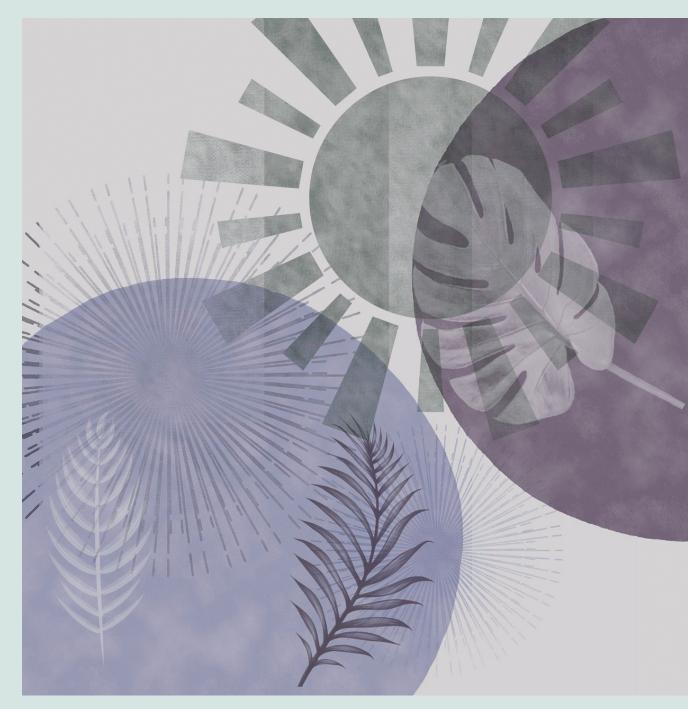
Guide to Food Import 2023





Issued by Manufactured Imports and Investment Promotion Organization (MIPRO)

Guide to Food Import

Import and sale of foods require more complicated procedures than those for such items as interior goods and clothes. This guidebook has been prepared for people who intend to import foods for the first time and outlines the import procedures and regulations imposed upon the import and sale of food. Please check the laws and regulations applicable to each food item and take necessary procedures based on relevant laws and regulations.

There may be changes to the content due to amendments of relevant laws or other reasons. Please make inquiries at relevant contact points to confirm the details.

March 2024 Manufactured Imports and Investment Promotion Organization (MIPRO)

Contents

:	 Laws Applicable to Food Import Food Sanitation Act Import Notification to Quarantine Stations Examination and Inspection at Quarantine Stations Implementation of Self-Inspections Preliminary Survey to Avoid Import of Violating Foods Plant Protection Act Act on Domestic Animal Infectious Diseases Control Act on the Protection of Fishery Resources Import and Labeling of Liquor Import of Rice and Wheat, Salt, Sugar and Starch, Dairy Products, Fisheries 	· 11 · 14 · 16 · 18 · 21
	Products, and Articles Covered by the CITES	
	1 Act on Stabilization of Supply, Demand and Prices for Staple Food 2 Salt Industry Act	· 24 · 25
	3 Act on Price Adjustment of Sugar and Starch	· 25
	 4 Act on Stabilization of Livestock Farming 5 Foreign Exchange and Foreign Trade Act 	
	6 Act on Proper Domestic Distribution of Aquatic Animals and Plants	· 20 · 27
	8 Customs Clearance Procedures	· 28
	9 Customs System Duty Rates; Duty Classification; Advance Ruling System; Preferential Duty	· 29
	Rates; Procedures for Proving the Place of Origin; Tariff Quota System	
1(D Labeling of Food	32
	 Food Labeling Act Commodity Quantity System under the Measurement Act 	· 32 · 35
	3 Misleading Representations under the Act against Unjustifiable Premiums and	00
	Misleading Representations	· 36
	4 Act on Record of Transaction Information and Dissemination of Origin	· 37
	5 Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical	0/
	Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products,	
	and Cosmetics 6 Organic JAS Standards Based on the Act on Japanese Agricultural Standards	· 38 · 39
1	 Laws that Need to be Noted in Marketing 	
	1 Major Regulations Concerning Permits, Notifications, Licenses, etc. Relating to	
	Food Business 2 Act on Specified Commercial Transactions	· 40 · 41
	3 Recycling-related Laws	· 42
	This Guide was compiled with subsidies for FY2023 provided by the Foundation for International Trade and Industrial Co-operation.	

