

1. Definition of Category

This report discusses foods designed for individuals being treated for specific medical maladies, and foods for elderly people who have difficulty in chewing or swallowing food.

HS Numbers

Foods for ill persons and the elderly are classified under many different HS numbers, according to their ingredients and their proportions, manufacturing method, physical shape and properties, and purposes. In addition, these HS numbers include products other than foods for ill persons and the elderly. Accordingly, no single HS number or numbers can be associated with this category of products. Most prepared food items for ill persons and that consist of homogenized mixtures of two or more meat, fish, vegetable or fruit constituents, are packaged in containers for retail sale, and contain no more than 250 mg of flavoring, are classified under HS No. 2104.20 (homogenized composite food preparations).

2. Import Trends

(1) Recent Trends

Thus, since there is no one HS Number that encompasses all of the products covered by this report, there are no accurate statistics that would enable discussion of import totals or trends. Imports of products classified as “homogenized composite food preparations” totaled only 36 tons with a value of ¥15 million in 2001, the highest value in recent five years.

(2) Imports by Place of Origin

The leading exporter of “homogenized composite food preparations” to Japan is the United States. In 2001, the United States accounted for 88% of total imports on both a volume and value basis. The remaining portion came from Brazil.

(3) Imports' Market Share in Japan

The market for foods for ill persons and the elderly has only just emerged in the past 2-3 years. There are no official statistics on the size of the domestic market. Consequently, imports' market share is unknown. Industry sources suggest, though, that finished product imports make up only a small portion of the total. Almost all of these products are manufactured in Japan due to compliance considerations with regulations under the Food Sanitation Law and the Nutrition Improvement Law.

3. Key Considerations related to Importing

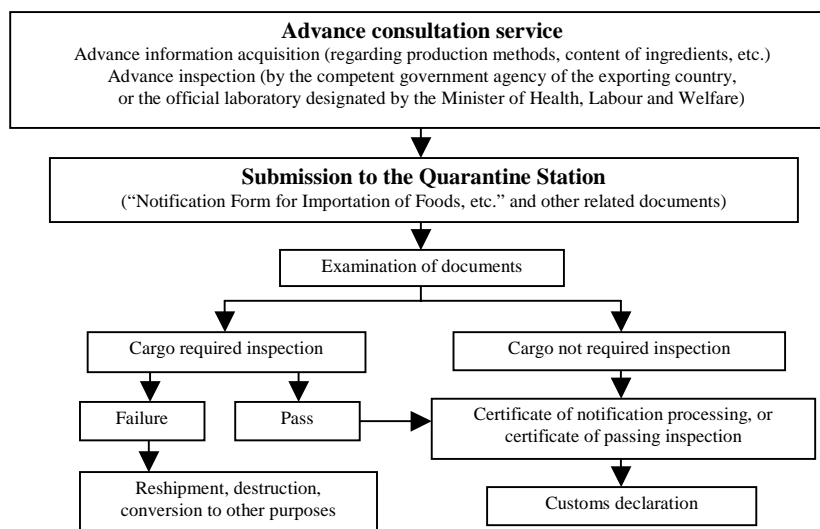
(1) Regulations and Procedural Requirements at the Time of Importation

Importation of foods for ill persons and the elderly is subject to provisions of the Food Sanitation Law.

1) Food Sanitation Law

The Food Sanitation Law treats foods for ill persons and the elderly in the same manner as all other foods. Under provisions of the Law, an import notification is required for these foods being imported for the purpose of sale or for other commercial purposes. Importers are required to submit the completed “Notification Form for Importation of Foods, etc.” to the Quarantine Station at the port of entry. A determination is made based on the document examination whether or not an inspection at the bonded area is required.

These foods sometimes contained vitamin, mineral and amino acid additives. Some of these additives are not approved for use in Japan, while some are subject to Japanese usage standards or restrictions. Prospective exporters need to check in advance about regulations governing the type and quantity of additives. Prior to importing, the importer may take a sample of forthcoming imports to official laboratories designated by the Minister of Health, Labour and Welfare in Japan or in exporting countries. Those test results may be substituted for the corresponding inspection at the port of entry, which expedites the quarantine clearance process.

Fig. 1 Procedures required under the Food Sanitation Law

In addition, importers who wish to submit their notifications by computer may make use of the computerized FAINS (Food Automated Import Inspection and Notification System) for processing import-related documentation. Importers who have the required hardware and software may apply for a security code from the Minister of Health, Labour and Welfare to access the system.

(2) Regulations and Procedural Requirements at the Time of Sale

The sale of the foods for ill persons and the elderly is subject to the Food Sanitation Law, the JAS Law, the Nutrition Improvement Law, and the Measurement Law. In addition, containers and packaging may be subject to provisions of the Containers and Packaging Recycling Law and the Law for Promotion of Effective Utilization of Resources. For more detailed information about the subject, scope, labeling method, etc., please consult the competent government agencies listed below.

