of cholesterol from the diet. The amount of stanols or sterols naturally present in foods isn't large enough to have a meaningful effect on cholesterol levels. However, food manufacturers have developed margarine-like spreads that contain larger amounts of either stanols or sterols. These special foods can help to reduce cholesterol levels if used correctly. In the year 2000, the FDA approved a health claim for foods containing stanol or sterol esters.

The use of foods containing stanol or sterol esters has been endorsed by the National Cholesterol Education Program (NCEP). The latest (2001) version of the NCEP's guidelines for the assessment and treatment of patients with high cholesterol levels suggests that people should consider the use of stanols/sterols as an option to enhance the effect of other cholesterol-lowering diet and lifestyle changes.

It's important to note that the wording of the health claim for stanol esters and sterol esters specifies that foods containing these ingredients should be consumed at least twice a day *with meals*. Since stanol and sterol esters exert their effect by blocking the absorption of cholesterol from other foods, they must be eaten along with other foods in order to work. If these substances are consumed alone, between meals, they wouldn't be in the digestive tract at the same time that cholesterol-containing foods are there, so they wouldn't be useful.

Sugarless Chewing Gum and Sugarless Candy. The idea that sugarless chewing gum is a functional food may seem a bit peculiar, but it makes sense.

Sugarless gums and candies are made with sugar alcohols such

as sorbitol, xylitol, or isomalt. These substances, which may also be called polyols or sugar replacers, can replace both the bulk and much of the sweetness of sugar. They are therefore quite different from the more familiar low-calorie sweeteners such as aspartame and saccharin, which replace only the sweetness of sugar, not its volume. The principal advantage of sugar alcohols as a food ingredient is that they do not promote tooth decay. The bacteria in dental plaque, which produce substantial amounts of decay-promoting acid from sugars and starches, produce little or no acid from sugar alcohols.

Tooth decay is a real disease, and reducing the risk of this disease is a real health benefit. Moreover, it's a benefit that has nothing to do with basic nutrition. Thus, sugarless gums and candies meet most people's definitions of functional foods.

Numerous scientific studies, including trials in human volunteers, show that sugar alcohols do not promote tooth decay. FDA approved a health claim for sugar alcohols in 1996.

Other Foods with Possible Benefits

The foods described in this section do not have FDA-approved health claims. However, their potential health benefits are currently being investigated.

Fatty Fish. Fatty fish such as salmon, tuna, mackerel, sardines, rainbow trout, and herring contain a special type of fatty acids called omega-3 or n-3 fatty acids. Omega-3 fatty acids are an essential component of cellular membranes, especially in the brain and retina of the eye, and are necessary for their proper functioning. However, it is not absolutely necessary for people to get the omega-3 fatty acids found in fish from their diets, since the body can synthesize them from precursors found in more commonly consumed foods such as soybean and canola oils.

Omega-3 fatty acids can have profound effects on many processes in the body, including blood clotting and inflammation. Scientists are investigating their possible benefits in a variety of chronic diseases, including cancer, rheumatoid arthritis, Crohn's disease, cognitive dysfunction, and, especially, cardiovascular disease. As part of its dietary guidelines for a healthy heart, the American

Facts About “Functional Foods”

Heart Association recommends two servings of fatty fish per week. The FDA, however, has taken a more cautious view. It has not authorized a health claim for omega-3 fatty acids in foods, and it has authorized only a qualified health claim for dietary supplements, which states that the evidence that omega-3 fatty acids may help to prevent heart disease is “suggestive but not conclusive.”

One of the reasons for the “qualified” health claim is that concerns have been raised about the safety of consuming large amounts of omega-3 fatty acids. Some scientific evidence indicates that high levels of these fatty acids might cause adverse effects including an increased risk of bleeding, an increased risk of hemorrhagic stroke, the formation of potentially harmful oxidation products, increases in blood levels of low-density lipoprotein (LDL) cholesterol (the so-called bad cholesterol), and impaired control of diabetes. Such effects are unlikely to occur in people who merely eat the recommended two servings of fatty fish per week. However, if people consume large doses of omega-3 fatty acids in dietary supplements, or if many functional food products with added omega-3 fatty acids were to come onto the market, it could be possible for people to get more of these fatty acids than they should. The American Heart Association does not recommend the use of fish oil supplements to lower cholesterol levels.

ACSH classifies the overall evidence for a beneficial effect of omega-3 fatty acids as strong but cautions against overconsumption of concentrated sources of these fatty acids.

Cranberry Juice. Since the 1920s, medical folklore has suggested that cranberries might be helpful in the prevention and treatment of urinary tract infections. In 1994, a formal clinical trial in elderly women supported this effect. More recent research has indicated that the biologically active components in cranberries are condensed tannins called proanthocyanidins, which decrease the ability of bacteria such as *E. coli* to adhere to the cells lining the urinary tract.

