Importing Health Foods

~ Laws and Regulations Importers Should Be Aware of ~

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Issued by
Manufactured Imports and Investment Promotion Organization (MIPRO)

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Overseas, health foods and supplements are sold based on the country's own laws and regulations befitting its climate, food culture and so on. Some of such products pose a concern about their safety; some contain special ingredients claimed to be good for human health, some are in a tablet or capsule form and contain concentrated ingredients, and some don't have any record of consumption in Japan.

An importer is required to assume equal responsibility for ensuring the safety of imported goods as the processor thereof. Therefore, import of health foods needs careful prior considerations.

Importing and selling health foods involve checking based on the Pharmaceuticals and Medical Devices Act, following procedures prescribed in the Food Sanitation Act, and complying with provisions in many other laws. An importer needs to check where necessary information can be obtained from and what are the legal points that must be observed.

This booklet outlines importing-related laws and regulations for importing and selling health foods in Japan and labeling-related laws and regulations for selling them in Japan as business. For details of these laws and regulations, please check the original laws and regulations or make inquiries to the relevant competent governmental department.

The content is subject to change due to amendments of relevant laws or other reasons. It is advisable to always check for the latest information.

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Contents

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In this booklet, health food products including supplements may be collectively referred to as "health foods."

❖What Are Health Foods?

In Japan, there is no specific legislative definition for health foods. Generally, the term "health foods" is used to refer to "any products that are sold and used as foods that broadly contribute to maintaining and promoting health."

Among health foods, food products for which labeling of their functions is permitted in accordance with the standards on the safety and functions determined by the national government are called "foods with health claims." (See page 36)

Meanwhile, some food products are not allowed to have function claims (hereinafter referred to as "other health foods"). As such, health foods can be divided into two, namely, foods with health claims and other health foods, by whether functions can be labeled on the food product or not.

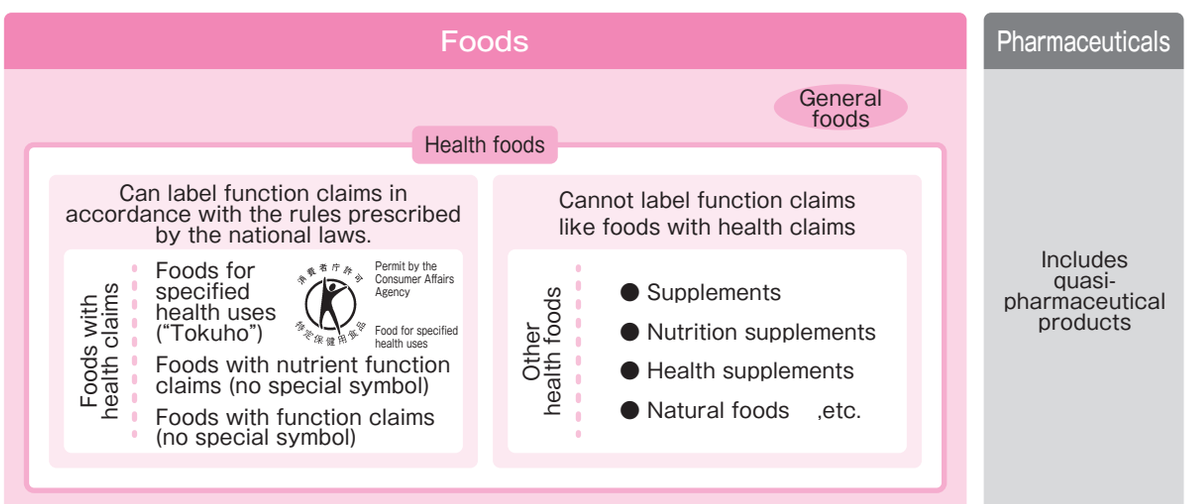
The "other health foods" include supplements, nutrition supplements, health supplements, and natural foods. However, there is no legislative definition for these names in Japan(Note).

(Note) There are some names a business operator may voluntarily label related to quality standards established by a food-related industry organization, such as "Certified Health Food (JHFA) Mark."

■ **Reference information**

MHLW's website: "Health foods" (English)
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/hokenkinou/index_00010.html

Classification of Health Foods



(Source) Consumer Affairs Agency's pamphlet "Health Foods Q&A" October 2017

❖What Are Supplements?

"Supplement" is a short form of "dietary supplement," which may also be called "health supplement" or "nutrition supplement." In EU or USA, supplements are placed as goods ingested mainly for the purpose of supplementing nutrition lacking in the daily diet, such as vitamins, minerals and amino acids. They are handled in a category separate from foods and pharmaceuticals, and regulated by independent laws specifically established for supplements. They are in a form of tablet, capsule, jelly, powder, etc. and are not clearly distinguishable as foods.

Different from overseas, in Japan, there is no clear definition for supplements, and there are no independent laws to regulate them either. Shapes like tablets and capsules used to be permitted for pharmaceuticals only, but they can now also be used for food products as a result of deregulation by the national government in March 2001, unless conflicting with the Pharmaceutical Affairs Act (current Pharmaceuticals and Medical Devices Act).

Since then, health foods in the form of tablet or capsule have widely spread in Japan, and the term "supplement" is widely accepted nowadays. Supplements are recognized by the general public as one type of health food.

I Laws and Regulations Related to Import of Health Foods

To import health foods into Japan for marketing, first of all, it is important to check that the goods do not fall in the category of pharmaceuticals. Importing health foods as foods is subject to the Food Sanitation Act, but the importer needs to check applicability of other relevant laws and regulations as well.

Fall into Foods When Orally-ingested Goods Do Not Fall into Pharmaceuticals

By Japanese laws and regulations, orally-ingested goods are classified into either pharmaceuticals or foods.
"Pharmaceuticals" are defined by the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Hereinafter referred to as Pharmaceuticals and Medical Devices Act) as (1) items intended for use in the diagnosis, treatment or prevention of disease or (2) items intended to affect the structure and functions of a body.
Meanwhile, "foods" are defined by the Food Sanitation Act as all foods and drinks, excluding pharmaceutical products, quasi-pharmaceutical products or regenerative medicine products specified by the Pharmaceuticals and Medical Devices Act.
Pharmaceuticals (including quasi-pharmaceutical products and regenerative medicine products; hereinafter the same shall apply) are subject to regulations of the Pharmaceuticals and Medical Devices Act and foods are subject to regulations of the Food Sanitation Act to ensure their safety.
Some health foods and supplements available overseas contain ingredients classified as pharmaceuticals in Japan or claim functions similar to pharmaceuticals, and importing and selling them as foods are subject to guidance and control as unapproved or unauthorized drugs under the Pharmaceuticals and Medical Devices Act.
Therefore, if orally-ingested goods are not clearly distinguishable as foods, the importer needs to check that they do not fall into the category of pharmaceuticals.

❖Division between Foods and Pharmaceuticals

The legal borderline between the Pharmaceuticals and Medical Devices Act and the Food Sanitation Act is called the "division between foods and pharmaceuticals."
The standards to determine the division between foods and pharmaceuticals are the "Standards on the Scope of Pharmaceuticals" attached to the MHW/DPAB Notice, "Guidance and Regulations on Unapproved or Unauthorized Drugs" (Yakuhatsu No. 476 dated June 1, 1971; so-called 46 (Yon-roku) Notice). From the viewpoint of the Pharmaceuticals and Medical Devices Act, whether the goods fall into the category of pharmaceuticals is determined. (See page 10)

❖Importing and Selling Pharmaceuticals Require Approval and Permit ⇒ Importing Pharmaceuticals Is Difficult

Pharmaceuticals are used for treatment of disease by affecting human bodies in principle. Though they are expected to provide their intended therapeutic effects, in some cases pharmaceuticals can cause unexpected side effects. Therefore, their quality, effectiveness and safety need to be ensured. For that reason, strict regulations are imposed on pharmaceuticals for each stage of their development, approval, manufacturing, distribution and use, based on the Pharmaceuticals and Medical Devices Act.
If the goods to be imported fall into the category of pharmaceuticals, approval and permit based on the Pharmaceuticals and Medical Devices Act will be needed.

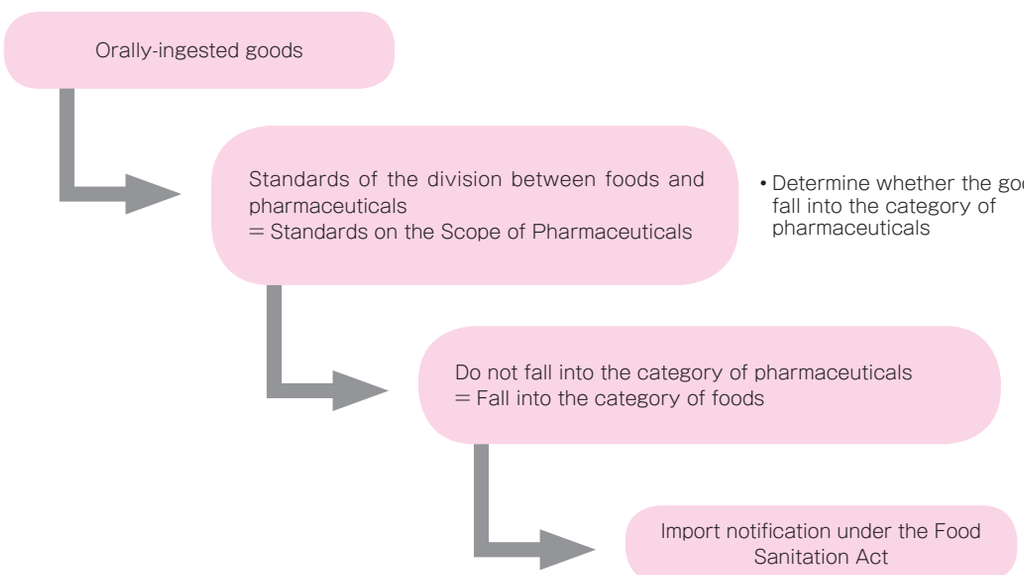
❖Importing and Selling Foods Require Import Notification

If the goods to be imported fall into the category of foods, the importer of the goods needs to submit an import notification based on the Food Sanitation Act, receive examination to prove that the goods are foods that comply with regulations of the Food Sanitation Act about the safety, and obtain a certificate of import notification. (See page 19)
As for health foods, there is no specific definition under the Food Sanitation Act or individual standard or criterion; safety regulations for general foods also apply to health foods.

Orally-ingested Goods Are Classified into Pharmaceuticals or Foods

Classification	Law to ensure safety	Procedures for importing into and selling in Japan	Matters to be checked for health foods	
Pharmaceuticals (Includes quasi-pharmaceutical products)	Pharmaceuticals and Medical Devices Act	· Requires a business license for manufacturing/marketing pharmaceuticals · Requires a business license for manufacturing pharmaceuticals, etc. for packaging, labeling and storage of pharmaceuticals · Requires an approval for each item regarding its manufacturing/marketing	Check that the goods do not fall into the category of pharmaceuticals (not an unapproved or unauthorized drug) from the viewpoint of the Pharmaceuticals and Medical Devices Act	See page 10 onward for details
Foods	Food Sanitation Act	Requires notification of import to a quarantine station on every import	Check the safety as foods (e.g., whether the goods comply with standards and criteria of the Food Sanitation Act, whether the goods contain a toxic or hazardous substance)	See page 19 onward for details

Which category do the goods to be imported fall into, pharmaceuticals or foods?
⇒ If the goods do not fall into the category of pharmaceuticals, the importer can proceed with import procedures for foods



Importing Goods Harmful to the Society (e.g., Narcotic Drugs, Hemp, Stimulants, Designated Drugs) Is Prohibited

Article 69-11 of the Customs Act bans import of narcotic drugs, psychotropic substances, hemp, opium, poppy straw, stimulants (including raw materials thereof) and designated drugs.
Some health foods such as herbs and oils sold claiming not to be illegal may fall into narcotic drugs or designated drugs, and import of such goods may be prohibited.

(Note) Designated drugs refer to substances, among ingredients contained in Kiken drugs (quasi-legal drugs), designated based on the Pharmaceuticals and Medical Devices Act as those having high probability of hallucinating and other effects and which could cause health hazards in the event such substances are used.

■ Reference information
Japan Customs' website: "Enforcement"
https://www.customs.go.jp/mizugiwa/index.htm

Be Careful of Laws and Regulations That Apply Depending on Raw Material, Item, etc.

Some Japanese laws and regulations regulate import of certain goods for the purpose of achieving the primary objective of the law or regulation, such as protection of domestic industries, ensuring the quality and safety of products, and preservation of nature or the social environment.

- Plant protection and animal quarantine for ensuring the safety of plants and livestock in Japan
- Trade control for items covered by the CITES
- For rice and wheat, salt, sugar and starch, and some dairy products, securing their stable supply to the general public, stabilizing their prices, ensuring stable management of domestic producers

An importer shall obtain information about the goods to be imported, such as an ingredient list and food production flow chart, and investigate what laws and regulations may apply other than the Food Sanitation Act.
Depending on applicable laws and regulations, importing the relevant goods may require a certificate from a foreign government organization, or import permission, approval, etc. by the Japanese government. It is advisable to check for necessary documents in advance.
For an overview of procedures and contact points, refer to "Guide to Food Import" issued by MIPRO.

Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and Import Restrictions

The CITES classifies endangered species of wild fauna and flora into three categories (Appendices I, II, and III) depending on the necessity of their protection and restricts their international trade. When importing anything regulated by the CITES, an importer needs to obtain an export permit issued by a government organization of the exporting country as specified in the Convention and a certificate of import approval issued by the Ministry of Economy, Trade and Industry. Upon making an import declaration, the importer must submit such documents to customs to seek confirmation therefrom.
Required procedures are specified in the Import Trade Control Order and the Points to Note on Import, etc. Procedures vary by classification of Appendices and country of origin or place of shipment.

○ Those designated in item (ii) or item (ii)-2 of the Public Announcement on Import
⇒ Application for import approval
○ Those designated in item (iii) of the Public Announcement on Import
⇒ Application for prior confirmation
○ Those listed in Appendix II or III other than those subject to prior confirmation
⇒ Confirmation upon customs clearance

It should be noted that if a person imports goods regulated by the CITES without obtaining an export permit or a certificate of import approval, the import is rejected at customs in Japan. Import is often rejected for crude drug raw materials such as musk deer, Saussurea costus, Gastrodia elata rhizome, aloe, and American ginseng.
How to check for items subject to the regulations is shown on the website below.

There is no document like a "non-applicability certificate" for items not covered by the CITES. It is recommended to prepare for giving explanations to customs that the goods to be imported are not covered by the CITES by, for example, describing the scientific name (internationally accepted Latin name), country of origin, origin of the animal or plant, etc. on a certificate of origin issued by the chamber of commerce or on customs clearance documents such as invoices.

■ Inquiries
Wild Fauna and Flora Trade Licensing Office, Trade Control Department, Trade and Economic Cooperation Bureau, Ministry of Economy, Trade and Industry: Tel: +81-3-3501-1723

■ Reference information
Ministry of Economy, Trade and Industry's website: "The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)"
https://www.meti.go.jp/policy/external_economy/trade_control/02_exandim/06_washington/index.html (Japanese)
https://www.meti.go.jp/english/policy/external_economy/CITES/index.html (English)

Major Laws and Regulations Related to Import Depending on Raw Materials and Item of Foods

For an overview of procedures and contact points, refer to "Guide to Food Import" issued by MIPRO.

