

9. Health Foods

1. Definition of Category

Health foods that are ingested for the purpose of recovering, maintaining and improving health are discussed here. There is no established definition for the word “health food” and it should be discussed to what extent the range of health food would be. In this guidebook, the range is not definitely classified but it is broadly recognized and legal restriction for it is mainly discussed. The “so-called- health food” discussed here is as follows.

1. Food itself, which is said to be good for health originally (e.g. prune, yogurt, etc.) or with a preservative method such as drying employed (e.g. chlorella, ginseng, Agaricus Blazei murill, etc.), and food that seems to be the same as general foods at a glance but containing additional ingredients considered healthy (e.g. calcium-enriched cookie, etc.) or reducing salt or oil (e.g. salt-reduced soy beans).
2. Not in the shape of general foods but in the shape similar to medicines, such as capsules and liquid that includes special ingredients or extracts (so-called supplement). A supplement is a food to supply nutrition such as vitamin or mineral (calcium or iron content), and not in the shape of general food, such as in a tablet or a capsule.

HS Numbers

As HS numbers discussed here are so many (for ginseng 1211.20, for prune 0813.20, etc.) and as not all of these numbers correspond to health foods, HS numbers are not listed here. In case of manufactured health foods, most fall into the category of HS 2106.90 “Food preparations – not elsewhere specified or included.”

2. Import Trends

(1) Recent Trends in Health Foods

HS number 2106.90 (classifying prepared health food) includes items other than health foods. Therefore, it is impossible to make exact statistics related to importing trend.

(2) Imports by Place of Origin

As the definition of the health food ranges very widely and exporting countries to Japan also ranges widely, a listing of exporting countries is omitted. For foods consisting of ingredients, the specified country is the main exporting country such as prunes from the United States and propolis from Brazil, etc. The main exporter of supplements to Japan is the United States.

(3) Imports' Market Share in Japan

In case of health food manufactured by extracting supplements and other ingredients, there are many cases of importing ingredients and produced in Japan, though there are some cases of importing manufactured preparations from the United States. As a whole, most of the products are made in Japan. For ingredients that are difficult to produce or gather in Japan (ginseng, propolis, chlorella, Agaricus Blazei murill, and prune), most of them are imported. According to the industry sources, this trend is marked for prune essence, royal jelly, propolis, and blueberry.

3. Key Considerations related to Importing

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

When importing health foods, they are subject to provisions of the Food Sanitation Law. In some cases, they are also subject to the Plant Protection Law, and the Domestic Animal Infectious Disease Control Law.

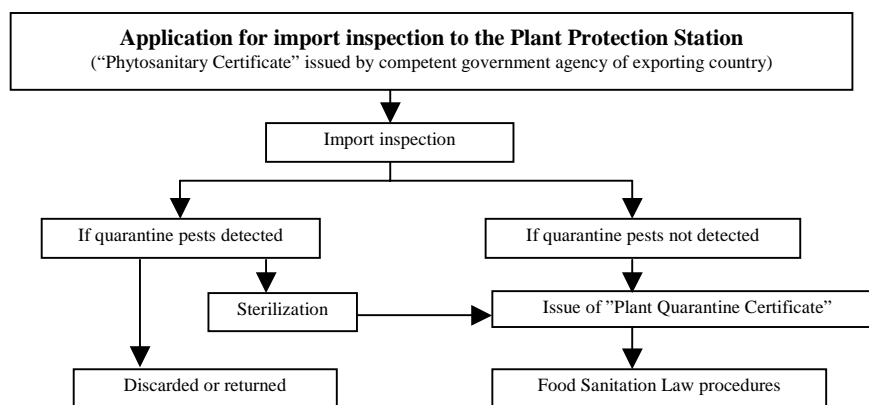
1) Plant Protection Law

Under the Plant Protection Law, in order to prevent the entry and spread into Japan of harmful microorganisms, insect pests, and parasites that would cause serious damage to crops and forest resources:

- No root crops with soil attached can be imported into Japan.
- No host fresh (frozen) vegetables of the Mediterranean fruit fly, the Colorado leaf beetle, the citrus burrowing nematode, etc. from or through the infested area are allowed into Japan.

