

Health Foods and Claims: the Malaysian Experience

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Abstract

A new dimension in the nutrition scene in many developing countries in Asia is the increasing prevalence of diet-related non-communicable diseases, related to the excessive consumption of various nutrients (e.g. fat and sugar) on the one hand and low levels of intake of other nutrients (e.g. complex carbohydrates and fibre) on the other. In Malaysia, for instance, epidemiological data show that rapid socioeconomic development in the country has brought about increasing prevalence of diseases such as obesity, diabetes mellitus, cardiovascular diseases and cancers. The rise of chronic diseases in recent years has brought about an increased interest in "health foods" and nutrient supplements. These foods with alleged health-promoting properties are freely available in pharmacies, medicinal halls and supermarket shelves and through "direct sales". The promotion and advertising of these foods, not infrequently by unqualified personnel, can be described as aggressive. Various foods have been promoted to have particular health properties, some of them claiming to be able to prevent and cure various chronic diseases. Health professionals are concerned with the increasing availability of these foods, particularly the health claims made in association with marketing strategies. National food and drug legislating bodies often have difficulty regulating the sale of these foods. Internationally, the Codex Alimentarius Commission has recently commenced deliberations on a guideline for dietary supplements. This paper discusses some aspects of the "Health food" industry in Malaysia, including the types and forms of these foods and health claims, as well as some efforts by the authorities to regulate the sale of these foods. It aims to highlight the importance of "Health foods" and claims and to stimulate nutrition scientists and health authorities to pay greater attention towards the issue. Some sharing of experiences and collaboration among authorities in different countries in the Asian region is important in order to have greater monitoring and control of these foods.

Introduction

Rapid changes have occurred in the lifestyles and the dietary and health patterns of the populations in many developing countries. These changes may be attributed to the rapid socioeconomic and demographic changes in these countries. There has been a huge increase in the numbers of people moving from rural to urban communities, where striking changes in diet often occur. While some developing countries remain concerned with the problems of hunger and undernutrition, and communicable diseases, in other countries there have been considerable increases in the prevalence of diet-related chronic diseases. WHO (1990) estimated that during the 1970s, mortality from these diseases underwent a relative increase of 105% in tropical South America and 56% in Central America, Mexico and Panama. Similar increases in these diseases are occurring in developing countries in all regions of the world.

The causes of these chronic diseases are complex and include an "affluent" diet of the developed industrialised countries. Such a diet is characterised by an excess of energy-dense foods rich in fat and free sugars, but a deficiency of complex carbohydrate foods (the main source of dietary fibre). The adverse health effects of this diet have become increasingly apparent over the last few decades. Epidemiological data have demonstrated a close and consistent relationship

between the establishment of this type of diet and the emergence of a range of chronic non-communicable diseases including coronary heart disease, cerebrovascular disease, various cancers, diabetes mellitus, gallstones, dental caries, gastrointestinal disorders, and various bone and joint diseases (WHO, 1990).

In Malaysia, similar changes in health patterns have occurred in the country. The overall nutrition situation in the country has greatly improved over the years. Frank nutrient deficiencies are rarely found, although pockets of moderate undernutrition exist in various parts of the country. On the other hand, the rapid socio-economic development in the country has brought about increasing prevalence of diet-related non-communicable diseases such as obesity, diabetes mellitus, cardiovascular diseases and cancers. An analysis of the mortality rates in the country indicates that cardiovascular diseases and malignant neoplasms have become the leading causes of death in the country (Tee and Cavalli-Sforza, 1993). In response to this new dimension in the nutrition scene in the country, the government launched the healthy lifestyle campaign, commencing in 1991 with the cardiovascular diseases.

Admst this changing nutrition scenario in many developing countries and greater awareness of the importance of nutrition among consumers, there is now available a wide variety of "health foods". This paper focuses on the use and misuse of these foods, many of which are nutrient supplements. Existing regulations in Malaysia and international guidelines on the sale of "health foods" are next described. Another focus of the paper is on health and nutrition claims, with examples from Malaysia and international guidelines.

The paper aims to highlight the importance of "Health foods" and claims and to stimulate nutrition scientists and health authorities to pay greater attention towards the issue.

