



Commentary

Scand J Work Environ Health [2000;26\(2\):178-180](#)

doi:10.5271/sjweh.528

Functional foods - blurring the distinction between food and medicine

by [Vainio H](#), [Mutanen M](#)

This article in PubMed: www.ncbi.nlm.nih.gov/pubmed/10817384



This work is licensed under a [Creative Commons Attribution 4.0 International License](#).

Functional foods — blurring the distinction between food and medicine

by Harri Vainio, MD,¹ Marja Mutanen, PhD²

Vainio H, Mutanen M. Functional foods — blurring the distinction between food and medicine. *Scand J Work Environ Health* 2000;26(2):178—180.

The difference between foods and medicines is becoming increasingly blurred. For thousands of years, food was fuel. It powered the manual labor that built the pyramids, laid railroads and constructed towns. But now, when we have learned more about the relationship between diet and health over the past 50 years, this traditional concept of food has tended to change. We fortify cereals, breads, and juices with essential vitamins and minerals. We reduce fat, sodium, and cholesterol content of a number of products.

Now, as we enter the new millennium, the foods of the future are emerging. Rather than taking out certain food ingredients, we are beginning to engineer such new foods or food components that would hopefully protect ourselves against disease. The main idea is that these new products, sometimes called “functional foods”, will be powerful tools that consumers can use to safeguard themselves against disease.

Why functional foods?

In developing functional foods, manufacturers are riding the wave of consumer interest in maintaining easily their own health without putting in too much effort (ie, like controlling body weight, having enough exercise and keeping rational food habits). Large cohorts of “baby boomers” are now in their 50s and are looking for ways to forestall the effects of aging. They constitute a huge market for products that maintain or improve health. One manufacturer has already introduced a red wine pill, made of the skins of merlot grapes, which could help counteract the damaging effects of cholesterol and keep blood vessels healthy. Many new functional foods will begin to appear on the market, but can we trust the manufacturers’ claims that they are not only safe, but also effective in improving health? The products that have appeared so far, such as sitostanol-ester-containing margarines, have been extensively tested for their efficacy, with

much solid science behind their introduction. But are they also tested adequately for safety? In the functional food “business”, problems can arise if added substances have been poorly tested or unsafe, if purported benefits are based on flimsy evidence, or if trivially small or dangerously large amounts are added to foods. As more companies scramble onto the market, we may see the introduction of products of increasingly questionable value or products for which little information is provided with which to evaluate their contribution to health.

Food with a purpose

If you can fight fire with fire, maybe it makes sense likewise to fight fat with fat. This seems to be the strategy behind recent functional food breakthroughs by Finnish scientists. They created the world’s first sitostanol-ester-containing margarine, which efficiently lowers blood cholesterol levels by blocking cholesterol absorption from the intestinal lumen. Although its mechanism of action is not fully known, its overall effect is to lower the plasma content of low-density lipoprotein (LDL) while leaving unaffected the concentration of high density lipid (HDL) cholesterol (1, 2). Sitostanol ester margarine does not decrease the fat-soluble vitamin concentrations in serum, but it reduces serum beta-carotene levels (3). Sitostanol ester, a derivative of sitosterol, belongs to a larger group of compounds called phytosterols. These compounds occur naturally in a variety of plants and vegetable oils, for example, soybeans and wood pulp are common sources. Now this active ingredient will be infused into the fats and oils of other products in addition to margarines to create “healthier” snack bars, chocolate, cheese spreads, and sausages. The question to be answered especially in regard to safety aspects is now “How do the clinical studies done with sitostanol-ester-containing margarines apply to the new situation where

1 International Agency for Research on Cancer, Lyon, France.

2 Institute of Environmental Medicine, Karolinska Institutet, Stockholm, Sweden.

Reprint requests to: Dr Harri Vainio, Unit of Chemoprevention, International Agency for Research on Cancer, 150 Cours Albert Thomas, 69372 Lyon, cedex 08, France. [E-mail: Vainio@iarc.fi]

sitostanol intake may be considerably higher and the spectrum of consumers much wider?"

Supplementing foods with ingredients that improve health is not a new practice. Supplementing milk with vitamin D helped eliminate rickets. Iodine has been added to salt to prevent hypothyroidism. Functional foods differ from these examples in that they blur, to a greater extent, the distinction between food and medicine by incorporating ingredients such as phytosterols that act more like drugs than nutrients. Thus the terms "nutraceuticals", "designer foods", "biochemopreventatives", and "pharmafoods" have also been used to refer to functional foods. The display of functional foods in ordinary food stores is a relatively recent phenomenon.

Do we need them?

The cholesterol-lowering properties of Benecol® (Raisio Group), Take Control® (Unilever Company), and other similar margarines are aimed at reducing the risk of heart disease, the main killer in western societies. These 2 products are among the first major foods designed to act like drugs. The consumption of phytosterol or phytostanol-enriched versions of common foods is considered a practical means of improving the health of the many people who are at risk of cardiovascular disease, particularly if these foods are incorporated into a diet low in saturated fats and cholesterol (2, 4, 5). Nevertheless, there are well-known ways of maintaining optimal cholesterol levels that do not require the purchase of specially fortified foods. Decreasing the amount of saturated fatty acids (hard fat) in the diet with a subsequent increase of unsaturated fatty acids (oils, soft margarines) is an efficient and safe way for all consumers to lower cholesterol levels. Furthermore, engaging in aerobic exercise results in better ratios of HDL and LDL cholesterol.