There is a separate list of import-prohibited items for every infested area. If one of these import-prohibited items is brought to Japan, an order will be issued to burn and the like. When importing health foods derived from plants, the importer must promptly submit to the Plant Protection Station an “Application for Import Inspection of Plants and Import-Prohibited Articles” along with a “Phytosanitary Certificate” issued by the competent government agency of the exporting country. Importers should note that only certain ports of entry equipped with plant quarantine facilities are designated for plant imports. If an infestation is detected, and then the importer will be ordered to decontaminate, discard, or return to the shipper.

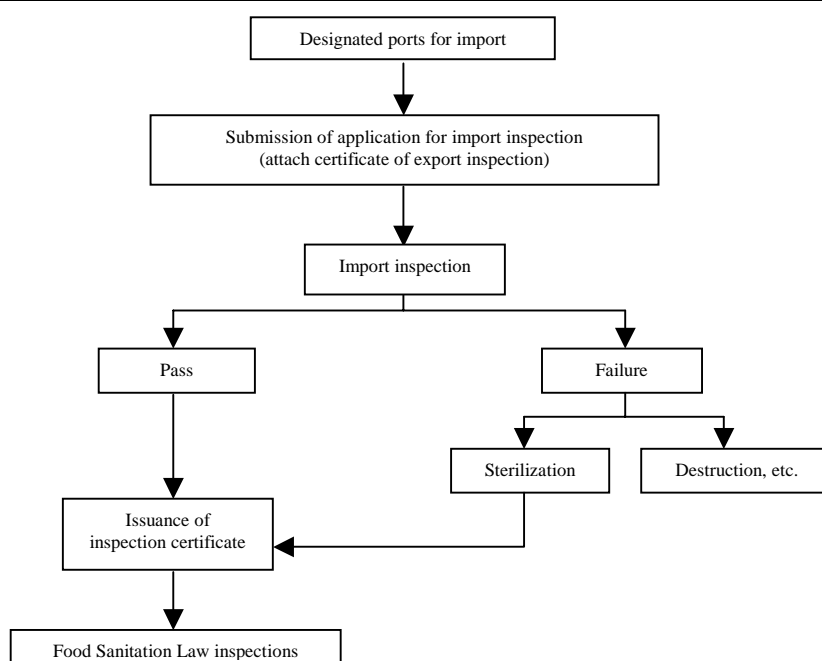
Fig. 1 Plant Protection Law Procedures



2) Domestic Animal Infectious Disease Control Law

In order to prevent infectious diseases of livestock from being brought into the country, some of health foods derived from animals or their ingredients are subject to inspections mandated by the Domestic Animal Infectious Diseases Control Law. The importer must submit an application for import quarantine inspection along with an inspection certificates issued by the competent government agency of the exporting country to Animal Quarantine Station at the port of entry. Note that animal inspections can only be performed at ports of entry with facilities to carry out required processes. If the product passes inspection, an import quarantine certificate is issued. If the product fails inspection, an order will be issued to destruct, bury, or return to the shipper, depending on the product and the nature of the violation. Note that the import-prohibited areas are frequently changed, so check with the appropriate Animal Quarantine Station.

