

Guidebook for Export to Japan (Food Articles) 2011
<Health Foods and Dietary Supplements>

Japan External Trade Organization (JETRO)

Development Cooperation Division
Trade and Economic Cooperation Department

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Written and Published by:
Japan External Trade Organization (JETRO)
Development Cooperation Division
Trade And Economic Cooperation Department

Ark Mori Building 6F, 12-32 Akasaka 1-CHOME, Minato-Ku, TOKYO
107-6006 JAPAN
TEL:+81-3-3582-5770
FAX:+81-3-3585-1630

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10. Health Foods and Dietary Supplements

Health foods and dietary supplements are products of food standards that are consumed for the purpose of maintaining good health by supplementing nutrients that may often be lacking in one's daily diet. Although they are often consumed for purposes and uses similar to those in the case of pharmaceutical products, health foods and dietary supplements are not subject to the Pharmaceutical Affairs Act.

There are ambiguous areas where the definition of health foods and dietary supplements are concerned. In this chapter, however, they are defined as products of food standards that are not included in the categories of pharmaceutical products or quasi drugs, and are clearly not regarded as food. Individual raw ingredients shall be handled in the appropriate chapters herein and are not discussed here.

Dietary supplements are defined as products in forms similar to those of pharmaceutical products such as tablets and capsules, whose primary purpose is to provide nutrients such as vitamins and minerals.

Health foods are those foods in general that are advertised as having functions that are widely beneficial for the maintenance and improvement of health, and distributed and marketed as such.

Discussions on trade trends cover homogenously-mixed prepared food products and vitamins and other nutritional supplements that are imported as health food products, as well as vitamins, etc. that are imported as food additives or ingredients that are used most commonly for the purpose of nutrition support and similar benefits.

I. Points to Note in Exports to and Sales in Japan

1. Relevant Laws and Institutional Regulations

(1) Regulations and Procedural Requirements for Importing to Japan

The importing of health foods and dietary supplements is regulated primarily by the following two laws: 1) Food Sanitation Act; 2) Customs Act.

<Food Sanitation Act>

In compliance with Notification No. 370 of the Ministry of Health, Labour and Welfare, "Standards and Criteria for Food and Additives" issued under the Food Sanitation Act, and the standards for pesticide residues, etc. (including feed additives and drugs for animals) which are included therein, health foods and dietary supplements are subject to food sanitation, which is conducted to assess the types and details of the raw ingredients, and to test the types and contents of additives, pesticide residues, mycotoxins, and so on. Import bans may be imposed on food in the event of an additive, pesticide, or other contents which are prohibited in Japan, when their levels exceed approved limits, or when the presence of mycotoxins, etc. is above allowable levels. Accordingly, health foods and dietary supplements should be checked at the production site prior to import. If levels exceed the limits of Japanese standards, guidance should be given.

Pesticide residue standards adopted a negative system until 2006, under which pesticides would not be subject to control if there was no requirement for them. Amendments to the law introduced a positive list system, however, and the distribution of products is now prohibited in principle if they contain a specific level of pesticides, etc. even if there is no established requirement.

<Customs Act>

Under the Customs Act, the importing of cargo with labeling that falsifies the origin of the contents, etc. is banned.

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

Regulations and restrictions relevant to the sales of health foods and dietary supplements are explained below.

<Food Sanitation Act>

Under the Food Sanitation Act, sales of products that contain harmful or toxic substances or those with poor hygiene are prohibited. Sales of health foods and dietary supplements in containers and packaging are subject to mandatory labeling under the Food Sanitation Act, and provisions concerning safety labeling such as indication of food additives, allergy information, raw ingredients and source, and genetic modification, etc. are applicable.

The Food Sanitation Act allows certain foods to be labeled as Food for Specified Health Use or Food with Nutrient Function Claims, which are regarded as being in-between food and pharmaceuticals.

Foods that are expected to have specified health uses are allowed to be labeled as Food for Specified Health Use and indicate such claims for specific dietary uses as "helps improve digestive regularity" and "for those concerned about blood glucose level." In order for a product to bear the Food for Specified Health Use label, approval from the Secretary General

of the Consumer Affairs Agency is required, which can be very difficult as it is necessary to conduct a human clinical study, which often costs hundreds of million yen. Given this situation, measures have been taken to promote a wider application of Food for Specified Health Use, by recognizing Qualified Food for Specified Health Use, for products that have been shown to have certain health effects though not at a level of scientific evidence as required in the review process for Food for Specified Health Use applications.

For Food with Nutrient Function Claims, meanwhile, products are only required to contain certain nutritional components that meet the standards set forth by the Secretary General of the Consumer Affairs Agency; it is not necessary to file an application for permit or notification, but is permissible to produce and sell such products at one's own discretion.

<Pharmaceutical Affairs Act>

To prevent pharmaceutical products and dietary supplements from being mixed up, it is prohibited under the Pharmaceutical Affairs Act to label or advertise dietary supplements in a manner that misleadingly promotes them as having an effect or efficacy of a pharmaceutical product.

<Product Liability Act>

The Product Liability Act stipulates liability of manufacturers, etc. for damages to consumers in association with product defects, and importers are included in the category of manufacturers, etc.

While unprocessed agricultural products are exempt from the Act, heat-processed health foods and dietary supplements are included in items subject to the Product Liability Act, and care should be taken with regard to safety management of relevant contents, containers, and packaging.

<Act on Specified Commercial Transactions>

The Act on Specified Commercial Transactions stipulates the protection of interest of purchasers in the direct commercial transactions made with consumers. Sales of health foods and dietary supplements in such routes as mail-order, direct marketing, telemarketing, etc. are subject to provisions of the Act on Specified Commercial Transactions.

<Act on the Promotion of Sorted Garbage Collection and Recycling of Containers and Packaging>

Under the Act on the Promotion of Sorted Garbage Collection and Recycling of Containers and Packaging, importers, etc. that sell contents using containers and packaging that are controlled by the Act (paper containers and packaging and plastic containers and packaging, etc.) shall be liable for recycling (however, small-scale enterprises of below a certain size are excluded from among enterprises subject to the Act).