"Health Foods" and Nutrient Supplements

The public is now more health conscious, and in recent years, are pursuing good health through proper nutrition in greater earnest. The consumer is keen to seek knowledge on how to obtain optimum nutrition. There is a great deal of fear amongst consumers towards chronic diseases. Within this scenario, there is now available a wide variety of "health foods" in the market (Tee, 1993). These foods with alleged health-promoting properties are freely available in pharmacies, medicinal halls and supermarket shelves. There are also numerous "direct sale" companies that market their products through a network of sales staff that reach the consumers directly to their homes or work place. There is a large variety of these foods, the majority being various nutrient supplements, particularly several vitamins and minerals. Many of these are frequently advertised in the local press, e.g. multi-vitamins, vitamin C, antioxidant vitamins, and minerals such as calcium, magnesium, zinc, selenium, and chromium.

Vitamins are essential organic substances found in food and are required by man in amounts ranging from micrograms to milligrams per day. All are essential for the normal growth, development, and maintenance of the human organism. The trace minerals are essential inorganic substances that are required by man in amounts that also range from micrograms to milligrams per day.

However, advocates of nutrient supplements are promoting the consumption of high doses of several vitamins for the prevention or treatment of diseases. For instance, there has been a great deal of publicity on the role of various vitamins in cancer prevention, particularly vitamin C (ascorbic acid) and vitamin E. Vitamin C has already received much attention since its usefulness

in high doses to treat the common cold and influenza was proposed some years ago. Vitamin E is highly promoted to prevent or cure a number of degenerative diseases, such as heart disease, muscle weakness, ulcers, balding, cancer, arthritis, diabetes and skin disorders. The best known are the claims related to increased virility and sexual endurance. Vitamin A and carotene are also currently receiving much publicity as possible preventive agents for cancer.

Two particular compounds that have been claimed to be vitamins in human nutrition and alleged to provide a "cure" for cancers are of interest. These are laetrile and pangamic acid, also known as "vitamin B17" and "vitamin B15" respectively. Laetrile has received much publicity in recent years as a cancer cure. It even became a political and emotional issue in the United States. Pangamic acid has been promoted as a dietary supplement to cure cancer and a host of other disorders, and even claimed to be able to inhibit and reverse the aging process.

As a result of such claims, a large number of people are taking mega- (large) doses of these vitamins (especially vitamin C) daily. Such advices are considered to be unsound and may give false hopes to the consumer. Consumers should be informed that when vitamins are taken in such large doses, they act more like drugs than nutrients. Indeed, they should be made aware that vitamins, particularly the fat-soluble vitamins, can be toxic and interfere with various metabolic processes in the body. Even the water-soluble vitamin C, when taken in large doses, has been known to produce adverse effects including increase in serum uric and oxalic acid levels, and the development of kidney stones. Chronic high level intake of some vitamins have also known to create a dependence syndrome, whereby acute deficiency symptoms appear when a person returns to normal doses.

With regards to pangamic acid and laetrile, it has been pointed out that neither substance is a vitamin, according to accepted definition, nor are they effective in the prevention or treatment of cancers or any other condition. They may in fact be toxic. The real tragedy, e.g. of laetrile is that people with essentially curable cancers have refused conventional therapy and have taken this compound until it was too late to benefit from established therapy.

Presently available evidence does not support the promotion of any vitamin supplement as an effective or rational approach to reducing risk of cancers or other diseases in humans, provided the diet is based on a wide selection of foods (Olson, 1993; Tee, 1993). A recent report of a large scale dietary supplementation of over 29,000 male smokers with alpha-tocopherol or beta-carotene showed no reduction in incidence of lung cancer (Heinonen and Albanes, 1994). It must be emphasized that indiscriminate supplementation of large doses of vitamins, especially for extended periods, should be avoided.

Several minerals have also been promoted as having particular health-promoting properties. Various studies are being carried out in experimental animals on the role of various trace elements, especially dietary zinc and selenium in cancer and various diseases. Evidence is still scanty, but there has been abundant speculations, and dietary supplementation of these minerals has been advocated. Selenium supplementation has been advocated as a preventive measure and cure against cancer, heart disease, sexual dysfunction, skin and hair problems and even aging. Promoters of zinc supplementation claim that large doses of the mineral increase virility and improve the sex drive. To date, there is no evidence to suggest that selenium or zinc supplementation offers benefit to healthy people with adequate intakes of these minerals. At the same time, their potential toxicities should be borne in mind.