Laws Applicable to Food Import

When importing foods into Japan for the purpose of marketing, etc., an importer is subject to regulations under the Food Sanitation Act which are imposed for the purpose of ensuring safety concerning human health and preventing the occurrence of health problems.

Additionally, with regard to some items, regulations under other laws, such as those aiming to ensure the safety of plants and livestock in Japan, sound development of external transactions, trade control for maintaining peace and safety in Japan as well as in the international community, protection of domestic industries, or proper assessment and collection of taxes, are imposed, and the importer needs to follow prescribed procedures when importing such items.

In advance, the importer should check what regulations are to be imposed on each item that he/she intends to import.

	Food Sanitation Act → P.5	Plant Protection Act → P.16	Act on Domestic Animal Infectious Diseases Control \rightarrow P.18	Foreign Exchange and Foreign Trade Act → P.26	Other
Vegetables, fruits, nuts, grain, beans, tea, coffee beans(raw), herbs, spices, etc.	0	O ⁽¹⁾		△ ⁽⁴⁾	
Meat, processed meat products, dairy products, etc.	0		0	△ ⁽⁴⁾	
Fishery products	0			△ ⁽⁴⁾	Act on Proper Domestic Distribution of Aquatic Animals and Plants $^{(5)} \rightarrow P.27$
Aquatic animals					Act on the Protection of Fishery Resources ⁽⁶⁾ \rightarrow P.21
Liquor	0				Liquor Tax Act → P.22
Rice, wheat, etc.	0	O ⁽¹⁾			Act on Stabilization of Supply, Demand and Prices for Staple Food $\rightarrow P.24$
Salt	0				Salt Industry Act \rightarrow P.25
Sugar, starch, sweetened preparations	0				Act on Price Adjustment of Sugar and Starch \rightarrow P.25
Butter, skim milk, etc.	0		$\bigcirc_{(3)}$		Act on Stabilization of Livestock Farming \rightarrow P.25
Other processed foods	0	△(2)	$\triangle^{(2)}$	$\triangle^{(4)}$	

Major Laws Applicable to Food Import

1

Notes (1) Excluding those highly processed (e.g., tea and spices packed in containers for retail, roasted coffee beans)

(2) An inspection may be required depending on how they are processed. Please inquire at the plant protection station or animal quarantine service when you are not sure.

(3) As butter oil and other certain items are excluded from application of the law, please inquire at the animal quarantine service,

(4) Those announced by import notice

(5) Applicable to business operators handling class I aquatic animals and plants (abalone and sea cucumber, and their processed products) and importers of class II aquatic animals and plants (squid and cuttlefish, Pacific saury, mackerel and sardine, and their processed products)

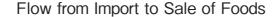
(6) Out of living aquatic animals for human consumption (abalone, oysters, prawns, etc.), those stored in waters for public use or at facilities draining water directly into waters for public use

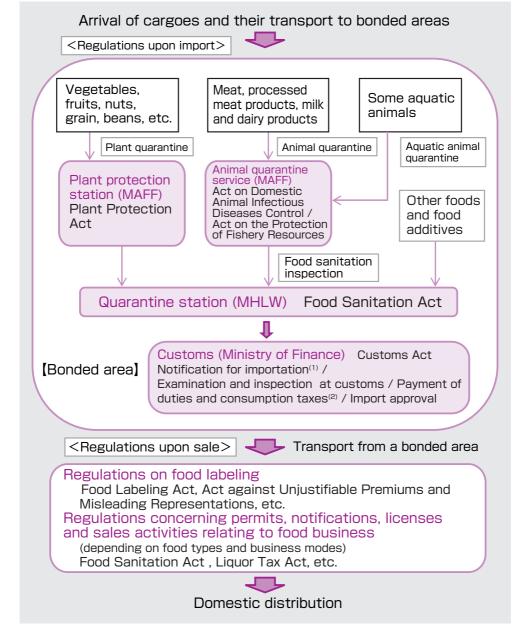
Flow from Import to Sale of Foods

Cargoes that arrive at Japan by ship or by air are transported into bonded areas. Import procedures differ by types of foods.