2. Procedures

(1) Procedures for Authorization of Importing and Sales

<Food Sanitation Inspection>

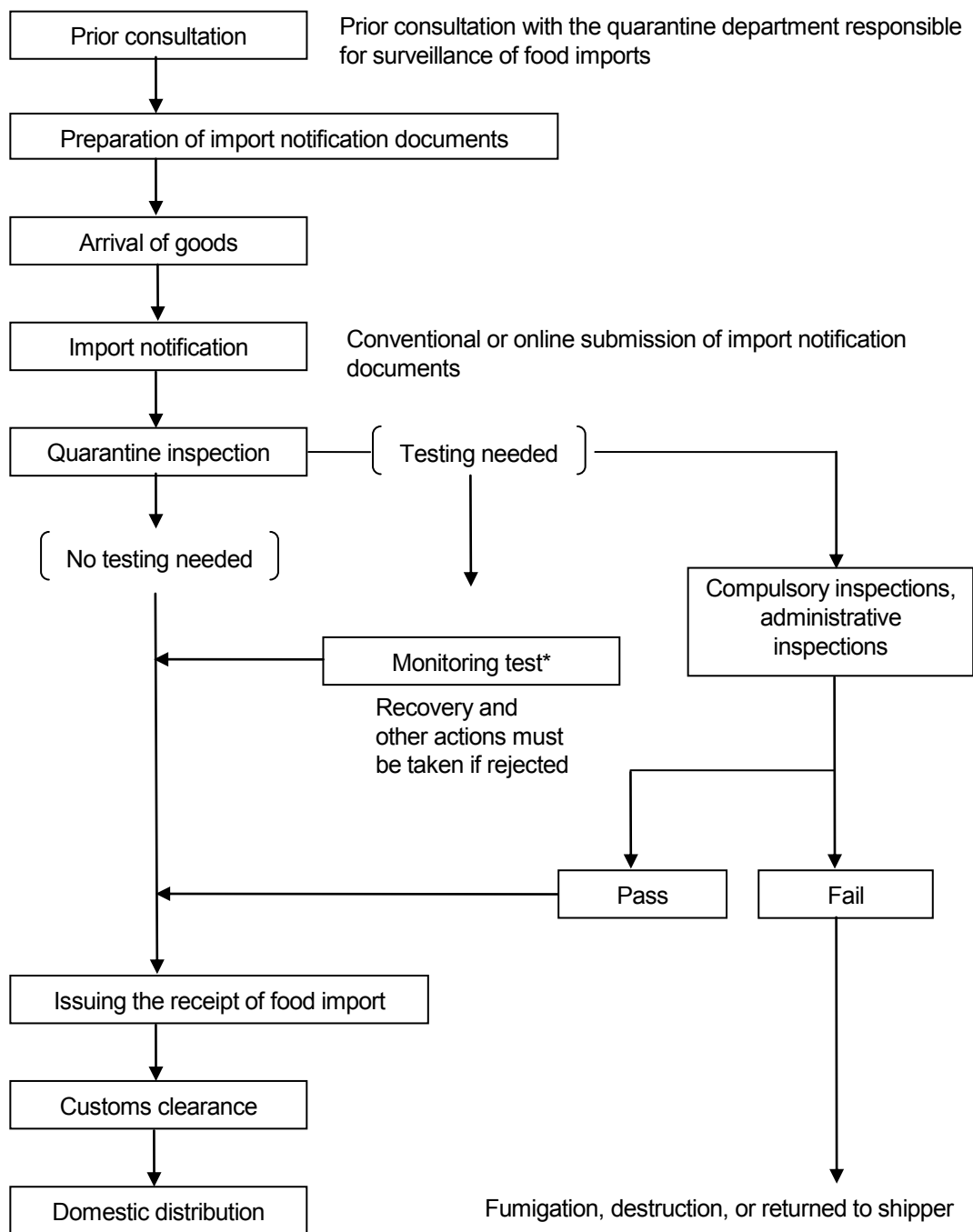
Under the Food Sanitation Act, the required documents (Fig. 10-2) must be submitted when filing an application for inspection with the imported food monitoring departments of Quarantine Stations, Ministry of Health, Labour and Welfare. Inspection is conducted where it has been decided necessary to check the standards and criteria or safety issues at the initial review stage. If, as a result of the initial review and inspection, no issue has been detected under the Act, the registration certificate is returned, which the applicant shall submit, along with customs documents, upon filing an application for import with Customs. In the event that it has been ruled unfit for importing, measures such as destruction or return to the shipper are taken (Fig. 10-1).

<Customs>

Under the Customs Business Act, import declaration must be made by importers themselves or commissioned to those qualified as registered customs specialists (including customs brokers).

To accept the entry into Japan of incoming cargo arriving from a foreign country, an import declaration must be made to the competent Customs office for the bonded area where the cargo is stored. Cargo for which customs inspection is required shall undergo required inspections first, and upon payment of customs duty, national and local consumption taxes, an import permit may be given in principle.

Fig. 10-1: Flowchart of import procedure



Source: Ministry of Health, Labour and Welfare

* Import food inspection following notification, conducted by MHLW Quarantine Stations according to the annual plan.

(2) Required Documents

Documents required for importing are summarized below in Fig. 10-2 according to the authorities to which each document is submitted.

Fig. 10-2: Documents required for import clearance

Submitted to	Required documents
Imported food monitoring departments of Quarantine Stations, Ministry of Health, Labour and Welfare (Food sanitation inspection under the Food Sanitation Act)	Notification form for importation of foods
	Material/ingredient table
	Production flow chart
	Table of analysis results issued by the designated inspection institute (if there is a past record of import)
Local customs offices (Customs clearance under the Customs Act)	Declaration of import
	Invoice
	Packing list
	Bill of lading (B/L) or airway bill

Source: Ministry of Agriculture, Forestry and Fisheries, Ministry of Health, Labour and Welfare, Ministry of Finance

(3) Competent Authorities

Fig. 10-3: Contacts of competent authorities

Plant Protection Act		
	Plant Protection Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries	TEL: +81-3-3502-8111 http://www.maff.go.jp
Food Sanitation Act		
	Inspection and Safety Division, Department of Food Safety, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare	TEL: +81-3-5253-1111 http://www.mhlw.go.jp
Customs Tariff Act		
	Customs and Tariff bureau, Ministry of Finance Japan	TEL: +81-3-3581-4111 http://www.mof.go.jp
Act for Standardization and Proper Labeling of Agricultural and Forestry Products		
	Labelling and Standards Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries	TEL: +81-3-3502-8111 http://www.maff.go.jp
Measurement Act		
	Measurement and Intellectual Infrastructure Division, Industrial Science and Technology Policy and Environment Bureau, Ministry of Economy, Trade and Industry	TEL: +81-3-3501-1511 http://www.meti.go.jp
Health Promotion Act		
	Food and Labeling Division, Consumer Affairs Agency	TEL: +81-3-3507-8800 http://www.caa.go.jp
Pharmaceutical Affairs Act		
	Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare	TEL: +81-3-5253-1111 http://www.mhlw.go.jp
Act against Unjustifiable Premiums and Misleading Representations		
	Representation Division, Consumer Affairs Agency	TEL: +81-3-3507-8800 http://www.caa.go.jp
Product Liability Act		
	Consumer Safety Division, Consumer Affairs Agency	TEL: +81-3-3507-8800 http://www.caa.go.jp
Act on Specified Commercial Transactions		
	Consumer Advice Office, Ministry of Economy, Trade and Industry	TEL: +81-3-3501-1511 http://www.meti.go.jp
	Consumer Safety Division, Consumer Affairs Agency	TEL: +81-3-3507-8800 http://www.caa.go.jp

Fig. 10-3: Contacts of competent authorities (continued)

Act on the Promotion of Sorted Garbage Collection and Recycling of Containers and Packaging / Act on the Promotion of Effective Utilization of Resources