1) Food Sanitation Law

The Food Sanitation Law prohibits the sale of foods containing toxic or harmful substances and foods that are unsafe for human health. When selling foods for ill persons and the elderly, it must be labeled in accordance with provisions of the Food Sanitation Law. In addition, as of April 2001, the Law mandates or recommends raw material labeling for foods that contain allergens. (see 4. Labeling)

2) JAS Law

The JAS Law establishes quality labeling standard for all food and beverage products sold to ordinary consumers. (see 4. Labeling)

3) Nutrition Improvement Law

When employing labeling for nutritional ingredients or calories in Japanese, either on the packaging or in accompanying documentation, labeling must be in accordance with the requirements under the Nutrition Improvement Law. Labeling must contain the quantities of calories, proteins, fats, carbohydrates, sodium, and other nutritional ingredients present, in descending order by content volume.

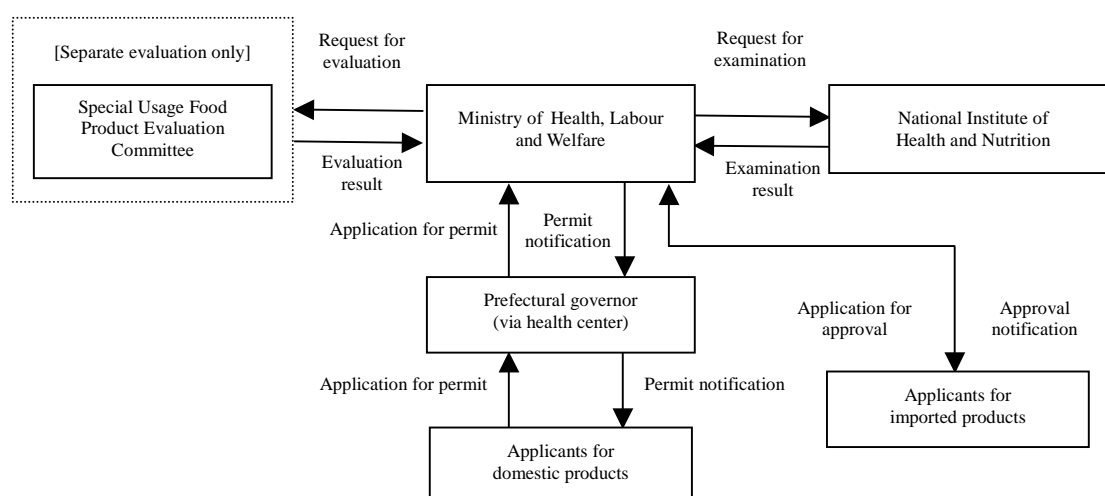
If a manufacturer or importer wishes to place language on the container indicating the product is especially suited for use by ill persons, the elderly, or infants, the Nutrition Improvement Law mandates that the product be approved for by the Minister of Health, Labour and Welfare for such labeling as a "special usage foods." This labeling must employ medical or nutritional terminology indicating the product contributes to the growth of infants, or the maintenance or recovery of health by ill persons and the elderly. No permission (for domestic foods) or approval (for imported foods) is required simply to label a product as "for use by the elderly." Labeling of foods for ill persons must correspond to one of the special usage categories shown below. Special usage foods for ill persons that fail to obtain a labeling permit or approval violate labeling restrictions under the Nutrition Improvement Law.

- Labeling simply indicating suitability for ill persons generally. Examples: "For ill persons," "Food for the infirm"
- Labeling indicating suitability for particular illnesses. Examples: "For diabetics," "For patients with hypertension"

- Labeling conveying the impression that the food is for ill persons, by use of labeling similar to foods subject to labeling permit or approval requirements.

The procedure for applying for a labeling permit or approval for special usage foods is shown in Fig. 2 (classification of special usage foods is discussed in section 6. Product Characteristics). In order to obtain a labeling permit for “permit standard type foods for ill persons,” importer must submit an application form listing the product name, the ingredients and their proportions, the manufacturing method, nutritional content and calorie content, and the content of the labeling, along with a sample of the product. In the case of imported products, the application must be submitted to the Department of Food Sanitation, Pharmaceutical and Medical Safety Bureau, Ministry of Health, Labour and Welfare. In addition, if the applicant is applying for a labeling permit for “separate evaluation type foods for ill persons,” the applicant must also submit, in addition to the above, supplemental materials objectively demonstrating compliance with permit conditions. The application is then subject to separate evaluation by specialists under the auspices of the Special Usage Food Evaluation Examination Committee.

Fig. 2 Procedures of labeling permit for special usage foods



<Reference>

[Labeling standards for permit standard type foods for ill persons] (excerpts)

- Foods appropriate for ill persons who require special nutritional consideration from a medical or nutritional standpoint.
- Labeling that indicates the special usage is appropriate for a food for ill persons.
- Ingredients and properties are confirmed by a valid testing method.
- The product is effective when used strictly as indicated, and the usage method is simple and clear.
- Product quality is no less than ordinary foods.
- Labeling indicates whether the product is intended for a broad range of users, or is specially needed by ill persons.