Fig. 2 Procedures under the Domestic Animal Infectious Diseases Control Law

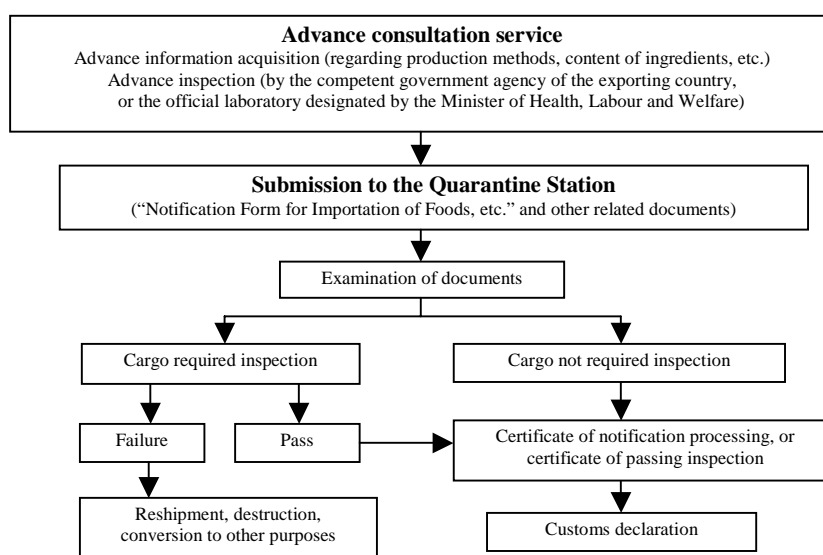


3) Food Sanitation Law

The Food Sanitation Law treats health foods in the same manner as all other foods. Under provisions of the Law, an import notification is required for health 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.

Additives used in health foods include all types of vitamins, minerals, and amino acids, some of which are not approved for use in Japan, and others of which have defined usage standard. Thus, importers need to pay close attention in advance to the types and amounts of additives used in products. 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. 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.

Fig. 3 Procedures required under the Food Sanitation Law



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

The sale of health foods is subject to the Food Sanitation Law and the JAS Law. Also, the Nutrition Improvement Law and the Measurement Law may apply depending on characteristics and forms of products. 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 packaged health foods, they must be labeled in accordance with provisions of the Food Sanitation Law. (see 4. Labeling)

Japan introduced a health functional foods program as of April 1, 2001. Under this program, health foods that comply with established standards are allowed to make certain health benefit claims on their labeling. The special foods for good health program allowed benefit claims only after each individual product had undergone very rigorous testing (separate permit model). In contrast, this new health functional foods program allows foods with contents that comply with standards to make claims of health benefits without having to obtain a permit from the Ministry of Health, Labor and Welfare (standards compliance model). There is no restriction on physical form, so the program applies to all food products, including those packaged as tablets or capsules, as well as confections, soft drinks, and dairy products. However, at the present time vitamin and mineral content is covered, and labeling content is limited to describing the nutritional role of those vitamins and minerals.

2) JAS Law

(Law Concerning Standardization and Proper Labeling of Agricultural and Forestry Products)

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

3) Nutrition Improvement Law

The Nutrition Improvement Law sets the standards for the foods for sale (excluding the special usage foods mentioned later). When employing labeling for nutritional ingredients or calories, labeling must be in accordance with the requirements under the Nutrition Improvement Law. (see 4. Labeling)

“Special usage foods” are used for special occasion such as for babies, infants, pregnant women, nursing mothers, the elderly, and ill persons. When labeling the “special usage foods,” it is required to obtain approval from the Minister of Health, Labour and Welfare through a governor of the prefecture. For acquiring the approval, application form should be submitted, denoting product name, combination ratio of the ingredient, manufacturing method of the product, ingredient analysis table, contents of the special usage labeling to be approved, and other items specified by the ministerial ordinance of the Ministry of Health, Labour and Welfare. Assessment report of the appropriate people of experience or academic standing should be attached for the designated documents. 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.

4) Measurement Law

Health foods sealed in wrapping or containers are required the labeling of the net content to certain accuracy (range of error specified by Cabinet Ordinance).

5) Containers and Packaging Recycling Law

(Law for Promotion of Sorted Collection and Recycling of Containers and Packaging)

The Containers and Packaging Recycling Law was enacted to promote recycling of container and packaging waste materials. It provides for sorting by consumers, sorted collection by municipalities, and product reuse (recycling) by product makers and distributors for glass bottles, PET bottles, paper and plastic containers and packaging. Consequently, health food importers incur the obligation for recycling of containers and packaging (although stipulated small-scale importers are exempt). Please consult the competent government agencies listed below for more information.