Recycling Promotion Division, Industrial Science and Technology Policy and Environment Bureau, Ministry of Economy, Trade and Industry	TEL: +81-3-3501-1511 http://www.meti.go.jp
Office for Recycling Promotion, Waste Management and Recycling Department, Ministry of the Environment	TEL: +81-3-3581-3351 http://www.env.go.jp
Food Industry Policy Division, General Food Policy Bureau, Ministry of Agriculture, Forestry and Fisheries	TEL: +81-3-3502-8111 http://www.maff.go.jp

Unfair Competition Prevention Act / Trademark Act

Intellectual Property Policy Office, Economic and Industrial Policy Bureau, Ministry of Economy, Trade and Industry	TEL: +81-3-3501-1511 http://www.meti.go.jp
General Affairs Division, Japan Patent Office, Ministry of Economy, Trade and Industry	TEL: +81-3-3581-1101 http://www.jpo.go.jp

II. Labeling

1. Labeling under Legal Regulations

Quality labeling of health foods and dietary supplements, must be in Japanese and conform to the following laws and regulations: 1) Act for Standardization and Proper Labeling of Agricultural and Forestry Products, 2) Food Sanitation Act, 3) Measurement Act, 4) Health Promotion Act, 5) Act on the Promotion of Effective Utilization of Resources, 6) Act against Unjustifiable Premiums and Misleading Representations, 7) Pharmaceutical Affairs Act, and 8) intellectual asset-related laws (e.g., Unfair Competition Prevention Act, Trademark Act).

When importing and selling health foods and dietary supplements, the importer must provide the following information on labels in accordance with the quality labeling standards for fresh foods of the Act for Standardization and Proper Labeling of Agricultural and Forestry Products and Food Sanitation Act: 1) product name, 2) country of origin, 3) content, and 4) expiration date, 5) storage method, 6) country of origin, and 7) name and address of importer..

<Product name>

The name of the product must be provided on the label in accordance with the Act for Standardization and Proper Labeling of Agricultural and Forestry Products and Food Sanitation Act.

<Ingredients>

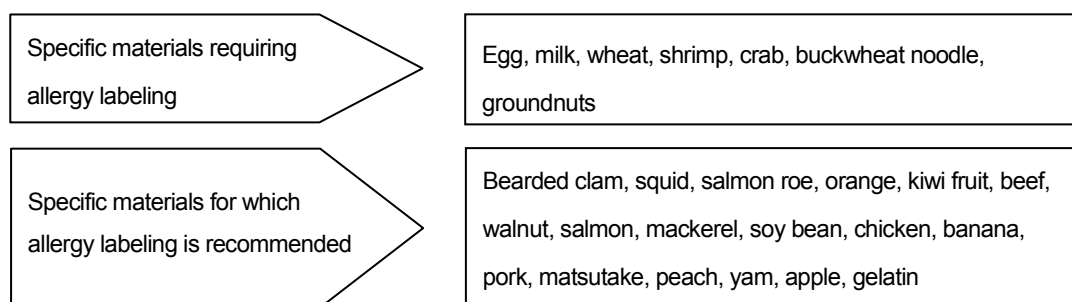
The ingredients of the product must be listed in descending order from highest to lowest content on the label in accordance with the Act for Standardization and Proper Labeling of Agricultural and Forestry Products and Food Sanitation Act.

<Additives>

The substance name of additives used must be listed in decreasing order from highest to lowest content on the label in accordance with the Food Sanitation Act. The substance name and use of the following eight additives must be indicated on the label: sweeteners, antioxidants, artificial colors, color formers, preservatives, whiteners, thickeners/stabilizers/gelators/bodying agents, antifungal agents, and antimold agents). For details on usage and storage standards of additives, Notification No. 370 of the Ministry of Health, Labour and Welfare "Standards and Criteria for Food and Additives" prescribes the maximum allowable limit of approved additives for each food article.

<Allergies>

When products containing the specific ingredients shown in Fig. 10-4 are sold, it is required or recommended that ingredients be labeled in accordance with the Food Sanitation Act to prevent health hazards among consumers with specific allergies. However, omission of labeling is allowed if such ingredients can be easily identified in the products.

Fig. 10-4: Specific materials related to allergy labeling

Source: Ministry of Health, Labour and Welfare

<Content weight>

When importing and selling health foods and dietary supplements, the importer must weigh the product in accordance with the Measurement Act and indicate the weight in grams or liters on the label. The product must be weighed so that the difference between the actual weight of the product and the figure indicated on the label is within the prescribed range.

<Expiration date>

The expiration date of the product when stored according to the given preservation method in the unopened state must be indicated on the label in accordance with the Act for Standardization and Proper Labeling of Agricultural and Forestry Products and Food Sanitation Act. As the quality of health foods and dietary supplements does not deteriorate easily, the “best by” date should be indicated on the label.

<Preservation method>

The preservation method for maintaining flavor in the unopened state until the best-by date must be indicated on the label in accordance with the Act for Standardization and Proper Labeling of Agricultural and Forestry Products and Food Sanitation Act. For products which can be stored at room temperature, the preservation method can be omitted from the label.

<Country of origin>

The quality labeling standards for processed foods, specified by the Act for Standardization and Proper Labeling of Agricultural and Forestry Products, require the country of origin to be indicated on the labels of import foods.

This Act also requires the country of origin to be labeled for the vegetables, fruits, and processed foods listed in Fig. 10-5. All other processed foods do not require labeling. Such information must be labeled either by stating in brackets on the list of ingredients or by stating the name of country of origin in a specified column of the labeling.

Fig. 10-5: Processed foods made from vegetables and fruits requiring country of origin labeling

Labeling standards	Applicable processed foods	For example
Quality labeling standards for processed foods	Dried mushrooms, vegetables, fruits	Dried shiitake
	Salted mushrooms, vegetables, fruits	Salted mushrooms
	Boiled or steamed mushrooms, vegetables, and beans; and sweet bean pastes	Boiled bamboo shoots, raw bean pastes
	Mixture of cut vegetables and fruits, mixture of vegetables, fruits, and mushrooms	Cut vegetable/fruit mix
	Konjac	Konjac bar, konjac ball

Source: Ministry of Agriculture, Forestry and Fisheries, Consumer Affairs Agency

Such information must be labeled either by stating in brackets on the list of ingredients or by stating the name of country of origin in a specified column of the labeling.

<Importers>

The name and address of the importer must be indicated on the label in accordance with the Act for Standardization and Proper Labeling of Agricultural and Forestry Products, and the Food Sanitation Act. For products processed in Japan using imported ingredients, the name and address of the manufacturer or dealer must be indicated on the label.

<Nutrition facts>

The nutritional components and calorie count must be indicated on the labels of soft drinks in accordance with the nutritional labeling standards prescribed by the Health Minister. The required information includes nutritional components,

structural components (e.g., amino acids in protein), and types of components (e.g., fatty acids in fat). If general names such as “vitamin” are labeled instead of describing the specific names of nutrients, ingredients must be labeled.

Components must be indicated in the following order and unit:



- a) Calories (kcal or kilocalories)
- b) Protein (g or grams)
- c) Fat (g or grams)
- d) Carbohydrate (g or grams)
- e) Sodium
- f) Other nutritional components to be indicated on labels

The Health Ministry also prescribes standards on the labeling of other nutritional components and on information to be highlighted.