[Permit conditions for separate evaluation type foods for ill persons]

- Product fulfills the goals of nutritional therapy for a specific medical malady, and can be expected to improve nutritional life.
- The anticipated nutritional benefit has a clearly demonstrated medical or nutritional basis.
- The appropriate usage method in terms of medical or nutritional therapy for the patient can be medically or nutritionally established.
- The product can be ingested as food routinely and on an ongoing basis (no damage to health or nutritional imbalance results from over-ingestion).
- The physical and chemical properties of the active ingredients, and qualitative and quantitative testing methods, have been clearly established.
- Product does not differ dramatically from similar foods in a form for normal consumption.
- Food product and active ingredients are not included in a list of compounds used exclusively as pharmaceuticals.

4) Measurement Law

Foods for ill persons and the elderly sealed in wrapping or containers are required the labeling of the net content to certain accuracy (range of error specified by Cabinet Ordinance).

(3) Competent Agencies

- Food Sanitation Law
Department of Food Sanitation, Pharmaceutical and Medical Safety Bureau, Ministry of Health, Labour and Welfare
TEL: 03-5253-1111 <http://www.mhlw.go.jp>
- JAS Law (Law Concerning Standardization and Proper Labeling of Agricultural and Forestry Products)
Standards and Labeling Division, General Food Policy Bureau, Ministry of Agriculture, Forestry and Fisheries
TEL: 03-3502-8111 <http://www.maff.go.jp>
- Nutrition Improvement Law
Department of Food Sanitation, Pharmaceutical and Medical Safety Bureau, Ministry of Health, Labour and Welfare
TEL: 03-5253-1111 <http://www.mhlw.go.jp>
- Measurement Law
Measurement and Intellectual Infrastructure Division, Industrial Science and Technology Policy and Environment Bureau, Ministry of Economy, Trade and Industry
TEL: 03-3501-1511 <http://www.meti.go.jp>
- Containers and Packaging Recycling Law / Law for Promotion of Effective Utilization of Resources
Recycling Promotion Division, Industrial Science and Technology Policy and Environment Bureau,
Ministry of Economy, Trade and Industry
TEL: 03-3501-1511 <http://www.meti.go.jp>
Recycling Promotion Division, Waste Management and Recycling Department, Ministry of the Environment
TEL: 03-3581-3351 <http://www.env.go.jp>
Food Industry Policy Division, General Food Policy Bureau, Ministry of Agriculture, Forestry and Fisheries
TEL: 03-3502-8111 <http://www.maff.go.jp>

4. Labeling

(1) Legally Required Labeling

1) JAS Law, Food Sanitation Law

When selling foods for ill persons and the elderly sealed in wrapping or containers, following items must be listed all together on the label, under provisions of the Food Sanitation Law, the JAS Law, and the Measurement Law.

<Labeling items to be listed all together>

- | | |
|---|------------------------|
| 1) Product name | 2) List of ingredients |
| 3) List of food additives (if used) | 4) Net content |
| 5) Date of minimum durability or best-before date | |
| 6) Preservation method | 7) Country of origin |
| 8) Importer's name and address | |

<Labeling of foods containing allergens>

The Food Sanitation Law mandates or recommends raw material labeling for 24 foods that contain allergens. Processed foods containing the foods listed in the following table, and processed foods containing additives derived from these foods are either required or advised to bear labeling to the effect that they contain allergenic foods. This provision was adopted as of April 2001, and from April 1, 2002 onward, it will apply to all manufactured, processed and imported processed foods and food additives.

Labeling mandatory (5 products)	Wheat, buckwheat, eggs, milk, peanuts
Labeling recommended (19 products)	Abalone, squid, salmon roe, shrimp, crabs, salmon, mackerel, oranges, kiwi fruit, peaches, white potatoes, apples, walnuts, soybeans, gelatin, beef, pork, chicken, <i>matsutake</i> mushroom

<Labeling requirements for genetically modified foods>

The JAS Law classifies genetically modified foods into three categories according to their scientific properties, and stipulates labeling method for soybeans (including green soybeans and soybean sprouts), corn, potatoes, rapeseed, cottonseed, and processed foods made from these designated agricultural products.

- 1) For the genetically modified organism (GMO) and processed foods made from GMO as a main ingredient, if they are produced or distributed without segregation between GMO and non-GMO, it shall be declared that segregation has not been made. (Compulsory labeling)

- 2) For the genetically modified organism (GMO) and processed foods made from GMO as a main ingredient, if they are confirmed that they have been treated under a identity preserved handling, it shall be declared as the ingredient is GMO. (Compulsory labeling)
- 3) For the non-GMO and foods made from non-GMO as a main ingredient, if they are confirmed that they have been treated under a identity preserved handling, labeling is not required. But they may voluntarily declare as the ingredient is non-GMO. (Voluntary labeling)

2) Nutrition Improvement Law

The Nutrition Improvement Law mandates the following labeling items for products subject to labeling approval requirements. Labeling must employ the markings shown below to identify foods for the ill persons and foods for the elderly, etc.