6) Law for Promotion of Effective Utilization of Resources

As of April of 2001, new identifier labeling requirements apply to paper (not including beverage containers not containing aluminum) and plastic container materials, in addition to previously existing labeling requirements for steel and aluminum cans. (see 4. Labeling)

(3) Competent Agencies

- Pharmaceutical Affairs Law

General Affairs Division, Pharmaceutical and Medical Safety Bureau, Ministry of Health, Labour and Welfare (Pharmaceutical Affairs Law in general)

Evaluation and Licensing Division, Pharmaceutical and Medical Safety Bureau, Ministry of Health, Labour and Welfare (Import approval procedures)

TEL: 03-5253-1111

<http://www.mhlw.go.jp>

- 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>

- Plant Protection Law

Fruit and Flower Division, Agricultural Production Bureau, Ministry of Agriculture, Forestry and Fisheries

Plant Protection Division, Agricultural Production Bureau, Ministry of Agriculture, Forestry and Fisheries

TEL: 03-3502-8111

<http://www.maff.go.jp>

- **Domestic Animal Infectious Diseases Control Law**
 Animal Health Division, Livestock Industry Department, Agricultural Production Bureau, Ministry of Agriculture, Forestry and Fisheries
 TEL: 03-3502-8111 <http://www.maff.go.jp>
 Animal-Products Inspection Division, Department of the Quarantine, Animal Quarantine Service, Ministry of Agriculture, Forestry and Fisheries
 TEL: 045-201-9478 <http://www.maff.qas.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

When selling health foods 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

Example label for health foods

Product name	Royal jelly
Net contents	100 capsules (includes equivalent 20mg of natural royal jelly per capsule)
List of ingredients	Royal jelly powder, apiarian pollen
Additives	Soybean oil, bees wax
Storage instructions	Store at cool and dark place.
Date of minimum durability	2001. 1. 23
Vendor:	ABC Corp., Ltd. A-A, BB-machi, CC Prefecture
Importer:	XYZ Corp., Ltd. X-X, YY-machi, ZZ Prefecture
Country of origin:	China

<Labeling of food products containing allergens>

The Food Sanitation Law mandates or recommends raw material labeling for 24 food products that contain allergens. Processed food products 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 food products 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

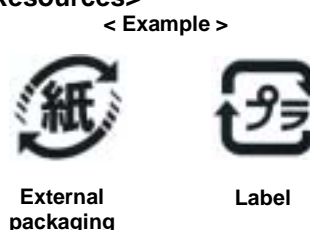
<Labeling requirements for genetically modified foods>

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 food products 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)

<Labeling under the 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.



(2) Voluntary Labeling based on Provisions of Law

1) 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.

Contact:

Center for Food Quality, Labeling and Consumer Services Headquarters
Standard and Labeling Department TEL: 048-600-2371 <http://www.cfqlcs.go.jp>

Organic JAS Mark



2) Nutrition Improvement Law

Labeling based on the Nutrition Improvement Law should be made according to the Nutrition Labeling Standard. Contents of the labeling should be as follows.

- a) Scope of nutrition ingredient
It is applied not only ingredients which is noticed as general nutrition ingredient, but also construction ingredient (such as amino acid in protein, etc.) or its types (fatty acid in lipid., etc.)
When general name of vitamin, etc. is used and its type is not specified, labeling of ingredient of the 11 ingredients specified in the Nutrition Improvement Law should be made. However, labeling related to taste (light flavor, etc.) is excluded.
- b) Order and unit of labeling
Order and unit of labeling is specified for some ingredients. Care should be made, as when labeling which is used in overseas is used as it is, it may be not applicable.
- c) Emphasized labeling
When emphasized labeling is made in the explanation of the ingredient, not the health food itself, the health food itself should satisfy the standard of the emphasized labeling. (When it is labeled that “There are plenty of protein contained in the chlorella which is the ingredient”, quantity of the protein should satisfy the high quality standard.) When labeling, target of the comparison, quantity of increase (decrease) or rate should be also made.

3) Health functional foods program (Food Sanitation Law, Nutrition Improvement Law)

Products designated as health functional foods must contain the following labeling items.