Labels for specified health foods or those for special dietary uses must follow the respective standards and be screened for approval.

Specific health foods consist of general and conditional specific health foods. Conditional specific health foods are foods verified to have certain effectiveness, but are not scientifically proven to have the effectiveness needed by the requirements for specific health foods. They are permitted to use the specific health food mark if they are stated as having been scientifically proven with limited evidence of the effects. The mark also differs from conventional specific health foods including low disease risk labeling or codes/standards labeling (Fig. 10-6).

Fig. 10-6: Specific health food marks

Mark	Category	Remarks
	Specific health food mark	Including low disease risk labeling or codes/standards labeling
	Conditional specific health food mark	Approved if verified to have certain effectiveness, but are not scientifically proven to have the effectiveness required by the requirements for specific health foods.

Source: Consumer Affairs Agency

<Organic labeling>

The Act for Standardization and Proper Labeling of Agricultural and Forestry Products defines organic agricultural products and organic health foods and dietary supplements, which include soft drinks, as Specified JAS (JAS-certified organic). Only products which meet these standards and affixed with the JAS-certified organic mark can be labeled as “organic” in Japanese.

Organic agricultural products produced abroad and imported must be graded by one of the following methods and affixed with the JAS-certified organic mark (Fig. 10-7), to be permitted to have the organic labeling.

- a) Labelling of JAS-certified organic mark and distribution of organic foods produced/manufactured by overseas manufacturers certified by JAS registered certifying bodies inside and outside Japan.
- b) Labelling of JAS-certified organic mark and distribution of products by importers certified by registered certifying bodies in Japan (limited to organic agricultural products and organic agricultural processed foods).

For approach b), certificates issued by the government of a country with a grading system recognized to be of the equivalent level as that based on the Japanese Agricultural Standards (JAS), or copies must be attached as a prerequisite. As of March 2011, the following countries are identified by the ministerial ordinance to have equivalent grading systems for organic agricultural products as Japan in accordance with Article 15-2 of the Act for Standardization and Proper Labeling of Agricultural and Forestry Products: 27 countries in the EU, Australia, U.S.A., Argentina, New Zealand, and Switzerland.

Fig. 10-7: JAS-certified organic mark**<Containers and packaging>**

The Act on the Promotion of Effective Utilization of Resources requires labeling for promoting sorted collection on specified containers and packaging. Import products which meet the following conditions are required labeling for identification by law.

- When administrative instructions have been given on the materials and structure of containers and packaging and the use of trademark for the imported product.
- When the containers and packaging of the import product is printed, labeled, or engraved with Japanese.

When the following two types of containers and packaging are used for cereals, either or both marks (Fig. 10-8) must be labeled on one area or more of the containers and packaging in the designated format.

Fig. 10-8: Labels for promoting sorted collection

Plastic containers and packaging



Paper containers and packaging

<Description>

Product descriptions with false or misleading expressions are prohibited by the Health Promotion Act, Act against Unjustifiable Premiums and Misleading Representations, and intellectual property-related laws and regulations (e.g., Unfair Competition Prevention Act, Trademark Act), which is applicable to all articles in addition to food products.

2. Labeling under Industry Voluntary Restraint**<Japan Health Food and Nutrition Food Association certified mark>**

The Japan Health Food and Nutrition Food Association, an industrial health food organization, sets standards on safety, hygiene, and labeling for each item, and certifies health supplementary foods meeting these standards by granting labeling of the JHFA mark (Fig. 10-9).

Fig. 10-9: JHFA mark

Contact

Japan Health Food and Nutrition Food Association

TEL: +81-3-3268-3134

<http://www.jhnfa.org>

<Japan Propolis Conference>

The Japan Propolis Conference, comprised of companies manufacturing and selling propolis products, sets voluntary standards on quality and labeling, and grants labeling of the mark on the containers and packaging of products which have been certified as meeting its standards (Fig. 10-10).

The Conference only certifies propolis extracted by ethanol as a voluntary standard, and requires the labeling “Processed propolis food” for products containing over 8% standard propolis and “Food containing propolis” for products containing 1% or more but less than 8% propolis.

<Labeling details>

(1) Product name, (2) Ingredients, (3) Country of origin, (4) Content, (5) Weight, (6) How to use, (7) Using precautions, (8) “Best by” date for best quality, (9) Distributor, and (10) Manufacturer

Fig. 10-10: Japan Propolis Conference certificate of authorization



Contact:

Japan Propolis Conference

TEL: +81-3-3384-8964

<http://www.propolis.or.jp>

<Japan Royal Jelly Fair Trade Council>

The Japan Royal Jelly Fair Trade Council prescribes the Fair Competition Code for Royal Jelly Labeling, sets down provisions for labeling on containers and packaging, and grants the fair trade mark (Fig. 10-11) to the products of members certified as following its standards (raw royal jelly, dried royal jelly, and adjusted royal jelly)

<Labeling details>

(1) Product name, (2) Ingredients, (3) Content, (4) “Best by” date for best quality, (5) Preservation method, (6) Country of origin, and (7) Name and address of manufacturer

Fig. 10-11: Japan Royal Jelly Fair Trade Council fair trade mark



<Fair Competition Code for Royal Jelly Labeling>

<http://www.jfftc.org/cgi-bin/data/bunsyo/A-7.pdf>

Contact:

Japan Royal Jelly Fair Trade Council

TEL: +81-3-3561-5556

<http://www.rjkoutori.or.jp/>

III. Taxation System

1. Tariff duties, consumption tax, and other relevant taxes

Tariff duties on items that are imported as health food or dietary supplement products and vitamins, etc. for the purpose of nutrition support and enhancement are shown in Fig. 10-12.

In order to apply for preferential tariff rates on articles imported from preferential treatment countries, the importer should submit a Generalized System of Preferences (GSP) Certificate of Origin issued by the customs or other issuing agency in the exporting country, to Japan Customs before import clearance (not required if the total taxable value of the article is no greater than ¥200,000). Details may be checked with the Customs and Tariff Bureau of the Ministry of Finance.

If the importer wishes to check the tariff classifications or tariff rates in advance, it may be convenient to use the prior instruction system in which one can make inquiries and receive replies in person, in writing, or via e-mail.