Firstly, an importer files an application for inspection [i] at a plant protection station under the jurisdiction of the Ministry of Agriculture, Forestry and Fisheries (MAFF) for plant foods such as vegetables and fruits, and [ii] at an animal quarantine service under the jurisdiction of MAFF for livestock products such as meat, processed meat products, and dairy products, and for some aquatic animals, and undergoes inspections.

Regarding those inspected at a plant protection station or an animal quarantine service, and other foods, i.e., all foods imported for the purpose of marketing, import notifications need to be submitted to quarantine stations under the jurisdiction of the Ministry of Health, Labour and Welfare (MHLW). Quarantine stations examine whether the relevant food items comply with the Food Sanitation Act and make judgments regarding whether an inspection is required or not. 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. Then, the importer makes an import declaration at customs by attaching this certificate to the declaration form. When the import is permitted, the importer is allowed to transport imported foods out of a bonded area. The importer is required to comply with regulations on food labeling, etc. when selling imported foods.





- Notes (1) When any permission or approval is required under laws and regulations other than those related to tariffs and duties, an importer must obtain the required permission or approval under relevant laws and regulations and obtain confirmation by proving such fact upon making an import declaration or receiving an examination and inspection at customs.
 - (2) In the case of importing liquor, an importer must affix a label in Japanese under the Act on Securing of Liquor Tax and on Liquor Business Associations, and the Food Labeling Act, etc. 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.

Food Sanitation Act

2

1 Import Notification to Quarantine Stations

When importing foods into Japan for the purpose of business, an importer must make an import notification to a quarantine station.

It is prohibited to use any imported foods in business by selling them to a third party or using them in dishes served at a restaurant, etc. without making an import notification.

Obligation Concerning Import Notification (Article 27 of the Food Sanitation Act)

A person who intends to import food, additives, apparatus or containers and packaging to serve for the purpose of marketing or to use in business shall make a notification to the Minister of Health, Labour and Welfare on a case-by-case basis, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

Food Items Requiring Import Notification

As provided for in Article 27 of the Food Sanitation Act, import notifications need to be made for imported foods that are to be served for the purpose of marketing or to be used in business. The term "marketing" as prescribed in Article 5 of said Act includes delivery other than sales to many and unspecified persons. Therefore, notifications are also required for foods that are to be delivered to many and unspecified persons for free.

Food Items Not Requiring Import Notification

Whether notification is required or not is generally determined in consideration of the item's shape, purpose of use, labeling and other objective circumstances found in relevant documents, etc. However, the following are excluded.

- The following that will not in any case be served for the purpose of marketing or used in business as food, etc. in Japan
 - Food items for personal use:
 - Limited to cases where a person who imported the item consumes it personally, where the item is a gift from overseas, or where a tourist, etc. brings in the item as a souvenir or for personal use
 - Food items for test and research:

Limited to cases where the item is used for test and research in a laboratory or research room Food items for in-house discussions:

- Limited to cases where the item is imported for in-house discussions
- Food items for display:
 - Limited to cases where the item is used solely for display

Note! Notification is required when the item is delivered or served for tasting purposes to many and unspecified persons at an exhibition, etc.

Food items weighing 10kg or less

Food items whose entire amount imported is evidently for re-export.

- \circ Raw materials for food additives
- Food items set forth in Appended Table 10 of the Ordinance for Enforcement of the Food Sanitation Act: Raw salt; Copra; Fats or oils of animal origin or plant origin which are used in the production of edible fat and oil; Raw sugar; Crude alcohol; Molasses; Malt; Hops

"Confirmation certificate" whose submission may be requested at customs for a food item not requiring import notification

With regard to a food item not requiring import notification, an importer, who makes an import declaration at customs, may be requested to submit a "confirmation certificate," which proves that the item does not require import notification under the Food Sanitation Act. In such a case, the importer must first submit two copies of a written application for a confirmation certificate prepared in a prescribed format to a quarantine station to receive its confirmation that the item does not require import notification. When the quarantine station finds said fact, it affixes a confirmation seal on each copy of the written application and returns one of them to the importer. The importer must submit this to customs.

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 an import notification 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.

An importer needs to secure the effectiveness of a disposal order, etc. Accordingly, a non-resident who does not have a domicile or residence in Japan and an Attorney for Customs Procedures (ACP) (prescribed in Article 95 of the Customs Act: A person who undertakes procedures for making an import/export declaration to the customs, witnesses an inspection, pays customs duties, etc. on behalf of a person not residing in Japan) are not permitted to file an import notification.