- 1) Product name
- 2) Date of minimum durability or best-before date
- 3) Preservation method (except when label indicates product can be stored at room temperature)
- 4) Name and address of manufacturer
- 5) Permit (approval) certificate
- 6) Permitted (approved) label content
- 7) Reason for permit (approval) granted
- 8) Nutritional content and calories
- 9) Special warnings (when caution is needed in regard to method of ingestion, preparation or storage)
- 10) Name and address of permit grantee, if different from manufacturer

Labeling of special usage foods



Identification of foods for ill persons or the elderly

Example labeling for low-sodium food product

<p>Product name: Low-sodium soy sauce</p> <p>Ingredients: De-fatted soybeans, soybeans, wheat, salt, vinegar, alcohol</p> <p>Net content: 1 liter</p> <p>Date of minimum durability: 11-30-2001</p> <p>Preservation method: Avoid storing in direct sunlight, store at room temperature.</p> <p>Reseller: XX Foods, Ltd.</p> <p>Address: YY City, ZZ Prefecture</p> <p>Importer: AA Trading Co., Ltd.</p> <p>Address: BB City, CC Prefecture</p> <p>Country of Origin: USA</p> <p>For customer service call: Tel. Xxx-xxxx</p>	<p>This product contains approximately half the sodium of regular soy sauce. It is appropriate for the following persons who are on a low-salt diet.</p> <ul style="list-style-type: none"> • Individuals with hypertension • Individuals with cardiovascular disorders, kidney disorders, and pregnant women <p><Nutritional Content> (per 100 g)</p> <table style="width: 100%; border: none;"> <tr> <td>Calories</td> <td>63 kcal</td> <td>Protein</td> <td>8.2 g</td> </tr> <tr> <td>Fat</td> <td>0 g</td> <td>Sugar</td> <td>8.9 g</td> </tr> <tr> <td>Sodium</td> <td>3.00 g</td> <td>Ash content</td> <td>9.1 g</td> </tr> <tr> <td>Potassium</td> <td>495 mg</td> <td>Chlorine</td> <td>4.68 g</td> </tr> <tr> <td>Sodium chloride</td> <td>7.63 g</td> <td></td> <td></td> </tr> </table>	Calories	63 kcal	Protein	8.2 g	Fat	0 g	Sugar	8.9 g	Sodium	3.00 g	Ash content	9.1 g	Potassium	495 mg	Chlorine	4.68 g	Sodium chloride	7.63 g		
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<Warnings>

1. Please follow your doctor's recommendation if the doctor or a nutritionist has placed you on a low-sodium diet.
2. This product is suitable for use as part of nutritional therapy. It will not cure your illness if used frequently or in large quantities.
3. This product contains no preservatives. Please refrigerate after opening.

Contact:

Japan Health Food and Nutrition Food Association

TEL: 03-5410-8231

<http://www.health-station.com/jhnfa>

3) Law for Promotion of Effective Utilization of Resources

When paper or plastic is used as a packaging material for wrapping of individual product items, or for labels, tags, external packaging or elsewhere, a material identifier mark must be displayed with information where the material is used.

< Example >



External packaging



Label

(2) Voluntary Labeling based on Provisions of Law**<Inspection and Certification of Organic Agricultural Products and Processed Organic Agricultural Products>**

The JAS Law establishes a “special JAS standard” for organic agricultural products and processed organic agricultural products. Only those products that comply with this standard are allowed to include in their labeling the phrase “organic” and to display the Organic JAS Mark.

Organic JAS Mark



Contact:

Center for Food Quality, Labeling and Consumer Services Headquarters
Standard and Labeling Department

TEL: 048-600-2371 <http://www.cfqlcs.go.jp>

(3) Voluntary Industry Labeling

There is no voluntary industry labeling for foods for ill persons and the elderly.

5. Tax Laws and Regulations**(1) Customs Duties**

Tariff rates on foods for ill persons and the elderly can vary according to the proportions of the ingredients and the physical form of the products. Therefore, it is important to confirm the applicable tariff rate in advance. As an example rate, the following shows tariff rates on homogenized composite food preparations (prepared nutritionally therapeutic food product containing a mixture of at least two varieties of meat, fish, vegetable, or fruit, finely homogenized, packaged in containers for retail sale, and with at most 250 g of flavoring).

Fig. 3 Customs duties on foods for ill persons and the elderly

HS No.	Description	Rate of Duty (%)			
		General	WTO	Preferential	Temporary
2104.20-000	Homogenized composite food preparations	12.8%	12%	9.6% *Free	

Note 1: “*Free” in Preferential Rate is applicable only for Least Less Developed Countries.

Note 2: Refer to “Customs Tariff Schedules of Japan” (published by Japan Tariff Association) etc. for interpretation of tariff table.

(2) Consumption Tax

$(\text{CIF} + \text{Customs duties}) \times 5\%$

6. Product Characteristics**(1) Types and characteristics of special usage food product**

The term “foods for ill persons and the elderly” corresponds to the definition of a “special usage foods” under the Nutrition Improvement Law. Figure 4 shows the main categories of special usage foods. Foods for the elderly are divided into two main categories. The first is “permit standard type” foods, the labeling of which is governed by established standards. The second is “separate evaluation type” foods, which are granted a labeling permit after separate scientific evaluation by specialists. Permit standard type foods are further classified into single item foods and multiple item foods.