Although the scientific studies supporting a beneficial effect of cranberries are of good quality, the quantity of research is much smaller than the amount that has been conducted on foods that have qualified for FDA health claims. ACSH therefore classifies the scientific evidence for a beneficial effect of cranberry juice in reducing urinary tract infections as “moderate.” ACSH also cautions that

anyone who has symptoms suggestive of a urinary tract infection should consult a physician rather than attempting to manage the problem by self-treatment alone.

Garlic. Garlic has been thought to have medicinal properties for thousands of years and has been used for a wide variety of purposes. Its best-documented effect is its potential ability to lower blood cholesterol levels to a modest extent. Several studies in human volunteers have demonstrated this effect, but experts disagree on whether a clinically meaningful benefit has been proven. Their differences of opinion are likely due to the fact that various studies of garlic have used different types of preparations and different study designs, making it difficult to compare their results. Because the findings of studies on garlic have not been completely consistent, ACSH regards the evidence for a beneficial effect of garlic on blood cholesterol as “moderate.”

When consumed in large amounts, garlic may interact with some medications, such as anticoagulants and drugs used in the treatment of HIV infection. The normal culinary use of garlic is unlikely to cause problems, but people who take garlic supplements or make a deliberate effort to consume unusually large amounts of garlic as a food might run into difficulties. ACSH recommends that anyone who is taking any type of medication should consult with a physician before consuming garlic or any other herb in quantities beyond those ordinarily used in cooking.

Green Tea. Studies in experimental animals have suggested that substances in green tea, especially polyphenolic components known as catechins, may reduce the risk of various types of cancer. Studies in human populations have had conflicting results, however. Some have not shown any reduction in cancer risk among green tea drinkers as compared to nondrinkers, even in parts of the world where green tea is popular, such as Japan. The overall evidence for a cancer-protective effect of green tea is weak to moderate.

Tomatoes and Tomato Products. Tomatoes and tomato products are the most important sources of the carotenoid lycopene. Like the better-known carotenoid beta-carotene, lycopene is a strong antioxidant. Unlike beta-carotene, however, lycopene cannot be transformed into vitamin A in the human body. Studies in human popula-

Facts About “Functional Foods”

tions suggest that high intakes of tomato products or high blood levels of lycopene may be associated with reduced risks of various types of cancer, especially prostate cancer. Not all of the evidence is consistent, however, and no clinical trials (studies in which people are given lycopene under controlled conditions) have been completed. The overall strength of the evidence for a cancer-protective effect of lycopene is weak to moderate.

Vegetables Containing Lutein. Like lycopene, lutein is a carotenoid with antioxidant activity. It is found in dark-green leafy vegetables such as spinach and collard greens, and it is also the predominant carotenoid in the macula of the eye. (The macula is a part of the retina; it is critically important for central vision.) Some evidence indicates that lutein might help to protect against age-related macular degeneration, an eye disease that is an important cause of blindness among older people. However, this evidence is very preliminary in nature. In March 2000, the National Eye Institute of the National Institutes of Health issued a statement cautioning that the potential benefits of lutein on the eye remain uncertain. That conclusion is still valid today. ACSH classifies the evidence on lutein as weak.

Animal Products Containing Conjugated Linoleic Acid. Many of the functional food components discussed in this report are “phytochemicals”—that is, chemicals derived from plants. Conjugated linoleic acid (CLA), on the other hand, is a “zoochemical.” It is found primarily in dairy products and in meats from ruminant animals (e.g., beef or lamb). Preliminary research, conducted mostly in experimental animals, suggests that CLA might help to inhibit breast cancer, increase muscle mass, decrease body fat, and increase bone density. Only a small amount of research has been conducted on the effects of CLA in humans, however, and the results of that research have not been completely consistent. The evidence for a beneficial effect of CLA is therefore regarded as weak.

Cruciferous Vegetables. A great deal of scientific evidence indicates that the consumption of fruits and vegetables is associated with a reduced risk of cancer. Whether certain types of fruits or vegetables are more beneficial than others is less clear. One group of vegeta-

bles that has been suggested to be particularly valuable is the cruciferous vegetables. This group includes arugula, bok choy, broccoli, Brussels sprouts, cabbage, cauliflower, collards, kale, kohlrabi, mustard greens, radishes, rutabaga, turnip, turnip greens, and watercress. Cruciferous vegetables have been thought to be especially good cancer-fighters because they contain phytochemicals that may protect against cancer, including isothiocyanates and indoles. These vegetables also provide vitamin C and fiber, and some provide vitamin A-precursor carotenes, folic acid, calcium, and/or iron as well. Nobody disputes the fact that cruciferous vegetables are nutritious and healthful. However, the evidence that they have a specific cancer-fighting effect that is greater than that of other vegetables is weak.