Item	Name of law or regulation	Major regulations
Plants Fruits (fresh, frozen, and dried), vegetables (fresh, frozen, and dried), nuts, grain, beans, coffee beans (raw), herbs, spices, rapeseed, sesame, etc.	Plant Protection Act	· Restrictions of import, prohibition of import, import quarantine such as inspection of imported plants · Importing not permitted without a phytosanitary certificate issued by a government organization of the exporting country
Designated quarantine items · Cloven-hoofed animals (e.g., cattle, pig, sheep, goat, and deer), horse · Chicken, quail, pheasant, ostrich, guinea fowl, turkey, duck, goose and other anserine birds (Anseriformes) · Dog, rabbit, honey bee · Bone, meat, fat, blood, skin, fur, feather, horns, hooves, tendons and organs of animals above · Fresh milk, milk, etc. (e.g., milk, skim milk, cream, butter, cheese, condensed milk, powdered milk; excluding goods brought in with people) , semen, fertilized eggs, unfertilized eggs, dung and urine of animals above · Bone meal, meat meal, meat-and-bone meal, blood meal, hide powder, feather powder, hoof and horn meal and organ powder of the above animals · Eggs of chicken, quail, pheasant, ostrich, guinea fowl, turkey and anserine birds · Sausage, ham, bacon, etc. made from meat or the like of a designated quarantine item	Act on Domestic Animal Infectious Diseases Control	· Prohibition of import, inspection of products, import quarantine such as limitation of importing sites · Importing not permitted without a health certificate or veterinary certificate issued by a government organization of the exporting country
Rice (e.g., rice grains, rice powder, rice cake, cooked rice), wheat variety (barley, wheat, naked barley, meslin, triticale and their processed or prepared foods)	Act on Stabilization of Supply, Demand and Prices for Staple Food	Notification of import quantity and payment of import levy for import exceeding the minimum access quota Rice Retailers Notification System
Sugar, starch Preparations containing added sugar	Act on Price Adjustment of Sugar and Starch	Contribution to adjustment funds for importing designated sugar and starch (transaction agreement in writing with the Agriculture & Livestock Industries Corporation)
Butter, skim milk, condensed milk, etc.	Act Concerning the Stabilization of Price of Livestock Products	Contribution to adjustment funds for designated dairy products (procedures of purchasing and sell-back with the Agriculture & Livestock Industries Corporation)
Salt	Salt Industry Act	Registration as a specified wholesaler of salt Notification of specified wholesale of special-purpose salt Registration as a salt wholesaler
Liquor (drinks with an alcoholic content of one percent or higher)	Liquor Tax Act	Obtainment of liquor sales license Payment of liquor tax
	Act on Securing of Liquor Tax and on Liquor Business Associations	Labeling of liquor item name
Items covered by the CITES (e.g., aloe, musk deer, American ginseng, Saussureae costus, Gastrodia elata rhizome, crocodile)	Foreign Exchange and Foreign Trade Act Import Trade Control Order	· Regulation of international trades depending on the need for protection of plants and animals covered by the CITES · Importing not permitted without a CITES export permit issued by the exporting country
Fisheries products		Import quota, import approval, prior confirmation system

II Flow of Import Procedures of Health Foods

Before Importing

- For goods that cannot be clearly distinguishable as foods, it is important to check that they do not fall into the category of pharmaceuticals before importing them for smooth customs clearance procedures.
- For notification of food import, prepare necessary documents such as ingredient list and food production flow chart.
- If the goods to be imported are subject to laws and regulations that require permission, approval or inspection for importing (e.g., items covered by the CITES, goods subject to plant quarantine or animal quarantine), prepare documents necessary for the relevant procedures.

At Importing

- Cargo that arrives in Japan is transported into bonded areas.
- Import procedures differ by types of food.
  (1) Plant foods such as vegetables and fruits are subject to the Plant Protection Act, and the importer files an application for inspection at a plant protection station under the jurisdiction of the Ministry of Agriculture, Forestry and Fisheries (MAFF) and undergoes inspections.
  (2) Livestock products such as meat and processed meat products are subject to the Act on Domestic Animal Infectious Diseases Control, and the importer files an application for inspection at an animal quarantine service under the jurisdiction of MAFF and undergoes inspections.
  (3) All foods (including foods in (1) and (2) above) imported for the purpose of marketing (including delivery) are subject to the Food Sanitation Act, and the importer submits import notifications to quarantine stations under the jurisdiction of the Ministry of Health, Labour and Welfare (MHLW).
  If the import is judged as being legitimate as a result of an examination and inspection at a quarantine station, a certificate of notification for importation of foods is returned to the importer.

Import Clearance

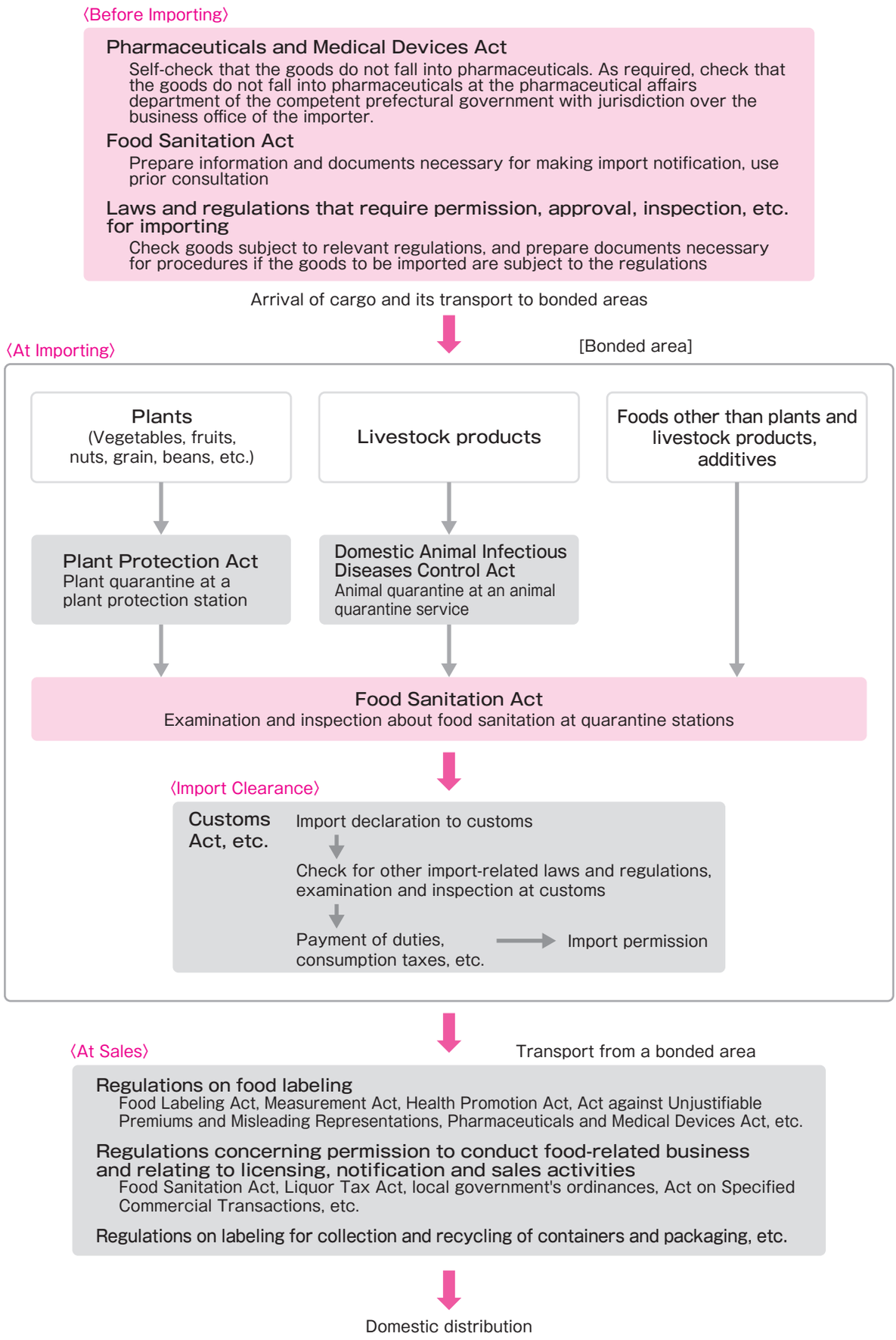
- When making an import declaration at customs, the importer presents a certificate of notification based on the Food Sanitation Act returned from quarantine stations for foods, a certificate for goods that underwent plant quarantine or animal quarantine, or a proof of permission or approval for goods that require them for importing (e.g., items covered by the CITES) and customs checks them.
- In the case of importing liquor, the importer must affix a label in Japanese under the Act on Securing of Liquor Tax and on Liquor Business Associations and other laws to the products within a bonded area, and is permitted to transport them out of the bonded area only after paying duties, consumption taxes and liquor tax.
- When the import is permitted after paying duties, consumption taxes, etc., the importer is allowed to transport imported foods out of a bonded area.

At Sales

- Foods need to carry labels compliant with regulations on food labeling while being marketed.
- Careful attention is required for representations and advertisements of health foods not to violate relevant regulations of the Health Promotion Act, Act against Unjustifiable Premiums and Misleading Representations (hereinafter referred to as Premiums and Representations Act) , and Pharmaceuticals and Medical Devices Act.
- Depending on the food type or business mode, a business permit or notification may be required.
- Certain sales activities such as online sales are subject to regulations under the Act on Specified Commercial Transactions.
- Containers and packaging are subject to regulations on identification marks for recycling.

For the laws above, their information is provided at websites of governmental agencies that have jurisdiction over the laws, or websites of or pamphlets available at the competent division of prefectural government.

Flow of Import Procedures of Health Foods



III Applicability of Pharmaceuticals and Medical Devices Act and Whether the Goods Fall into Pharmaceuticals

Some health foods and supplements available overseas contain ingredients classified as pharmaceuticals under the Pharmaceuticals and Medical Devices Act of Japan or claim functions similar to pharmaceuticals. Such products fall into the category of pharmaceuticals in Japan, and cannot be imported as foods.

When one desires to import goods that are not clearly distinguishable as foods (e.g., supplements in a form of tablet or capsule, those that contain oriental drug(Note) or herbal raw materials, those that contain raw materials that are not familiar in Japan), the person needs to check whether the goods fall into the category of pharmaceuticals.

(Note) Oriental drugs: Crude drugs used in Japan or China (a part of natural plant, mineral or animal which is simply processed and used as a drug)

Four Elements for Determining Whether the Goods Fall into Pharmaceuticals

As described in the section about the division between foods and pharmaceuticals on page 4, the criteria of whether goods fall into the category of pharmaceuticals are the "Standards on the Scope of Pharmaceuticals" included in the MHLW's Notice, "Guidance and Regulations on Unapproved or Unauthorized Drugs."

The judgment is made by whether the goods have a purpose as a pharmaceutical or whether people usually recognize the goods to have a purpose as a pharmaceutical, and there are four determination elements.

If goods are judged to fall into the category of pharmaceuticals as a result of comprehensive consideration on the four elements, the goods cannot be imported as foods into Japan.

(1) Ingredient essences (raw materials) of the goods

Whether the goods to be imported are pharmaceuticals or not is judged from their raw materials and ingredients.

Specifically, two lists (list of division between foods and pharmaceuticals) are provided, and goods containing ingredients classified into "list of ingredient essences exclusively used as pharmaceuticals" are regarded as pharmaceuticals.

(2) Efficacy and effects labeled on the goods

If efficacy or effects for the purpose of therapy or prevention of disease or for the primary purpose of general strengthening or promotion of tissue functions in the body are represented or described on the product container, packaging, package insert, brochures, pamphlets, and/or advertisements (including those on the Internet), the goods are regarded as pharmaceuticals, whether such claims are explicit or implicit.

The same applies when such claims are made in a non-Japanese language.

(3) Form (e.g., dosage form, container, packaging, design)

Ampules, sublingual tablets, those sprayed into the oral cavity after filling into a spray tube are regarded as pharmaceuticals.

(4) Dosage and administration labeled on the goods

If detailed dosage and administration (e.g., administration time, administration intervals, dosage) are labeled, the goods are regarded as pharmaceuticals.

■ Reference information

MHLW's Notice "Guidance and Regulations on Unapproved or Unauthorized Drugs," Attachment "Standards on the Scope of Pharmaceuticals"
(MHW/DPAB Notice of 1971, Yakuseihatsu No. 0418-4, amended on April 18, 2018)
MHLW's website "Food > Health foods > Information on unapproved or unauthorized drugs > Notices"
(Note) This notice has been amended multiple times since it was first issued in 1971. Always check for the latest amendment.
https://www.mhlw.go.jp/kinkyu/diet/musyounin.html

Goods That Are Not Judged as Pharmaceuticals in Principle

Like those that are clearly recognizable as foods from their appearances or forms, such as vegetables, fruits and cooked products, goods that fall into one of the items below are not judged as pharmaceuticals in principle.

1 Those that are clearly recognizable as foods from their appearances or forms, such as vegetables, fruits and cooked products
2 Foods for special dietary uses that carry labels permitted under the provisions of Article 26 of the Health Promotion Act (Act No. 103 of 2002)
3 Foods with function claims that carry labels permitted under the provisions of Article 2, paragraph (1), item (x) of the Food Labeling Standards (Cabinet Office Ordinance No. 10 of 2015) that was established based on the provisions of Article 4, paragraph (1) of the Food Labeling Act (Act No. 70 of 2013)

(Source) MHLW's Notice "Standards on the Scope of Pharmaceuticals"

Items whose essences are well recognized from experience in a normal diet and that are easily recognizable as foods from their appearances or forms do not cause misunderstanding about the essence of the items as foods, and there is no concern for normal persons to misinterpret such items as pharmaceuticals. Therefore, it is clear that such items that pose no concern over giving interpretation of having pharmaceutical purposes do not fall into pharmaceuticals and there is no need to individually examine their ingredient essences (raw materials), forms, effects and efficacy, or dosage and administration and to make judgment in accordance with the "judgment method" described below.

(Source) MHLW's Notice "Manual of Supervision and Guidance on Unapproved or Unauthorized Drugs," Chapter II-4 "Interpretation of Items Clearly Recognizable as Foods"

Items to Check for Determining Whether Goods Fall into Pharmaceuticals

1 Do the goods contain an ingredient on the "list of ingredient essences exclusively used as pharmaceuticals" ? ⇒ Yes ⇒ Fall into pharmaceuticals

↓ No

2 Are the goods labeled with or advertised for pharmaceutical effects or efficacy? ⇒ Yes ⇒ Fall into pharmaceuticals

↓ No

3 Are the goods in a pharmaceutical form? ⇒ Yes ⇒ Fall into pharmaceuticals

↓ No

4 Does the description of the goods include pharmaceutical dosage and/or administration? ⇒ Yes ⇒ Fall into pharmaceuticals

↓ No

Do not fall into pharmaceuticals. However, checking of related laws and regulations is needed regarding the raw materials used, labeling and advertisement.