Labeling items for health functional foods

Nutrition function foods	Special foods for good health
1. Description of “health functional foods” (nutrition functional foods) 2. Nutritional ingredients (including ingredients to be functional) 3. Nutritional function 4. Standard of quantity to intake in one day 5. Method of intake 6. Ratio to standard nutrition quantity per day 7. Caution to intake 8. Statement that this product has not received separate examination by the Ministry of Health, Labour, and Welfare as special foods for good health	1. Description of “health functional foods” (special foods for good health) 2. Nutritional ingredients (including ingredients to be functional for good health) 3. Specific usage (labeling permit) 4. Standard of quantity to intake in one day 5. Method of intake 6. Ratio to standard nutrition quantity per day 7. Caution to intake

Mark of special foods for good health

**(3) Labeling based on a “Guide” of the former Ministry of Health and Welfare**

The former Ministry of Health and Welfare establishes “Guide to label the quantity and method to take the health food” (1988) and “Guide to the labeling of the health food” (1989). Marking items and basic items included here are as follows.

1) Guide to label the quantity and method to take the health food

For health foods, following items should be labeled in addition to items to be labeled according to laws such as the Food Sanitation Law, etc.

- Upper limit or standard of quantity to intake in one day
- Method to intake, when it is not taken by the normal method
- It should be noticed if it gets in trouble to health when it is taken too much
- It should be marked that it is “food”

2) Guide to the labeling of the health food

Labeling of the health food should be based on balanced eating habits to maintain health and should be made as follows.

- In accordance with the Food Sanitation Law, the Nutrition Improvement Law, and the Pharmaceutical Affairs Law
- Among the attribute having a complementary color normally, it is the item to be the characteristic of the health food
- It is appropriate scientifically and fact is denoted
- Correct words should be used and sentences should be clear, so that consumers can easily understand

(4) Voluntary Industry Labeling

Only for the foods satisfied the standard of safety, hygiene and marking contents specified for each types of foods by the Japan Health Food and Nutrition Food Association according to the guidance of the Ministry of Health, Labour and Welfare can attach the approval mark (JHFA mark). Labeling items are specified in detail according to the type. General labeling items are as follows.

JHFA Mark

**Labeling items of the JHFA mark**

Mandatory items	Optional items
<ul style="list-style-type: none"> • Product name • Name of ingredients • Net content • Date of minimum durability or best-before date • Name and address of the manufacturer • Specified ingredients and contents • Caution in preservation 	<ul style="list-style-type: none"> • Ingredient contents (excluding specified ingredients) and the quantity • Effectiveness (note) • Dose • Method of dose • Country of origin

Note Effectiveness of the contained ingredient can be denoted for the purpose of nutrition supply and health maintenance based on academic reason. However indication should not conflict with the Pharmaceutical Affairs Law, Act Against Unjustifiable Premiums and Misleading Representations, and Nutrition Improvement Law, etc.

Contact:

- Japan Health Food Association TEL: 03-3268-3131 <http://www.health-station.com/jhnfa>

For honeys and royal jellies, there is individual labeling in the industry. For details, refer to “I-28 Bee Products” in this guidebook.

5. Taxes

(1) Customs Duties

In the case of the health foods, rate of customs duties differs according to combined ingredients form of products. Please check customs authorities in advance.

(2) Consumption Tax

(CIF + Customs duties) x 5%

6. Product Characteristics

(1) Types and characteristics of health foods

As there are many types, ingredients, usage of the health foods discussed here, it is difficult to denote general product characteristics. Figure 4 below provides a broad classification of health foods, with descriptions of those with distinctive characteristics.

