Positive and Negative Aspects of Food with Health Claims in Japan

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Summary
Developments in food science and technology have accelerated the production and availability of health foods. Although consumers may acquire health benefits from some products, they may also suffer adverse health effects and economic losses. Unlike medicines, which are administered by health professionals, foods are chosen directly by the consumer and can be used at their own discretion. Food labeling plays a major role in providing consumers with proper information when choosing the desired products; however, the food labeling system is complex and inadequately understood by consumers. Moreover, there are some products that do not follow food labeling laws and contain ingredients that have not undergone proper effectiveness and safety evaluations. With the increasing popularity of health foods, it is becoming more important to ensure that they are effective and safely used. The biggest concern is that some consumers may mistake health foods for medicines that can cure or prevent diseases. The main reason that consumers are confused and misled is due to the vast amount of information that is available. This paper provides an overview of the following four approaches that we have taken in order to develop countermeasures against health foods being used improperly by consumers: (1) conducting a survey of actual health food use; (2) collecting data on adverse events suspected to be caused by health foods, and evaluating the causal relationship with methods suited to investigating health foods; (3) examining the safety of natural ingredients used in health foods; and (4) constructing an online database that compiles information on the safety and effectiveness of health foods and/or ingredients, and sharing such information with consumers and health professionals.

Key Words
health foods, health claims, consumer, safety, information

Recent developments in food science and technology have revealed various functionalities of the foods we eat and their impact on our health. Foods that contain or are enriched with functional ingredients are generally recognized as health foods or functional foods. These foods are produced based on evidence from in vitro studies, animal studies, and human studies with small sample sizes. Consumers have a strong desire to take advantage of health foods and expect them to improve and maintain their health, and in some cases, even prevent disease. Consumers tend to think that health foods work like medicine, yet are as safe as ordinary foods, especially those made with natural ingredients. This perception is not always true and although results are obtained from experimental data, the health benefits are often exaggerated and details such as a lack of data regarding the digestion and absorption of ingredients and the intake dose ranges for effectiveness and safety are ignored. Consequently, the effectiveness and safety of health foods are often overestimated. Unlike medicines, which are administered under the control of health professionals, health foods can easily be purchased and used by consumers at their own discretion. Thus, health claims on food packaging play an important role in providing consumers with correct information. Although the progression of globalization has lead to a variety of food products being distributed worldwide, health claims are governed by laws established in each individual country.

In this paper, we provide an overview of the current status of health foods and the health food labeling system in Japan, clarify the advantages and disadvantages of current health food claims, and introduce countermeasures to prevent problems related to health foods.

Overview of Current Health Food Claims in Japan

In Japan, various terms are used for foods that claim to have beneficial effects on health. Under the Japanese Health Promotion Act, foods that have been approved to state on the label that they promote and maintain health are known as “Food with Health Claims” and are divided into two main categories: “Food with Specified Health Uses” (FoSHU) and “Food with Nutrient Function Claims” (FNFC).

FoSHU are foods that claim to have specified physiological effects on the human body, contain functional ingredients for health, and have been approved by the Consumer Affairs Agency to explicitly state on their label that they have physiological effects on the human body. At present, FoSHU are further divided into four categories: FoSHU, Standardized FoSHU, Reduction of Disease Risk FoSHU, and Qualified FoSHU. The effectiveness and safety of FoSHU are evaluated based on the final product, not individual ingredients, and these products are designed to improve dietary habits and to contribute to health maintenance and enhancement. More detailed information on FoSHU is available on the Consumer Affairs Agency website (http://www.caa.go.jp/en/index.html).
FNFC are labeled by the functions of the nutrients (vitamins and minerals) they contain, which have accumulated evidence for their effectiveness and safety in humans, and are designed to be taken as dietary supplements. FNFC must meet the established standards and specifications for the minimum and maximum levels of nutrients per daily portion usually consumed. In contrast to FoSHU, FNFC are freely manufactured and distributed without any approval from the national government.

In April 2015, another Food with Health Claims labeling category is introduced. Under this new category, manufacturers can state that their food has certain health benefits as long as the claims are substantiated by a body of scientific evidence that meets the system's guidelines. The onus is on the manufacturer to collect scientific evidence and prove the product's health claims. However, manufacturers will also be required to insert a disclaimer on their labels stating that the product is not officially endorsed by the government, notify the Consumer Affairs Agency before putting the product on the market, and make the scientific information regarding the product's safety and effectiveness available to the public.

In addition to Food with Health Claims, there is another health food category, "Food for Special Dietary Uses" (FOSDU), which was established in 1991. FOSDU refers to foods that have received approval to explicitly state on the label that they are appropriate for special dietary uses and include medical foods for the diseased, formulas for pregnant and lactating women, infant formulas, foods for elderly persons who have difficulty masticating or swallowing, and FoSHU. FoSHU are a subcategory of FOSDU for the product approval process, and are also categorized as Food with Health Claims. FOSDU are slightly different from FoSHU and FNFC in that the labels for these foods are permitted to include a medical aim and that they are intended to be used under the advice of a health professional such as a medical doctor or registered dietitian.

Foods other than FoSHU, FNFC and FOSDU are not allowed to state any health promotion or maintenance effects or special dietary uses on their labels, and are regarded as so-called functional foods or health foods. The term “health food” currently has no legal definition and for many years has been used as a generic term for any food that has alleged health benefits. The actual status of so-called health foods available on the market is not known because the manufacturers of these products are not required to register with or receive approval from government. However, there seem to be many more health foods than FoSHU with government approval available on the market.