Probiotics. The term “probiotics” refers to viable microorganisms in fermented dairy products. The bacterium *Lactobacillus acidophilus*, which is found in acidophilus milk, is an example. It has been claimed that probiotics may support the health of the gastrointestinal tract, boost immunity, and have other beneficial health effects. However, the scientific evidence on probiotics consists largely of animal and laboratory studies; very few human studies have been completed. Because of the lack of convincing data from research in humans, ACSH regards the overall strength of the evidence for a beneficial effect of probiotics as weak. Despite the weakness of the scientific evidence, probiotics are by far the most popular type of functional food in some countries, such as Japan and Australia.

Other Potentially Functional Foods. In addition to the foods described in detail above, a variety of other potential functional foods are currently under investigation. The evidence for health benefits of any of these foods is speculative, at best, but it’s possible that future research may provide stronger evidence of desirable effects. Examples include the following:

- *Prebiotics.* These are nondigestible food components that may promote the growth of desirable bacteria in the gastrointestinal tract
- *Synbiotics.* Mixtures of probiotics and prebiotics.
- *Walnuts, hazelnuts, and almonds.* Despite their relatively high fat content, they may have cholesterol-lowering effects.

Facts About “Functional Foods”

- *Polyphenolics from red grape skins.* These compounds may have useful antioxidant and anticoagulant properties. It has been speculated that polyphenolics in red wine may contribute to the protective effect of red wine against heart disease. However, since the alcohol in wine has a known protective effect, it has been difficult to determine whether polyphenolics also play a role.
- *Chocolate.* Like grape skins, it also contains polyphenolics.
- *Lignans from flaxseed.* These substances are being investigated for their potential anti-cancer effects.
- *Limonoids from citrus fruit.* Another possible anti-cancer agent.

Biotechnology and Functional Foods

New developments in biotechnology should greatly influence the future of functional foods. Recent examples of biotechnology-derived crops that have tremendous potential to improve the health of millions worldwide include golden rice and iron-enriched rice. These grains are genetically engineered to provide enhanced levels of iron and beta-carotene (a precursor of vitamin A), which could help prevent iron deficiency anemia and vitamin A deficiency-related blindness worldwide. In the future, other foods enhanced with other nutritive or non-nutritive substances may help to prevent chronic diseases such as heart disease, osteoporosis, or cancer. The acceptance of biotechnology by consumers will be important if the potential of this powerful methodology is to be realized.

Putting Functional Foods in Perspective

The idea that foods might have therapeutic benefits is not a new concept; in fact, it was embraced approximately 2,500 years ago by Hippocrates, the father of medicine. Many cultures can trace the history of foods utilized for medicinal purposes for thousands of years. However, this “food as medicine” philosophy fell into relative obscurity in the 19th century with the advent of modern drug therapy.

In the latter part of the 20th century, interest in the medical effects of foods was revived when diseases linked to dietary excess-

es, such as obesity and coronary heart disease, became a major public health concern. At about the same time, scientists also began to identify physiologically active components in foods from plants and animals that potentially could reduce risk for a variety of chronic diseases. These events, coupled with an aging, health-conscious population, changes in food regulations, numerous technological advances, and a marketplace ripe for the introduction of health-promoting products, coalesced in the 1990's to create the trend we now know as "functional foods."

Numerous surveys have shown that American consumers are increasingly interested in taking as much responsibility as possible for their own health and well-being. This "self-care" trend is a welcome one, since research has shown that unhealthful lifestyles play a major role in many health problems.

The use of functional foods can be a part of a health-conscious lifestyle. However, the potential benefits of functional foods should not be oversold. In most instances, these products are merely adjuncts to other, better-established dietary and lifestyle measures to promote good health. Moreover, the benefits of many of the foods currently being promoted as "functional" have not been conclusively established by scientific research. In some instances, even the safety of the products has been questioned.

ACSH recommends that consumers who are interested in incorporating functional foods into a healthy lifestyle should first consider products that carry FDA-approved health claims. These foods have been convincingly demonstrated to be beneficial for their intended purposes if consumed at sufficient levels on a regular basis, as part of a generally well-balanced and healthful diet. If you choose to use any of them, and if you use them correctly, you are likely to achieve the promised health benefits.

ACSH is far more reluctant to recommend any of the functional foods that do not carry FDA-approved health claims. Incorporating a functional food into your diet on a regular basis takes considerable effort; ACSH hesitates to suggest that you make such an effort when there is only limited evidence that the food that you're eating will have the special benefits that are implied for it.

Of course, if you happen to like a particular functional food and if the food is nutritious and healthful (as most of the foods discussed in this booklet are), there's no reason why you shouldn't enjoy it regularly. It might be best, however, to regard its alleged

Facts About “Functional Foods”

special health benefits as merely a possible bonus, rather than making them your principal reason for choosing the food. If your main interest is reducing your risk of disease, you would be better off focusing your attention on lifestyle changes that are of proven value (e.g., exercising regularly, abstaining from the use of tobacco, maintaining a healthy body weight), rather than making major efforts to eat functional foods for which the evidence of beneficial effects is limited.