(2) Characteristics of foods for ill persons

“Foods for ill persons” is a general term for foods that are suitable for patients whose doctors prescribe either restricted or supplemental intake of nutrients, such as sodium, protein, etc. There are a great number of so-called low-sodium and low-calorie diet products on the market. However, not all of these products would qualify for designation as special usage foods. The Ministry of Health, Labour and Welfare will only grant a labeling permit to products that meet stipulated standards. As of January 21, 2002, the Ministry had approved a total of 375 applications for designation as special usage foods on behalf of foods for ill persons. Figure 5 provides a statistical breakdown of these applications.

Fig. 4 Classification of special usage foods

			Categories	
Special usage foods	Foods for ill persons	Permit standard type	Single item foods for ill persons	1. Low-sodium foods
				2. Low-calorie foods
				3. Low-protein foods
				4. Low-protein (or no-protein) high-calorie foods
				5. High-protein foods
				6. Non-allergenic foods
				7. Non-lactose foods
			Multiple-item foods for ill persons	8. Adiabatic foods
				9. Adult obesity foods
				10. Low-sodium foods
				11. Liver disorder foods
		12. Separate evaluation type		
Foods for the elderly	1. Foods for those with difficulty in chewing			
	2. Foods for those with difficulty in chewing and swallowing			
Foods for pregnant women or nursing mothers	Milk formula for pregnant women or nursing mothers			
Foods for infants	Infant formula			
Special foods for good health	Foods with oligo saccharides and lactobacillus, designed to improve digestion, etc.			

<Single item foods for ill persons>

• **Low-sodium foods**

Low-sodium foods have sodium content levels 50% or less of normal products of the same type. This is the most common and widely used variety of foods for ill persons. Users include not only hypertension and kidney disease patients, but also the elderly and a wide range of other persons who for one reason or another need to watch their salt intake. Recent years have seen increased popularity for products that offer not only reduced sodium levels but also other forms of added value, such as organic methods of cultivation. Of the 99 products in this category that have obtained labeling permits, the majority consists of varieties of soy sauce. Leading domestic soy sauce makers have a substantial share of the low-sodium soy sauce market. Dead Sea salt from Israel (which is 47% sodium chloride and 50% calcium chloride) that is imported and refined domestically has also been granted a labeling permit as a low-sodium product. The market for low-sodium foods is estimated at ¥10.0 billion in 2000, making it the largest sector of the market for foods for ill persons.

• **Low-calorie foods**

Low-calorie foods have a calorie level 50% or less than regular products of the same type. Of the 31 products in this category that have obtained labeling permits, the majority consists of sweeteners. Sold in syrup, powder and syrup form, sweeteners can be used in place of sugar in coffee, cakes and other types of foods. Users include not only diabetics and the obese, but also many diet-oriented women. The market for low-calorie foods is estimated at ¥6.0 billion in 2000. Recently, one leading food product maker (Ajinomoto) has newly obtained a labeling permit for a sweetener with approximately 1/10 the calorie level of sugar. Accordingly, future market growth can be expected.

• **Low-protein foods**

Low-protein foods have protein levels 50% or less than regular products of the same type, but with the same or similar calorie levels. The 7 products in this category that have obtained labeling permits include noodles, rice and low-protein mix powdered milk. Demand for these products is limited to patients with renal insufficiency. The size of the market in 2000 is estimated at ¥200 million.

• **Low-protein (or no-protein) high-calorie foods**

These products have protein levels 50% or less than regular products of the same type, but also are high in calories. They are used by patients on a combination low-protein and high-calorie diet (end-stage renal disease, kidney dialysis, etc.). Only one product in this category has obtained a labeling permit. The market is very small.

Fig. 5 Labeling permits for special usage foods

(As of January 21, 2002)

		No. of labeling permits	Suitable patients	Main varieties	
Permit standard type	Single item foods for ill persons	1. Low-sodium foods	99	Patients requiring low-sodium intake diets (hypertension, kidney disease, heart disease, etc.).	Soy source, soy bean paste, salts
		2. Low-calorie foods	31	Patients who need to restrict energy intake (diabetics, the obese).	Sweeteners
		3. Low-protein foods	7	Patients who need to restrict protein intake (kidney disease, etc.).	Milk, rice, noodles,
		4. Low-protein (or no-protein) high calorie foods	1	Patients on a low-protein, high-calorie diet (end-stage renal disease).	Flour
		5. High-protein foods	6	Population: patients who need high protein intake (liver disease, gastric ulcers, nephrosis).	Protein, biscuit
		6. Non-allergenic foods	22	Patients with specific food allergies (to milk, eggs, soybeans, etc.).	Prepared flour, ham, margarine
		7. Non-lactose foods	2	Patients with lactose intolerance and galactosemia.	Prepared flour
	Multi-ple-item foods for ill persons	8. Diabetic foods	197	Diabetics	Daily household dish set
		9. Adult obesity foods	6	Obese	Diet foods
		10. Low-sodium foods	0	Hypertension, kidney disorder, cardiovascular disease, and other patients on restricted sodium intake diets	None
		11. Liver disorder foods	0	Hepatitis, gallstones	None
12. Foods for ill persons (separate evaluation type)		4	Fine Rice (for atopic dermatitis patients), Low-Phosphorus Milk L.P.K (for chronic kidney failure patients), Barley Malt GBF (for ulcerative colitis patients)		

- Non-allergenic foods

Non-allergenic foods have had removed allergens that cause specific food allergies. Food allergens are idiosyncratic, but common sources include eggs, milk, soybeans, wheat and rice. These are known as the five main food allergens. Products in this category that have obtained labeling permits include prepared flour, as well as processed foods made from non-allergenic milk, eggs and soybeans (margarine, sausage, crackers, etc.). These products are meant for adults suffering from food allergies and for children with atopic disorders. The market is growing, and is estimated at ¥2.3 billion in 2000.