(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 7days 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 a 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
 - How to obtain and fill in a notification form is explained on the webpages relating to imported foods of the Ministry of Health, Labour and Welfare and individual quarantine stations. → https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/yunyu_kanshi/kanshi/index_00004. html
- Documents to be attached vary depending on 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.

In the case of unprocessed foods, a document showing the names and locations of the exporter and the packager and a document concerning the scientific names and varieties of the relevant foods are required. If additives are used, an ingredient list is also necessary.

Ingredient list

• A document showing such information as specific chemical names and compositions of raw materials (ingredients) and additives used in the processed foods

- When any processed food is used as a raw material, information on its ingredients, additives used, and production flow (for food items for which production criteria are defined) is required.
- When any additive for which utilization criteria are defined is used, purposes of its use, the amount used, and at what stage it was used should be stated.

Food production flow chart

- A chart that describes a series of production flows, such as through what production and processing processes raw materials are made into products and are packed
- For food items for which production criteria are defined (soft drinks, mineral water, retort foods, etc.), the disinfecting method (temperature and heating time, etc.), handling of raw materials, and other detailed information are required.

[Examples of documents to be attached as necessary]

- For meat, processed meat products, milk, dairy products, oysters to be eaten raw and pufferfish (fugu), a sanitary (health) certificate issued by a government organization of the exporting country
- In the case where a herb or spice from a country where radicidation is permitted was used, a document issued by the producer to the effect that radicidation was not conducted for the relevant herb or spice
- For some raw materials, a document stating the content confirmed by the department in charge of pharmaceutical affairs regarding whether anything in the relevant food item falls under the category of pharmaceutical ingredients as prescribed in the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices
- In the case of an additive, a document specifically stating its chemical name, origin and manufacturing method, and in the case of an additive preparation, a table of ingredients (compounding ratio)

[Points to note regarding attached documents]

- A document should contain the producer's company name (letterhead) or signature, etc, that clearly show who prepared and issued it
- The producer, product name, product number, etc. should be clearly indicated in an ingredient list, food production flow chart, results of past self-inspections, and product description so that they can be identified as documents for a cargo that arrived in Japan.
- When a document is in any language other than English or Japanese, a translation thereof should also be attached.