Fig. 10-12: Tariff duties on health food or dietary supplements (FY2011)

H.S. code			Description	Tariff rate				
				General	Temporary	WTO	GSP	LDC
21.04	20	-000	Homogenised composite food preparations	12.8%		12.0%	6.0%	Free
21.06	90		Food preparations not elsewhere specified or included					
			Containing added sugar					
	90	-251	1. Bases for beverage, containing Panax Ginseng or its extract			(28.0%)		
		-259	- Those, the largest single ingredient of which is sugar by weight			23.8%		
			- Other	12.5%				Free
			2. Food supplement with a basis of vitamins					
		-261	- Those, the largest single ingredient of which is sugar by weight			(12.5%)		
		-262	- Containing lactose, milk protein or milk fat			(12.5%)		
		-269	- Other			(12.5%)		
			3. Other					
		-292	- Bases for beverage, non-alcoholic	12.0%		(12.0%)		Free
		-295	- Containing Panax Ginseng or its extract					
			- Food supplement with a basis of vitamins					
29.36			Provitamins and vitamins, natural or reproduced by synthesis, derivatives thereof used primarily as vitamins, and intermixtures of the foregoing, whether or not in any solvent.					
			Vitamins and their derivatives	Free		(Free)		
	21	-000	Vitamins A and their derivatives	Free		(Free)		
	22	-000	Vitamin B1 and its derivatives	Free		(Free)		
	23	-000	Vitamin B2 and its derivatives	Free		(Free)		
	24	-000	D- or DL-Pantothenic acid (Vitamin B3 or Vitamin B5) and its derivatives	Free		(Free)		
	25	-000	Vitamin B6 and its derivatives	Free		(Free)		
	26	-000	Vitamin B12 and its derivatives	Free		(Free)		
	27	-000	Vitamin C and its derivatives	Free		(Free)		
	28	-000	Vitamin E and its derivatives	Free		(Free)		
	29	-000	Other vitamins and their derivatives	Free		(Free)		
30.03	90	-010	- Preparations with a basis of vitamins (bulk)	Free		(Free)		
30.04	50	-000	Preparations with a basis of vitamins, put up in forms or packings for retail sale	Free		(Free)		

Source: Ministry of Finance

Note 1) Special emergency tariffs may be imposed on articles if their import volume has increased by more than a specified percentage or their import price has decreased by more than a specified percentage.

Note 2) Special preferential rate is applicable only for the Least Developed Countries.

Note 3) Normally the order of precedence for application of tariff rates is Preferential, WTO, Temporary, and General, in that order. However, Preferential rates are only eligible when conditions stipulated by law or regulations are met. WTO rates apply when those rates are lower than Temporary or General rates. Refer to "Customs Tariff Schedules of Japan" (by Customs and Tariff Bureau, Ministry of Finance) for a more complete interpretation of the tariff table.

2. Consumption Tax

(CIF + Tariff duties) × 5%

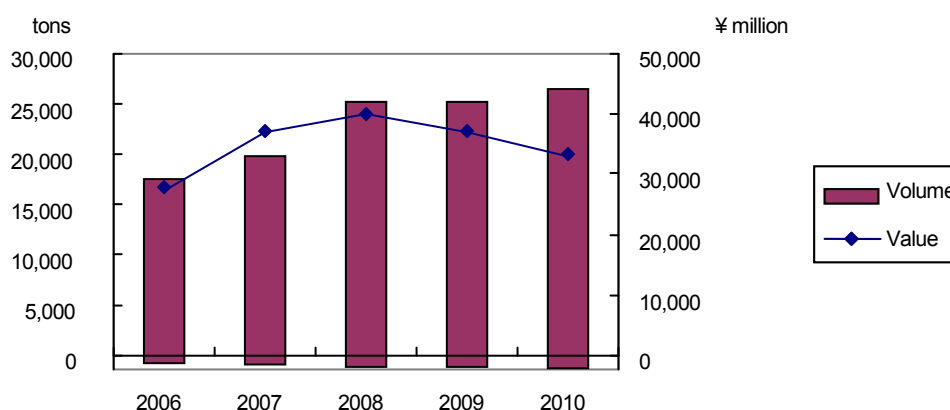
IV. Trade Trends

1. Changes in Imports

Imported health foods as commercialized products include homogenized composite food preparations, Asian ginseng extract, and vitamin/nutrition supplements, as illustrated in Fig. 10-14. Most of them are imported from the U.S. and the overall composition remains the same. There has been no significant change in recent years; growth remains steady.

On the other hand, vitamins are used for a variety of purposes which include use as a food additive to supplement and fortify the nutrition of general products. The import volume is increasing favorably: the total amount of imported vitamin powder in 2010 was 17,480 tons (107.9% vs. previous year). However, on a value basis, the total amount of imported vitamin powder decreased in 2010. The reason for the decrease is a fall in unit price due to price competition for end-products, among others.

Fig. 10-13: Change in health food / vitamin imports



Source: Trade Statistics (MOF)

Fig. 10-14: Change in health food / vitamin import by item

Units: volume = tons, value = ¥ million

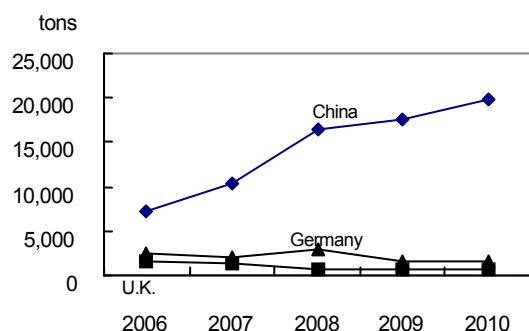
Item	Volume					Value				
	2006	2007	2008	2009	2010	2006	2007	2008	2009	2010
Homogenised composite food preparations	0	1	0	0	0	0	2	0	0	0
Panax Ginseng and its extract	1	1	0	0	0	2	2	0	0	0
Food supplement with a basis of vitamins	908	990	896	983	996	6,921	8,241	6,828	7,368	6,942
Total, vitamin powder	12,548	15,419	16,468	16,203	17,480	11,072	15,914	22,992	22,440	19,859
Vitamin A	85	91	73	49	57	394	413	382	314	302
Vitamin B ₁	321	262	291	339	267	757	723	832	911	643
Vitamin B ₂	246	239	195	177	189	1,050	1,718	1,749	1,144	1,177
Vitamin B ₃ / Vitamin B ₅	189	213	148	196	206	210	439	245	204	181
Vitamin B ₆	215	207	229	278	309	467	492	574	673	672
Vitamin B ₁₂	2,503	3,208	2,882	2,447	2,439	2,072	2,339	1,941	1,936	1,766
Vitamin C	6,460	8,957	10,533	9,877	11,443	3,745	7,420	13,029	11,911	10,148
Vitamin E	2,528	2,241	2,117	2,839	2,571	2,376	2,369	4,241	5,346	4,969
Total, vitamin preparations	4,027	3,468	7,922	7,917	8,046	9,894	13,179	10,143	7,380	6,460
Other vitamins	1,159	1,177	1,110	879	1,105	3,054	3,086	3,537	3,091	2,595
Vitamin preparations	2,868	2,292	6,813	7,038	6,940	6,840	10,093	6,606	4,288	3,865
Total	17,484	19,879	25,286	25,103	26,522	27,888	37,337	39,963	37,187	33,261

Source: Trade Statistics (MOF)

2. Regional breakdown

As for the breakdown by country of origin, China occupies an overwhelming share with 19,865 tons (112.8% vs. previous year) in 2010, and imports from Germany follows with 1,547 tons in 2010. However in general, imports from Germany have decreased substantially. As a result, Germany falls further behind China in terms of import volume.

