

Dietary Supplements in Japan

International Business Strategies

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SUMMARY

Japan represents a challenging, but significant market for U.S. dietary supplements companies. American firms have captured roughly a \$500 million share of Japan's \$7.5 billion annual market for these products. Reflecting a trend in recent years of modest market openings achieved through eased regulatory restrictions on dietary supplements, U.S. sales in Japan have been increasing and were up about 5% in 2000.

With per capita consumption of dietary supplement by Japanese consumers still only about one-sixth the level found in the United States, the potential for continued growth in this market is enormous, especially as Japan's aging population turns increasingly to preventative nutritional and healthcare measures. The range of supplement products being marketed in Japan is quite extensive, with over 100 separate products achieving annual sales of at least 500 million yen (US\$ 4.67 million @107 yen/US\$).

Despite a number of encouraging market trends, the regulatory environment for nutritional supplements in Japan remains opaque and cumbersome. Many products freely sold in others markets must be reformulated before they can be sold in Japan. End of summary.

Japan – Fast Facts

Geography

Area: 377,864 sq. km. (145,902 sq. mi.); slightly smaller than California.

Cities: *Capital*--Tokyo.

Other cities--Yokohama, Osaka, Nagoya, Sapporo, Kobe, Kyoto, Fukuoka.

Terrain: Rugged, mountainous islands.

Climate: Varies from subtropical to temperate.

People

Nationality: *Noun and adjective*--Japanese.

Population (2000): 129.9 million.

Population growth rate (2000): 0.18%.

Ethnic groups: Japanese, Korean (0.6%).

Religions: Shinto and Buddhist, Christian (about 1%).

Language: Japanese.

Education: *Literacy*--99%.

Health (1999): *Infant mortality rate*--3.4/1,000. *Life expectancy*--males 77 yrs., females 84 yrs.

Work force (64 million, 2001):

Services--23%; *trade, manufacturing, mining, and construction*--56%; *agriculture, forestry, fisheries*--6%; *government*--3%

Economy

GDP (2000): \$4.7 trillion.

Real growth rate (2000 est.) 0.9%

Per capita GDP (1999): \$25,170

Purchasing Power Parity Basis

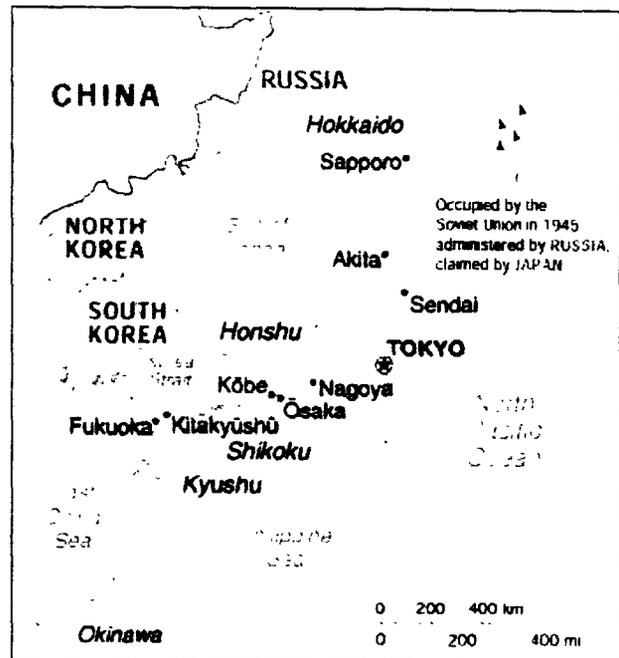
Natural resources: Negligible mineral resources, fish

Agriculture. *Products*--rice, vegetables, fruit, milk, meat, silk

Industry: *Types*--machinery and equipment, metals and metal

MARKET OVERVIEW

Japan's nutritional supplements sector is a major market for U.S. firms and one that appears likely to continue to exhibit steady growth for the foreseeable future. The American dietary supplements sector generates annual sales estimated at \$28 billion, four-times the size of Japan's \$7.5 billion market. Japanese prices for these products tend to be quite expensive, with prices on average being three times those in the United States. Per capita consumption by volume in Japan is calculated to be about one-sixth the level found in the U.S., suggesting that significant prospects for market expansion exist.