Results of past self-inspections as necessary

(1)Notification	Pecoint										me and address of importe								
Number	Trecept	*1									(2)Name								
(3)Classification	n of Notification	Prio	r Notif	icatio	n / Ger	ieral No	tificatio	on / Pla	nned l	mport	Address								
(4)Code of Im	porter										(Telephone Number)								
(5)Name and Country of Pre	Code of oduction										(6)Registration Number of Importer Responsible for Food Sanitation								
(7)Name, Add Code of Manu																			
(8)Name, Add Code of Manu Factory																			
(9)Name, Add Code of Shipp																			
(10)Name, Ad Code of Pack																			
(11)Name and Port of Loadir	ng										(12)Date of Loading		_(N	1onth)		(D	ay)	(Yea
(13)Name and Port of Discha											(14)Date of Arrival		(N	1onth)_		(D	ay)	()	/ea
(15)Name and	d Code of										(16)Date of Storage		(N	1onth)		(D	ay)	(/ea
Warehouse											(19)Date of Notification		_(N	1onth)		(D	ay)	0	/ea
(17)Marks and of Cargo	d Numbers										(20)Accident Brief Explanation (if Yes)	Yes	7	No					
(18)Ship Nam Number of Air											(21)Name and Code of Submitter								
Number of All	Crait										Subinitier	:			:				
(22)Class	sification of		Feed	Addit	ive /	(23)	Contir	nuous		First /	(33)Sanitary Certificate		Т		Π			Т	1
	anicau011 0I									ontinue/									
1 Cargo	anicauOII OI	Food / Appara Contai	itus /	ackaç	e/ Toy	Impo	ort	_	Ű	Jpdate	Number (34) If the cargo includes								-
		Appara	itus /	ackaç	ie/ Toy	Impo	ort		U	Ipdate	(34) If the cargo includes processed food,								
1 Cargo	3	Appara	itus /	ackaç	ie/ Toy	Impo	ort		U	Jpdate	(34)If the cargo includes processed food, describe its ingredients and their codes.		 						
1 Cargo (24)Item Code (25)Descriptio (26)Shipped \	e n of Article /olume	Appara	itus /	ackaç	je/ Toy	Impo	ort			Jpdate	(34)If the cargo includes processed food, describe its ingredients and their codes. If the cargo includes apparatuses,								
1 Cargo (24)Item Code (25)Descriptio	on of Article /olume nits)	Appara	itus /	ackaç	ie/ Toy	Impo	ort			lpdate kg	(34)If the cargo includes processed food, describe its ingredients and their codes. If the cargo includes								
Cargo C	on of Article /olume nits) /olume	Appara	itus /	ackag	le/ Toy	Impo	ort			Jpdate	(34)If the cargo includes processed food, describe its ingredients and their codes. If the cargo includes apparatuses, containe/packages or toys, describe the raw materials and their codes. (35)If the cargo includes food with additives,	*2							
1 Cargo (24)Item Code (25)Descriptio (26)Shipped \ (Number of U (27)Shipped \ (Weight)	of Article /olume nits) /olume d its Code	Appara	itus /		le/ Toy	Impo	ort			Jpdate	(34)If the cargo includes processed food, describe its ingredients and their codes. If the cargo includes apparatuses, container/packages or toys, describe the raw materials and their codes. (35)If the cargo includes food with additives, describe the names and codes of additives.	*2							
Cargo Cargo (24)Item Code (25)Descriptio (26)Shipped \ (Number of U (27)Shipped \ (Weight) (28)Usage and (29)Kind of Pa	n of Article /olume nits) /olume d its Code ackage and	Appara	itus /		je/ Toy					Jpdate	(34)If the cargo includes processed food, describe its ingredients and their codes. If the cargo includes apparatuses, container/packages or toys, describe the raw materials and their codes. (35)If the cargo includes food with additives, describe the names and codes of additives. If the cargo includes manufacturing agents in the additives, describe								
1 Cargo (24)Item Code (25)Descriptio (26)Shipped \ (Number of U (27)Shipped \ (Weight) (28)Usage and (29)Kind of Pa iis Code (30)Registration	on of Article /olume nits) /olume d its Code ackage and n Number 1	Appara	itus /							Jpdate	(34)If the cargo includes processed food, describe its ingredients and their codes. If the cargo includes apparatuses, container/packages or toys, describe the raw materials and their codes. (35)If the cargo includes food with additives, describe the names and codes of additives. If the cargo includes manufacturing agents in anufacturing agents in the cargo includes								
1 Cargo (24)Item Code (25)Descriptio (26)Shipped \ (Number of U (27)Shipped \ (Weight) (28)Usage and (29)Kind of Pa iis Code (30)Registration	e nof Article /olume /olume d its Code ackage and number 1 number 2	Appara	itus /	ackag						Jpdate	(34)If the cargo includes processed food, describe its ingredients and their codes. If the cargo includes apparatuses, container/packages or toys, describe the raw materials and their codes. (35)If the cargo includes food with additives, describe the names and codes of additives. If the cargo includes manufacturing agents in the additives, describe the names and codes of additives.								
1 Cargo (24)Item Code (25)Descriptio (26)Shipped \ (Number of U (27)Shipped \ (Weight) (28)Usage and (29)Kind of Pa Its Code (30)Registration (31)Registration	a of Article /olume /olume d its Code ackage and Number 1 Number 2 Number 3 jo includes od, nethod of g or	Appara	itus /	ackag						Jpdate	(34) If the cargo includes processed food, describe its ingredients and their codes. If the cargo includes apparatuses, container/packages or toys, describe the raw materials and their codes. (35) If the cargo includes food with additives, describe the names and codes of additives. If the cargo includes manufacturing agents in the additives, describe the names and codes of additives.								

An importer is obliged to ensure the safety of the imported foods and prepare and retain records

(Source: Ministry for Health, Labour and Welfare website)

7

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.

Based on Article 3, paragraph (2) of the Food Sanitation Act, 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.

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, etc. 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, etc. as well.
- Inquiries: Quarantine station of the MHLW having jurisdiction over the port where the importer imports a cargo

Offices to accept import notification: Food Inspection Division (32 locations nationwide) https://www.mhlw.go.jp/english/topics/importedfoods/1-2.html

Prior consultation: Offices of Imported Food Consultation (13 locations nationwide as below; ©: Dedicated phone numbers)

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	

Reference information: MHLW Website: "Imported Food Safety"

https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/yunyu_kanshi/index 00017.html FAQ

Is notification for importation of foods required even in the case where an individual is doing business personally?