(Source) MHLW's Notice "Standards on the Scope of Pharmaceuticals" Chapter II "Judgment method" Edited by MIPRO.

Self-checking Whether the Goods Fall into Pharmaceuticals

To investigate whether the goods to be imported fall into pharmaceuticals, it is highly recommended to refer to the Attachment "Manual of Supervision and Guidance on Unapproved or Unauthorized Drugs" of MHLW's Notice "Supervision and Guidance on Unapproved or Unauthorized Drugs." The Attachment includes explanations on the basic approach of judgment, interpretations, points of note and other useful information.

■ Reference information

MHLW "Supervision and Guidance on Unapproved Medicine and Unauthorized Drugs," Attachment "Manual of Supervision and Guidance on Unapproved or Unauthorized Drugs" (last amendment, Yakushokukanmahatsu No. 0401-3, April 1, 2015).
https://www.mhlw.go.jp/kinkyu/diet/dl/kanshishidou.pdf

Obtain an ingredient list (see page 20), photos, user's manual and the like of the product from the exporter (e.g., relevant overseas manufacturer). To judge whether the goods contain pharmaceutical ingredients or not, also obtain information on the Japanese name and scientific name of raw materials, classification (family, genus) of raw materials of plant or animal origin, used parts, purpose of use, etc.

Checkpoint 1: Whether Raw Materials or Ingredients Fall into Pharmaceuticals

Check whether raw materials or ingredients fall into pharmaceuticals using two lists provided by the "Standards on the Scope of Pharmaceuticals."

(1) **List of ingredient essences (raw materials) exclusively used as pharmaceuticals** = Pharmaceuticals list
(2) **List of ingredient essences (raw materials) not judged as pharmaceuticals unless claiming pharmaceutical effects or efficacy** = Non-pharmaceuticals list

Pharmaceuticals list	Uncategorized (new) raw materials and ingredients	Non-pharmaceuticals list
· List in which an item is judged as a pharmaceutical if it contains or is labeled to contain any one of raw materials or ingredients in the list	· Not being included in the pharmaceuticals list or non-pharmaceuticals list does not automatically mean the raw material or ingredient is usable in food products.	· List in which an item is not judged as a pharmaceutical unless pharmaceutical effects or efficacy are included in product descriptions on the outer box or in advertisements

[If raw materials and ingredients are not categorized into the list of division between foods and pharmaceuticals (new ingredients)]
Not being included in the two lists does not automatically mean the raw material or ingredient is usable in food products. To determine whether raw materials and ingredients not included in the two lists fall into pharmaceuticals, the importer will have to inquire MHLW via the competent prefectural office. When inquiring MHLW, the importer needs to obtain documents containing information on such raw materials and ingredients, including scientific names of raw materials, used parts, pharmacological or physiological action, toxicity, narcotic or stimulative action, precedents of approval as pharmaceuticals in Japan or overseas, and dietary habits from the processor and submit them. Please contact the pharmaceutical affairs department of the competent prefectural government with jurisdiction over the business office of the importer for details.

Also check whether the raw materials and ingredients are the same as those found to have unapproved or unauthorized drugs detected from health foods and others or reported to have caused health damage.

❖How to Read the List of Division between Foods and Pharmaceuticals

Judge as pharmaceuticals from the names and parts of raw materials.
In the example case of senna below, it falls into pharmaceuticals because products using the fruit, leaflet, petiolule, or rachis of senna are included in the pharmaceuticals list. Meanwhile, the stem of senna is shown as "non-pharmaceutical" and therefore falls under the non-pharmaceuticals list. Unless claiming pharmaceutical effects or efficacy, it can undergo import procedures as foods. However, it must be noted that, even if the stem of senna is used, if the used part is not labeled on the product, the product will be judged as a pharmaceutical.
The Panax ginseng in the example case for the non-pharmaceuticals list is also called as Korean ginseng or Asian ginseng. The fruit, root, root stalk and leaf of Panax ginseng fall under the non-pharmaceuticals list, and can undergo import procedures as foods unless pharmaceutical effects or efficacy are claimed.

(Example case of senna which is included in the pharmaceuticals list)

Name	Other names	Part	Remarks
Senna	Alexandria senna, tinnevelly senna	Fruit, leaflet, petiolule, rachis	Stem is "non-pharmaceutical"

(Example case of Panax ginseng which is included in the non-pharmaceuticals list)

Name	Other names	Part	Remarks
Panax ginseng	Korean ginseng, Asian ginseng	Fruit, root, root stalk, leaf	

(Source) MHLW's Notice "Standards on the Scope of Pharmaceuticals"

❖Points to Note about Raw Materials

Attention needs to be paid not only on whether pharmaceutical ingredients are contained but also on how raw materials are handled.
・Crude drug names must not be used in the ingredient list of foods
If crude drug ingredients that fall into non-pharmaceuticals are to be used as foods, the names of sourced plants, etc. are to be used in principle so that they can be easily recognized as foods.

(Examples)

Crude drug name (Not acceptable - representation regarded as pharmaceuticals)	Name of sourced plant, etc. (Acceptable - representation permitted for foods)
Dioscorea rhizome	Japanese yam, Chinese yam
Zingiberis rhizoma	Ginger
Zizyphi fructus	Red dates
Ostreae Testa	Oyster shell
Coix seed	Job's tears

(Source) MHLW's Notice "Manual of Supervision and Guidance on Unapproved or Unauthorized Drugs"
Edited by MIPRO.

・Other matters that should be noted include handling of raw materials that were extracted using a solvent other than water and ethanol and handling of raw materials that are used for the purpose of coloring or flavoring.

Checkpoint 2: Whether the Goods Are Labeled with or Advertised for Pharmaceutical Effects or Efficacy

(1) Efficacy or effects for the purpose of therapy or prevention of disease
(2) Efficacy or effects for the primary purpose of general strengthening or promotion of tissue functions in the body
(3) Implication of pharmaceutical effects or efficacy

Claiming for the above falls under claiming pharmaceutical effects or efficacy.
Even when such claims are made in a non-Japanese language, they are treated in the same manner.

Claims (labeling and advertisements subject to regulations)

(1) In this standard, claims refer to all representations and descriptions by means written below related to sale of the goods.
[1] Representations on the container, packaging, package insert, etc. of the goods
[2] Brochures, pamphlets, etc. of the goods
[3] Advertisements of the goods by TVs, radios, newspapers, magazines, the Internet, etc.
[4] Booklets and books titled "Miraculous XX," "All About XX," etc.
[5] Special member magazines such as "XX Community," information magazine such as "XX News" and "XX News Flash"
[6] Clippings of newspapers, magazines, etc., extracts from books, academic papers, etc.
[7] Product description (related) documents distributed to agents and retailing stores under the name of training materials
[8] Collections of thank-you letters and experience stories of users
[9] Hung posters in stores, public transport, etc.
[10] Slides, videos, etc. used or verbal sales talks performed at stores, door-to-door sales, explanatory sessions, consultation sessions, unsolicited sales in public places, etc.
[11] Those equivalent to the previous items that are used in relation to sales of specified commodities
(2) Regarding claims performed by [4] to [10] in (1), even if the name of specified commodity is not shown, when explanations of a specified commodity is provided to those requesting them, when they are placed in the same place as the specified commodity as explanation of the commodity, or when explanations of a specified commodity are given by, for example, sending them along with an offer to purchase for the specified commodity, these acts are regarded as claiming pharmaceutical effects or efficacy for the relevant specified commodity.

(Source) MHLW's Notice "Manual of Supervision and Guidance on Unapproved or Unauthorized Drugs"

(Examples of unacceptable descriptions)

(1) Efficacy or effects for the purpose of therapy or prevention of disease

For people with diabetes/hypertension/arteriosclerosis, prevention of gastric and duodenal ulcers, heals liver/kidney disorders, improves cancers, for people with eye diseases, relieves constipation, etc.

(Source) MHLW's Notice "Standards on the Scope of Pharmaceuticals"

(2) Efficacy or effects for the primary purpose of general strengthening or promotion of tissue functions in the body

Note that, although expressions about nutritional supplementation, health maintenance, beauty and the like do not fall into pharmaceutical effects or efficacy, false or exaggerated expressions may conflict with the Premiums and Representations Act or Health Promotion Act.

Recovery from fatigue, invigorating (aphrodisiac) tonic, physical strength enhancing, appetite-promoting, anti-aging, improves studying performance, rejuvenating, improves libido, improves metabolism, improves secretory functions, enhances detoxification functions, improves heart functions, purifies the blood, improves natural healing power against diseases, improves gastrointestinal digestion and absorption, calms gastric and intestinal disorders, for during and after disease, promotes growth, etc.

(Source) MHLW's Notice "Standards on the Scope of Pharmaceuticals"

(Examples of unacceptable descriptions)

(3) Implication of pharmaceutical effects or efficacy

[1] Those implied by the name or catch phrases	Medical XX, secret Chinese medicine therapy
[2] Those implied by ingredient representations or descriptions	Using XXXX known to have effects to improve physical constitution and calm gastric and intestinal disorders as a raw material, active ingredients are added to provide synergy effects.
[3] Those implied by description of manufacturing method	Using the plant XX that grows wild on deep mountainous highlands of Japan as the main ingredient, this product was prepared by a unique manufacturing method (patent pending) from various herbs such as YYY and ZZZ.
[4] Those implied by description of the origin, history, etc.	An ancient natural scientific book XXX states this opens up the stomach, disperses low spirits, helps with digestion, kills worms, and eliminates phlegm. Such experiences have been passed down since ancient times and this was always included in meals.
[5] Those implied by citation or quotation of an article in a newspaper or magazine, talk, doctrine or experience by a physician or academic, etc.	MD XXXX says: "It has been said since before that eating red rice with XXX on top prevents cancer. [...] It is possible that XXX is related to lipid metabolism disorder, and further carbohydrate and protein metabolism disorders of cancer cells."
[6] Those implied by expressions stating to have medical efficacy equivalent to or better than Korean ginseng	This ingredient is known to have better effects than Korean ginseng.
[7] Those implied by making people to check their physical conditions or symptoms under the name of "health check" and recommending to consume the product depending on the symptom, etc.	
[8] Those implied by expressions like "for persons with XXX" ・Expressions like the product is for persons with a disease, for persons who desire to prevent a disease, or for persons in undesirable physical conditions fall into claims of pharmaceutical effects or efficacy.	For persons tending to have constipation, for persons concerned about XX disease, for persons who feel listless and cannot recover from fatigue (Note) Expressions mainly aiming at health maintenance, beauty, or nutritional supplementation do not immediately fall into claims of pharmaceutical effects or efficacy.
[9] Those implied by expressions about "healing crisis"	Those giving explanations like "Taking this product may temporarily cause reactions like diarrhea and pimples, but they are initial symptoms as a result of the product's internal cleansing and constitution improving effect, and it is essential to keep taking the product" that discomforts are claimed as "healing crisis," "cleansing reaction," etc. and a proof of effects.
[10] Those implied by expressions like "effect," "efficacy" or "benefit" of taking a specific product, without clearly stating the name of disease, etc.	The product needs to be taken for at least 1 month for it to take effect. The efficacy is proven at university hospitals. Although the product does not take effect immediately like pharmaceuticals, if you keep taking it for 2 to 3 months, you will surely feel the benefit.
[11] Those implied by words "medicine" and "drug"	Crude drug, miracle drug, folk medicine, medicinal herb, Chinese medicine

(Source) "Manual of Supervision and Guidance on Unapproved or Unauthorized Drugs" Edited by MIPRO.

Checkpoint 3: Whether the Form Is Misleading as Pharmaceutical

The term "form" here refers to the dosage form (e.g., ampule, hard capsule, soft capsule, tablet, pill, powder and granules and their sachets, liquid), as well as the shape of container or encapsulation (e.g., glass bottle, paper box, plastic bag), and the patterns, photos, drawings and the font, design, etc. of letters shown on the container or encapsulation, all inclusive.
Whether the form of the goods is pharmaceutical or not is determined by comprehensively taking into account the dosage form of the goods and design and shape of the container or encapsulation.

(1) Forms that fall into pharmaceuticals

Forms like ampule that are not used in distribution of normal foods are regarded as attempting to mislead consumers to believe the product is a pharmaceutical, and judged as pharmaceutical.

(Examples of forms that fall into pharmaceuticals)

- Ampules
- Sublingual tablets
- Liquid to be absorbed from mucosa (e.g., those to be dropped sublingually)
- Spray (those sprayed into and act on the oral cavity)

(Source) MHLW's Notice "Manual of Supervision and Guidance on Unapproved or Unauthorized Drugs" Edited by MIPRO.

(2) Forms that are not judged as pharmaceuticals by clear statement of "food"

Even if the product is in a form used for pharmaceuticals (e.g., tablet, capsule, pill, powder and granules and their sachets, liquid), if a statement of the product being "food" is clearly shown on its container, in principle, the product will not be judged as pharmaceuticals by the form alone.

Checkpoint 4: Whether Use Method Falls into Pharmaceutical Dosage and/or Administration

Pharmaceuticals are provided with administration time, administration intervals, and dosage to draw out the best performance. Therefore, if the use method of goods contains administration time, administration intervals, dosage and the like, it is regarded as pharmaceutical dosage and administration in principle.

(Examples of unacceptable descriptions)

2–3 times a day, 2–3 tablets per day
2 pieces a day
2 spoonfuls after each meal, using the enclosed spoon
3–6 tablets a day for adults
1–2 pieces each before and after meal
1–2 tablets before sleep

(Source)
MHLW's Notice
"Standards on the Scope of Pharmaceuticals"

Contact Points for Determining Whether the Goods Fall into Pharmaceuticals before Importing

When one desires to import goods that are not clearly distinguishable as foods (e.g., supplements in a form of tablet or capsule, those that contain oriental drug or herbal raw materials, those that contain raw materials that are not familiar in Japan), the person needs to check whether the goods fall into the category of pharmaceuticals.
Prepare documents for checking and self-check the judgment points on whether the goods fall into pharmaceuticals before importing. As required, consult the pharmaceutical affairs department of prefectural government that has jurisdiction over the business office of the importer with notifying the department that it is an inquiry about whether the goods to be imported fall into pharmaceuticals.

❖Documents for Checking Whether the Goods Fall into Pharmaceuticals

For the goods to be imported, prepare documents describing the elements (raw materials and ingredients, representations, form) for determining whether the goods fall into pharmaceuticals.

- Ingredient list: Document that gives descriptions about all the raw materials and ingredients used. Clearly states the name (Japanese name, scientific name, classification (family, genus)), and used parts and purpose of use for raw materials of plant or animal origin.
- Product photos, outer packaging photos, user's manual, package insert, advertisements, pamphlets, etc.
- As what kind of product the goods will be marketed in Japan (marketing representations and advertisements prepared in Japanese)
- In what state the goods will be imported (individual packaging, imported in bulk and divided into smaller portions in Japan)
- In what form the goods are (tablet, capsule, powder, etc.)

