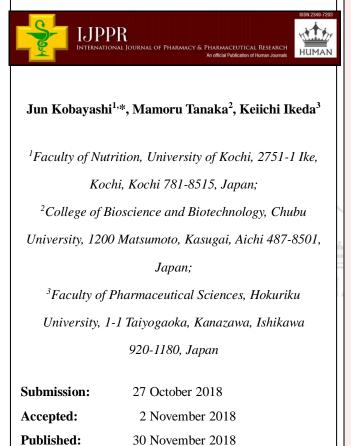
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# Types and Problems for Healthy Foods Distributed in Japan



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**Keywords:** classification of foods for health, health-promoting foods, foods for specified health uses, foods with nutrient function claims, functional foods

## ABSTRACT

In recent years, more foods that are considered healthy are being distributed in Japan. The classification of healthy foods into "foods for specified health use", "foods with nutrient function claims", functional foods and general foods, have different definitions, market positioning, and methods of safety assessment. However, very few general consumers understand the differences between the various types available. Because some consumers think that healthy foods are equivalent to pharmaceuticals, clarification is necessary. In this study, we will describe the differences between these healthy foods, and summarize their status for consumers in Japan.

## **INTRODUCTION**

Humans need to eat food and take in nutrients in order to live. Nutrients are substances necessary for the continuation of human physical functions (maintenance of life), the growth of the body, and the creation of offspring. In general, the term, healthy food, refers to food that is considered to contribute to the maintenance and promotion of health. Until a regulatory system on health-promoting foods based on the Nutrition Improvement Act was established in 1991 in Japan, they were considered as mere foods in legal terms. Although healthy foods can be considered as intermediate between medicines and foods, in Japan, there is no intermediate classification–of healthy food under laws such as the Pharmaceutical Medical Equipment Law and the Food Sanitation Act. Therefore, it is considered that only foods and medicines should be ingested orally.

Despite these legal definitions, Japanese consumers are highly conscious of their health and so are very interested in healthy foods. The difference between the average lifespan and of those leading a healthy life is about 9 years more for men and about 11 years more for women [1], so increasing healthy life expectancy is an important issue in Japan. A healthy lifespan is the period of time during which daily life is not restricted by health problems. Using healthy foods is possibly one means of extending the healthy lifespan. The market size for healthy foods was 660.5 billion Japanese yen (about 7 billion dollars) in 2014 [2] because they can be easily purchased in pharmacies, convenience stores, supermarkets, and by mail order, and are heavily advertised on television and in magazines [1]. However, doubts on how well these products contribute to human health remain, with cases of fraud occurring.

This paper aims to introduce and discuss the current classification and positioning of healthy foods in Japan.

#### Historical background of healthy foods

In Japan, a system for classifying health-promoting foods was established in 1991, after which it became possible for manufacturers and retailers to display information on the health functions of foods meeting standards set by the government. A health function can be thought of as a particular ability to maintain health [3]. Initially, the system started by covering "foods for specified health use" (so-called Tokuho) which had been approved after conducting scientific research. Then "foods with nutrient function claims" containing nutrients

considered to be good for specific health functions were included in 2001. The system then expanded further in 2015 to include "functional foods" where information can be displayed is based on scientific evidence carried out elsewhere. However, food supplements are healthy foods that can supply nutrients, with many of them being treated just as foods. In contrast, in the United States, a system for indicating the efficacy of health foods started in 1994 based on the Dietary Supplement Health Education Law. Since 1999, even when the scientific basis is weak, the effect of the food on health after ingestion is indicated on the food label.

#### Current classification of healthy foods

Table 1 shows how Japanese healthy foods are classified as of 2017. Supplements are substances that provide nutrients such as vitamins or extract from animals and plants. They are classified as foods, not medicines, and are partly included as health-promoting foods. In Japan, foods for specified health use have to receive individual approval from the government (the Ministry of Consumer Affairs) regarding how their beneficial effects compared with presently accepted healthy foods. This procedure is followed to the strictest standards. However, the procedure for foods is different from that used for medicines, because the healthful effects allowed to be listed are limited to those shown in Table 2. These are not intended to diagnose, treat, or prevent diseases: if any such claims were displayed, it would be a violation of the law. Foods with nutrient function claims and functional foods, Japan only accepts notification of the claims and does not examine the safety and functionality of the food so the manufacturer or retailer is responsible for guaranteeing the healthful effect [4].

	Pharmaceuticals (Broad)		Foods			
	Pharmaceuticals Quasi-		Health-promoting foods			General
	(Narrow)	drugs	Foods for	Foods	Functional	foods
			specified	with	foods	(including
			health use	nutrient		so-called
			(Tokuho)	function		healthy
				claims		foods)
Defining Japanese law	Pharmaceuticals Medical Health Pro			notion Act / Food Sanitation		Food
	Equipment Law		Act			Sanitation
						Act
Indication of efficacy				Only	Possible by	Not
	Can only be authorization by the term of the second	•	prescribed nutritional	notifying the national	allowed	
				functions allowed	authority	
Limits to sales locations	Pharmacy and		1			
	drugstores only (with	Available				
	exceptions)					

## Table 1. Classification of pharmaceuticals and foods in Japan.

## Differences between medicines and healthy foods

Table 2 shows some of the effects claimed for these healthy foods through strengthening and increasing nutritional ingredients, and through the consumption of a large number of components originally contained in foods to maintain health, such as vitamin preparations. Therefore, a healthy food is considered to be a product containing substances that are ingested even in small amounts. In addition, the "Health function" described above would be a gentle action, unlike a medicinal effect. These foods can be thought of as foods with effects strongly thought to be efficacious through scientifically clarifying their ingredients but the reasons for their efficacy are not known, like traditional folk medicine. What a healthy person without disease has to ingest to maintain health can be considered a healthy food, not one necessarily taken by a sick person for therapeutic purposes. A healthy food would have no basis for curing a disease. If a poor physical condition occurs because of a disease, it would not be natural to think of treating it with healthy foods. Pharmaceuticals are substances that can cure diseases in many patients, but also involve certain risks. Consumers must therefore

properly understand that healthy foods are positioned differently from pharmaceuticals.