Suggestions for Further Reading:

American Dietetic Association. Position of the American Dietetic Association: Functional Foods. *J Am Diet Assoc* 99:1278-1285, 1999. Available online at <http://www.eatright.com/adap1099.html>

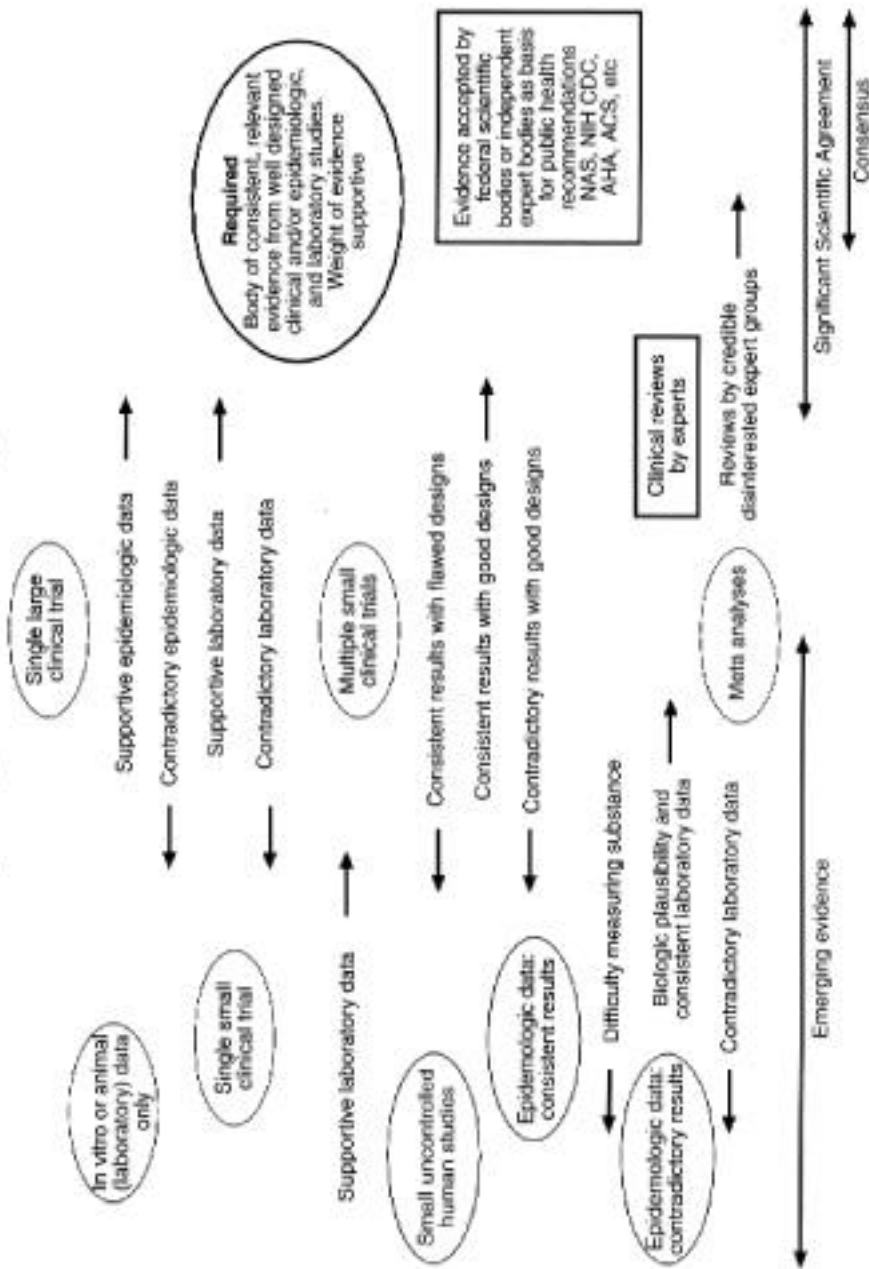
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APPENDIX

This schematic shows how the FDA assesses the scientific evidence pertaining to a potential health claim to determine whether it meets the standard of “significant scientific agreement.” The scheme differentiates “emerging evidence” on the left (e.g., animal and test tube studies, uncontrolled human studies) from data on the right that represents “consensus” and includes evidence accepted by federal scientific bodies responsible for public health recommendations. Thus, the strength of the evidence for a diet-disease relationship strengthens as one moves from left to right on the schematic.

Schema for Assessing Strength and Consistency of Scientific Evidence Leading to Significant Scientific Agreement



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