■ Inquiries (about whether the goods to be imported fall into pharmaceuticals)
Pharmaceutical affairs department of prefectural government with jurisdiction over the business office of the importer

❖Make Sure to Consult Pharmaceutical Affairs Department When Importing Goods in a Pharmaceutical Form

If an importer is thinking to import goods in a pharmaceutical form (e.g., tablet, capsule, powder), before starting importing, the importer must consult the pharmaceutical affairs department of prefectural government that has jurisdiction over the business office of the importer on whether the goods fall into pharmaceuticals.
The importer records the details of checking whether the goods fall into pharmaceuticals (when and to whom the importer made inquiries, raw materials and ingredients in question and handling thereof and others in any format) and prepares a document.
The importer must submit this document when submitting an import notification to a quarantine station.

■ Reference information
MHLW's Notice "Handling of Import Notification Pertaining to Health Foods" (Shokukenhatsu No. 0719001, July 19, 2002).
https://www.mhlw.go.jp/kinkyu/diet/index.html

❖Self-inspection for Not Containing Pharmaceutical Ingredients for Weight-loss Related Goods in Pharmaceutical Form

In response to many incidents of health damage caused by weight-loss related health foods, MHLW requests importers to voluntarily check (self-inspect) that pharmaceutical ingredients (e.g., fenfluramine, N-nitroso-fenfluramine, sennoside, triiodothyronine, thyroxine) are not contained if the representations are clearly indicative of the goods being weight-loss related health foods in a form of tablet, capsule, powder, etc.

■ Reference information
MHLW's Notice "Handling of Import Notification Pertaining to Health Foods" (Shokukenhatsu No. 0729001, July 29, 2002).
https://www.mhlw.go.jp/kinkyu/diet/index.html

Contact Points for Determining Whether the Goods Fall into Pharmaceuticals for Cargo That Has Arrived and was Suspended at Customs Clearance

The pharmaceutical affairs department of prefectural government is unable to answer to consultations about cargo that was imported without an inquiry or consultation to the pharmaceutical affairs department and suspended by customs indicating the possibility of falling into pharmaceuticals, etc. or to consultations about goods for which a prior inquiry has been made by customs or the quarantine station.
Regarding whether the cargo suspended at customs clearance falls into pharmaceuticals, the section in charge of the Import Report of Medication (Yakkan Shoumei) of the Regional Bureau of Health and Welfare covering customs that has jurisdiction over the port the cargo has arrived at will answer. Consultation requires the documents below.

1. Name and contact address (telephone number) of the importer
2. Contact address (telephone number) of the customs office at which the cargo is stopped (or customs or quarantine station from which a prior inquiry has been made), the details of inquiry (why customs, etc. suspended the cargo) from customs, etc., (for goods about which a prior inquiry has been made by customs or the quarantine station, include the contact address of the customs office at which the cargo will undergo customs clearance)
3. A copy of invoice
4. A copy of AWB (or notice from B/L or customs)
5. Photos of the goods stopped at customs, outer packaging photos, user's manual, package insert, etc. (if content inspection and checking is performed by the transportation company, make sure to send the report of content inspection as well)
6. Advertisement materials in Japan and overseas of the goods stopped at customs (advertisement plan is acceptable) , pamphlets, etc. (printouts of relevant websites are acceptable)

(Source) Website of Kinki Regional Bureau of Health and Welfare "Consultation about Import Procedures for Cargo Suspended at Customs Clearanc"

■ Inquiries (about whether cargo stopped at customs falls into pharmaceuticals)
Section in charge of the Import Report of Medication (Yakkan Shoumei) of the Regional Bureau of Health and Welfare covering customs that has jurisdiction over the port the cargo has arrived at

Cargo cleared at Hakodate Customs, Tokyo Customs, or Yokohama Customs	Kanto-Shinetsu Regional Bureau of Health and Welfare	Pharmaceutical Inspector Section of Inspection and Guidance +81-48-740-0800 e-mail: yakkan@mhlw.go.jp
Cargo cleared at Nagoya Customs (including Chubu Airport), Osaka Customs (including Kansai Airport), Kobe Customs, Moji Customs (including Fukuoka Airport), or Nagasaki Customs	Kinki Regional Bureau of Health and Welfare	Pharmaceutical Inspector Section of Inspection and Guidance +81-6-6942-4096 e-mail: kiyakuji@mhlw.go.jp
Cargo cleared at Okinawa Regional Customs	Kyushu Regional Bureau of Health and Welfare Okinawa Narcotics Control Office	Pharmaceutical Inspector Section of Inspection and Guidance +81-98-853-7100 e-mail: okinawa-yakuji@mhlw.go.jp

Health Foods That Fall into the Unapproved or Unauthorized Drugs Cannot Be Sold, Delivered, etc.

The concern health foods have in relation to the Pharmaceuticals and Medical Devices Act is that goods that should be approved as pharmaceuticals are manufactured, imported and marketed under the name of foods. If such health foods are distributed, problems like;

- general consumers confuse the basic concept of pharmaceuticals and foods, which could lead to distrust in pharmaceuticals;
- consumers who bought health foods believing misleading claims for therapeutic effects on diseases without actually confirming the efficacy could become victims of sanitary and health hazards by losing opportunities of receiving proper medical treatments and the disease becoming worse will emerge.

Health foods that were judged to fall into pharmaceuticals are regarded as "unapproved or unauthorized drugs," and Article 55, paragraph (2) of the Pharmaceuticals and Medical Devices Act prohibits their sales, delivery, or storage or display for the purpose of selling or delivering.

■ Reference information
MHLW's website "Health foods" > "Information on health damage, unapproved or unauthorized drugs"
https://www.mhlw.go.jp/kinkyu/diet/musyounin.html

Ⅳ Food Sanitation Act and Import of Foods

It is important for all food importers to understand the food import notification system under the Food Sanitation Act and the gist of food safety-related regulations.
The importers should prepare all documents necessary for making a notification, and investigate the possibility of the goods to be imported complying with regulations of the Food Sanitation Act before Importing.
Careful and thorough preparation helps with minimizing financial and time losses.

Import Notification System for Foods

When importing foods for the purpose of selling or business (including handing them over to many and unspecified persons at exhibitions or in town), the importer is obliged to make an import notification to a quarantine station each time. (Article 27 of the Food Sanitation Act)
It is prohibited to use any imported foods for sales or business without making an import notification.

❖Notification Procedures (Article 32 of the Ordinance for Enforcement of the Food Sanitation Act)

Right after the arrival of a cargo,(Note) an importer must submit a "written notification for importation of foods, etc." prepared in a prescribed format, together with the necessary documents depending on food items, to the quarantine station that has jurisdiction over the place for customs clearance of said cargo.

(Note) Notification must be made right after the arrival of a cargo, in principle, but there is an Advance Notification System, under which notification is accepted from 7 days prior to the scheduled arrival of the cargo. When using this system, a certificate of notification for importation of foods, etc. is issued promptly for cargo that does not require an inspection prior to arrival or after the transport into a bonded area. However, where any change arises in the content of the notification after arrival of the cargo, an importer must report to that effect to the quarantine station to which the importer made the advance notification.

❖Documents Required for Making Notification

☐ Written notification for importation of foods, etc.: 2 copies

All required fields must be filled, including the name and address of importer, item name, product name, quantity, weight, exporting country, name and location of processor and processing facility, port of loading, and, for processed foods, processing/production methods, raw materials, and additives.

Where to obtain and how to fill in a notification form

⇒ MHLW's website "Import Procedures under the Food Sanitation Act"
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000144562.html (Japanese)
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/yunyu_kanshi/kanshi/index_00004.html (English)

☐ Documents to be attached vary depending on food type, item name, country of origin, processing method, etc.

In the case of processed foods, an ingredient list and a food production flow chart are required.

Formats are not specified but those prepared and issued by the processor or the exporter (with the company name and a signature of a responsible person) are preferable.

Additional documents may be requested as a result of an examination.

☐ Reports of past self-inspection results as necessary

(Note) Self-inspection refers to an inspection that the national government instructs an importer to conduct upon importing a cargo for the first time and regularly thereafter as part of the importer's own efforts for sanitary control.

Documents to be attached to import notification (examples)

Processed foods	〈For all processed foods〉
	・**An ingredient list** An ingredient list refers to a list of all raw materials (ingredients) and additives (specific substance name, E number, etc.) used in the food. If additives subject to specified utilization criteria are used, names of the substances, purposes of their use, their amounts, and stages where they are used must be stated. For raw materials not familiarized in Japan, documents and photos containing information such as Japanese names, scientific names, classification (family, genus), used parts, and history of consumption in Japan and overseas, by which their safety as food can be confirmed. For documents in a language other than Japanese or English, Japanese translations must be attached. ・**A food production flow chart** A food production flow chart refers to a chart showing the whole process of producing processed food from raw materials. For food items for which production criteria are specified (such as soft drinks and retort foods), detailed information on the content of sanitary control during the production and processing processes (e.g., washing, sterilization conditions, pH, water activity, freezing (refrigeration) temperature, X-ray) is required. ・**A document by which the item name (commodity name and number, etc.), name and location of the processor, name and location of the processing facility, and materials of container and packaging can be confirmed**
	〈Depending on the item and raw materials〉
	・For items using processed foods as ingredients, a document by which the raw materials, additives used, and production process (if production criteria are specified) of the processed foods can be confirmed ・For items using herbs and/or spices from countries where sterilization by irradiation is permitted, a document issued by the processor stating that the item is not sterilized by irradiation ・For items subject to an inspection order, a document by which the country of origin and ratio (%) of raw materials can be confirmed ・For items using soy, potato, rapeseed, corn, cotton, sugar beet, alfalfa, or papaya as raw materials, a document by which whether they are genetically modified food or not can be confirmed ・For items containing beef or beef derived ingredients, a document by which the countries where the beef cattle were bred and slaughtered and the beef meat was processed and the parts of the meat used as ingredients can be confirmed ・For extracts or items using extracts, extraction method ・For items in a pharmaceutical form (tablet, capsule) or depending on the raw materials of health foods, a document stating the results of whether they fall under the category of pharmaceutical ingredients as specified by the Pharmaceuticals and Medical Devices Act (see page 17)
Perishable foods	・A document by which the exporter, packager, and country/region of origin can be confirmed ・A document by which the Japanese name, scientific name, classification (family, genus) and used part can be confirmed ・A document and photos by which their safety as food can be confirmed (e.g., history of consumption in Japan and overseas) ・For items containing additives, an ingredient list and a document by which the details of the additives can be confirmed ・A sanitary certificate issued by a government organization of the exporting country depending on the item name and country of origin (e.g., dairy products, meat and processed meat products)

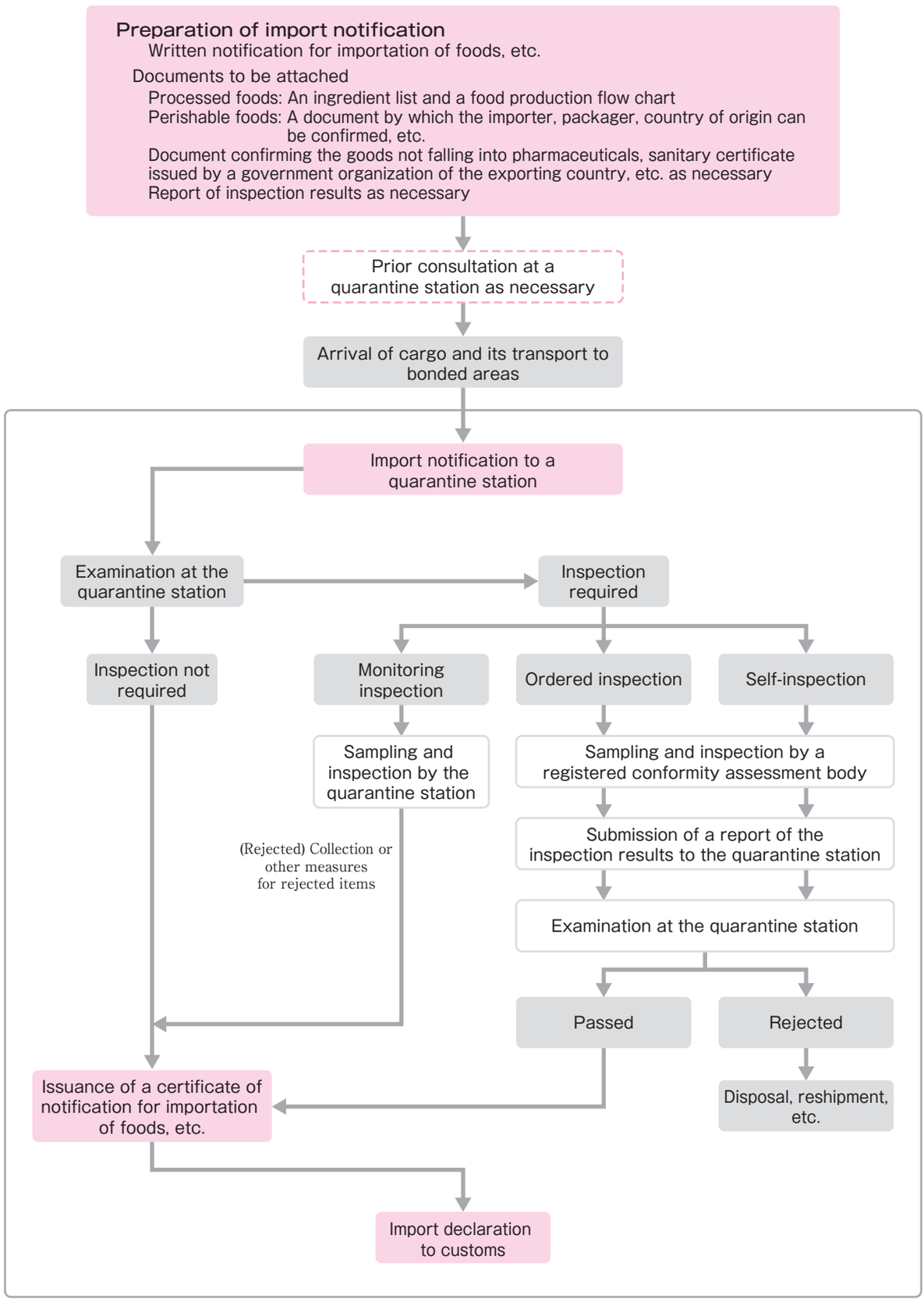
Note: Perishable foods refer to meat, vegetables, fish and seafood, and their simple processed food.
(Source) Data held at quarantine stations. Edited by MIPRO.

❖Notification Method

・Ask a customs broker, etc.(Note) to submit documents by proxy (an importer must prepare documents to be attached)
・Bring in documents directly to a quarantine station
・Send documents by post (enclose a return envelope with a stamp)
・Submit documents online using the Food Automated Import Notification and Inspection Network System (FAINS)
(Need to register the relevant terminal equipment and others with the MHLW in advance)

(Note) A customs broker refers to a person engaging in custom-house business with a license granted by the director-general of customs. A customs broker undertakes affairs concerning import declaration (tax filing), etc. in place of the importer and often engages in international forwarder business, warehousing business, harbor transport business as well.

Flow of Import Notification for Foods



(Source) MHLW document. Edited by MIPRO.

Examination and Inspection at Quarantine Stations

A quarantine station of the MHLW checks the details of an importer's notification and examines whether the relevant food items contain any toxic or hazardous substances, whether they conform to the standards and criteria under the Food Sanitation Act and other regulations. (See page 24)

The quarantine station decides whether additional documents are required, inspection is required and so on, as a result of the documentary examination. The decision will be notified to the importer directly or via a customs broker, and the importer complies with the decision. If an inspection order or an instruction on self-inspection was received, the importer requests an inspection to a registered conformity assessment body (at the expense of the importer).