Content displa	yed (with detailed	Representative components		
classification)		involved		
Tones stomach		Oligosaccharides, lactic acid bacteria, dietary fiber, indigestible dextrin, etc.		
Helps to	Improves excretion	Indigestible dextrin, etc.		
maintain good excretion	Improves the intestinal environment	oligosaccharide		
Helps to	Increases absorption of calcium	Vitamin K <sub>2</sub> , casein phosphopeptide, etc.		
maintain bone health	Helps to maintain levels of calcium in the body	Soy isoflavone		
	Increase bone density	Milk-derived basic protein		
	Keeps teeth healthy and tough	Xylitol, calcium monohydrogen phosphate, etc.		
Helps to keep	Helps to prevent tooth decay	Fluorine, maltitol, etc.		
teeth healthy	Normalizes mouth environment	Phosphorylated oligosaccharide calcium		
Suitable for peo	ple with elevated blood	Lactotripolypeptide, sesame		
pressure		peptide, etc.		

Table 2. Examples of information displayed on foods for specified health use

## Problems of healthy foods in Japan

Fig. 1 shows that the number of consumers complaining of health hazards due to healthy foods has increased in recent years [5]. It has been reported that commodities that were certified as health-promoting foods (foods for specified health uses) contained more glycitol fatty acid esters than other commercial edible oils in Japan. Glycitol fatty acid ester is a substance that can possibly be converted into the carcinogen, glycitol, in the body [6]. Therefore, its distributor refrained from selling it and notified its cancellation as a food for specified health use. There have also been several consumer reports that many healthy foods have not had their declared health function confirmed [7]. In some cases, the body fat

increased despite drinking tea that was claimed to have the effect of helping to reduce body fat. It was found that the data on the food's functionalities submitted to the Minister of Consumer Affairs was biased as it was based only on people with obesity. It was also pointed out that the effect could not be confirmed for those who were young or not obese by external replicating examinations. It is known that consuming healthy foods containing St. John's Wort (*Hypericum perforatum*) can attenuate the effects of pharmaceuticals being taken [8]. This shows the need for consumers to be aware that there can be synergies and additive effects combined with the effects of pharmaceuticals.

It is also clear that the term "Tokuho" has had a positive influence on consumer purchasing behavior in Japan, and its degree of influence has been high [3].

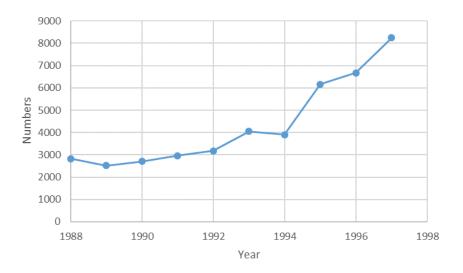


Fig. 1. A number of complaints regarding healthy foods in Japan

Source of data: National Lifestyle Center. Figure adapted from https://matome.naver.jp/odai/2139564356955052901/2139564862460008303

#### Our opinion on healthy foods distributed in Japan

We feel that that the amount of material publicizing the introduction of healthy foods based on printed paper media, such as magazines and newspapers, may not change very much, but the amount using digital media such as TV commercials is dramatically increasing, especially with the advent of more TV channels with 24-hour broadcasting of TV programs in Japan. In other countries, the range of media output, such as television programs, may not be the same

as in Japan. In Japan, not only doctors and university professors but also famous athletes and actors have provided their "individual opinion" in television commercials that health conditions can be improved by ingesting healthy foods. But these are merely words spoken by a person hired by a content management company to suggest these are the actual feelings of the performer and so persuade the viewer to become a future consumer of the product. As a result, there are concerns that consumers may be misled by this incorrect knowledge. Attention must also be paid to the views of manufacturers and consumers' thinking that the efficacy of a product is superior if its price is high. Consumers, who are concerned about obesity, are always on a diet, have busy jobs and lack enough sleep, might think that healthy foods are magical items offering an easy way to maintain health. However, examining the ingredients properly will reveal that most of the nutritional components of healthy foods were present in the original foods, thus hardly justifying the high costs of these healthy foods. In Japan, healthy foods providing nutritional advantages certainly exist, such as garlic and soft-shelled turtle. Consumers need to choose the kind of foods they really need with regard to their physical condition, diet, and lifestyle. In our opinion, we should first review the individual's lifestyle, such as the content of meals and amount of exercise, then consider the use of healthy foods later. Even though healthy food is not a medicine, if it has efficacy (this should be obvious), its overconsumption may produce side effects. However, even if ingested in large amounts, its preventative effect will increase or the health condition will not change. Consumers should also be careful when it is not clear what kind of harm is caused by an overdose because sometimes it has not been examined [9]. When using healthy foods, it is necessary to always check and keep to the standard daily amount and method of ingestion. For Tokuho products, it is mandatory to display the phrase "Eating habits are based on consuming staple foods, main dishes, and side dishes, and paying attention to the balance of the meal". Overall, it is important to review the individual's daily diet then decide whether to rely on healthy foods after consuming a balanced diet [10].

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