Possible Countermeasures for Issues Related to Food with Health Claims

FoSHU and FNFC are both merely foods that have weak physiological effects, and can thus be chosen directly by the consumer without the advice of a health professional. However, some consumers expect such products to have the same effects as medicine (1). FoSHU should be used to improve dietary habits and lifestyle, and FNFC should be used as vitamin and mineral supplements if habitual intake levels are lower than the recommended levels. Our survey of FoSHU usage showed that only consumers who appropriately referred to product labels and adjusted their lifestyle accordingly noticed the beneficial effects of FoSHU (1). Our survey also showed that FNFC users seemed to have high health awareness but did not use the appropriate amounts of FNFC to make up for the vitamins and minerals they did not obtain from their ordinary staple foods. Inappropriate use of FNFC was clearly observed in the case of folic acid. The labels of FoSHU containing folic acid are permitted to list reduced risk of neural tube defects in fetuses and those for FNFC containing folic acid are permitted to list nutrient functions. Many pregnant women in Japan start taking folic acid supplements after they find out they are pregnant, which is too late to reduce the risk of neural tube defects (2, 3). Another inappropriate use of FNFC was observed in preschool children who have to learn balanced eating habits from staple foods (4). These surveys revealed issues related to food with health claims that need improvement.

It is critical to avoid health hazards and promote the appropriate use of health foods. All foods have adverse effects depending on the amount consumed; therefore,
we must inform consumers who are sensitive to health damage about the kind and amount of products that may cause adverse health effects while taking their specific characteristics and intake dosages into consideration. It would be helpful to publically identify any inferior health food products that cause adverse events. Recently, we proposed a constructive system for collecting case reports of adverse events suspected to be caused by health foods and evaluating the causal relationship between the adverse events and the foods (5, 6). This system might be useful for rapid administrative action to prevent adverse events and to secure safety not only in so-called health foods, but also in Food with Health Claims that follow government regulations. Consumers perceive natural ingredients as safe and do not recognize the risks of simultaneously consuming health foods with medicines. When considering adverse reports, we tried to examine the safety of natural ingredients, in particular herbal ingredients, used in health foods (7, 8).

The most important issue related to health foods is the transfer of accurate information so that consumers do not misunderstand the nutritional and health benefits of Food with Health Claims. As a countermeasure, we have constructed an online database (https://hfnet.nih.go.jp/) that compiles reports of the safety and effectiveness of health foods and their ingredients in order to share information with consumers and health professionals. Our online database promotes consumer education and communication between health professionals and consumers. An outline of the database is shown in Fig. 1.

**Conclusion**

A variety of foods claiming beneficial effects are distributed worldwide. Health claims for food are directed towards consumers and should therefore be correctly labeled so that consumers know how to use them safely and effectively. If foods with health claims are used properly and effectively, they can contribute to the maintenance and promotion of health in the general population, and in turn, the reduction of medical expenses. The understanding and cooperation of all concerned parties are necessary to achieve these goals.

**REFERENCE**

1) Chiba T, Sato Y, Nakainishi T, Yokotani K, Karino T, Suzuki S, Umegaki K. 2014. Inappropriate application of food for specified health uses. *Nippon Eiyo Shokuryo Gakkaishi (J Jpn Soc Nutr Food Sci)* **67**: 177–187 (in Japanese).

2) Sato Y, Nakainishi T, Chiba T, Yokotani K, Ishinaga K, Takimoto H, Itoh H, Umegaki K. 2013. Prevalence of inappropriate dietary supplement use among pregnant women in Japan. *Asia Pac J Clin Nutr* **22**: 83–89.

3) Sato Y, Nakainishi T, Chiba T, Umegaki K. 2014. Attitudes of pregnant Japanese women and folic acid intake for the prevention of neural tube defects: a nationwide Internet survey. *Nihon Kosho Eisei Zasshi* **61**: 321–332 (in Japanese).

4) Sato Y, Yamagishi A, Hashimoto Y, Virgona N, Hoshiyama Y, Umegaki K. 2009. Use of dietary supplements among preschool children in Japan. *J Nutr Sci Vitaminol* **55**: 317–325.

5) Umegaki K, Yamada H, Chiba T, Nakainishi T, Sato Y, Fukuyama S. 2013. Information sources for causality assessment of health problems related to health foods and their usefulness. *Shokuhin Eiseigaku Zasshi (J Food Hyg Soc Jpn)* **54**: 282–289 (in Japanese).

6) Ichimaru K, Ide K, Ono A, Kitagawa M, Narushima D, Matsumoto K, Umegaki K, Yamada H. 2013. Modification of a dendritic algorithm for evaluation of causal relationships of adverse events with health food. *Jpn J Clin Pharmacol Ther* **44**: 405–410.

7) Taki Y, Yokotani K, Yamada S, Shinozuka K, Kubota Y, Watanabe Y, Umegaki K. 2012. Ginkgo biloba extract attenuates warfarin-mediated anticoagulation through induction of hepatic cytochrome P450 enzymes by bilobalide in mice. *Phytotherapy* **19**: 177–182.

8) Yokotani K, Chiba T, Sato Y, Taki Y, Yamada S, Shinozuka K, Murata M, Umegaki K. 2012. Hepatic cytochrome P450 mediates interaction between warfarin and Coleus forskohlii extract in vivo and vitro. *J Pharm Pharmacol* **64**: 1793–1801.