Trends in the Development of Foods for Specified Health Uses

Japan and Its Challenges

It is 18 years since the regulatory system of health food, the Foods for Specified Health Uses (FOSHU) came into force in Japan in 1991. However, the comprehensive law specifying and defining ‘supplements' has not yet been established, except for FOSHU, which is only the system permitting health claims for ‘supplements', whereas the United States (US), European Union (EU), and several other Asian countries such as Korea and China have enacted laws specifically regulating supplements. In this paper, recent trends of the development of FOSHU in Japan and some of the key issues of the FOSHU system are discussed.

Outline of FOSHU System

Functional claims for both foods and food ingredients are permitted for Food for Special Dietary Uses (FSDU) and the Foods with Health Claims (FHC) according to the Health Promotion Law in Japan. FSDU, for which a preceding regulatory system was introduced in 1952, is a system with allowed claims, which was established in 1973 to regulate foods especially necessary for persons who are positioned in particular categories such as patients, infants, pregnant women, nursing mothers, etc. FOSHU was at first established as a part of FSDU. While FSDU is for patients and other people who fall into the particular categories, FOSHU is for the foods intended to be used by healthy people with the aim of keeping and promoting health based on the function of respective food ingredients.

Initially one of the important requirements for the approval of FOSHU was the product form, which was taken as conventional foods and not in the form of tablets and capsules. On the other hand, the form of tablets and capsules has been an essential criterion for defining dietary and food supplements in the US and EU respectively. Concomitantly, the health claims have been permitted for such supplements both in the US and EU. In Japan, the establishment of a law
specifically for supplements was discussed extensively. Through the discussion, the Ministry of Health, Labour and Welfare (MHLW) decided in 2001 to permit the adoption of shapes of tablets and capsules as FOSHU products. Simultaneously, the MHLW also decided to introduce another regulatory system for the new category of foods, known as Foods with Nutrient Function Claims (FNFC), which was composed of 12 vitamins and five minerals as nutrients and which was permitted to claim particular nutrient functions determined by the MHLW.

![Webinar Image]

Then, the new regulatory category of foods, called Foods with Health Claims (FHC) consisting of FOSHU and FNFC, was established by the MHLW. The positioning of FOSHU is illustrated in figure 1.

**Requirements for the Approval of FOSHU**

The approval of FOSHU is given to a finished product but not to a food ingredient. To acquire FOSHU approval, data regarding efficacy and safety of the product and the crucial ingredient of the product related to the claim for health-related uses are required to be submitted. After evaluation of the data from point of view of scientific evidence, the health-related claim is determined by the MHLW. The essential requirements for acquiring the approval of FOSHU products are listed in table 1.

The assessment of the safety of a product is carried out by the Food Safety Committee which is the organisation for the risk assessment of foods and is established by the Cabinet Office, while the efficacy of the product is evaluated by the special committee established by the MHLW. Finally, the product is examined by the Pharmaceutical Affairs and Food Sanitation Council of the MHLW in accordance with the assessment of safety and efficacy, and the Minister of Health, Labour and Welfare grants an approval to the product.
Various data and documents including a randomised placebo controlled clinical trial (RCT) are necessary for obtaining a FOSHU approval and selling such FOSHU products. Thus, it takes a long period of time and requires a huge amount of developmental cost to launch FOSHU products into the marketplace and consequently, products approved as FOSHU did not exceed 500 in the first 13 years following establishment of the system. In 2005, the MHLW introduced two subcategories into the framework of the previous FOSHU system, that is, Qualified FOSHU and Standardised FOSHU, for the relaxation of the requirements of the FOSHU system. The purpose of introducing the subcategories is to make it easier for applicants to obtain approvals. In addition, the disease risk reduction claims were simultaneously permitted for the existing FOSHU products (but not for the Qualified and Standardized FOSHUs) under limited conditions. The disease risk reduction claims are currently limited to calcium for the reduction of risk of osteoporosis and folic acid for the prevention of the risk of neural tube defect. The daily intakes of calcium and folic acid must be in the ranges of 300 to 700 mg and 400 to 1,000 μg, respectively, as conditions for the permission.

To approve products under the FOSHU system, the MHLW requires the RCT to be at a less than 5% significance level and the elucidation of the mode of action of the crucial ingredient, as conditions for the approval. By contrast, the approval of the Qualified FOSHU requires an RCT at a P-value less than 0.1, while the clarification of the mode of action of the crucial ingredient is not mandatory. Further, a placebo controlled clinical trial other than RCT is also acceptable for the approval, if the mode of action of the crucial ingredient is explained. The Qualified FOSHU is required to express a disclaimer on the label, such as "This product contains XXX, but the scientific evidence of the efficacy is not established. However, this product is suggested to be appropriate for YYY health condition." Differences in criteria between existing and Qualified FOSHUs are illustrated in table 2.

The Standardised FOSHU is approved if the following criteria are fulfilled,

- over 100 kinds of products with the same functional claim have been permitted;
- such FOSHU products have been distributed for more than six years and more than two companies have been granted approvals in the same category of health-related claim.