Within the supplements sector the current five top selling items in Japan (annual sales) are:

Table 1: Current Five Top Selling Items in Japan (annual sales)

- 1) Vitamin C: 48 billion yen (\$450 million @ \$/107 yen)
- 2) Calcium: 42 billion yen
- 3) Chlorella: 40 billion yen
- 4) Royal Jelly: 40 billion yen
- 5) Dietary Fiber: 38 billion yen

In the United States multi-vitamins are the largest selling item, representing 30% of total market, followed by single vitamins with 21% of the market. However, in Japan the multi-vitamin market (18 billion yen/\$168 million annually) is only one third that of the largest selling single vitamin. In fact, multi-vitamins are only Japan's 8th largest seller among supplement products.

REGULATORY ENVIRONMENT

U.S. firms will encounter a vastly different regulatory and commercial environment than that of the United States. Partly owing to the implementation of the Dietary Supplement Health and Education Act (DSHEA) of 1994, the U.S. market has expanded at double-digit growth rates for each of the past 5 years. Japan's more restrictive regulatory environment places a number of limits on product formulations and labeling, although shape and dosage restrictions have been eased in recent years.

At one time, most vitamins, minerals and herbs were regulated as drugs in Japan. A long-term effort undertaken by U.S. industry, with the active support of the U.S. Department of Commerce, has resulted in significant liberalization in recent years. Presently, almost all vitamins (13), minerals (13) and 101 herbs are now regulated as food products, instead of as drugs. Still, Japan remains a difficult market, governed by a restrictive and opaque regulatory regime.

Two major regulatory obstacles continue to impede firms operating in the Japanese market. These are restrictions or prohibitions on the use of many food additives or excipients commonly marketed outside of Japan, and strict limitations on product labeling (see "new regulations" section below for more labeling details). As a result, virtually all U.S. nutritional supplement products require reformulation and changes in labeling and packaging before they can be sold commercially in Japan.

With regard to food additives, only those substances that are included on a "positive list" covering 350 synthetic food additives plus 490 natural origin additives can be used in supplements marketed in Japan. Any item not on this list is not permitted as an ingredient in supplement products. Many additives commonly used in the United States and elsewhere are not on this list. In addition, additives which have been approved for use in Japan in pharmaceuticals are not permissible for use in supplements unless they are on the positive list.

Despite these restrictions there exists a major loop-hole in Japan's regulatory system that allows many products to reach the market despite being noncompliant with ingredient and labeling regulations. Consumers may import for personal use a four-month supply of nutritional supplements. These products cannot be re-sold. Products bought by individual consumers for personal use may be brought into Japan from foreign travel or purchased via the mail or internet. As a result, an enormous mail order business has developed, expanded considerably in recent years by the rapid spread of internet access. Most American supplement products sold in Japan are purchased via this personal use exemption, often through multi-level or direct marketing firms.

Given the substantial portion of dietary supplements purchased via non-retail channels, it is clear that Japan's regulatory system is viewed as outmoded by many consumers. Even Japan's supplements industry appears to be by-passing the regulatory system. A recent survey conducted by the Tokyo municipal government found that almost 70% of the supplement products on the market at retail outlets were not compliant with labeling requirements.

JAPAN'S NEW REGULATORY SYSTEM

On April 1, 2001, Japan implemented new regulations allowing dietary supplement labels to provide health or efficacy information for the first time. These labeling changes are a component of a complicated new system for regulating nutritional supplements and natural foods implemented by Japan's Ministry of Health, Labor and Welfare on April 1, 2001. The new regulatory regime classifies all drugs and foods into four categories, identified below. Dietary supplements that are allowed to indicate nutritional claim are those categorized in the middle two columns presented in the table below.

Table 2: Regulatory Regime

Drug (Including quasi-drug)	Food for Specified Health Uses.	Nutritional Function Food	Other food
	(Individual product approval system) Required labels: Nutrient contents Nutrition claim Health claim Attention and warning	(Standard type approval system) Required labels: Nutrient contents Nutrition claim Attention and warning	(Including so-called health food) Required labels: Nutrient contents

Under the new system, in order to make a health claim given products must be classified as a Food for Specified Health Uses. And in order to make a nutrition claim, given products must be classified either as a 1) Food for Specified Health Uses or 2) Nutrition Function Food.