Fig. 10-15 Trends in leading partner imports



Source: Trade Statistics (MOF)

Fig. 10-16: Shares of imports in 2010 (value basis)

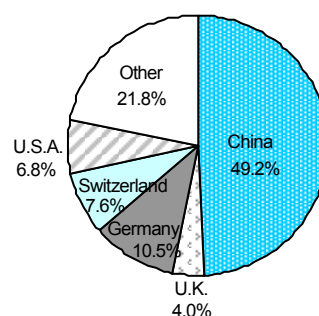


Fig. 10-17: Principal places of origin of vitamins

Units: volume = tons, value = ¥ million

Country	Volume					Value				
	2006	2007	2008	2009	2010	2006	2007	2008	2009	2010
China	7,106	10,354	16,330	17,606	19,865	4,138	8,040	15,179	14,498	12,947
Germany	2,590	2,117	2,928	1,651	1,547	2,441	2,468	2,920	3,098	2,776
Switzerland	961	898	853	721	682	1,990	2,470	2,408	2,488	2,005
U.K.	1,573	1,284	705	710	581	1,306	1,406	1,177	1,332	1,050
U.S.A.	467	257	262	271	227	2,943	2,278	2,368	2,190	1,796
Other	3,879	3,976	3,311	3,160	2,624	8,147	12,431	9,083	6,212	5,744
Total	16,575	18,887	24,390	24,120	25,526	20,965	29,092	33,135	29,819	26,319

Source: Trade Statistics (MOF)

3. Import Market Share in Japan

According to interviews with domestic sales companies, the share of health foods and dietary supplements imported from the U.S. and Europe is considered to be slightly over 10%, estimated from the sales results of Japanese subsidiaries and sales agents that are selling products in Japan.

4. Background of Changes in Volume of Imports and Other Trends

Many companies which are involved in the import and sales of health foods and dietary supplements use door-to-door sales (also called network sales, where products are sold to members), including Amway Japan and Neways Japan. Despite the rise of health consciousness, the expectation for sharp growth is minimal due to a decline in business confidence and other reasons. The total volume of imported vitamins increased slightly, to 26,522 tons (105.6% vs. previous year) in 2010.

V. Domestic Distribution

1. Trade Practice, Etc.

Sales of health foods and dietary supplements have 2 patterns: non-store retailing such as door-to-door sales and mail order sales, and store sales in pharmacies and drugstores. The share of non-store retailing is greater. While non-store retailing doesn't require intermediary distributors and their margins, products are sold through specialized intermediary medicine/health food distributors for store sales, where the intermediary distributors receive 20-30% of the sales value as their margins.

2. Domestic Market Situations

Japan has the longest life expectancy in the world. The percentage of seniors above 65 years old in the overall population is 23.1% (as of September 15, 2010, data published by Ministry of Internal Affairs and Communication). Due to the influence of the declining birthrate and aging population, the percentage is expected to rise in the future as well. As there are many seniors with lifestyle-related diseases such as hypertension, heart disease, diabetes and obesity, the demand for health food and supplements for health maintenance is increasing.

When dividing health foods and dietary supplements into smaller markets by indication and efficacy, the market for nutritious fortification and revitalization against fatigue is the largest, followed by the skin care market for women, and the market for lifestyle-related diseases. Since taking health foods and dietary supplements is already widespread in Japan, there has been no significant change; there is a trend that the market will expand for a product category where ingredients were featured in mass media or in an aggressive advertisement campaign. In recent years, expansion is seen in the health foods and dietary supplements markets for improving hepatic functions, where products with sesame extract are selling well, as well as for preventing lifestyle-related diseases, where products with DHA are selling well. On the other hand, the immunostimulator market is shrinking since the carcinogen of agaricus was pointed out by the Ministry of Health, Labor and Welfare in 2006 (later the Ministry announced that agaricus does not promote cancer). The etiquette market is also shrinking after the products with champignon (mushroom) extract was pointed out by the Fair Trade Commission as not having grounds for what the producers claim in the advertisement.

The majority of health foods and dietary supplements in the Japanese market are made in Japan. Import products are sold through the Japanese subsidiaries of international companies, and pharmaceutical companies with distributor contracts. The share of import products is considered to be over 10 %.

Major domestic producers of health foods and dietary supplements include DHC, FANCL, Kobayashi Pharmaceutical, Asahi Food and Healthcare, Otsuka Pharmaceutical, Amway Japan, Neways Japan, and Nu skin Japan. Otsuka Pharmaceutical imports and sells the "Nature Made" products of Pharmavite from the U.S.

Fig. 10-18: Size of the health food and dietary supplement market

Unit: ¥ million

Indication / efficacy	2006	2007	2008	2009	2010 forecast	Ratio
Nutritious fortification and revitalization	85,110	84,750	84,250	85,950	91,550	14.2%
Skin care	65,500	71,150	78,900	83,800	86,700	13.5%
Prevention of Lifestyle-related diseases	74,300	69,400	71,200	75,200	79,150	12.3%
Weight loss	83,200	74,700	70,800	70,250	72,400	11.2%
Multi-balance	77,950	76,350	70,550	65,500	64,500	10.0%
Eye-care	36,450	36,800	40,350	40,550	41,250	6.4%
Improvement of hepatic functions	28,700	29,700	33,250	36,400	37,450	5.8%
Bones & joints support	27,900	29,600	31,950	35,600	40,300	6.3%
Blood circulation promotion	36,600	35,300	33,750	32,850	32,000	5.0%
Other	112,570	108,850	105,150	102,450	99,200	15.4%
Total	628,280	616,600	620,150	628,550	644,500	100.0%

Source: 2011 H/B Food Marketing Handbook No. 2, Fuji Keizai

(1) Nutritious fortification and revitalization

Ingredients used	Asian ginseng, royal jelly, garlic, maca, soft-shell turtle, Japanese plum extract
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The leading products are the ones which contain Asian ginseng, royal jelly, and others which supplement nutrition quickly to enable recovery from fatigue. In recent years, the positive effect of maca not only for men's invigoration but also for women's hormone imbalance and infertility are being recognized, and supplements using maca for menopausal symptoms, sensitivity to cold, and infertility are being sold, targeting women.

One of the main ingredients, royal jelly, is mostly imported from China, South Korea, Taiwan, and Thailand, among which more than 90% is from China. Most of maca distributed and sold in Japan is from Peru. However, it is believed that Bolivian maca is also used.

(2) Skin Care

Ingredients used	hyaluronic acid, collagen, vitamin C, astaxanthin, placenta
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This is the market consisting of products which have positive effects against spots, freckles, wrinkles, acne, and skin irritation. The use of hyaluronic acid, collagen, and vitamin C are widespread and occupy more than 90% of this market. In recent years, products with astaxanthin, the use of which is becoming more popular for cosmetics, are increasing.

As for hyaluronic acid, reasonable materials from China are increasing. The demand for marine collagen (from tilapia, sea bream, salmon, Japanese sea perch, and catfish) is expanding.