If the foods were found to conform to the Food Sanitation Act based on the documentary examination and inspection, a certificate of import notification is returned from the quarantine station and the importer may proceed with customs clearance procedures.

On the other hand, if the cargo is rejected, it is shipped back or disposed of and the importer must bear the expenses therefor.

■ Reference information

MHLW's website: "Imported Foods Safety"
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/yunyu_kanshi/index.html (Japanese)
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/yunyu_kanshi/index_00017.html (English)

■ Inquiries

Quarantine station of the MHLW having jurisdiction over the port where the importer imports cargo
Offices that accept import notification: Food Inspection Division (32 offices in Japan)
https://www.mhlw.go.jp/topics/yunyu/soudan/index.html (Japanese)
Prior consultation: Office of Imported Food Consultation
(established inside the 13 Food Inspection Divisions below; ◎ indicates a dedicated telephone number)

Otaru Quarantine Station; Food Inspection Division	TEL:+81-134-32-4304	
Sendai Quarantine Station; Food Inspection Division	TEL:+81-22-367-8102	
Narita Airport Quarantine Station; Food Inspection Division	TEL:+81-476-32-6741	◎ +81-476-32-6728
Tokyo Quarantine Station; Food Inspection Division	TEL:+81-3-3599-1520	◎ +81-3-3599-1519
Yokohama Quarantine Station; Food Inspection Division	TEL:+81-45-201-0505	
Niigata Quarantine Station; Food Inspection Division	TEL:+81-25-244-4405	
Nagoya Quarantine Station; Food Inspection Division	TEL:+81-52-661-4133	◎ +81-52-661-4132
Osaka Quarantine Station; Food Inspection Division	TEL:+81-6-6571-3523	◎ +81-6-6571-3554
Kansai Airport Quarantine Station; Food Inspection Division	TEL:+81-72-455-1290	◎ +81-72-455-1295
Kobe Quarantine Station; Food Inspection Division	TEL:+81-78-672-9655	
Hiroshima Quarantine Station; Food Inspection Division	TEL:+81-82-255-1379	
Fukuoka Quarantine Station; Food Inspection Division	TEL:+81-92-271-5873	
Naha Quarantine Station; Food Inspection Division	TEL:+81-98-868-4519	

Testing and Inspections Directed by Quarantine Station

Ordered inspection	An inspection that a quarantine station orders an importer to conduct, on each occasion, based on Article 26 of the Food Sanitation Act, with regard to cargo that is considered to be highly likely to violate a law, such as cargo found to violate a law as a result of a self-inspection or a monitoring inspection, or a random inspection(Note) in Japan. Items subject to ordered inspection, matters to be inspected, sampling methods, and inspection methods are publicized on the MHLW website.	Sampling and inspection: Registered conformity assessment bodies Expenses: To be borne by importers Import is not permitted until the inspection results are obtained.
Self-inspection (instructed inspection)	An inspection that the national government instructs an importer to conduct upon importing a cargo for the first time and regularly thereafter as part of the importer's own efforts for sanitary control	Sampling and inspection: Registered conformity assessment bodies Expenses: To be borne by importers Import is not permitted until the inspection results are obtained.
Monitoring inspection	An inspection that the national government conducts based on an annual plan for the purpose of monitoring food sanitation conditions widely and taking measures, such as the strengthening of inspections upon import, as necessary	Sampling: Quarantine stations Expenses: To be borne by the national government Import is permitted without needing to wait for inspection results.

(Note) A random inspection refers to an inspection that a food sanitation inspector of a public health center conducts based on the Food Sanitation Act by collecting the required amount of foods as samples from processing facilities and retailing stores, etc.

FAQ

Q What should an importer do when having received an inspection order or an instruction on self-inspection?

A The importer must request an inspection to a registered conformity assessment body (a fair and neutral third-party body that satisfies certain requirements clarified in the Food Sanitation Act and other laws and is registered by the national government). The registered conformity assessment body collects samples from the relevant cargo stored in a bonded warehouse, inspects it and issues a report of the inspection results. The importer should submit this report to the quarantine station.

Please contact the relevant registered conformity assessment body for the necessary amounts of samples, inspection fees, the number of days required for an inspection, necessary documents and so on. A list of registered conformity assessment bodies is available on the MHLW website. As matters covered by inspections vary by body, please check in advance when choosing a body to request an inspection.

■ Reference information

MHLW website "List of Registered Conformity Assessment Bodies"
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/jigyousya/kikan/index.html

Q We have a report of the inspection results conducted in the exporting country. Do we have to undergo an inspection in Japan again?

A When an importer has undergone an inspection by an official laboratory in the exporting country (by an official laboratory that the government of the exporting country has registered with the MHLW of Japan as a body having a certain level of inspection capability) and attached a report of said inspection results upon making an import notification, the importer is exempted from undergoing an instructed inspection at a quarantine station in Japan. However, matters to be inspected for which changes may occur during transportation (bacteria, mycotoxins, etc.) are excluded. The following should be noted when an importer intends to receive an exemption. Please contact the relevant quarantine station for details.

- The name and location of the relevant laboratory should be the same as those stated in the list of foreign official laboratories.
- An inspection by a branch or local office of an official laboratory is not accepted.
- The inspection method employed should be equivalent or superior to those methods specified by the Food Sanitation Act.
- In order to check the consistency between inspected samples and products to be imported into Japan, the report of the inspection results contains data by which the processor's name, commodity name and number, and inspected samples can be identified.

■ Reference information

MHLW website "List of Foreign Official Laboratories"
https://www.mhlw.go.jp/topics/yunyu/5/index.html (Japanese)
https://www.mhlw.go.jp/english/topics/importedfoods/1-10.html (English)

MHLW website "Matters to Be Included in Report of Inspection Results Issued by Foreign Official Laboratory"
https://www.mhlw.go.jp/file/06-Seisakujouhou-11130500-Shokuhinanzenbu/gaikokuseisekisho170428.pdf (Japanese)
https://www.mhlw.go.jp/english/topics/importedfoods/dl/1-9.pdf (English)

Securing Safety of Foods by Food Sanitation Act

Each exporting country has original laws concerning food sanitation based on their climate and food culture and so on. Import or sale of food items that do not conform to the Food Sanitation Act is not permitted in Japan, even if they can be marketed in the exporting country.

To prevent the sanitation hazards resulting from eating and drinking, the Food Sanitation Act stipulates:

- measures to prohibit distribution of foods that cause damage to health, such as rotten, deteriorated, toxic or hazardous foods (Articles 6 to 9);
- prohibition of sale, production, importing, processing of foods, additives, etc. that do not conform to standards and criteria specified by the Minister of Health, Labour and Welfare (Articles 10 and 11);
- approach and systems of supervision and guidance for imported foods in Japan to ensure food sanitation.

(See page 25)

❖Matters to Be Checked At Importing

For imported foods, importers are obliged to make an import notification of the foods, and quarantine stations established at ports check their safety. Specifically, quarantine stations check such matters as below. (See pages 19 to 23)

Examination of documents	· Whether the used raw materials conform to the Food Sanitation Act · Whether additives are used in a proper manner · Whether the item conforms to production criteria · Whether the processor or the processing facility has any history of causing sanitary problems · Whether the item is subject to an order for recall in the exporting country · Whether required documents are attached
On-the-spot inspection at locations such as a warehouse where foods are stored	· Whether the item is not suited for human consumption due to being rotten or other reasons · Whether any foreign substances are mixed in · Whether the storage environment (temperature, etc.) is appropriate · Whether there is no errors in the content of the notification
Checking conformance with standards and criteria through testing and inspection (ordered inspection, self-inspection)	· Agricultural chemicals and veterinary drugs remaining in foods · Food additives · Pathogenic microorganisms such as enterohemorrhagic Escherichia coli and Vibrio parahaemolyticus · Bacterial counts and coliforms, etc. specified by the standards for constituents · Hazardous substances such as aflatoxin and other mycotoxins, and shellfish poisons · Mixing of genetically modified foods whose safety has yet to be approved

(Source) MHLW "Quarantine Stations' Efforts for Ensuring Safety of Imported Foods" (January 2016). Edited by MIPRO.

❖Health Damage by Health Foods and Response by National Government

For supplements in a form of tablets, capsules, powder, etc., excessive intake of a certain ingredient may cause adverse effects on the body. Since in some cases immediate action needs to be taken against foods suspected to be causing health damage, Article 7 of the Food Sanitation Act stipulates measures to ban marketing of such foods.

Additionally, in response to health damage caused by health foods such as Sauropus androgynus and Symphytum, MHLW has provided business operators with initiatives and methods for ensuring the safety of raw materials and ensuring the safety through manufacturing process management (Good Manufacturing Practice (GMP)), and requested business operators to introduce third-party certificate on safety assurance through GMP. (See pages 30 to 31)

■ Reference information

(Third-party GMP certifying bodies for health foods)
Japan Health and Nutrition Food Association http://www.jhnfa.org/
The Japanese Institute for Health Food Standards http://www.jihfs.jp/

Outline of Food Sanitation Act

Purpose

To prevent the sanitation hazards resulting from eating and drinking by enforcing the regulations and other measures necessary, from the viewpoint of public health, to ensure food safety and thereby to protect citizens' good health. (Article 1)

Definition of food

All food and drink (excluding pharmaceutical products and quasi-pharmaceutical products) (Article 4, paragraph (1))

Prohibition of sale, etc. of food, etc.

Sale, etc. is prohibited for the food, etc. below.

○Food and additives for which sale is prohibited (Article 6)
Sale is prohibited for rotten/deteriorated or toxic food, etc.
○Prohibition of sale of novel food (Article 7)
○Prohibition of sale, etc. of specific food, etc. (Article 8)
○Prohibition of sale, etc. of diseased meat, etc. (Article 9)

Formulation of Standards and Criteria

Stipulates criteria, standards, etc. of production, storage, etc. for food, etc. distributed in Japan (Article 10, Article 11)

- The Minister of Health, Labour and Welfare may establish the criteria and standards pertaining to production, etc. of food, etc., and sale, etc. is prohibited for food, etc. that do not conform to the said standards or criteria.
- Regarding agricultural chemicals, feed additives and veterinary drugs, only those designated by the Minister of Health, Labour and Welfare and for which the standards and criteria have been specified by the Minister of Health, Labour and Welfare can be used (positive list system).

Monitoring and Guidance

[In Japan]
○Approval of comprehensive sanitatary control and production process, etc. (Article 13, Article 14)
○Establishment of guidelines and plans related to monitoring and guidance (Article 22, Article 24)
○On-site inspections and removal (Article 28)
○Establishment of the criteria for business facilities (Article 50, Article 51)
○ Approval of business (Article 52)
○ Investigation on food poisoning (Article 58, Article 60)

[Imported Food]
○Establishment of the Imported Food Monitoring and Guidance Plan (Article 23)
○Notification of import (Article 27)

Measures, Penalties, etc.
●Inspection order (Article 26)
●Disposal order, etc. (Article 54)
●Rescission of business approval, suspension of business, etc. (Article 55, Article 56)
●Provisions of criminal penalties (Articles 71 to 79)

(Source) MHLW "Current Status and Problems Surrounding the Food Sanitation Act" (September 14, 2017)

Health Damage by Health Foods and Current System

⟨Outline of Current System⟩

➢ Article 6 of the Food Sanitation Act ⟨Prohibition of sale of insanitary food⟩
· Prohibits sale, production, etc. of insanitary food, etc. containing toxic or hazardous substances. (Example applicable case: Symphytum)
➢ Article 7 of the Food Sanitation Act ⟨Prohibition of sale of novel food⟩
· Prohibits sale of food for those not having a history of consumption or those served in a manner extraordinarily different from ordinary manners, when they have not been proved to not involve risk to human health and deemed necessary to prevent food sanitation hazards. (Example applicable case: Processed Sauropus androgynus foods)
➢ Reporting damage information (Administrative guidance: Iyakuhatsu No. 1004001 dated October 4, 2002)
➢ Quality control of production process and safety of raw materials (Administrative guidance: Shokuanhatsu No. 0201003 dated February 1, 2005)

⟨Major response cases⟩

Name	Advertisement phrase	Outset・health damage	Response
Sauropus androgynus (9.12.2003)	Weight reduction effect, constipation relief	· Bronchiolitis obliterans occurred in 200 people in Taiwan	**Provisional prohibition of distribution (Article 7, paragraph (2) of the Law)**
Symphytum (6.18.2004)	Longevity, invigorating	· Many reports of liver disorders overseas	**Prohibition of sale (Article 6, item (ii) of the Law)**
Garcinia cambogia (3.7.2002)	Weight reduction effect, etc.	· Effects on testes of rats · No report of health damage	· Raised consumer awareness · Administrative guidance to business persons
Coenzyme Q10 (8.10.2006)	Anti-aging, antioxidant effect, etc.	· Reports of diarrhea, vomiting, etc. · Trade association discussed and reported a tolerable upper intake guidance level	· Raised consumer awareness · Administrative guidance to business persons
Cedar pollen (4.19.2007)	Alleviation of pollen allergy symptoms	· Products aiming desensitization therapy of pollen allergy were distributed · Severe allergic symptoms	· Raised consumer awareness · Guidance on appropriate labeling to business persons * Products for therapy or prevention were suspended from being sold as pharmaceuticals and recalled
Agaricus subrufescens (7.3.2009)	Immune strength improvement, anticancer activity, cholesterol reduction, etc.	· Promotion of carcinogenic action · No report of health damage	· Raised consumer awareness · Administrative guidance to business persons
Pueraria mirifica (9.22.2017)	Breast enlarging effect, alleviation of menopausal symptoms, etc.	· Reports of metrorrhagia, irregular menstruation, etc.	· Raised consumer awareness · Administrative guidance to business persons

(Source) MHLW "Material at the Explanatory Session on the State of Reviewing Governmental and Ministerial Ordinances Based on the Act for Amending Part of the Food Sanitation Act, etc." (November 2018)

Carefully Perform Preliminary Survey to Avoid Import of Violating Foods

When importing processed food, the importer gathers information referring to "Prior consultation survey sheet" and "Documents to prepare when consulting" posted on the website of quarantine station, in addition to obtaining an ingredient list and a food production flow chart.
The importer should check for the standards and criteria for foods and additives related to the foods to be imported. (See pages 27 and 28)
The Imported Foods Monitoring and Guidance Plan(Note) established every year by MHLW lists up causes of hazards, matters to be checked in advance and other points to note in its Appended Schedule 2 (Basic Guidance for Importers), which provides useful information.
If processed foods are used as ingredients, investigation must be done tracking back down to raw materials of such ingredients. For example, if a sausage is used as an ingredient, raw materials, additives, and production method of the sausage need to be investigated to check whether the sausage meets the standards and criteria for processed meat products and additives.
After gathering all necessary documents, the importer may seek advice from the Imported foods inspection section of a quarantine station about information on standards and criteria, method to confirm the safety, and points of note.
Upon executing import transactions, it is important to select reliable processors and other business partners who comply with quality requirements on the Japanese side.

(Note) The Imported Foods Monitoring and Guidance Plan is a plan established by the national government with regard to measures to be taken by the MHLW and quarantine stations. A plan for the following fiscal year is publicized at the end of every fiscal year.