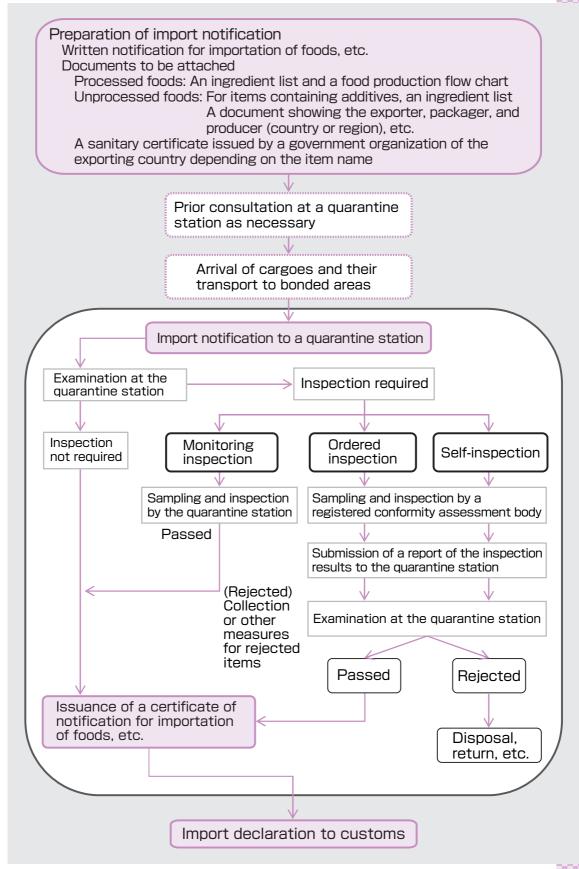
A Under the Food Sanitation Act, notification is required when goods are imported for the purpose of marketing or use in business, or for the purpose of delivery other than sales to many and unspecified persons. Therefore, import notification needs to be made even if the importer is an individual. It is prohibited to use any imported foods in business by selling them to a third party or serving them at a restaurant that the importer runs, without making an import notification.

On the other hand, in the case where a person imports goods only for personal use, the person shall take full responsibility for the safety of the goods for human consumption and is not required to make a notification.

We want to import foods that are already being sold in Japan. Do we need to make an Q import notification?

A As prescribed in Article 27 of the Food Sanitation Act, an importer must prepare necessary documents for cargoes to be imported and make an import notification on each occasion. Furthermore, as prescribed in Article 3 of said Act, an importer is obliged to ensure the safety of the foods that his/her company imports (see the previous page).

Flow of Import Notification Procedures under the Food Sanitation Act



(Source) Prepared by processing the Ministry of Health, Labour and Welfare's webpage "Flow of Import Notification Procedures"

2 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 and whether they conform to the standards and criteria under the Food Sanitation Act.

When the quarantine station finds the necessity to confirm any matters through an inspection, it gives direction on the required inspection, and makes a judgment on legality based on the inspection results.

When the cargo to be imported is found to conform to the Food Sanitation Act, a certificate of notification is returned and the importer may proceed with customs clearance procedures.

On the other hand, when the cargo is found to violate a law, it is shipped back or disposed of and the importer must bear the expenses therefor.

Checking of notification details (documentary examination) A food sanitation inspector conducts an examination based on the item, exporting country, processor and processing facility, raw materials, production method, additives, etc. stated in a written notification for importation of foods, etc.

- < Examples of matters to be checked >
 - $\odot\,$ Whether the used raw materials conform to the Food Sanitation Act
 - $\, \odot \,$ Whether additives are used in a proper manner
 - $\, \odot \,$ Whether the item conforms to production criteria
 - $\,\circ\,$ Whether the processor or the processing facility has any history of causing sanitary problems
 - \circ Whether the item is subject to an order for recall in the exporting country
 - $^{\odot}\,$ Whether required documents (such as a sanitary certificate issued by the exporting country) are attached, etc.