Fig. 4 Classification of health foods

		Examples	
Health foods in the form of normal food products	Foods generally considered healthy in their ordinary form	Honey, unprocessed royal jelly, prunes	
	Foods processed to add or remove certain ingredients	Foods with extra calcium, vitamin C or other nutritional enhancements; low-salt foods	
	Special usage foods	Foods for ill persons	Non-allergenic foods, low-calorie foods
		Foods for pregnant women or nursing mothers	Milk formula for pregnant women or nursing mothers
		Foods for infants	Infant formula
		Foods for the elderly	Foods for those with difficulty in chewing or swallowing
Special foods for good health	Foods with oligo saccharides and lactobacillus, designed to improve digestion, etc.		
Health foods delivered in medicinal form (granules, liquid, capsules) rather than in the form of food	Supplements	Vitamins, calcium	

<General health foods>

Health foods are controlled legally in greater or less degree, from the viewpoint of security and health promotion or for the purpose to submit proper information to customers, regardless of imported product or not. Standard conformance duty of the Food Sanitation Law and quality labeling according to the JAS Law are applied to all health foods. But most of the health foods distributed in Japan are not restricted legally other than them. There are plenty of health foods, which are included in this category. Their ingredients, shapes and dose method also vary. Each customer should judge if it is health food or not for themselves, according to labeling of ingredients and additives.

<Special usage foods>

The Nutrition Improvement Law defines a category of “special usage foods” and specifies special usage such as for ill persons and the elderly. Foods approved to use in these purposes are permitted to make labeling of special usage foods (see 4. Labeling). For “foods for ill persons,” combination foods such as low sodium foods (such as salt-reduced soybean paste, salt-reduced soy sauce), low calorie foods (diet sweetener, etc.), foods for an allergic disease (foods excluding allergen) and others for adjusting salt-reduced foods or for adjusting diabetes are designated. For “foods for the elderly,” foods considering especially for aged person who has weak chewing strength or swallowing strength are designated. Though there are many salt-reduced foods or low calorie diet foods in the Japanese market, not all of them can label the “special usage foods” when application is made. Only foods, which cleared strict standard and inspection, are permitted to make the labeling. As of January 2002, 403 products are permitted to make the labeling of “special usage foods.”

<Special foods for good health>

When the purpose of the special foods for good health can be expected when taking the health food, labeling of “special foods for good health,” for the characteristics, usage, and effect, is permitted. (This is based on the above Nutrition Improvement Law and is categorized as one of “special usage foods.”)

For the purpose of the special foods for good health, there are “medical function for intestinal disorders,” “effective to cholesterol,” “hard to have bad tooth,” and “help absorbing mineral,” etc. As foods for special usage other than foods for special foods for good health assumes the special user (ill persons, aged persons or pregnant women and nursing mothers), special foods for good health does not define the user, as labeling is permitted by paying attention to characteristics, usage and effect of the product. Approval standard of the “special foods for good health” is also strict and not all the health foods can make labeling just having above effects. As it is specified that it should “have a shape of general foods” and “be taken daily, not rarely” in the approval standard, the health food so-called supplement can not make marking of such as having the effect on intestinal disorders, as a food for special health. As of the end of January 2002, there are 289 foods, which are permitted to make labeling of “special foods for good health” (foods using lactic acid bacterium, chlorella, foods processed with Reino), including one imported product.

<Supplements>

Supplements belonging to group II of Figure 4 are increasing recent health food market in Japan. At present, there are no legal restrictions for supplement, regardless of imported products or products made in Japan. Some health foods such as vitamin are seen at the store as medicine, on one hand and as food, on the other hand, having similar ingredients and shapes. Due to such situation, it is now considered to classify the supplement as the third category of “nutrition supplement food,” between medicine and foods, and clarify the definition, to settle a kind of restriction, including labeling method.

(2) Characteristics of health food

Though the health foods include similar ingredient and quantity, it is typical that prices of such products differ greatly. As is clear from Fig. 4, among the health foods, (1) foods with normal shape are the cheapest, which customers select such group easily. For (4) the supplement, it is expensive compared to (1) foods with normal shape but the supplement is cheaper when compared to medicine with same ingredient and same quantity. The price of this group is getting cheaper every year.

<Classification of foods and medicines>

As health foods are foods, and not medicine, discrimination with medicines should be made clear. Even though it is classified as health food in overseas, the Pharmaceutical Affairs Law may restrict it in Japan in some cases, so care should be made. For the classification of health foods and medicines, there are following four check points as judgment standard, according to the notification by the former Ministry of Health and Welfare.