The natural ways of optimizing cholesterol levels are not the easiest, and some people feel that they are far too complicated. For this group, functional foods may provide a helping hand in the form of palatable, easy-to-use products. However, it is of the utmost importance that the benefits always outweigh the risks. The products should be studied with extreme care for any possible toxicity or other side effects. Unfortunately, regulatory authorities around the world tend to be years behind the companies introducing these products. Thus, after sitostanol-ester-containing margarine was already on store shelves in Finland (since 1995) and in some other countries, Johnson & Johnson's McNeil Consumer Healthcare (who bought its international marketing rights) sought initially to market this product in the United States as a dietary supplement, rather than as a food, because supplement ingredients do not have to be tested for safety and more adventurous claims can be made without government approval (6). However, the United States Food and Drug Administration (FDA) advised the company

that it regarded this margarine (Benecol®) as a food product and that the plant stanol esters added to it must therefore be approved as food additives or shown to be "generally regarded as safe". The FDA then reviewed the testing conducted by McNeil and considered that it had no more questions about the product's safety, but that it would be prudent to continue to monitor, through scientific studies, consumers' dietary exposure to plant stanol esters.

A cautionary note

Since it is likely that many new functional foods will begin to appear on the market, the American Dietetic Association (1995) (7) has warned that "As the evidence of the health benefits of functional foods and phytochemicals grows, Americans will be easy prey for supplementation abuse. The public must be convinced that the more appropriate choice would be to increase fruit and vegetable consumption (currently, 11% or less of the population consumes no fruits or vegetables) and to incorporate other foods (in addition to fruits and vegetables) containing beneficial health components as part of varied diet based on the principles of the Food Guide pyramid."

The protection of consumers in Europe may require new regulations and the establishment of organizations similar to the FDA in the United States. For functional foods that expose humans to ingredients at dosages to which they would not normally be exposed, the need to demonstrate safety may mean that it will take years rather than weeks to introduce a new product and that some products may never be introduced. This seems to be a reasonable cost to protect public health. Demonstrating safety will also be in the interest of the manufacturers of functional foods. A functional food that harms a large number of people, with ensuing bad publicity, could result in a public reaction that would damage the marketplace for all dietary supplements. In addition, in the absence of a requirement to prove efficacy or safety, companies are unlikely to invest in research and development with respect to better functional foods because competitors would be able to jump in with no research costs to amortize (8).

In the United States, the Center for Science in the Public Interest (9) has formulated the recommendations that the FDA "require that functional ingredients be proven safe and that label claims be approved by the agency prior to marketing; prevent companies from selling functional foods as dietary supplements or medical foods to escape the FDA regulations for food products; work with the US Federal Trade Commission to develop a consistent policy for claims in advertising and labeling; and require that labels list the amount of functional ingredients contained in a serving and, if appropriate, recommend usage or warning information." These recommendations should also be adopted in other countries.

References

1. Gylling H, Miettinen TA. Cholesterol reduction by different plant stanol mixtures and with variable fat intake. *Metabolism* 1999;48:575—80.
2. Miettinen TA, Gylling H. Regulation of cholesterol metabolism by dietary plant sterols. *Curr Opin Lipidol* 1999;10:9—14.
3. Gylling H, Puska P, Vartiainen E, Miettinen TA. Retinol, vitamin D, carotenes and alpha-tocopherol in serum of a moderately hypercholesterolemic population consuming sitostanol ester margarine. *Atherosclerosis* 1999;145:279—85.
4. Ayesh R, Weststrate JA, Drewitt PN, Hepburn PA. Safety evaluation of phytosterol esters, part 5: faecal short-chain fatty acid and microflora content, faecal bacterial enzyme activity and serum female sex hormones in healthy normolipidaemic volunteers consuming a controlled diet either with or without a phytosterol ester-enriched margarine. *Food Chem Toxicol* 1999;37:1127—28.
5. Weststrate JA, Meijer GW. Plant sterol-enriched margarines and reduction of plasma total- and LDL-cholesterol concentrations in normocholesterolaemic and mildly hypercholesterolaemic subjects. *Eur J Clin Nutr* 1998;52:334—43.
6. Jacobson MF, Silverglade B. Functional foods: health boon or quackery? *BMJ* 1999;319:205—6.
7. Position of the American Dietetic Association: phytochemicals and functional foods. *J Am Diet Assoc* 1995;95:493—6.
8. Zeisel SH. Regulation of “nutraceuticals”. *Science* 1999;285:1853—5.
9. Heller IR, Taniguchi Y, Lobstein T. Functional foods: public health boon or 21st century quackery? In: Silverglade B, Jacobson M, editors. *International Association of Consumer Food Organizations*. Center for Science in the Public Interest, 1999.