On-the-spot inspection by food sanitation inspector

With regard to a food item requiring on- the- spot checking or a food item imported for the first time, and in cases where any accident occurred during transportation, a food sanitation inspector checks the relevant item on the spot, in locations such as a warehouse where it is stored, concerning whether there is any problem in appearance. A food sanitation inspector also collects samples for a monitoring inspection, etc.

< Examples of matters to be checked >

- $\odot\,$ Whether the item is not suited for human consumption due to being rotten or other reasons
- $\,\circ\,$ Whether any foreign substances are mixed in
- $\, \odot \,$ Whether the storage environment (temperature, etc.) is appropriate
- $\, \odot \,$ Whether there are no errors in the content of the notification, etc.
- $\, \odot \,$ Whether any poisonous fish, etc. are mixed in (fish)
- $^{\circ}$ Whether any dangerous parts are mixed in (beef)

Checking through testing and inspection

When a quarantine station finds the necessity to confirm any matters through an inspection, it orders and guides a required inspection or carries out an inspection by itself, and checks the conformity to the Food Sanitation Act based on the inspection results.

< Examples of matters to be checked >

- \circ Agricultural chemicals and veterinary drugs
- $\, \odot \,$ Food additives
- Pathogenic microorganisms such as enterohemorrhagic Escherichia coli and Vibrio parahaemolyticus
- \odot Bacterial counts and coliforms, etc. specified by the Standards for Constituents
- $\, \odot \,$ Hazardous substances such as aflatoxin and other mycotoxins, and shellfish poisons
- $\,\circ\,$ Mixing of genetically modified foods whose safety has yet to be approved
- $\, \odot \,$ Whether the item is sterilized by irradiation, etc.



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 cargoes that are considered to be highly likely to violate a law, such as those found to violate a law as a result of a self-inspection or a monitoring inspection, or a random inspection ^(Note) in Japan, etc. 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 supervision	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.

3 Implementation of Self-Inspections

Self- inspection is also called instructed inspection because it is an inspection that the quarantine office instructs importers to conduct periodically (including at the time of first import into Japan) while referring to whether there are any applicable standards and criteria, the status of using additives, agrochemicals and veterinary drugs, etc., and information on legal violations of food items of the same type, etc.

There are three ways to conduct self-inspections: Inspection before or after notification at registered conformity assessment bodies in Japan, or inspection before importation at foreign official laboratories.

When conducting inspections in Japan, the importer can select and request inspections at their discretion from among the registered conformity assessment bodies listed on the website of the Ministry of Health, Labour and Welfare. Please check with a registered conformity assessment body regarding the sample quantities and documents required for testing before importing. Also, please contact a registered conformity assessment body regarding expenses and the number of days required for inspection.

If the importer underwent an inspection at a foreign official laboratory and a report of inspection results issued by the foreign official laboratory is attached to the import notification, instructed inspection for the relevant matters will be exempted. However, as some inspection results by a foreign official laboratory are not accepted, please be sure to consult with a quarantine station in advance. ■ 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(Japanese)

Self-inspection (i) Implementation of inspection of samples collected from notified cargo at registered conformity assessment bodies

- The importer requests a registered conformity assessment body to inspect matters to be inspected as instructed by the quarantine station after import notification.
- The registered conformity assessment body collects and inspects samples from the cargo in a bonded warehouse.
- The importer submits the report of inspection results for the cargo to the quarantine station.

Self-inspection (ii) Implementation of inspection of samples imported prior to notification (advance samples) at registered conformity assessment bodies

Samples that are imported for inspection prior to importing the cargo for sale are called "advance samples."

Import notification is not required for inspection samples, and the Ministry of Health, Labour and Welfare refers to inspections conducted on advance samples as "inspections conducted on food, etc. without import notification." Since it can be confirmed that the products conform to the Food Sanitation Act before import notification, this inspection has the advantage of avoiding the risk of disposal or shipping back due to the import of non- conforming products. Please note that matters that may change during transport (bacteria, mycotoxins, etc.) cannot be inspected using advance samples.

The quarantine station will only accept the results of an inspection conducted on an advance sample if the prescribed "confirmation certificate" is attached and it is possible to confirm that certain requirements are satisfied with regard to the matters stated in the report and the documents to be attached. Please make inquiries at the relevant registered conformity assessment body to confirm the details. Please consult with the quarantine station in advance about matters to be inspected.