Checkpoint 1: Whether Pharmaceutical Ingredients are Contained

As described in Chapter III, when one desires to import goods that are not clearly distinguishable as foods (e.g., supplements in a form of tablet or capsule, those that contain oriental drug or herbal raw materials, those that contain raw materials that are not familiar in Japan), the person needs to check whether the goods fall into the category of pharmaceuticals under the Pharmaceuticals and Medical Devices Act. (See page 10)
Obtain documents for checking whether the goods fall into pharmaceuticals, and self-inspect first. (See pages 12 to 16)
As required, consult the pharmaceutical affairs department of prefectural government that has jurisdiction over the business office of the importer before the cargo arrives, or department in charge of certificate for import of medicines and medical devices of the Regional Bureau of Health and Welfare covering customs that performs import clearance for the cargo after the cargo has arrived. (See pages 17 and 18)
The importer must record the details of checking with the competent administrative department (when and to whom the importer made inquiries, raw materials and ingredients in question and handling thereof, etc.). (See page 17)
Note that quarantine stations cannot make a judgment on whether goods fall into the category of pharmaceuticals.

Checkpoint 2: Whether Toxic or Hazardous Substances are Contained (Article 6, item (ii) of Food Sanitation Act)

Items which contain or are covered with toxic or hazardous substances or are suspected to contain or be covered with such substances cannot be sold (including cases of being delivered but not being sold to many and unspecified persons), or collected, produced, imported, processed, used, cooked, stored, or displayed for the purpose of marketing.
Many things in the nature contain toxic or hazardous substances. If the food to be imported contains an ingredient not generally consumed as food in Japan, it is advisable to check the history of its consumption in the exporting country, health hazard information and others.
To investigate information on the safety or effectiveness on humans for an ingredient, the database "Information system on safety and effectiveness for health foods" of the National Institutes of Biomedical Innovation, Health and Nutrition may prove useful.

■ Reference information
Website of National Institutes of Biomedical Innovation, Health and Nutrition
"Information system on safety and effectiveness for health foods"
https://hfnet.nibiohn.go.jp/
Website of Food Safety Commission of Japan "Hazard Information on Health Foods"
http://www.fsc.go.jp/kigai_jyoho/

Checkpoint 3: Whether the Additives Can Be Used in Japan and Comply with Utilization Criteria (Article 10 of Food Sanitation Act)

Additives that can be used in Japan are limited to those designated by the national government, in principle. Exceptionally, only "existing food additives," "natural flavoring agents," and "items that have generally been served for human consumption and are used as additives" may be used without obtaining designation.
For some additives, utilization criteria (maximum limits and food items in which they may be used, etc.) are specified. The latest version of a list of designated additives and utilization criteria are available on the MHLW website. As needed, the importer shall perform self-inspection to check whether additives are used within permitted ranges. (See page 28)

Types of Additives

Designated additives (Appended Table 1 of the Ordinance for Enforcement of the Food Sanitation Act)	Additives permitted to be used by the Minister of Health, Labour and Welfare based on Article 10 of the Food Sanitation Act. If a synthetic flavoring agent is used, check which one of 18 categories specified by collective names (e.g., "Esters") the flavoring agent falls under.	
Existing food additives	Additives permitted to be used as natural additives that have been used for a long period of time in Japan.	Outside the scope of the designation system
Natural flavoring agents	Natural substances obtained from animals or plants, which are used for the purpose of adding flavor to foods. (e.g., vanilla flavor, crab flavor)	
Ordinary foods used as food additives	Items that have generally been served for human consumption and are used as additives. (e.g., strawberry juice, agar)	

■ Reference information
MHLW's website: "Food Additives"
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/syokuten/index.html (Japanese)
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/syokuten/index_00012.html (English)

Website of The Japan Food Chemical Research Foundation: "List of Food Additives"
https://www.ffcr.or.jp/tenka/index.html (Japanese)
https://www.ffcr.or.jp/en/tenka/index.html (English)

Cases of Violation by Health Foods

The item name, processor's name, violation content of items that were found to be violating relevant laws and regulations at import notification were listed on the MHLW website. The most common violation by health foods is "Use of non-designated additive."

[Typical Cases of Violation at Import Notification: Health Foods]

Description of Item	Exporting Country	Content of Violation	
Spirulina tablets	United States of America	Production agent: croscarmellose sodium is contained	Non-designated additive
Processed tablet-shaped herb food	United States of America	Production agent: calcium stearate is contained	Non-designated additive
Processed shark cartilage product	Australia	Nutrition enhancer: chondroitin sulfate is used	Non-designated additive
Agaricus liquid preparation (Mushroom extract)	Brazil	Production agent: magnesium stearate is contained	Non-designated additive
Encapsulated propolis: used in the capsule	Brazil	Preservative: methyl paraoxybenzoate is contained	Non-designated additive

(Source) MHLW's website: "Typical Cases of Violations of Food Sanitation Act in Import Notifications" Edited by MIPRO.

Checkpoint 4: Whether Standards for Constituents, Production Criteria, etc. of Foods Are Met (Article 11 of the Food Sanitation Act)

Under Article 11 of the Food Sanitation Act, as matters that cover all food products, standards for constituents for food in general, production criteria for food in general, processing standards, and criteria for preserving food in general are established.
For items requiring special efforts for ensuring safety (such as soft drinks and retort pouch foods), standards for constituents, production criteria, processing standards, and preserving criteria are established separately. Details of the standards and criteria are shown in the MHLW Notice No. 370.

❖First, Check Using Ingredient List, Food Production Flow Chart, etc. Obtained from Processor

Whether standards and criteria are met is to be checked using information obtained from the processor, etc.
For foods subject to the established production, processing or preservation criteria, conformity to such criteria is to be checked based on their production flow chart.
If soy, potato, rapeseed, corn, cotton, sugar beet, alfalfa, papaya, etc. is used, the importer should check with the processor whether they are genetically modified food or not.
If herbs and/or spices from countries at which sterilization by irradiation is permitted are used, the importer needs to confirm with the processor in writing that the item has not been sterilized by irradiation.
As for agricultural chemicals, antibiotics and the like remaining in food, an importer should check the status of sanitation management with the processor, such as the use of agricultural chemicals, antibiotics, etc. at the production stage, potential spraying or migration of agricultural chemicals from nearby farms, and use of pesticides, etc. during storage and transportation.

❖Self-inspection (Testing and Inspection) As Necessary

Regarding conformance with the criteria of residual agricultural chemicals, antibiotics, etc. and standards for constituents, an importer shall consult a quarantine station through prior consultation or a registered conformity assessment body, and perform self-inspection as needed.
When an importer decides to do self-inspection before starting importing, the self-inspection can be performed:
(1) using unopened samples directly sent to a registered conformity assessment body from the processor or exporter; or,
(2) using samples at an official laboratory of the exporting country.
In either method, it is important to ensure that the samples are identical to the goods to be imported. Note that all relevant requirements need to be satisfied to minor details for inspection results to be accepted. For details, please inquire at a quarantine station or registered conformity assessment body.

"Specifications and Standards for Foods, Food Additives, etc." (Public Notice No.370) - No.1: Outline of Food

No. 1 Food

A. Standards for constituents for food in general

Regarding constituents of food, stipulates regulations about antibiotics and the like, genetically modified food, residual agricultural chemicals, and radioactive substances.

B. Criteria for producing, processing, and cooking food in general

Regarding production, etc. of food, prohibits irradiation in principle, prohibits use of eggs not suited for human consumption, removal of dangerous parts of cow, prohibits use of additives that do not conform to standards and criteria for additives and so on.

C. Criteria for preserving food in general

When food is to be stored, stipulates standards of ice, prohibits use of antibiotics, prohibits irradiation.

D. Other standards and criteria

Stipulates respective standards and criteria for soft drinks; powdered soft drinks; ice; ice confectionery; processed meat and whale meat; processed meat to be eaten raw; edible avian eggs; blood, blood cells, and blood plasma; processed meat products; whale meat products; fish paste products; salmon roe, salted salmon roe, and salted cod roe; boiled octopus; boiled crab; fresh seafood to be eaten raw; oysters to be eaten raw; agar; grain, beans, and vegetables; azuki bean paste; tofu; instant noodles; frozen food; and retort pouch food.

(Note) Standards and criteria for milk and dairy products are separately specified in the Ministerial Ordinance Concerning the Ingredient Standards for Milk and Dairy Products (Ordinance of the Ministry of Health, Labour and Welfare No. 52).

■ Reference information

MHLW's website: "Specifications and Standards for Foods"
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/jigyousya/shokuhin_kikaku/index.html

MHLW's website: "Agricultural Chemical Residues in Foods"
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/zanryu/index.html (Japanese)
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/zanryu/index_00016.html (English)

Website of The Japan Food Chemical Research Foundation: "Search engine for MRLs"
http://db.ffcr.or.jp/front/ (English)

MHLW's website: "Foods Produced by Recombinant DNA Techniques"
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/bio/idenshi/index.html (Japanese)
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/idenshi/index_00002.html (English)

An importer is obliged to ensure the safety of the imported foods and prepare and retain records on the import and sale of food items.

Article 3 of the Food Sanitation Act provides that a food business operator shall, on his/her own responsibility, endeavor to ensure the safety of the food, and for that purpose, he/she shall endeavor to (i) obtain the knowledge and technologies on food sanitation, (ii) ensure the safety of raw materials to be used, (iii) conduct self- inspections, and (iv) take other necessary measures.

With regard to imported foods, the importer must confirm their safety including their conformity to the Food Sanitation Act. Article 8 of the Food Safety Basic Act also provides for the obligations of the food importer.

The MHLW established the guidelines concerning sanitary control of imported processed foods to emphasize basic matters for guidance on processed foods required of importers under the Imported Foods Monitoring and Guidance Plan, and thereby requests importers to take voluntary initiatives.

Additionally, the importer is required to endeavor to make a proper record of the import and sale of the foods they import and retain such record so that the status of distribution of imported foods can be checked at any time. When any violation of the Food Sanitation Act is detected, the importer must submit the relevant information promptly to the related quarantine station or prefectural government, etc.

■ Reference information

MHLW "Guidelines on Hygiene Control of Import Processed Foods"
https://www.mhlw.go.jp/english/topics/importedfoods/guideline/01.html (English)
(Note) Guidelines that request importers to undertake necessary confirmation about the state of sanitary control in order to ensure and confirm the safety of imported processed foods in the exporting country at all stages of the food supply process including manufacturing and processing, storage and transportation.

MHLW "Guidelines concerning Preparation and Retention of Records by Food Business Operators, based on Provisions in Paragraph 2, Article 1-3 of the Food Sanitation Act"
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/yunyu_kanshi/sankou/index.html (Japanese)

Use import consultation services and information on monitoring and guidance available at quarantine stations.

The Offices of Imported Food Consultation in quarantine stations provide prior consultations to people intending to import foods, etc. with regard to import procedures, inspection systems, and standards and criteria for foods, etc. under the Food Sanitation Act. Reservation is required for an over-the-counter consultation. Check the method for making a reservation in advance by phone or on the website of the relevant quarantine station. A prior consultation does not substitute a preliminary survey or ensure import permit.

Websites of the MHLW and quarantine stations also provide information on monitoring and guidance, such as items subject to ordered inspection or monitoring inspection and past cases of violations of the Food Sanitation Act.

■ Reference information

MHLW's website: "Imported Food Safety"
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/yunyu_kanshi/index_00017.html

Checkpoint 5: Safety of Concentrated Foods such as Tablets and Capsules

Supplements in a form of tablets, capsules, etc. often undergo processes such as concentration and processing. If thereby trace amount toxic substances, etc. contained in raw materials are concentrated or the composition of ingredients becomes nonuniform at the level of individual product, that may lead to health hazard due to excessive intake.

To promote voluntary control by business operators in accordance with GMP (Good Manufacturing Practice) as a manufacturing and control method of pharmaceuticals, the MHLW has established the "Basic Approach to Proper Manufacturing of Food in Tablet, Capsule and other Forms" and "Guidelines of Self-inspection concerning the Safety of Raw Materials of Food in Tablet, Capsule and other Forms."

In these, the MHLW requests "the importer shall confirm with the processor, import source, that the products to be imported are manufactured under proper manufacturing process control, and endeavor to ensure the quality equivalent to that of products manufactured in Japan by, for instance, preparing documents including necessary items such as product information (e.g., raw materials, processing facility) and storage method."

When importing supplements in a form of tablets, capsules, etc., the importer is required to take voluntary initiatives for ensuring their safety in accordance with the said Guidelines, including gathering information on the safety, toxicity of source raw materials used in manufacturing through literature review, performing toxicity tests using raw materials, etc. when the safety cannot be ensured based on the history of consumption, and establishing a GMP system for ensuring the quality of the products.

(Note) GMP is a summary of requirements needed for manufacturing quality products in all processes from acceptance of raw materials to packaging and shipping of final products.

■ Reference information

MHLW Notice "Basic Approach to Proper Manufacturing of Food in Tablet, Capsule and other Forms" and "Guidelines of Self-inspection concerning the Safety of Raw Materials of Food in Tablet, Capsule and other Forms"
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/hokenkinou/kankeihourei.html

Website of National Institutes of Biomedical Innovation, Health and Nutrition
"Information system on safety and effectiveness for health foods"
https://hfnet.nibiohn.go.jp/

(Third-party GMP certifying bodies for health foods)
Japan Health and Nutrition Food Association http://www.jhnfa.org/
http://www.jhnfa.org/english-info.html
The Japanese Institute for Health Food Standards http://www.jihfs.jp/
http://www.jihfs.jp/indexen.html

For foods that contain ingredients, etc. requiring special attention, the importer is obliged to make an notification of health hazard information.

In June 2018, the Act for Amending Part of the Food Sanitation Act, etc. was promulgated for the first time in 15 years. By this amendment, notification of health hazard information by business person was institutionalized in order to prevent occurrence and expansion of health damage by health foods.

This is a system to obligate business persons who engage in sale, etc. of food containing ingredients, raw materials that require special attention to report to the MHLW via the prefectural government, etc. when information is received about health damage or potential health hazard caused by the product (to come into effect in FY2020).

Ingredients covered by this system are to be designated by the Minister of Health, Labour and Welfare by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council or the Food Safety Commission of Japan. For example, alkaloids and hormone-like activity ingredients that may cause health damage when more than a certain amount is consumed are expected to be included.

The summary of the round-table conference on amendment of the Food Sanitation Act published in November 2017 stated that "because there are no standards and criteria set up or preliminary regulations such as approval or certification of individual products in the current system for so-called 'health food,' the possibility of such cases of health damage emerging in the future is undeniable."

The report mentioned the possibility of obligating GMP and the necessity for establishing a new risk assessment system for food with no past record of consumption in Japan or their consumption method (e.g., concentration); the health food industry is carefully watching the direction of legal regulations.

