Current Marketplace for Probiotics: A Japanese Perspective

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In Japan, probiotics are available as both foods and drugs. Unlike in the United States, probiotics have a long history of cultural acceptance and safe use in Japan. Sales are booming, which may reflect the inception of the regulatory category “foods for specialized health use” (FOSHU), which permits labeling with claims that describe health benefits. A total of 65 probiotic products, containing 16 different strains, are listed among the 579 FOSHU products. Since the US market for probiotics is still small, it has substantial room to grow.

In Japan, fermentation using various microorganisms is a traditional method to produce sake (wine made from rice), miso (soybean paste), natto (fermented soybean), pickles, and many other products. Fermented dairy products, which were reintroduced to Japan ∼300 years ago after an extended absence, are also quite popular [1]. In the early 1990s, Japan established the regulatory category “foods for specialized health use” (FOSHU), which permits labeling with health claims on foods that meet specific requirements for safety and efficacy [2]. As of 1 September 1991, to be called “FOSHU,” products must be approved by the Japanese Minister of Health, Welfare, and Labor. Products containing ingredients identical to those in approved products must still undergo this process. The categories of claims include blood pressure, cholesterol, triglycerides, blood sugar, bone minerals (especially calcium), and dental health.

Recently, Japan has witnessed a significant increase in the market for health foods, including FOSHU products, which has outpaced sales of over-the-counter (OTC) drugs. In 2005, the Japan Health Food and Nutrition Food Association estimated the Japanese market for probiotics at US$5.3 billion, up from $1.12 billion in 1997. As of 27 February 2006, a total of 579 FOSHU products have been approved, including 65 probiotic products containing ≥1 of the 16 approved bacterial strains: Lactobacillus rhamnosus GG, Bifidobacterium longum BB536, Lactobacillus delbrueckii subsp. bulgaricus 2038, Streptococcus salivarius subsp. thermophilus 1131, Lactobacillus casei Shirato, Bifidobacterium breve Yakult, Bifidobacterium lactis FK120, B. lactis LKM512, Lactobacillus acidophilus CK92, Lactobacillus helveticus CK60, L. casei SBR1202, Lactobacillus gasseri SP, Bifidobacterium SP, L. casei NY1301, Lactobacillus LC1, and B. lactis Bb-12 [2, 3].

In recent years, Japan has undergone regulatory reform. One of the driving forces behind these changes has been the country’s rising costs of health care [4]. Ward and Piccolo summarized the current situation by noting that, “[l]ike most industrialized countries, Japan is faced with a rapidly aging population and a declining birthrate” [5]. In 2005, people aged ≥65 years represented 19.9% of Japan’s population; however, this segment is predicted to increase to 26.0% by 2015 [6]. The increase in elderly persons combined with Japan’s stagnant and slow economic growth are creating a financial crisis for the country’s health care system [5].

Government deregulation of some OTC drugs has been used as a means to reduce health care costs. Some of the OTC drugs with well-established safety records have been reclassified as the category of “quasi-drugs” or as functional foods. These products are no longer limited to being sold at drug stores and pharmacies but can be sold anywhere, including convenience stores,
health targets for probiotic FOSHU marketed in Japan include gastrointestinal conditions, immunity, allergy, cold and influenza-like symptoms, cholesterol levels, blood pressure levels, and diabetes. Recent correspondence with Japanese authorities highlights the current and future directions for probiotics in Japan (Japanese Regulatory Authority, personal communication):

1. Probiotics (lactic acid–producing bacteria) are used as medicines and can be used as foods without medicinal claims.
2. As foods, probiotics have no specific restrictions. However, fermented milk or lactic acid drinks are required to have a lower limit of lactic acid bacteria.
3. If probiotics are marketed as foods, efficacy claims are prohibited on the labeling. To make claims about efficacy, one must obtain special permission from the Ministry of Health and Welfare for the product to be considered FOSHU, for which substantiation of efficacy and safety is mandatory.
4. Good manufacturing practices are required for drugs but not for foods.

On the basis of the Japanese experience, there are issues that the United States will need to address with regard to probiotics. Good manufacturing practices, including regulatory audits, should be required for probiotics. Testing should address stability and cell viability, which are important not only for shelf-life determination but also for efficacy. Cell viability is determined during stability testing, and numbers of viable cells should be included on the label, reflecting the numbers at the time of consumption, not at the time of manufacture. Because probiotics exert their effects through the secretion of substances such as vitamins and bacteriocins, viable-cell counts reflect this capacity. The source of the cell line is also important. It may affect how the strain implants in the luminal epithelial cells of the human intestinal tract, which can, in turn, influence the probiotic efficacy. Efficacy should be presented in scientific publications.
To date, Japan has been the global market leader in probiotics. Although safety considerations remain a concern of the US medical and scientific communities, most probiotics sold today as FOSHU in Japan and as foods or dietary supplements in the United States and Europe have a long history of safe use. With more education about probiotics, in conjunction with new scientific findings and changing consumer demands and social attitudes, the US market, currently estimated at $700 million, is poised to expand [21].

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