1) Food for *Specified Health Uses* are defined as "foods containing functional ingredients which affect physiological and other functions of the body and which can be used to promote and maintain health or for specific healthcare purposes." Approval to include an item in this category and to present health claims on a product label requires that each individual item be reviewed and approved by the Ministry of Health Labor and Welfare. Japanese regulatory officials have indicated that herbs will be reviewed under this category.

2) *Nutritional Function Foods* are defined as "food products with supplement nutritional components which are likely to be deficient in the elderly and other persons who deviate from normal eating habits due to irregular lifestyle." Currently 12 vitamins (A, B1, B2, B6, B12, C, D, E, Niacin, Folic Acid, Biotin and Pantothenic Acid) plus 2 minerals (Ca, Fe) have been placed in this group. Permissible nutrition claims for these items are listed in Appendix 1 of this report.

Even for seasoned observers of Japan's nutritional supplements sector, the new regulatory system has generated many uncertainties regarding how it will function. The products affected under the "nutritional function foods" category compose only an estimated 20% of the nutritional supplements market. The remaining 80% of the market is classified by the new systems as either "food for specified health uses" (requiring individual approvals to make health claims) or "other food" category for which no health or efficacy claims are allowed.

While these new regulations represent another in a series of recent steps Japan has taken to ease regulatory burdens affecting the nutritional supplements sector, many industry representatives were disappointed by the limited scope of the measures. Even more worrisome to many companies is the perception that the documentary requirements for most supplement products to include labeling information are so onerous as to effectively preclude qualification for such labeling. Under the new category of "food for specified health uses," applicants are required to submit safety and efficacy data that some observers believe could result in regulatory scrutiny almost as comprehensive as required for pharmaceuticals.

One result of this new system is that market access conditions for herbs continue to be less favorable than for vitamins and minerals. In Japan just over 100 herbs can be sold commercially in Japan and health claims or efficacy claims are not allowed. In contrast, some 400 herbs are now commonly sold in Europe.

MARKETING AND DISTRIBUTION

Given the restrictive regulatory environment and mail order/personal use exemptions to these regulations, most dietary supplements sold in Japan are marketed through non-retail means.

Table 3: Japan's Distribution Channel Of Dietary Supplements

Channels	Amount (US\$ billion)	Market share
Drug Stores	\$1.5	20%
Retail Stores	\$1.1	14%
Non-store channels	\$5.0	66%
Total	\$7.6	100%

Source: U.S. Industry Estimates 9/01

Among those firms active in non-store sales are most major U.S. multi-level marketing firms, including Amway, Herbalife and NuSkin. Amway has achieved annual sales in Japan as high as \$150 million. Although in recent years some multi-level marketers have seen sales decline.

CONSUMER PROFILES

There are several conspicuous new trends in the market, including an increased consumer interest in prevention of "life style diseases." Japanese consumers increasingly view dietary supplements as an important component to maintaining good health. According to the results of market research conducted recently by the Health Industry News, the most popular items among Japanese consumers are products that are presumed to treat the following conditions:

1. High blood pressure
2. Weight control items
3. Diabetes
4. Immune strengthening
5. Cancer prevention
6. Blood circulation
7. Nutrition supplements
8. Constipation
9. Menopause

Each year Japan's Ministry of Health Education and Welfare publishes a report entitled "Outline of Survey Regarding National Nutritional Intake." According to the latest edition, many Japanese people are deficient in their intake of such minerals as calcium and iron. This is especially true of women between the ages of 15 and 19, who are taking only 73% of the recommended levels of calcium. The report also pointed out that the portion of Japan's population that is considered obese has reached 23 million. In the past, weight control was viewed as a concern primarily by young women. But, recently middle-aged consumers have been buying more weight control items than any other generational group.

The National Laboratory for Health and Nutrition in Tokyo recently disclosed the result of their research "Studies on manufacturing, importing, sales, and intake of health foods and dietary supplements." This study was conducted in both Tokyo and Osaka and surveyed more than 13,000 persons.