One of the most popular item in the diet to attract the public's attention today is dietary

fibre, or roughage. It is generally the plant cell wall materials, as found in whole grains, vegetables, fruits and nuts. Fibre is not a nutrient, as it is not available for digestion and absorption by the enzymes secreted by the stomach or intestines. It is known to have a number of effects on bowel function and nutrient metabolism, although the physiological effects of dietary fibre as well as its relation to human health and disease are not well understood.

However, in recent years, fibre has received much attention regarding claims that it can prevent a variety of conditions and diseases, particularly atherosclerosis, cancer of the colon and diabetes mellitus. Most of these claims are based on a comparison of diet and the incidence of disease between people consuming high fibre and low fibre diets. For example, the incidence of colon cancer is said to be high in low-fibre-consuming communities, and low in high-fibre-consuming communities. Various commercial preparations of bran have been marketed for dietary supplementation.

Epidemiological data linking dietary fibre to these diseases are however still limited. Moreover, the composition of dietary fibre is very complex and variable, and much more research need to be carried out. Thus, the role of dietary fibre in susceptibility to, prevention of, or beneficial effects related to cancer and other diseases remain to be established. Nevertheless, publicity and an abundance of speculation on the role of dietary fibre in the prevention of disease have run ahead of the available facts, and the imagination of the lay person has been captured by the belief that fibre is a "health food".

Consumers should consider dietary fibre as being an important part of a well-balanced diet and playing a role in normalizing gut function and stool bulk and consistency and in preventing constipation. And a variety of fruits, vegetables and whole-grain cereal products would provide a variety of fibre to the daily diet.

It is unfortunate that there are physicians and nutritionists who promote the general consumption of these "Health foods" without any investigations into the nutritional status of the consumer. It should be emphasized that before deciding whether a nutrient supplement should be recommended to an individual, a history regarding the adequacy of dietary intake, usual dietary practices, and specific issues of lifestyle must be carefully evaluated. If the individual appears to be not meeting his recommended intake of vitamins and minerals in the diet, an attempt to correct the situation by improving the selection of foods and the pattern of eating should be made before recommending a supplement. For a busy executive who claims to have no time for proper meals, recommending nutrient supplementation will certainly not solve the problem. Consumers should be reminded that a handful of synthetic nutrients will in no way be able to replace good nutrition from the variety of foods and the nutrients available in any one meal. There are many components in foods whose physiological functions in the human body have yet to be identified but are vital to the well-being of mankind.

The term "health food" is also used to describe several other preparations that are supposed to have health-promoting properties. Some of these preparations that have been advertised in the local newspapers include royal jelly, evening primrose oil, starflower oil, garlic, fish oil, lecithin, collagen, garlic etc. Traditional medicinal preparations have been omitted from this list, but many of these preparations are combined with several herbs e.g. ginseng. These preparations have been promoted to have particular health properties, including dissolving fat, improving sexual potency, and even for longevity. The active principles in many of these substances have yet to be identified and their benefits to human health remain controversial.

Regulating Sale of "Health Foods" in Malaysia

Under the Malaysian Food Regulations 1985, there are no standards for "Health foods" as a group of distinct foods. The closest to these foods are several "special purpose foods" covered by regulations 388-393, which include infant formula, canned food for infants and children, cereal-based food for infants and children, low energy food, and formula dietary food.

There are however specific regulations for "nutrient supplements". According to regulation 26, "nutrient supplement" includes any mineral, vitamin, essential amino acid or essential fatty acid which, when added either singly or in combination to food, improves or enriches the nutrient content of food. The nutrients that are permitted to be used as described are listed in Table 1 of the Twelfth Schedule and composed 46 vitamins and minerals, 2 essential amino acids and 2 essential fatty acids. The use of these nutrients are therefore for the purposes of food enrichment or fortification, and Table II of the Twelfth Schedule stipulates the minimum quantity of the nutrient that shall be added in order to claim that the food is enriched or fortified. Regulation 26 (11) further stipulates that no preparation in the form of any vitamin or mineral shall be labelled and sold as food if the largest recommended daily dosage of the preparation as stated on its label furnishes an amount of vitamin or mineral which exceeds the amount specified in Table III to the Twelfth Schedule.