Proper Manufacturing Control of Food in Tablet, Capsule and other Forms

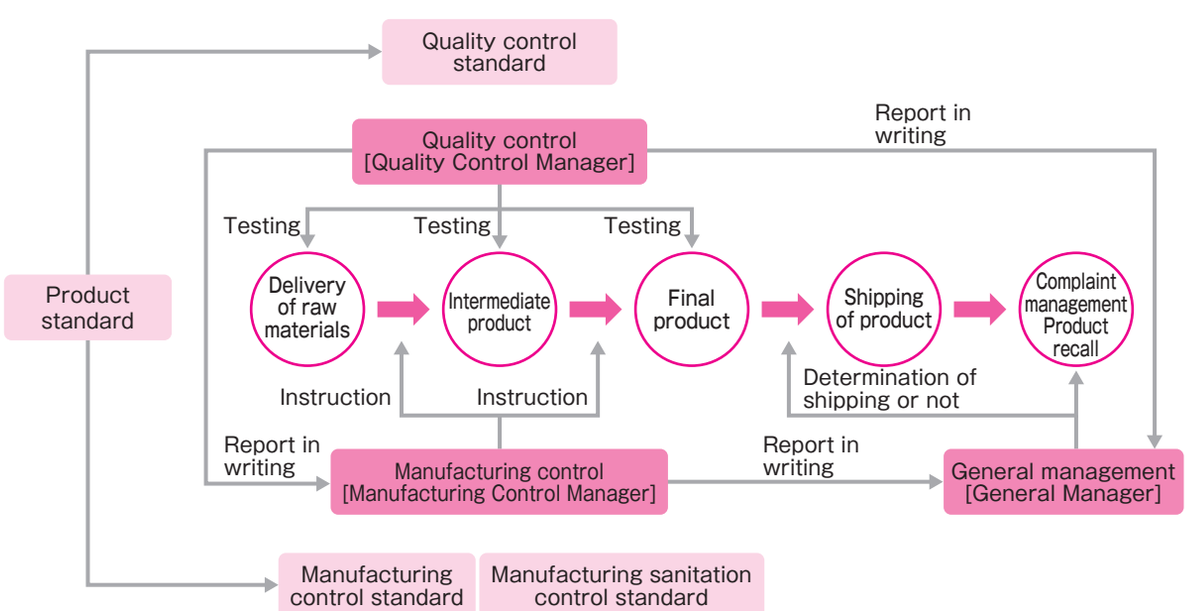
Outline of "Basic Approach to Proper Manufacturing of Food in Tablet, Capsule and other Forms" and "Guidelines of Self-inspection concerning the Safety of Raw Materials of Food in Tablet, Capsule and other Forms" (February 1, 2005. Shokuanhatsu No. 0201003)

Manufacturing process control	
Establishment of control organization and implementation of work control (intangible) · Establishment of quality control department · Clarification of responsibility-allocation system · Documentation of plan and work procedures and implementation · Checking and recording by multiple workers · Arrangement and preservation of records · Lot management · Implementation of sanitary control such as cleaning and washing · Hygiene and health control of workers · Site entry restrictions · Inspection of equipment, machinery, tools, etc. · Quality check at each stage of process · Preservation of samples · Collection of complaints and improvement · Self-inspection · Training	**Appointment of responsible persons** **Preparation of standard documents** **Preparation and preservation of records** **Establishment of structure and facility (tangible)** · Space and structure of workroom · Contamination prevention (e.g., dust) · Cross-contamination prevention measures · Cleaning and sterilization · Structure of machinery and tools to prevent contamination of product · Allocation of machinery and equipment · Bathrooms and changing rooms
Safety check of raw materials	
(1) Clarification of raw materials **(2) Confirmation of division between foods and pharmaceuticals** **(3) Assurance of sources, used part, raw material manufacturing method, etc.** · Quality assurance by the morphology or DNA analysis, production history control, etc. · GMP control of raw materials	**(4) Confirmation of dietary habits and intake amount** **(5) Implementation of literature review** · Confirmation of safety and harmfulness **(6) Literature review and composition analysis (qualitative, quantitative) for ingredients** **(7) Implementation of safety tests** **(8) Checking of final product**

(Source) MHLW "Reference Material from the National Meeting of Division Directors in Charge of Environmental Health and Food Safety in FY2017"

Securing Safety by GMP

Regarding "health foods" in a form of tablet, capsule, etc. which undergo processes like concentration of ingredient, in order to stabilize the product quality across batches and to improve their safety and reliability, it is important to establish production control and quality control systems for all processes from acceptance of raw materials to packaging and shipping of final products (GMP = Good Manufacturing Practice).



(Source) MHLW "Current Status and Problems Surrounding the Food Sanitation Act" (September 14, 2017)

V Laws and Regulations Related to Labeling of Health Foods

Labeling of health foods is subject to regulations under the Food Labeling Act similar to normal food. There are other laws and regulations that stipulate rules on labeling; importers need to check outline of their regulations. Careful planning and considerations are required on how to label and advertise health foods on the food markets in Japan, while complying with regulations on food labeling,

Food Labeling Act

"Food" covered by the Food Labeling Act include all kinds of food and drinks (including additives) excluding pharmaceuticals and quasi-pharmaceutical products, etc. Liquor specified by the Liquor Tax Law is also included.
Concrete labeling rules are specified in the Food Labeling Standards and any food that is not labeled in accordance with said standards may not be marketed. For details, refer to the website of the Consumer Affairs Agency.
When marketing "processed foods (those listed in Appended Table 1 of Food Labeling Standards)" placed in a container or packaging for general consumers, labeling must be in Japanese using proper and easy-to-understand terms, and item name, names of raw materials, additives, net content and other information must be displayed in a prescribed format at a location easily visible without opening the container or packaging.

Basic items on labeling of processed foods for general consumers

Item name	General name. Not the commodity name.
Names of raw materials	Present the names of raw materials used in the order of high to low weight percentage in the raw materials. Allergens: The 7 items (e.g., egg, wheat) must be labeled. Genetic modification: For the 33 processed foods subject to regulations, label if relevant plants that are genetically modified or not distinguished from genetically modified organisms are contained.
Additives	Present the names of additives used in the order of high to low weight percentage in the additives. They may be presented in the section of names of raw materials clearly separating from raw materials. Allergens: The 7 items (e.g., egg, wheat) must be labeled.
Net content	Weight (g, kg), volume (mL, L), quantity (e.g., number of pieces)
Best-before date	Present in the order of year, month and day. Presenting only year and month is acceptable if the time from manufacturing to expiration date exceeds 3 months.
Preservation method	Present detailed conditions of preservation until the expiration date. No cautions after opening.
Name of country of origin	Must be labeled for imported goods.
Importer	Importer if the importer is the person engaged in food-related business and responsible for the content of labeling. Present the address (business location) and name (person's name for private person or corporate name for corporation; presenting trade name only is not acceptable) of the importer.

The Food Labeling Standards also stipulates labeling rules for nutrients, nutrition emphasis, foods with nutrient function claims, and foods with function claims. (See pages 34 to 37)

■ Reference information
Website of the Consumer Affairs Agency: "Food Labelling"
https://www.caa.go.jp/policies/policy/food_labeling/information/ (Japanese)
https://www.caa.go.jp/en/policy/food_labeling/ (English)

❖Be Careful with Laws and Regulations Other Than Food Labeling Act

Other laws and regulations that set forth labeling rules include the "Pharmaceuticals and Medical Devices Act" that prohibits labeling pertaining to pharmaceutical efficacy or effects on non-pharmaceutical goods, "Measurement Act" that stipulates proper weighing and labeling, "Act on Securing of Liquor Tax and on Liquor Business Associations" that stipulates labeling of liquor, "Rice Traceability Act" for providing information on places of production for rice, etc., and various local government's ordinances.
When it comes to labeling of health foods, special attention needs to be paid not to violate provisions of the Health Promotion Act, which prohibits false or exaggerated representations regarding health maintenance and promotion effects, or provisions of the Premiums and Representations Act, which prohibits misrepresentations concerning quality.

Major Laws and Regulations That Stipulate Obligation or Prohibition of Special Labeling Items for Sale of Food

Law or regulation	Jurisdictional governmental agency or contact point	Content of regulations
Food Labeling Act	Food Labeling Division, Consumer Affairs Agency: +81-3-3507-8800 (main) Food labeling department of prefectural government with jurisdiction over the location of the head office, etc. that is responsible for the content of labeling Health center with jurisdiction over the said location for sanitation matters and health matters	For all foods marketed to consumers and business persons, obligates basic labeling items based on the Food Labeling Standards ・Quality-related items Item name, names of raw materials, name of country of origin, net content, name/address of food-related business person, any item quality labeling standards specify for the food category, etc. ・Sanitation-related items Additives, preservation method, expiration date, allergen, information on genetic modification, etc. ・Labeling of nutrients
		Voluntary labeling by business person: Stipulates labeling rules for nutrition emphasis, foods with nutrient function claims, foods with function claims, etc.
Pharmaceuticals and Medical Devices Act	Pharmaceutical affairs department of prefectural government with jurisdiction over the location of the head office, etc. that is responsible for the content of labeling	Prohibits labeling of pharmaceutical effects or efficacy for goods that do not fall into the category of pharmaceuticals.
Measurement Act	Metrology Policy Office, Industrial Science and Technology Policy and Environment Bureau, METI: +81-3-3501-1688 Prefectural Weights and Measures Inspection Office	Obligates labeling based on the regulations for "specified commodities" in sealed container as stipulated by Cabinet Orders.
Act on Securing of Liquor Tax and on Liquor Business Associations	Customs having jurisdiction over the place to receive imported liquor	Obligates labeling of liquor item name, etc.
Act on Japanese Agricultural Standards, etc. (JAS Act)	Regional Center with jurisdiction over the location of the business office, Food and Agricultural Materials Inspection Center	Obligates the JAS standards and relevant labeling.
Rice Traceability Act	(Method to provide or label information on places of production) Food Labeling Division, Consumer Affairs Agency: +81-3-3507-8800 (main)	Obligates preparation and preservation of transaction records and provision of information on places of production for rice, cooked rice, rice processed food, etc.
Local Governments' Ordinances	Jurisdictional department of relevant local government	Obligates quality-related labeling for commodities which are not regulated by other relevant laws and ordinances. (In the case of Tokyo Metropolis) Subjects of quality-related labeling: cooked frozen foods, honey, cut vegetables, cut fruits, etc.
Act on the Promotion of Effective Utilization of Resources	Food Industrial Policy Office, Biomass Policy Division, Food Industry Affairs Bureau, MAFF: +81-3-3502-8499	Obligates displaying identification marks for materials (paper, plastic) of containers and packaging.

Main Laws and Regulations That Prohibit False or Exaggerated Labeling and Misrepresentation Concerning Quality

Law	Jurisdictional governmental agency or contact point	Content of regulations
Health Promotion Act	Food Labeling Policy Office, Representation Division, Consumer Affairs Agency: +81-3-3507-8800 (main) Health center with jurisdiction over the location of the head office, etc. that is responsible for the content of labeling	Prohibits false or exaggerated representations regarding health maintenance and promotion effects.
Act against Unjustifiable Premiums and Misleading Representations (Premiums and Representations Act)	Guidance Desk, Representation Division, Consumer Affairs Agency: +81-3-3507-8800 (main) Department in charge of the Premiums and Representations Act, prefectural government	・Covers various representations used as means of attracting customers. ・Prohibits representations that may mislead general consumers into believing that the product is significantly high in quality or advantageous, whether it was intentional or not of the person who labeled (business person who involved with decision making on the content of labeling). ・Prohibits misleading representations concerning the country of origin of goods.

Obligation of Labeling for Nutrients

The Food Labeling Standards under the Food Labeling Act obligate, in principle, labeling the content of five items, namely, energy, protein, fat, carbohydrate, and sodium (in sodium chloride equivalent), for packaged processed foods and additives for general consumers (the transitional measure period is until March 31, 2020). Nutrients can be voluntarily labeled on perishable food or processed food for business use, but also in this case the labeling must comply with the Food Labeling Standards.

(Note) In some cases, nutrient labeling can be omitted (e.g., those with little contribution as a source of nutrients (such as liquor, coffee beans, spices), those sold by small-scale entrepreneurs (such as business persons exempted from the obligation of payment of consumption taxes)) or nutrient labeling is not required (e.g., when being delivered but not being sold to many or unspecified persons).

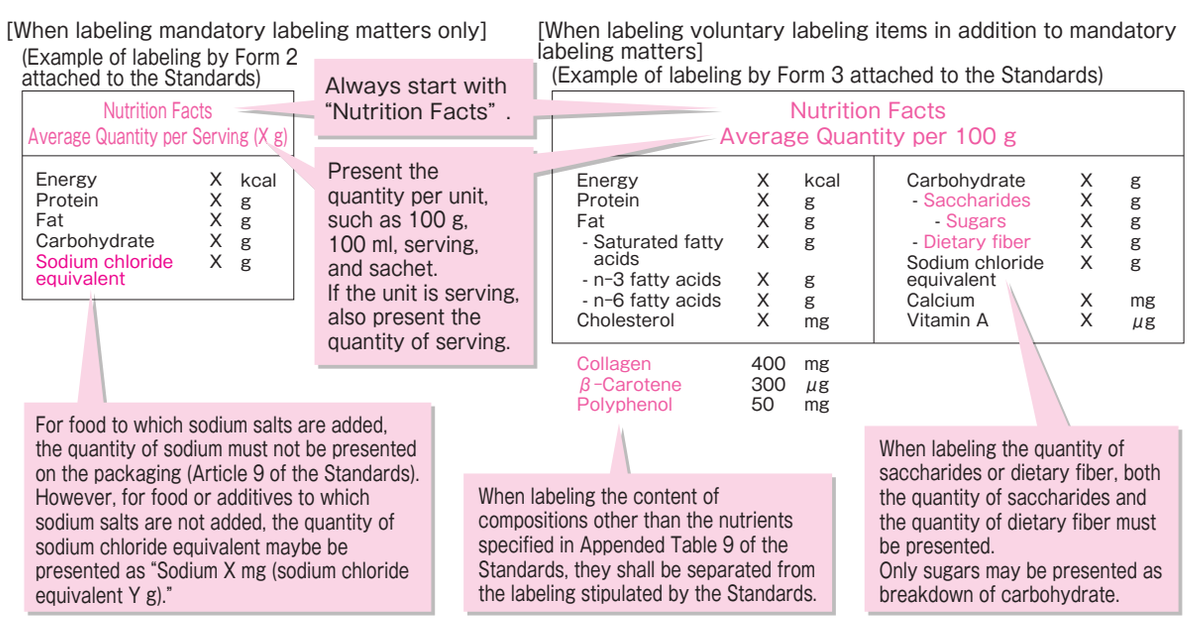
Nutrients Subject to Nutrient Labeling

Other than the obligated five items, recommended labeling and voluntary labeling are specified for some nutrients.

Mandatory labeling	Five elements that must be labeled on processed foods for general consumers	Energy, protein, fat, carbohydrate, sodium (in sodium chloride equivalent)
Recommended labeling	Nutrients recommended to be labeled considering the state of consumption by the Japanese or relation with prevention of lifestyle-related diseases	Saturated fatty acid, dietary fiber
Voluntary labeling	Nutrients other than the five mandatory labeling items among the nutrients and energy in Appended Table 9 of the Food Labeling Standards When labeling such nutrients on a container or packaging, they shall be shown within a frame in accordance with the method specified by the Standards.	Zinc, potassium, calcium, chromium, selenium, iron, copper, magnesium, manganese, molybdenum, iodine, phosphorus, niacin, pantothenic acid, biotin, vitamin A, B_1, B_2, B_6, B_{12}, C, D, E, K, folic acid, n-3 fatty acids, n-6 fatty acids, cholesterol, saccharides and sugars (monosaccharides or disaccharides, and not sugar alcohol)

(Source) Material of Consumer Affairs Agency. Edited by MIPRO.