Leading responses and the percentage of respondents stating these opinions, included:

--"Dietary supplements are effective in helping to maintain a well-balanced diet." 78%

--"Dietary supplements are easier to take than drugs." 68%

--"Dietary supplements are useful for health promotion." 55%

While many respondents regarded dietary supplements as useful products, there were some common concerns raised, such as:

--"Dietary supplements might have some safety problems." 54%

--"Prices are too expensive." 69%

Another indicator of market trends comes from a survey conducted by Dentsu, Japan's largest ad agency. This research found that the size of Japan's senior citizens food market, including dietary supplements and blended foods, will expand from the current 6.6 trillion yen to 10.9 trillion yen (\$100 billion) by 2015. Presently, the senior citizen share of Japan's total food market is 24.5%, projected to increase to 31% by 2015.

MARKET TRENDS AFFECTING INDIVIDUAL PRODUCTS:

Centering on those products that are viewed as beneficial for mental health, strengthening immune systems, and prevention of senility, a number of herb products have become increasingly popular in Japan. Examples include:

Table 4: Popular Herb Products in Japan

Product name	Market size (retail)	Function
Ginkgo Biloba	15.0 billion yen	Blood circulation in brain
Saw Palmetto	6.0 billion yen	Prostate
Blue Berry	5.0 billion yen	Healthy eyes
Soy Isoflabone	2.0 billion yen	Menopause
Echinacea	2.0 billion yen	Enhanced immune system
St. John's Wort	1.0 billion yen	Mental health well-being
Cimarin	1.0 billion yen	Liver function

Listed below are market conditions affecting an additional selection of the more popular dietary supplement products currently being marketed in Japan.

A) *Chlorella* is the fourth leading seller in Japan with an annual retail market size of \$37 million or 40 billion yen. In 1999, total imports of *Chlorella* were 1,107 tons, with Taiwan accounting for 785 tons, an increase of 37% over the previous year. Korea shipped 187 tons and Indonesia 134 tons. Japanese researchers are now investigating new functions for *chlorella*, such as expelling environmental toxins like dioxin

B) *Royal Jelly*: The retail market for *Royal Jelly* is the same as *Chlorella*, US\$37 million. The main suppliers to Japan are China, Taiwan, Hong Kong, North Korea and Thailand. Total annual sales to Japan during the past three years were as follows: 1997: 452 tons; 1998: 475 tons; 1999: 519 tons.

C) *Gingko*: The strongest competitors are American and Chinese firms. As in the U.S. market, the quality of Chinese origin *Gingko* being shipped to Japan has improved in recent years. Chinese suppliers are also quite price competitive, with Japanese produced *Gingko* wholesaling at 70,000 to 80,000 yen per/kilo, while Chinese wholesale prices are as low as 30,000 yen/kilo.

D) *Aloe*: The Japanese market for *Aloe* is estimated at \$150 million annually. The *Aloe* market is composed of two kinds of products, *Kidachi Aloe* and *Aloe Vera*. *Kidachi Aloe* is produced mainly in the Izu and Shizuoka areas of Japan, with some imports from Korea. *Aloe Vera* is imported almost exclusively from the United States and Mexico, although limited amounts are supplied from the Japanese island of Okinawa.

VITAMIN DRINKS

A new element in Japan's nutritional supplements sector is the rise of "vitamin tonic drink" market. Sales of vitamin drinks sold in 50ml and 100 ml bottles has expanded rapidly in the past couple years and now total about 235 billion yen (\$2.2 billion) annually. These drinks, which often boast 1000 mg vitamin C content, are sold via drug stores, convenience stores, vending machines, sports clubs and kiosks at train and subway stations. The leading player in this market is Taisho Pharmaceutical, which has captured about a 40% share.

TRADE SHOWS

Show Name: Kenho Haku
Show date: March, 2002
Location: Tokyo Big Site
Number of visitors: 40,000
Number of booths: 500
Number of exhibitors: 350 firms

Appendix 1: Nutritional Function Claims

Beginning April 1, 2001, Japan implemented new regulations allowing nutritional supplement manufacturers for the first time to include some health effect information on product labels. The revised regulations are limited to "nutritional function claims" on 12 vitamins and 2 minerals. The new regulations include upper and lower dosage limits, which means products whose dosage falls outside these ranges cannot include labeling information. Details on the affected vitamins and minerals, dosage limits and the text of permitted labeling (which must be in Japanese) is provided below.