1) Use of ingredient

Ingredient, which can be only used for medicine, cannot be used for health foods.

2) Marking of the effect

It is prohibited to denote that it aims to cure or prevent disease or it aims to strengthen body function or improvement on the container or attached documents, which is considered that it is professing to have effect as medicine. However, in case of “special foods for good health,” its effect can be indicated. (Refer to the previous clause.)

3) Similarity in shape

It is prohibited to process in a shape similar to medicine such as tablets or capsules, excluding some vitamins or herbs. However, when the trader judged that it is necessary to maintain quality, for a special ingredient, it can be processed to a medical shape.

4) Similarity in usage

Generally, recommended usage should not be the same as the dose used for medicine. However, the case when deciding dose for certain duration is excluded.

In March of 1999 the Pharmaceutical and Medical Safety Bureau of the former Ministry of Health and Welfare issued a notification ruling that vitamin A, B, C, D, E and niacin that are widely recognized as extracted from foods as well as products that clearly use the term “food product.” On the other hand, the items that make no claim of medicinal benefit do not constitute pharmaceutical products, even if they have the form of capsules, tablets or pills. Other vitamins are to be treated in the same manner provided that the daily intake is no greater than a stipulated amount.

7. Domestic Distribution System and Business Practices

(1) Domestic Market Conditions

For the market scale of health food field, it is very difficult to know the actual condition, as the definition of the health food itself is yet vague and most of manufactures and sales companies handling it are small and medium sized businesses. Market scale in 2001 is estimated to increase to approx. ¥800 billion judged from information in the industry. According to the survey by the Japan Health Foods Association, the size of the market for special foods for good health is estimated to rapidly increase from ¥131.5 billion in 1997, ¥226.9 billion in 1999, and finally to ¥412.1 billion in 2001. 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. The leading product category is foods for intestinal disorders (including foods containing lactic acid bacterium), accounting for 81.4 % (¥335.5 billion) of the total market. In the recent market, foods hard to have bad tooth and foods effective to cholesterol are also increasing.

Supplement market is increasing above all. Sales in Japan started regularly since the middle of 1990s and the market has been growing since then. Market scale at present is ¥10 billion or more and amount to ¥30 billion or more including mail-order business. This may be because types of supplement are increasing, as “compounded type supplement” such as multi-vitamin came up in the market and various industries (medicine manufacturers, milling manufacturers, cosmetic manufacturers) started to participate in the market. Also consumers have interest in health very much and as they are handy and convenient, they are induced to buy them.

(2) Distribution Channels

Distribution of health foods is roughly divided into non-storefront sales (door-to-door sales, mail-order sales, etc.) and storefront sales. Store front sales are divided to specialty stores for health foods, drug stores, general retail stores and convenient stores. As a whole, health foods are more often distributed through non-storefront channel, with a ratio of 6:4.