Discussions between the Food Quality Control (FQC) Unit and the Drug Control Authority (DCA) have been carried out to determine whether nutrient supplements and similar substances should be regulated as foods or drugs. A flowchart has been drawn up to assist health officials determine whether a dietary or health supplement is a food or drug. The first step in the flowchart is to examine the form of the product: if it is in pharmaceutical dosage forms (e.g. in the form of an injection, tablet, capsule, lozenges or syrup), the product is classified as a drug (except sugar confectionery, chocolates, artificial sweeteners); if the product is in the form of a powder, granules or a drink, it is identified as a food. The second important step is to check the ingredients contained in the product: if it contains pure forms of single nutrients or combination of nutrients, or if it is a herbal preparation, it should be classified as a drug. On the other hand, if the product is a food or drink base, it can be classed as a food. In addition, 2 types of products which are not in pharmaceutical dosage forms but will be classified as drugs are (a) those which make therapeutic claims, and (b) those containing nutrients in amounts exceeding the "maximum amount permitted daily" as stipulated in the Food Regulations 1985.

If the product is a food as identified by the process outlined above, it should comply with the Malaysian Food Regulations 1985. On the other hand, if the product is a drug, it is governed by the Control of Drugs and Cosmetics Regulations 1984 (Ministry of Health, 1984). Under Regulation 7 of these regulations, no person shall manufacture, sell, supply or import any product unless (a) the product is a registered product, and (b) the person holds the appropriate license required.

Registration of pharmaceutical products have been carried out in two phases. In phase 1, products that should be registered include pharmaceutical products which contain scheduled poison(s) as defined in the Poisons Act 1952. Products registrable under phase 2 are pharmaceutical products which do not contain scheduled poisons. These include the following borderline products which do not contain scheduled poisons:

1. dietary and health supplements in pharmaceutical dosage forms containing singularly or in combination vitamins, mineral salts and other nutrients (e.g. amino acids, etc.).

A product containing added vitamins and/or minerals not in pharmaceutical dosage forms, the quantity of which exceeds the "maximum amount permitted daily" as stipulated in regulation 26(11) of the Food Regulations 1985 as well as those making therapeutic claims.

2. dietary and health products in pharmaceutical dosage forms, other than those containing solely of natural substances of plant or animal origin in the unextracted or crude extract forms

Dietary and health products containing combinations of vitamins, mineral salts or other nutrients with natural substances of plant or animal origin are also registratable under phase 2.

International Guideline on Nutrient Supplements

Recognising the increasing presence and widespread use of nutrient supplements in many countries, the Codex Alimentarius Commission has taken an interest in the subject. The Codex Committee on Nutrition and Foods for Special Dietary Uses, in its 17th Session in 1991, decided to prepare a guideline for dietary supplements. A draft guideline was prepared by Germany (FAO/WHO, 1992) and discussed in detail during the 18th session of the Committee in September 1992. On the Scope and Definition of the guideline, members discussed whether nutrient supplements should be treated as foods or drugs. The Committee agreed that the supplements should be treated as foods within the codex system. Nevertheless, it was also agreed that the matter of whether or not to regulate them as drugs should be left to the discretion of national authorities. A member also expressed the view that if these supplements were not regulated as drugs, they should be at least regulated as foods for special dietary uses.

The meeting discussed in detail the various aspects of the draft, e.g. the vitamins and minerals to be included, the levels of these nutrients, and the structure of the guideline. The meeting requested the German delegation to re-draft the guideline, taking into consideration the deliberations of the meeting as well as recent scientific information on vitamins and minerals. The Committee will continue deliberations on the draft during the 19th Session of the Committee meeting in September 1994.

The guideline should be a useful document for many countries in their own efforts to regulate the sale of nutrient supplements.

Health and Nutrition Claims

There are no elaborate provisions for health and nutrition claims in the 1985 Malaysian Food Regulations. Nevertheless, there are several labelling requirements that are related to health and nutrition claims. For example regulation 18(3) prohibits the description of any food which includes the word "Compounded", "Medicated", "tonic" or "health" or any other words of the same significance. Regulation 26(7) also stipulates that no label on a food shall claim to be "enriched, fortified, vitaminised, supplemented or strengthened" or that the food is a source of one or more vitamins or minerals unless a reference quantity of the food contains not less than the amount of the nutrient in question specified in Table II to the Twelfth Schedule. However, the label on a food to which an essential amino acid or essential fatty acid or both has been added may bear a claim that the food is enriched or supplemented with these nutrients.