Up to now, a claim such as "maintaining good gastrointestinal condition" is only permitted as Standardised FOSHU for nine different crucial ingredients. Such ingredients of the Standardised FOSHU are listed in table 3.
Trends in the Development of FOSHU

As of the end of March 2009, a total of 847 products have been approved, as shown in table 4. A trend in development of FOSHU products, shown in figure 2, demonstrates that a majority of products are to be found in the category of the health-related claim, ‘maintaining gastrointestinal condition’ at an early stage of the introduction of the FOSHU system. On the other hand, the ratio of claims other than the gastrointestinal condition has substantially increased compared to several years ago and such claims comprise about 50% of the recently approved FOSHU products in the marketplace. The numbers of products in the respective FOSHU categories are shown in table 5. Disease risk reduction claims which are permitted by the MHLW were concentrated on the use of calcium for osteoporosis. A product claiming the prevention of the neural tube defect with folic acid has not yet been applied for by any company. From the point of view of types of foods, the major portion is represented by beverages, which comprise 60% of the total approved products, such as refreshing drinks, powdered soft drinks, dairy beverages, lactic acid drinks, etc.

From the beginning of January 2007 to the end of March 2009, 290 products were approved, as listed in table 6. Among the 290 products, 79 were existing FOSHU and 15 different crucial ingredients have been adopted, but only four were novel ingredients, which are L-arabinose (blood sugar level), β-conglycinin (serum triglyceride level), flavonoids extracted from Luobuma (Apocynum venetum L.) leaf (blood pressure) and isoleucyl-tyrosine (blood pressure). The major ingredients continued to be indigestible dextrin and mannooligo-saccharide which had been widely used in previous FOSHU products.

Key Issues of the FOSHU System

FOSHU is an approval system of products by the MHLW, based on evidence of safety and efficacy. Thus, consumers understand the efficacy of a product from its health-related claim on the label, encouraging them to purchase the product with confidence that it is safe. In view of evidence for safety based on submitted data and documents, it is conceivable that a product permitted under the FOSHU system is highly safe to ingest. However, it is an enigma that the total number of FOSHU products approved does not exceed 850 even though 18 years have passed since the introduction of the system. The market size of FOSHU products turnover had been growing steadily until 2007, but the growth almost ceased, showing a decline in the market size as observed after 2008. The market size of the products at the peak reached about US$ 7 billion in 2007. Against the above background, the
following points are raised for consideration.

- The expansion of a further range of functional claims: The Pharmaceutical Affairs Law (PhAL) prohibits foods from making the medicinal as well as structure function claims, in Japan. FOSHU is an exception to the PhAL for making the structure and function claims possible. The scope of such claims is now limited to eight functional categories. This situation discourages the food industry from developing new products containing new substances with new categories of functions, such as anti-fatigue and immune-activating functions.
- Time and cost necessary for the development of FOSHU: The approval of FOSHU requires voluminous data and documentation to scientifically substantiate safety and efficacy, as shown in table 1. Then, cost for the development and obtaining approval of a new product may exceed US$ 1 million and time needed for the approval after submission of data may range from two to three years. The difficult and costly process of obtaining the approval prevents most of the companies from developing products containing innovative ingredients and directs the interest of the company towards developing me-too-FOSHU, in other words, Standardised FOSHU. Most of the companies are reluctant to submit a product for approval as a Qualified FOSHU, thus as a result, only one product has been permitted under the Qualified FOSHU system up till now.
- Product form and functions of FOSHU: FOSHU approval is essentially based on the outcome of the RCT. In the study, the test substance is administered to subjects at regular intervals, such as three times a day, for at least one to three months. However, most of the products approved by the MHLW are distributed in product forms such as beverages, soup, jelly, chewing gum, etc. Foods with all of these forms are generally taken as personal preference, but not as foods for which some health-related function can be expected. In other words, it is fairly difficult to expect the appearance of the function demonstrated by the RCT, because these foods are not taken under the same condition as the RCT. This raises a question as to whether the above mentioned forms are appropriate for FOSHU, as the consumer expects that the efficacies of such products will be practically exhibited as observed in the RCT.

Other problems:

- (1) The FOSHU system requires products containing a single crucial ingredient. Accordingly, it is actually demanding that to acquire the approval of a product containing substances which consist of a wide variety of ingredients, for example, in herbs themselves or extracts from natural resources.
• A disease risk reduction claim is decided by the MHLW based on the concrete evidence for substantiation and then is only permitted for existing FOSHU products. On the other hand, a product with almost the same composition of ingredients and/or the same formula as that of a product claiming the disease risk reduction is distributed without claiming any efficacy, because the product is not approved as FOSHU. Therefore, in the market, it is possible that there can be similar, if not the same, two products, with one claiming disease risk reduction and another not, existing together. Thus, consumers are compelled to accept the ambiguous situation and get confused when choosing products. How do consumers understand the efficacies of such products without claims? It is preferable to permit a claim for disease risk reduction for any product if it contains an appropriate content or concentration of the ingredient for which the MHLW permits the claim, and it meets the condition required by the MHLW.

The recent trend of FOSHU products and key issues of the FOSHU system are summarised in this paper. Though health claims are allowed based on the scientific evidence, similar to those in the US and EU, the expansion of a further range of claims for FOSHU than already present in Japan is currently not expected. Notable discrepancies in regulations between Japan and both the US and EU lead to more comprehensive and serious discussions which are not avoidable in Japan if an international consensus of regulation of supplements is to be attained.

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