(3) Prevention of lifestyle-related diseases

Ingredients used	black vinegar/flavored vinegar, DHA, coenzyme Q10, ginkgo leaf, leithitin
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This is the market for products to prevent lifestyle-related diseases such as hypertension, diabetes, hyperlipidemia, and arterial sclerosis. Around 40% are occupied by products which contain traditional raw materials from Japan: black vinegar/flavored vinegar. Other products contain unsaturated fatty acid such as EPA, DHA,

γ -linolenic acid, and leithitin, as well as ginkgo leaf extract for their effect to prevent arterial sclerosis.

DHA, which is obtained from fish, originates from raw materials such as tuna, bonito, sardines, salmon roe, and mackerels. Many reasonable products of coenzyme Q10 obtained from sugar cane and sugar beets from China are also widely distributed.

(4) Weight loss

Ingredients used	calorie adjustment product, protein, garcinia cambogia, gymnemic acid
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In Japan, women have a strong desire to lose weight. Middle-aged men are starting to take interest in weight loss since a health examination to prevent and improve metabolic syndrome became obligatory in 2008, and abdominal girth became one of the criteria for the check-up. Calorie adjustment products include Sunny Health's "Microdiet", DHC's "Protein Diet", etc. which limits caloric intake.

In addition, the demand for protein is expanding among sports lovers. Garcinia cambogia, which extends the feeling of fullness, and gymnemic acid, which limits the intake of sugar, are also included in products in this category.

(5) Multi-balance

Ingredients used	vitamins, minerals
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Multi-balance products contain multiple essential vitamins and minerals. Complex type products such as Amway Japan's "Triple X" and Nu Skin Japan's "Lifepak", which provide both vitamins and minerals in one, occupy around 60% of the market. Others are products such as Neways Japan's "Maximol Solutions", which provides multiple essential amino acids, DHC's "Multivitamin", which provides only multiple vitamins and minerals, Otsuka Pharmaceutical's "Nature Made Multivitamin", and brewer's yeast.

(6) Eye-care

Ingredients used	blueberry, lutein
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The eye-care market is expanding to accommodate the needs to treat asthenopia caused by the use of office and home information appliances. Over 60% is occupied by products which contain blueberry and over 30% by lutein-containing products. Cassis-related products can be also found.

As for lutein, the raw material extracted from marigold is being sold. Cassis extract originates from Japan, as well as from materials imported from Scandinavia and New Zealand.

(7) Improvement of hepatic functions

Ingredients used	sesame extract, turmeric, oyster flesh extract, ornithine
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The market of products to improve hepatic functions consists primarily of products that are effective against hangover. In addition to fresh water clam extract, oyster flesh extract, and turmeric, the Suntory group is actively deploying "Sesamin E Plus", which contains sesame extract. Sesame-containing products occupy nearly 50% of this market. Since 2009, miso-soups and drinks containing ornithine are in sales. Products which contain ornithine, which are effective for hangover, are also increasing.

Apart from domestic produce, turmeric from China and India is also used as a raw material.

(8) Bone & joint support

Ingredients used	glucosamine, calcium
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As the number of senior citizens rises, the demand in bone & joint support market increases to prevent osteoporosis and arthralgia. In particular, glucosamine-containing products for arthralgia are already highly recognized due to the PR and advertising efforts of major manufacturers such the Suntory group, DHC, and Kobayashi Pharmaceutical, and occupy over 70% of this market. Their share is expanding in the market. Most of products containing devil's claw, which is said to be effective for arthritis, are mainly imported from the U.S. devil's claw powder as a raw material is imported from Peru and South Africa.

The raw material of glucosamine is extracted from either crustaceans such as crabs and shrimp, or vegetables such as corn. Reasonable raw materials from China and South Korea are increasing.

(9) Blood circulation promotion

Ingredients used	vitamin E
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People take products for blood circulation promotion to deal with sensitivity to cold temperatures, and to prevent artery sclerosis as well as aging. The market consists solely of vitamin E-containing products. However, products that use ingredients such as coenzyme Q10, lutein, and Astaxanthin that are purported to have similar effects are the center of focus now, and demand is shifting in that direction.

(10) Other

Fig. 10-19: Emphasized indications / efficacy and ingredients of other health foods and dietary supplements

Emphasized indications / efficacy	Ingredients
Immunostimulatory action	Propolis, agaricus, lingzhi mushroom, echinacea, β -carotene
Green charge	Chlorella, spirulina, vegetable tablets, green juice (kale)
Intestinal regulation	Prune, lactobacillus, alimentary fiber, aloe
Hormone balance	Saw palmetto, soy isoflavone, pomegranates, and kwao krua
Etiquette	Plant extract, champignon extract
Prevention/improvement of anemia	Nonheme iron, heme iron
Relaxation	St. John's wort, valerian, gyaba

Source: 2011 H/B Food Marketing Handbook No. 2, Fuji Keizai

The market of immunostimulators consists of products aiming to improve natural healing ability. The products are taken to prevent tumors and to improve the immune system. The main ingredient, agaricus, suffered from reduced trust and sales between 2005 and 2006 because of media coverage on the violation of the Pharmaceutical Law and on carcinogens, but the decrease in demand stopped when the final report on the safety

was published by the Ministry of Health, Labor and Welfare in 2009. In recent years, products for pollen allergy, a type of allergy disease of which the number of patients is increasing, is on the rise. Propolis-containing products amount to a little less than 50% of this market, followed by products with agaricus and lingzhi mushroom. Other products for pollen allergy include products with lactobacillus and herb material. Most propolis used in products is imported, especially from Brazil. Apart from agaricus from Japan, it is imported also from Brazil, China, and the U.S.

The so-called “green charge” is the range of products which replace the intake of vegetables. The majority is occupied by products containing chlorella and spirulina. “Vegetable tablets” use multiple vegetables as the raw material, and products which contain green juice (kale) are dominated by soluble powder and frozen drinks to be thawed.

As products with intestinal regulation effect are meant to treat constipation and prevent skin trouble, the demand from women is high. As the intake of yogurt, which has similar effects, is common, the share of products containing lactobacillus only amounts to a little more than 20%. Prune-containing products are the main products, which occupy 60% of this market.

As for products to improve symptoms caused by hormone imbalance, saw palmetto-containing products are sold for men, and products containing soy isoflavone, pomegranates, and kwao krua are sold for women.

Etiquette products include ones which deal with mouth and body odor. In 2009, the Fair Trade Commission banned the sales of that champignon (mushroom) extract containing products to respective companies for not having the effect which is displayed on packages, catalogs, and advertisements. As a result, the sales have decreased. The majority of products are in the form of chewing gum, gummy candy, and film rather than tablets. Products contain ingredients such as rose extract from Damascus rose, champignon extract from natural mushrooms, and extract of parsley and sunflower.

Products to prevent and improve anemia include products which contain nonheme iron with plant iron, and ones with heme iron with animal iron. More than 80% are supplements for younger women who tend to have iron deficiency.

The mainstream of products for stress relief and relaxation consists of products with herb extract such as extract of St. John’s wort and valerian.

<Food emphasizing health>

In addition to the above-mentioned health foods and dietary supplements, there are other drinks, snacks, yogurt, and jelly sold in the market which can provide healthy elements handily with these ingredients. They are easier to take than supplements, and many products contain healthy ingredients in order to differentiate from other products.