There are currently not many food products in the local market making health and nutrition claims. There are however several food products which make claims which can be misleading. One nutrient supplement has advertised its product to be the "art of living younger longer". One green pea snack food has claimed to be a "health food: rich in protein" and another as "no

cholesterol, high fibre, low fat, low salt". A processed guava was labelled as a "health snack". Another snack (a potato chip) has advertised its product to be able to "stay healthy the fun way". A candy imported from a neighbouring country claimed its product to contain "multivitamins". Various health and nutrition claims related to cooking oils have been made, e.g. "no cholesterol", "rich in monosaturates" and "rich in natural vitamin E". Indications are that the use of such claims will increase, since manufacturers may feel that they will have a competitive edge over other brands if they make some health or nutritional claims on their products. It is thus important to monitor the situation and to consider introducing guidelines or legislations on the use of such claims. While health claims on labels may provide consumers with some nutrition information, it is important to prevent abuse and thereby mislead the consumer.

Internationally, the Codex Alimentarius Commission, through the Codex Committee on Food Labelling, had deliberated on a "guideline for use of health and nutrition claims in food product labelling" (FAO/WHO, 1993). The draft guideline defines nutrition claim as *any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value, and to the content of protein, fat and carbohydrates, as well as vitamins and minerals*. Health claim refers to *any representation which states, suggests or implies that a relationship exists between a food or a nutrient or other substances contained in a food and a disease or health-related condition*. Nutrition claims are further divided into 3, namely (a) nutrient content claim is a nutrition claim that describes the level of a nutrient contained in a food (e.g. "source of calcium", "high in fibre and low in fat"); (b) comparative claim is a claim that compares the nutrient levels and/or energy value of two or more foods (e.g. "less than", "more than", "fewer"); and (c) nutrition function claim is a claim that sets out in general terms the nutritional consequences for good health of the intake of a particular nutrient (e.g. "calcium aids in the development of strong bones and teeth", "protein helps build and repair body tissues", "iron is a factor in red blood cell formation"). The draft was discussed in detail in the 22nd (latest) session of the Committee in April 1993. As agreement could not be reached on several items in the draft, particularly regarding the nutrient function claims and health claims, the meeting agreed to retain the draft at step 3 and re-circulate to member countries for further comments.

In the Nutrition Labelling and Education Act (NLEA) enforced several months ago, about 90% of processed foods sold in the United States is required to have nutrition labelling (Wilkening *et al.*, 1994). Under this Act, manufacturers are allowed to make positive claims about nutrient contents in a food. The Food and Drug Administration (FDA) has defined criteria for use of terms such as free, low, lean, extra lean, high, good source, etc. For the first time, food labels will also be allowed to make health claims. The FDA has authorised 8 of such claims for which the link between diet and disease risk is supported by scientific evidence.

Conclusions

Dietary factors may well have important causative and protective roles in various chronic diseases. There is indeed a great deal of research activities on the role of nutrition and diet in these diseases. However, information about specific dietary factors is generally inconsistent or incomplete. Available data are not sufficient to serve as a basis for the recommendation of specific dietary supplements for the prevention or cure of these diseases. Drastic changes in dietary habits or exclusion of individual foods are probably not necessary for the vast majority of individuals. Nutrient supplements are similarly not essential if one is able to have a diet consisting

of a variety of foods. Such supplements should only be considered for individuals in certain physiological conditions or stresses when nutritional needs are increased, e.g. during illness, the elderly, and pregnant/lactating women.

Nutrition science will continue to advance into the 21st century. New knowledge will be gained on the roles of various nutrients in metabolic processes. We will have a better understanding of the role of nutrition in health and disease. However, these facts on nutrition are not likely to change the attitude and beliefs of many people towards "health foods" and the fallacies and misuse of these foods is likely to continue. This is because irresponsible vendors of these foods will continue to misrepresent scientific findings for financial gains.

The challenge facing nutritionists in developing countries is to deal with a situation that is rapidly resembling that in industrialised countries. It is a situation that developing countries cannot afford to be in, as it would be too costly and difficult to control. Developing countries need to deal with the situation now. There has to be concerted efforts to monitor the sale of these foods. Health professionals e.g. nutritionists and medical doctors should be brave enough to tell the truth about these foods. It would be a challenge for us to educate consumers on the appropriate use of nutrient supplements. It would be a challenge for us to impress upon the promoters of nutrient supplements to be more ethical in the sale tactics and employ qualified personnel in the marketing of these products. The sharing of experiences and collaboration among authorities in different countries in the Asian region is important in order to have better monitoring and control of these products.

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