Method of Labeling for Nutrients



(Source) Consumer Affairs Agency "Nutrient Labeling (Food Labeling Standards)"

■ Reference information

Consumer Affairs Agency "Guidelines for Nutrient Labeling under Food Labeling Act, Version 2"
https://www.caa.go.jp/policies/policy/food_labeling/food_labeling_act/pdf/food_labeling_act_180518_0001.pdf

To Label with Emphasizing Nutrition

When labeling with emphasizing nutrition like containing more or less than a certain standard (e.g., lots of dietary fiber, 40% less salt, 50% less fat) or not adding certain nutrition (e.g., sugar not used, salt not added), the labeling needs to satisfy the conditions specified by the Food Labeling Standards.

Types and Wording Examples of Nutrition Emphasizing Labeling

Type of nutrition emphasis		Wording examples	Applicable nutrient, etc.
Able to supply	High	High in XX XX-rich Full of YY	Protein, dietary fiber, zinc, potassium, calcium, iron, copper, magnesium, niacin, pantothenic acid, biotin, vitamin A, B_1, B_2, B_6, B_{12}, C, D, E, K, folic acid
	Contains	Source of XX Supply of XX YY-containing	
	Enriched	XX 30% increased Double YY	
Able to intake properly	Does not contain	XX-free Zero YY Non-ZZ	Energy, fat, saturated fatty acids, cholesterol, sugars, sodium
	Low	Low in XX Less YY ZZ light	
	Reduced	XX 30% reduced Half YY	
Emphasis of not being added		Salt not added No sugar used	Sugars Sodium salts

(Source) Material of Consumer Affairs Agency. Edited by MIPRO.

■ Inquiries

Regarding the Food Labeling Act as a whole: Food Labeling Division, Consumer Affairs Agency: TEL: +81-3-3507-8800 (main)
Regarding individual commodities: Health center with jurisdiction over the location of the head office, etc. that is responsible for the content of labeling
Links on the website of the Consumer Affairs Agency: "Offices Accepting Inquiries about Food Labeling Act (Each Prefecture)"
https://www.caa.go.jp/policies/policy/food_labeling/information/contact/prefectures/

■ Reference information

Website of the Consumer Affairs Agency: "System of Labeling about Health and Nutrition"
https://www.caa.go.jp/policies/policy/food_labeling/health_promotion/

To Label Function Claims

Food has the primary function (nutrition function) to maintain human life by supplying nutrients and the secondary function to make the primary function pleasant by appealing to human senses with its taste, flavor, and appearance. In Japan, what is focused on when developing health food is the tertiary function - the function that involves with control of biorhythm, anti-aging, prevention of lifestyle-related diseases and recovery from disease. Labeling of food about its tertiary function is called "function claims."
As a system of function claims, health foods are divided into "foods with nutrient function claims" that does not require permit application or notification to the national government, "foods with function claims" that requires notification to the government before marketing, and "foods for specified health uses" that requires individual permit from the government, and these three types of food are collectively called "food with health claims."

❖Would like to label functions of nutrient

⇒ Foods with nutrient function claims do not require permit application or notification

Food allowed to claim functions of nutrient specified by the national government for the purpose of nutrient supply.
If the quantity of nutrient contained in the recommended daily intake of food complies with the standard set by the national government, the food can be marketed as food with nutrient function claims on the business person's own responsibility.
This claiming is self-certified and relatively easy to do, but claimable nutrients are limited. (See page 37)

❖Would like to label that functional ingredients are expected to improve and maintain good health

⇒ Foods with function claims need advance notification

Food allowed to claim on the company's own responsibility that its functional ingredient is expected to improve and maintain good health for undiseased people based on scientific evidence.
As part of regulatory reform by the Japanese government, this food category started from April 2015 referencing the dietary supplement labeling system in the USA.
The "scientific evidence" does not necessarily require tests on humans; it can be demonstrated by review of studies on the product or the functional ingredient.
The administrative burden on the business person is less compared to permit application for foods for specified health uses, but the Consumer Affairs Agency only accepts appropriately prepared notification documents. As such, the procedures aren't quite easy to go through.

❖Would like to label that certain health effects can be expected

⇒ Foods for specified health uses need examination and permission by the national government

Foods for specified health uses are foods that contain ingredients with health functions that affect physiological functions, etc. of the body to which labeling indicating expected achievement of specific health purposes (e.g., assisting maintaining blood cholesterol at a proper level, improving the gastrointestinal conditions) can be affixed. It's generally called Tokuho.
To market as Tokuho, the food must undergo examination by the national government to verify scientific grounds of its effectiveness and safety and receive approval by the government for the content of labeling.
Food approved as Tokuho must carry an approval symbol of the Commissioner of the Consumer Affairs Agency. Application for examination requires carrying out tests on humans using the product to verify the food's safety and effectiveness.
Because of the requirement for human tests, approval procedures will likely take a substantial amount of time and cost.

Nutrients Claimable in Foods with Nutrient Function Claims

Fatty acids (1 kind)	n-3 fatty acids
Minerals (6 kinds)	Zinc, potassium*, calcium, iron, copper, magnesium
Vitamins (13 kinds)	Niacin, pantothenic acid, biotin, vitamin A, B_1, B_2, B_6, B_{12}, C, D, E, K, folic acid

* While potassium is a nutrient necessary for maintaining normal blood pressure, active intake of potassium must be avoided by persons with kidney disorders, etc. As it is undeniable that tablet, capsule, or concentrated powder or liquid preparations could cause excessive intake of potassium, the Japanese government decided not to permit labeling functions of potassium in processed foods in such forms.

(Source) Consumer Affairs Agency "Guidelines for Nutrient Labeling under Food Labeling Act, Version 2"

Differences between Food with Health Claims and General Food

			Permitted function claim	Claimable components	Certification method
Foods (pharmaceutical effects or efficacy cannot be indicated)	Foods with health claims (functions may be indicated)	Foods for specified health uses	Claims about usefulness or suitability on maintaining or promoting health (including claims on contribution to reducing disease risks)	Components with known action mechanism(Note)	[Permission required] Business entities need to have each product undergo an examination concerning their effectiveness and safety, etc. and to obtain authorization for the labeling from the Consumer Affairs Agency.
		Foods with function claims	Claims about usefulness or suitability on maintaining or promoting health (excluding claims pertaining to reduction of disease risks)	Components with known action mechanism (excluding nutrients)	[Advance notification required] Based on the rules specified by the national government, business entities need to report necessary matters such as the scientific grounds for the safety and functional claims of food to the Consumer Affairs Agency before commencing sale of the relevant food.
		Foods with nutrient function claims	Claims about functions of nutrient (fixed phrases specified by the national government for each component)	Vitamins 13 kinds, minerals 6 kinds, fatty acids 1 kind	Business entities **do not need to file an application for authorization or make reports** to the Consumer Affairs Agency. Claimable components and the standards of content are set by the national government
	General foods	So-called health foods	Functions may not be indicated.	No specific rules	None

(Note) Action mechanism refers to a mechanism how a component acts in the human body.

(Source) Consumer Affairs Agency "Outline and Current Status of the System of Food with Function Claims" (January 2016, table on p. 19). Edited by MIPRO.

■ Inquiries

Regarding the Food Labeling Act as a whole: Food Labeling Division, Consumer Affairs Agency: TEL: +81-3-3507-8800 (main)
Regarding individual commodities: Health center with jurisdiction over the location of the head office, etc. that is responsible for the content of labeling
Links on the website of the Consumer Affairs Agency: "Offices Accepting Inquiries about Food Labeling Act (Each Prefecture)"
https://www.caa.go.jp/policies/policy/food_labeling/information/contact/prefectures/

■ Reference information

Website of the Consumer Affairs Agency: "System of Labeling about Health and Nutrition"
https://www.caa.go.jp/policies/policy/food_labeling/health_promotion/

Be Careful with False or Exaggerated Labeling and Misrepresentation Concerning Quality

While a certain level of expressions exaggerating the characteristics of commodity are expected in labeling and advertisement of health foods, attention needs to be paid as labeling or advertisement that affect selection of commodities by general consumers beyond the level acceptable by society in general conflict with the provisions of the Health Promotion Act or the Premiums and Representations Act.

❖Prohibition of False or Exaggerated Representations by Health Promotion Act

Article 31, paragraph (1) of the Health Promotion Act prohibits any persons from making "representations significantly different from the reality" or "significantly misleading representations" about health maintenance and promotion effects, etc.* when displaying advertisement, etc. regarding those sold as food.
The provisions of this Act are not to prohibit certain wordings or expressions in a blanket manner. Violation of the provisions is determined by the content of appeals in the overall representation, based on factors like whether the representation appropriately matches the actual effect. Be careful not to use representations or advertisements that may give excessive expectations or impressions to consumers.

* Health maintenance and promotion effects, etc. refer to effects for the purpose of therapy or prevention of disease, effects for the primary purpose of general strengthening or promotion of tissue functions in the body, effects of nutrients, quantity of contained food or components, and effects that contribute to beautifying human body. Those expressed implicitly or indirectly are included.

■ Inquiries

Regarding exaggerated representations under the Health Promotion Act: Food Labeling Policy Office, Representation Division, Consumer Affairs Agency: TEL: +81-3-3507-8800 (main)
Regarding individual commodities: Health center with jurisdiction over the location of the head office, etc. that is responsible for the content of labeling

■ Reference information

Website of the Consumer Affairs Agency: "Prohibition of Exaggerated Representations by Health Promotion Act"
https://www.caa.go.jp/policies/policy/representation/extravagant_advertisement/

❖Prohibition of Misrepresentation concerning Quality by Premiums and Representations Act

The "representations" under the Premiums and Representations Act cover advertisements and labeling in general made by a business person for notifying consumers of the quality, standards, etc. of commodity or service or transaction conditions like prices as means of attracting customers. They cover not only labeling on the commodity, container or packaging but also advertisements by samples, brochures and pamphlets, user's manuals, direct mail marketing, newspapers/magazines/TVs, advertisements and displays such as posters and sign boards, advertisement via the Internet, as well as verbal sales pitches.

[Prohibition of Misrepresentation concerning Quality] (Article 5, paragraph (1), item (i))
Regarding the quality and standards of commodity marketed, representations that make consumers to believe "this is very good quality" although the quality actually is not up to the claim are regarded misrepresentations and prohibited. Note that the point questioned by the Premiums and Representations Act is whether representations are misleading to general consumers about the quality, not whether the representations are made "intentionally or unintentionally" by the business person resulting in the outcome.

■ Inquiries

Guidance Desk, Representation Division, Consumer Affairs Agency: TEL: +81-3-3507-8800 (main)
Department in charge of the Premiums and Representations Act of prefectural government with jurisdiction over the location of the head office, etc. that is responsible for the content of labeling

■ Reference information

Website of the Consumer Affairs Agency: "Premiums and Representations Act"
https://www.caa.go.jp/policies/policy/representation/fair_labeling/
- "Matters to Note with Regard to Health Food under the Premiums and Representations Act and the Health Promotion Act" (June 30, 2016)
  https://www.caa.go.jp/policies/policy/representation/fair_labeling/pdf/160630premiums_9.pdf
- "Guidelines concerning Monitoring, Guidance, etc. for Prohibition of False or Misleading Advertising, etc. and Ensuring Proper Advertising, etc. about Health Maintenance and Promotion Effects, etc. Conducted for Those Served for Marketing as Foods" (April 20, 2016)
  https://www.caa.go.jp/policies/policy/representation/extravagant_advertisement/pdf/foods_extravagant_gl.pdf

State of Monitoring on False or Exaggerated Representations of Health Foods, etc. on the Internet

Through monitoring against false or exaggerated representations of health foods, etc. on the internet, the Consumer Affairs Agency requests making improvements for representations that may violate the Health Promotion Act and publicize them on its website. Request for improvement was made to 381 business persons, 425 commodities in FY2017.

Commodity category	Represented health maintenance and promotion effects, etc.
Perishable foods (agricultural produce) (2 commodities)	Representations claiming to have an effect for preventing myocardial infarction, cerebral infarction, arteriosclerosis, relief of constipation, recovery from fatigue, etc.
Processed foods (6 commodities)	Representations claiming to have an effect for preventing cancers, arteriosclerosis, myocardial infarction, cerebral infarction, improving immune strength, relief of pollen allergy, anti-aging, etc.
Beverages, etc. (tea, coffee and cocoa preparations, beverages, liquor) (12 commodities)	· Representations claiming to have an effect for preventing myocardial infarction, cerebral infarction and dementia by controlling level in blood, prevention of insomnia, etc. · Representations claiming to have an effect for preventing hypertension, menopausal symptoms, atopic dermatitis, constipation, summer heat fatigue, etc. · Representations claiming to have an effect for relieving stress, beautifying the skin, anti-aging, losing weight, etc.
So-called health foods (capsule, tablet, granules, etc.) (99 commodities)	· Representations claiming to have an effect for preventing depression, dementia, memory disorders, etc. · Representations claiming to have an effect for burning fat, improving metabolism, removing waste materials, etc. · Representations claiming to have an effect for enlarging the breasts, beautifying the skin, alleviating menopausal symptoms, preventing hypertension, arteriosclerosis, etc. by acting on activation of female hormones

(Source) Website of the Consumer Affairs Agency: "Requests for False or Exaggerated Representations of Health Foods, etc. on the Internet" (April to June, 2018)

Representations Without Reasonable Grounds Are Not Permitted

- Regulations on Undemonstrated Advertisements (Article 7, paragraph (2) of the Premiums and Representations Act)

When a misrepresentation concerning quality is suspected, the Consumer Affairs Agency and the prefectural government may request the relevant business entity to submit materials showing reasonable grounds for the labeling.

When the business entity fails to submit requested documents by the deadline or when the submitted documents fail to show reasonable grounds for the labeling, said labeling is considered to be a misrepresentation.

The basic concept of the application of these regulations is shown in "Guidelines in Article 7, paragraph (2) of the Act against Unjustifiable Premiums and Misleading Representations - Guidelines concerning Regulations on Undemonstrated Advertisements."

[Criteria for reasonable grounds] Both of the following requirements must be satisfied.

1. Submitted documents show objectively demonstrated facts.
   (content of documents may be either the results of testing or surveys, or the opinions or academic documents of an expert, expert body, or specialized organization)
2. Effects and efficacy in the labeling appropriately correspond to demonstrated facts.

[Deadline for the submission of documents]

By the elapse of 15 days from the day on which the Commissioner of the Consumer Affairs Agency issued a letter to request the submission of documents
(excluding cases where justifiable grounds are found (judgment is made on a case-by-case basis, but a need to conduct new or additional testing or surveys is not accepted as justifiable grounds))

■ Reference information
Website of the Consumer Affairs Agency: "Regulations on Undemonstrated Advertisement"
https://www.caa.go.jp/policies/policy/representation/fair_labeling/representation_regulation/misleading_representation/not_demonstrated_ad/

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〈Notes〉

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