- Non-lactose foods

Non-lactose milk is used with infants who experience diarrhea or abdominal pain due to inherited or secondary lactose intolerance. The market is small.

<Multiple-item foods for ill persons>

Multiple-item foods are prepared foods that combine more than one food into a prepared portion or portions for a single day or a single meal. Under the category of special usage foods, they are sub-classified into four subcategories: diabetic foods, adult obesity foods, low-sodium foods, and liver disorder foods. The main variety is diabetic foods, a category in which a rapidly growing number of foods have obtained labeling permits in the past few years.

As is apparent from Figure 5, of the 203 labeling permits granted to multiple-item foods for ill persons, 197 have gone to diabetic foods. Only six have gone to products classified as adult obesity foods, and none at all have gone to products classified as low-sodium (hypertension, kidney disorder, cardiovascular disease, and other patients on restricted sodium intake diets) or liver disorder (hepatitis, gallstones). Prepared multiple-item diabetic foods generally are a mixture of fish, meat or another main course item with small amounts of supplemental foods. The main course usually is Japanese food, but product lines also include Western and Chinese food main course items. Normally the patient is expected to prepare steamed rice, rice gruel, bread or other such items according to personal preference or the exigencies of the illness. Some prepared foods in this category are sold with *miso* soup, Western-style or Chinese soup, or jelly or other dessert-type items included. Their purpose is not merely nutritional or functional but also to improve taste and enhance flavor. Multiple-item foods for ill persons come in three different physical forms: retort-packaged, freeze dried, and frozen. Retort-packaged is the most popular, since it only has to be reheated. Freezing makes it possible to maintain the flavor of the ingredients, but retail stores lack the freezer capacity to stock these items on the shelves. As a result, they are generally sold by mail order or by food delivery services.

<Foods for ill persons (separate evaluation type)>

As of January 2002, only four products from three companies had been granted labeling permits as separate evaluation type food products. These products are Fine Rice from Shiseido Beauty Foods (for atopic dermatitis patients), Low-Phosphorus Milk L.P.K. from Morinaga Milk Industry (for chronic kidney failure patients), and Barley Malt GBF from Kirin Beer (for ulcerative colitis patients; two products, plain and coffee-flavored). Out of privacy considerations, these products are normally sold only by mail order. The market remains very small.

(3) Characteristics of foods for the elderly

Unavoidably, people's teeth weaken as they grow older, and sometimes people lose teeth completely. Nerves and muscles deteriorate, salivary excretion drops, and neurological pathologies develop. Because of these and other factors, chewing and swallowing capabilities often decline. If the ability to drink and swallow liquids declines dramatically, it produces an abnormal delay in the natural reaction to obstruction of the trachea that occurs when food or liquids close off the entrance. This in turn can cause choking or even damage to the broncheal tube. The phrase "foods for the elderly" is a general term for food that is designed to compensate for these declines in physical capabilities and functioning. Foods for the elderly are generally classified into a) foods that are cut into smaller sizes to make them easier to eat, b) texturized foods that are treated with mixers or blenders (mixed with food to make it softer and easier to swallow) or c) a gelatin agent (which turns the food into a gelatinous form). In addition, thick liquid foods designed for use as nutritional supplements by hospitals and eldercare facilities are sometimes sold on the consumer market as foods for the elderly.

Under the Nutrition Improvement Law's criteria for designation as special usage foods, foods for the elderly are classified into foods for those with difficulty in chewing and foods for those difficulty in chewing and swallowing.

- Foods for those with difficulty in chewing

Foods for the elderly whose chewing ability has diminished, or foods that can be eaten without being chewed. As of January 2002, 13 products from three companies have been granted labeling permits in this category. All consist of Japanese-style foods preferred by older adults, but with the food cut into smaller pieces and cooked differently to soften the food and make it easier to eat.

- Foods for those with difficulty in chewing and swallowing

In addition to the preceding properties, these foods are prepared so they are easier to swallow and less likely to block the windpipe. As of January 2002, the products that have obtained labeling permits in this category are meat paste and jelly.

The Ministry of Health, Labour and Welfare has established standards for "firmness" in addition to those for calories, nutritional ingredients, digestion and absorbency. In order to be qualified as a food product for those with difficulty in chewing and swallowing, the product can consist of no more than 50% solids by weight. Many foods for the elderly are marketed as suitable for older adults without obtaining a labeling permit as a special usage foods. Some demand for these products can also be expected from those interested in calorie control and from those who are too busy to cook.