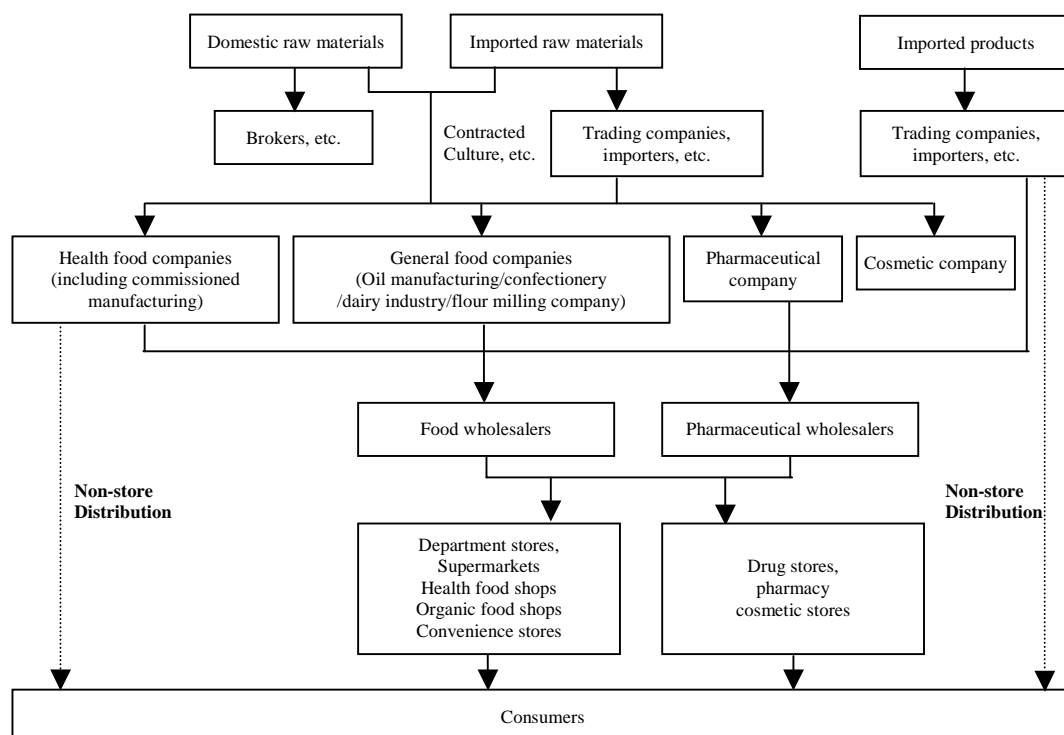
In March 1999 pharmaceutical categories have reclassified to allow the sales of 15 products, including vitamin-based health supplements and digestion-promoted soft drinks, to be sold at supermarkets, convenience stores and other consumer retail outlets. Previously these products can only be purchased at pharmacies, but now they can be purchased at convenience stores and other ordinary retail stores. This has expanded remarkably distribution channel for health foods. Now, many of convenience stores carry vitamin-based health supplements and other health foods. According to the Japan Health Foods Association, supermarkets, department stores, and convenience stores together account for 62% of total sales of special foods for good health, followed by food delivery service (31%), pharmacies (4%), and mail order companies (3%). Following chart illustrates principal distribution channel for health foods as a whole.

(3) Points to Consider when First Entering the Japanese Market

Though the health food is distributed as foods in other countries, the Pharmaceutical Affairs Law restricts it in Japan in some cases, so care should be taken when participating in this market. Care should be made that the Food Sanitation Law, JAS Law, Nutrition Improvement Law, and other laws restrict when importing and selling health foods.

8. After-Sales Service

Sales company in Japan and manufacturer care for after service and the consulting window is denoted on the product. Consumer Life Center, etc. in each prefecture consults with complaint for extravagant advertisement and selling method. When it is proved that the imported product damaged the human body due to defect, the manufacturer and importer should bear responsibility according to the PL Law. Care should be fully made for the quality control.

Fig. 5 Distribution channel for health foods

9. Related Product Categories

Nutrition beverages such as digestion-promoted soft drinks are sold sometime as pharmaceuticals, quasi-drugs, or as soft drinks in some cases in Japan. Pharmaceuticals and quasi-drugs are subject to provisions of the Pharmaceutical Affairs Law, while soft drinks are subject to provisions of the Food Sanitation Law. As a part of deregulation, pharmaceutical product categories have been revised in March 1999 to allow the sale of 15 products, including vitamin-based health supplements and digestion-promoting soft drinks, to be sold at supermarkets, convenience stores and other consumer related outlets. Thus, it is not required to obtain product-specific approval, but nutrition beverage imports still need an importer's license.

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. When importing health foods, which are treated as pharmaceuticals in Japan, individuals should note that quantity deemed appropriate for personal consumption may be imported without having to comply with requirements of the Pharmaceutical Affairs Law. For details, consult with the Evaluation and Licensing Division, Pharmaceutical and Medical Safety Bureau, Ministry of Health, Labour and Welfare.

11. Related Organizations

- 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>