3. Distribution Channels

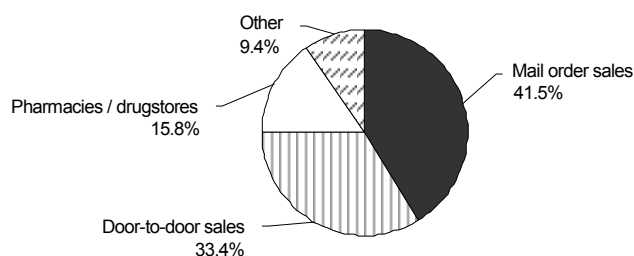
The distribution channels of health foods and dietary supplements are illustrated in Fig. 10-21. There are 2 patterns for supplements produced overseas; where up to packaging for Japan is done in the country of production, and another where only packaging is done in Japan. Usually, they are sold to consumers or wholesalers through Japanese subsidiaries or sales distributors.

As for the sales channel of health foods and dietary supplements, since the need for products varies depending on the individual situation, the main channel is mail order, where selection from a wide range of products is available. Mail order sales also have many repeat customers. Its share among different channels is expanding. As door-to-door sales, where a salesperson visits the consumer’s house (also called network sales, where products are sold to members), also enables consumers to choose according to individual situation, its share is second to mail order. In the actual stores, a good selection of products can be found in pharmacies and drugstores, thus these are the main channels. In mass retailers and convenience stores, selling spaces are smaller in comparison to pharmacies and drugstores, and so the selection of products is focused mainly on best-selling products. Especially in convenience stores, products which are judged as slow movers will be taken out of the store often, thus producers are not putting much effort into them.

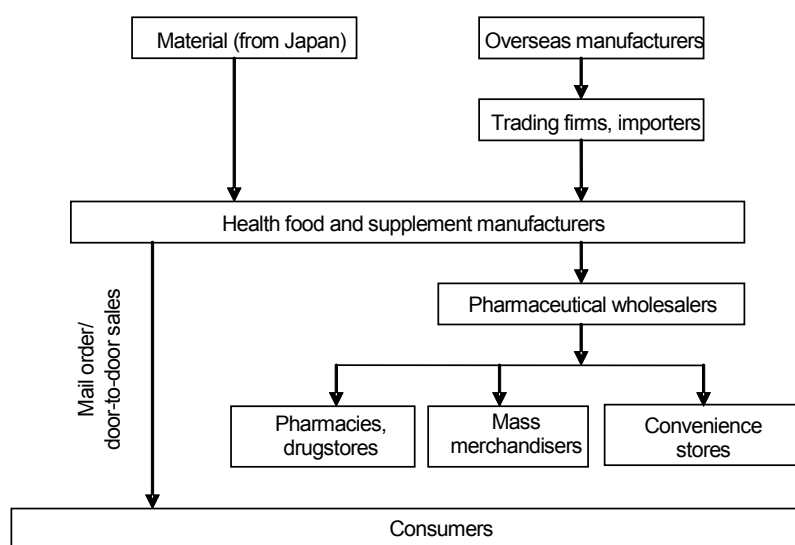
Fig. 10-20: Sales ratio for distribution channels for health foods and dietary supplements (2009)

Unit: ¥ million

Distribution channels	Sales	Ratio
Mail order sales	260,850	41.5%
Door-to-door sales	209,760	33.4%
Pharmacies / drugstores	99,070	15.8%
Mass merchandisers	9,330	1.5%
Convenience stores	12,290	2.0%
Other	37,250	5.9%
Total	628,550	100.0%



Source: 2011 H/B Food Marketing Handbook No. 2, Fuji Keizai

Fig. 10-21: Distribution channels for health foods and dietary supplements

Source: Fuji Keizai research data

4. Issues and Considerations for Entering the Japanese Market

Exporting health foods and dietary supplements to Japan is handled the same as the export of food products. Therefore, it is necessary to confirm that all ingredients including additives comply with the Japanese Food Sanitation Act. Since they are not medicines, it is forbidden to have markings regarding indication and efficacy, as well as using expressions which imply indication and efficacy.

When exporting health foods and dietary supplements, similar to the case of processed food, when pesticide residue is found, the product can be banned from entering the country. When the Japanese company which sells the final product is suspected of violation of the Pharmaceutical Affairs Act, trustworthiness of the actual efficacy, or for containing carcinogens, sudden cancellation of production and sales can occur.

<Exhibitions>

The Tokyo Health Industry Show, which will be held for the 29th time in 2011, can be referred to as the exhibition for health foods and dietary supplements. This exhibition is organized by UBM Media Co. Ltd. The exhibition is divided into following sections: health foods / raw material for cosmetics / OEM, health foods, organic & natural, wellness, health & beauty. Health foods and supplements are displayed in the health foods section.

Fig. 10-22: Exhibitions for health foods and dietary supplements

Overall food products	Tokyo Health Industry Show	
	http://www.this.ne.jp	TEL: +81-3-5296-1025
	HFE JAPAN (Health Food Exposition & Conference)	
	http://www.ifajapan.com/2011/jp	TEL: +81-3-6459-0444
Overall food products	Diet & Beauty Fair	
	http://www.dietandbeauty.jp/ja	TEL. 3-5296-1013

5. Failure Cases

<Violation of Food Sanitation Act>

In 2008, it was suspected that a raw material for health foods imported from the U.S. by a major food producer had been exposed to gamma rays, which is banned in principle by the Food Sanitation Act. Although it was picowaved for disinfection and the amount of gamma ray was within the standard set by the FAO, the use of gamma ray is not permitted in Japan. Related products became the target of a voluntary product recall.

<Suspected carcinogenicity>

In 2006, the Ministry of Health, Labor and Welfare (MHLW) ordered several manufacturers to voluntarily halt sales and recall products as “a health foods product, from a certain manufacturer which uses agaricus as the raw material, was proven in animal testing to have the effect of promoting carcinogens”. All related products were all banned from sales. Because other similar products suffered from negative rumors, the market shrunk significantly. However, in 2009, the MHLW announced that “agaricus itself was not the problem, but the individual product”. This announcement was considered practically as a declaration of safety.

<Violation of Act against Unjustifiable Premiums and Misleading Representations>

In 2009, the Fair Trade Commission pinpointed 7 companies selling products containing champignon (mushroom) extract for “not having rational grounds to prevent mouth or body odor” as displayed on the product packages, catalogues, and advertisements and ordered sales to be halted. Therefore, all respective products were banned from sales. The entire market is shrinking.

6. Import Associations & Related Organizations

Fig. 10-23: Health foods and supplements importer associations & related organizations]

Japan Health Food & Nutrition Food Association	http://www.jhnfa.org	TEL: +81-3-3268-3134
The Japanese Institute for Health Food Standards	http://www.jihfs.jp	TEL: +81-3-5803-1565
Japan Health Food & Nutrition Food Association	http://www.jhnfa.org	TEL: +81-3-3268-3131
Japan Propolis Conference	http://www.propolis.or.jp	TEL: +81-3-3384-8964