7. Domestic Distribution System and Business Practices

(1) Domestic Market Conditions

The Japanese have the longest life spans of any people in the world, both men and women. Interest in and concern about health is very keen. The proportion of Japan's population aged 65 and older overtook Western Europe in 2000, putting Japan on track to become the world's first hyper-aged society. Predictions say that by 2005 the population aged 65 and older will exceed one-fifth of the overall population, and Japan is confronted with the necessity to shift significantly from hospital and institutional-based care to home-based care. April of 2000 marked the introduction of the Long-Term Care Insurance Program, the first of a variety of systemic reforms in medical care and welfare programs. Given these trends, future growth is expected in the market for foods for ill persons and the elderly. The field has attracted attention from food product makers, pharmaceutical makers and other sectors. As mentioned previously, the leading products in today's market for foods for ill persons are low-sodium and low-calorie foods. The size of the market as a whole has been estimated at ¥23.0 billion in 2000. People in the industry expect growth to occur in foods for diabetes and other illnesses affected by life style habits. In 1998 the former Ministry of Health and Welfare published its first Diabetes Survey. This indicated that 2.18 million have been definitively diagnosed with diabetes, while another 6.9 million are strongly suspected of having diabetes, and still another 4.62 million may possibly have the disease.

All together, some 13.7 million people are affected, approximately 10% of the population of Japan. Of those aged 40 and over, about one in every 4 or 5 persons has diabetes or a precursor. Accordingly, this is a product sector with very high latent demand. Home-based care as well as hospital and institutional care are witnessing a shift away from meals prepared by hand and toward commercially available prepared foods, and toward usage of food delivery services.

Nevertheless, privacy considerations for users of foods for ill persons tend to limit retail distribution channels and sales promotional activities. Now, consumer awareness is low of the availability of commercial foods for ill persons, and of availability of delivery. For future market growth, new retail channels will have to be explored and market presence will have to be increased in order to enhance awareness and stimulate latent demand. Recently some makers have been doing direct sales through their Web sites, and expectations are for increased Internet sales and for growth in delivery services.

In the past, foods for the elderly consisted mainly of liquid foods intended for use by hospitals and institutional care facilities. In 1998 food product makers, pharmaceutical makers and sanitary product makers began selling foods aimed at older adults living at home. These products are now available at department stores, supermarkets, drugstores and mail order outlets. In 2000 existing makers were firming up their product lines, while baby food makers, frozen food makers, dairy product makers and other companies were just entering the market for foods for the elderly. The market for foods for the elderly is growing rapidly. The size of the market was only around ¥500 million in 1999 (including products not granted labeling permits as special usage foods), but it grew to ¥1.8 billion in 2000. Consumer awareness remains low of the existence and availability of commercial foods for the elderly, and both the number of retail outlets and allocated shelf space are still limited. Nevertheless, people in the industry mark 2000 as Year One of a full-fledged market for foods for the elderly. Forecasts call for the market to grow to ¥10.0 billion by 2005. There is no doubt that the number of older adults in home-based care will increase. New products need to be developed and retail channels need to be expanded in order to accommodate the needs of these purchasers. Recent years have seen growing use of the Internet by older adults, and this is expected to become a more promising distribution channel, as is the case with foods for ill persons.