List of items allowed nutritional function claims:

VITAMINS

1) Niacin

Upper limit: 15mg

Lower limit: 5mg

Nutrition function claim: Niacin is a nutrient that helps maintain health of skin and mucus membrane.

2) Pantothenic acid

Upper limit: 30mg

Lower limit: 2mg

Nutrition Function claim: Pantothenic acid is a nutrient that helps maintain health of skin and mucus membrane.

Precautions: Excessive intake of this product does not heal diseases or improve health. Follow the daily dosage as directed

3) Biotin

Upper limit: 500mcg

Lower limit: 10mcg

Nutrition Function claim: Biotin is a nutrient that helps maintain health of skin and mucus membrane.

Precautions: Excessive intake of this product does not heal diseases or improve health. Follow the daily dosage as directed

4) Vitamin A

Upper limit: 600mcg

Lower limit: 180mcg

Nutrition Function claim: Vitamin A is a nutrient that helps maintain night-time vision. Vitamin A is a nutrient that helps maintain health of skin and mucus membrane.

Precautions: Excessive intake of this product does not heal diseases or improve health. Follow the daily dosage as directed.

Women up to 3 months into pregnancy or considering conception should refrain from excessive intake of this product.

5) Vitamin B1

Upper limit: 25mg

Lower limit: 0.3mg

Nutrition Function claim: Vitamin B1 is a nutrient that aids energy production from carbon hydrate, and helps maintain skin health and mucous membrane

Precautions: Excessive intake of this product does not heal diseases or improve health. Follow the daily dosage as directed

6) Vitamin B2

Upper limit: 12mg

Lower limit: 0.4mg

Nutrition Function claim: Vitamin B2 is a nutrient that helps maintain health of skin and mucus membrane.

Precautions: Excessive intake of this product does not heal diseases or improve health. Follow the daily dosage as directed

7) Vitamin B6

Upper limit: 10mg

Lower limit: 0.5mg

Nutrition Function claim: Vitamin B6 is a nutrient that aids maintain health of skin and mucous membrane

Precautions: Excessive intake of this product does not heal diseases or improve health. Follow the daily dosage as directed

8) Vitamin B12

Upper limit: 60mcg

Lower limit: 0.8mcg

Nutrition Function claim: Vitamin B12 is a nutrient that helps red blood cell formation

Precautions: Excessive intake of this product does not heal diseases or improve health. Follow the daily dosage as directed

9) Vitamin C

Upper limit: 1,000mg

Lower limit: 35mg

Nutrition Function claim: Vitamin C is a nutrient that helps maintain health of skin and mucus membrane and has anti-oxidization effects.

Precautions: Excessive intake of this product does not heal diseases or improve health. Follow the daily dosage as directed

10) Vitamin D

Upper limit: 5.0mcg

Lower limit: 0.9mcg

Nutrition Function claim: Vitamin D is a nutrient that helps promote calcium absorption in intestines, and contribute to the development of bones.

Precautions: Excessive intake of this product does not heal diseases or improve health. Follow the daily dosage as directed

11) Vitamin E

Upper limit: 150mg

Lower limit: 3mg

Nutrition Function claim: Vitamin E is an anti-oxidant, which prevents oxidization of body fat, and helps maintain cellular health.

Precautions: Excessive intake of this product does not heal diseases or improve health. Follow the daily dosage as directed

12) Folic acid

Upper limit: 200mcg

Lower limit: 70mcg

Nutrition Function claim: Folic acid is a nutrient that helps the formation of red blood cells. Folic acid is a nutrient that contributes to normal fetal development

Precautions: Excessive intake of this product does not heal diseases or improve health. Follow the daily dosage as directed. This product contains a nutrient that contributes to a normal development of an embryo. However, its excessive intake does not improve fetal development.

MINERALS

(1) Calcium

Upper limit: 600mg

Lower limit: 250mg

Nutrition Function claim: Calcium is a nutrient necessary for the formation of bones and teeth.

Precautions: Excessive intake of this product does not heal diseases or improve health. Follow the daily dosage as directed

(2) Iron

Upper limit: 10mg

Lower limit: 4mg

Nutrition Function claim: Iron is a nutrient necessary for the formation of red blood cells.

Precautions: Excessive intake of this product does not heal diseases or improve health. Follow the daily dosage as directed