(2) Distribution Channels

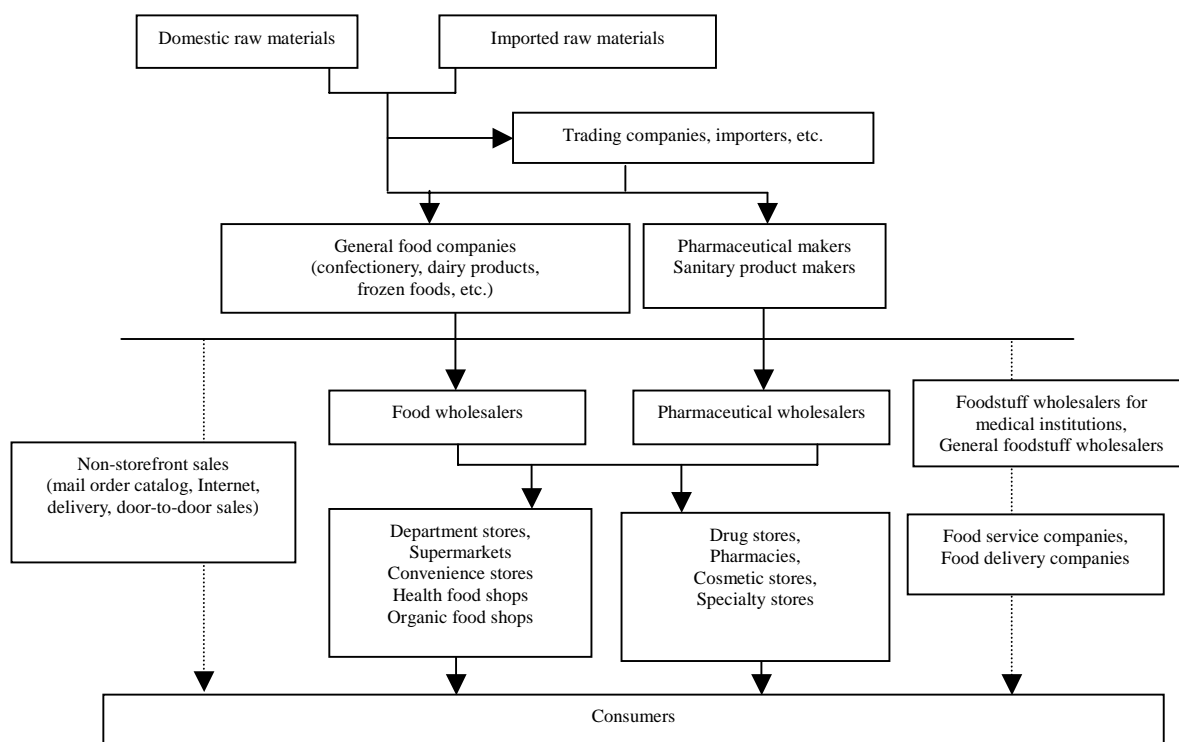
Distribution channels for foods for ill persons and the elderly can be broadly classified into non-storefront sales (mail order catalog sales, Internet sales, delivery sales, door-to-door sales) and storefront sales (pharmaceutical channels, general food channels). In the category of foods for ill persons, low-sodium foods (such as low-sodium soy sauce) and low-calorie foods (such as diet sweeteners) are most commonly distributed through supermarkets, department stores, convenience stores, and other storefront food outlets, just the same as ordinary foods. Other single-item and multiple-item foods for ill persons are mainly sold through non-storefront channels such as mail order outlets and the Internet, out of consideration for user privacy. Direct maker sales to users are also increasing. The most common type of storefront sales outlets is a medical product outlet, such as pharmacies, drugstores, hospital stores, and home health care product shops. Finally, food delivery services take orders by phone, fax and the Internet and then set up regular delivery schedules. These cases are gradually becoming more common. (see Fig. 6)

(3) Key Considerations for entering the Japanese Market

Of course, a food product for ill persons sold at retail with labeling indicating suitability for a particular malady must meet the criteria for designation as a special usage food and obtain a labeling permit from the Minister of Health, Labour and Welfare. This is true whether the labeling explicitly states it is for ill persons, or whether it implies this through similar language. Prospective importers should study and learn about this process thoroughly ahead of time.

Foods for the elderly do not have to be designated as special usage foods in order to be imported and sold as suitable for older adults to eat. However, prospective importers still need to find out in advance if some of the ingredients or additives must meet standards set forth under the Food Sanitation Law. Also, prospective importers need to study the latent needs of older adults. They should offer products that not only provide nutritional content and functionality, but also that look well, taste good, and are priced affordably. Also, many older adults complain that printing on food labeling is too small and hard to read, and that packaging is too difficult to open. Importers should take these complaints into consideration. Even though the Japanese population is aging rapidly, development of foods for the elderly has only just gotten under way. In the future, older adults will play a pivotal role in driving consumer life styles, and considerable room remains for further development in marketing of foods aimed at this consumer segment.

Fig. 6 Distribution for foods for ill persons and the elderly



8. After-Sales Service

In general, the manufacturer (or importer) or reseller deals with any product defects. Contact information is clearly indicated on product labels. Consumer Life Centers at prefectural government offices field complaints about bombastic advertising and marketing methods. Under the Product Liability Law, manufacturers and importers bear liability for any demonstrated imported product defect that harms human health. It is important, therefore, to pay careful attention to product quality control.

9. Related Product Categories

The Nutrition Improvement Law mandates that the product suited for use by infants, pregnant women or nursing mothers be approved for such labeling as a “special usage foods” by the Minister of Health, Labour and Welfare. Among the special usage foods, which can expect good health by taking it such as “foods to fix the stomach” or “foods for those who have higher cholesterol” may label “special foods for good health” by the approval of the Minister of Health, Labour and Welfare. (see Figure 4). As of January 2002, a total of 289 food products have received labeling permits as special foods for good health. The size of the market for these products is estimated to rapidly increase from ¥226.9 billion in 1999 to ¥412.1 billion in 2001. In contrast to the special usage foods discussed in this section, which are intended for consumption by the elderly or another specific group, special foods for good health are not intended for any special segment of the consumer population. They are useful in first-stage prevention of illnesses affected by life style habits, illnesses such as diabetes, cancer, heart disease, liver disease, gum disease and osteoporosis. Please note, however, that special foods for good health are subject to strict permit standards based on scientific foundations. Not all products that offer the benefits mentioned above are eligible for designation as special foods for good health. Please refer to the separate section on “VI-9 Health Foods” for more information about health foods and supplements.

10. Direct Imports by Individuals

There is no restriction in importing when it is used individually. However, when it is distributed to the public, the Food Sanitation Law restricts it.

11. Importer Organization and Industry Contacts

- Japan Health Food and Nutrition Food Association
TEL: 03-5410-8231 <http://www.health-station.com/jhnfa>
- Japan Food Sanitation Association
TEL: 03-3403-2111 <http://www.jfha.or.jp>