< Basic requirements for advance samples >

- Advance samples must be unopened (except for those opened due to inspection by customs or other administrative agencies) and sent directly from the manufacturer or exporter to the registered conformity assessment body.
- Documents relating to samples (documents indicated in confirmation item 2 of the quarantine station form "Written confirmation of inspection results conducted on food, etc. without import notification") prepared by a manufacturer, etc. (manufacturer, manufacturing facility, exporter) in the exporting country must be enclosed with advance samples.
- **Reference information:** MHLW Website,

"Written confirmation of inspection results conducted on food, etc. without import notification"

https://www.mhlw.go.jp/file/06-Seisakujouhou-11130500-Shokuhinanzenbu/170831.pdf(Japanese)

Procedure for conducting inspections on advance samples

inspection results

Importer	 Conduct preliminary survey (1) Survey of cargo to be imported Raw materials, manufacturing method, etc. (2) Setting matters to be inspected *Please use Quarantine Station Consultation Room. (3) Confirmation of number of inspection samples *Consult with registered conformity assessment body
	\downarrow
Manufacturer	 Deliver inspection samples and related documents (1) Attachment of invoice and B/L (2) Enclosure of sample information documents Product name, product code, JAN code, manufacturer name, catalog, photograph, etc. If the sample is a part of a product (e. g. a component), information showing the correlation with the completed product (developed figure, drawing) Raw materials, quality, and manufacturing method
	↓ Direct delivery
Registered con assessment bo	- Conduct inspection issue of report of inspection results
	\downarrow
Importer	Submit written notification for importation of foods, etc. Attach report of

(Source) Excerpt from Kobe Quarantine Station "Imported Food Consultation Q&A"

Self-inspection (iii) Implementation of inspection at foreign official laboratories

A foreign official laboratory is a conformity assessment body recognized by the government of the exporting country as a testing institution with a certain level of inspection capacity in its own country, and regarding which a request has been made in advance by the government of the exporting country to the Ministry of Health, Labour and Welfare.

If a report of inspection results from a foreign official laboratory is attached to the import notification and the inspection results conform to the Food Sanitation Act, instructed inspection for the relevant matters will be exempted. Please note that matters that may change during transport (bacteria, mycotoxins, etc.) cannot be exempted at the time of importing a cargo.

There are certain acceptance requirements for inspection results. For details, please contact the quarantine station.

- \cdot The name and address of the relevant laboratory are the same as those on the list.
- Records of inspections conducted by a branch or local office of laboratories on the list are not accepted.
- The inspection method employed is equivalent or superior to test methods specified by the Food Sanitation Act of Japan.
- The report of inspection results contains information with which inspected goods can be identified, such as the manufacturer name, product name and code, etc., for the purpose of confirming the identity between the inspected samples and the goods to be imported to Japan.
- \cdot The report of inspection results is written in English or Japanese.

Minimum matters that should be stated on the foreign official laboratory report of inspection results

(1)	Information relating to conformity assessment body
	Name and location
(2)	Information relating to requester
	Name and address (for business operators, name and location of principal office)
(3)	Information relating to samples
	Country of origin
	Name and location of the manufacturing or processing facility, or country of origin
	Name (including information that can identify the sample, such as a code, $$ etc.)
(4)	Information relating to tests
	Tested item
	Test method (including source and rationale)
	Test results (including the limit of detection or limit of quantification)

Date of preparation and issuance and number of report of inspection results

(Source) Ministry of Health, Labour and Welfare "Minimum Preferably Required Information in Test Certificates Issued by Foreign Official Laboratories"

Reference information: MHLW Website,

"Foreign official Laboratories" https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/yunyu_kanshi/index_00017.html "Minimum Preferably Required Information in Test Certificates Issued by Foreign Official Laboratories" https://www.mhlw.go.jp/content/000532508.pdf

4 Preliminary Survey to Avoid Import of Violating Foods

Each exporting country has original laws concerning food sanitation based on their climate and food culture, etc. Some food items that can be distributed in a certain exporting country may not conform to the Food Sanitation Act and their import and sale may not be permitted in Japan.

An importer assumes equal responsibility for the safety of imported foods as the processor thereof. Therefore, the importer him/herself must have knowledge concerning food sanitation and needs to conduct a sufficient preliminary survey on such matters as where, how, and by whom the relevant food item was processed or produced, whether its quality conforms to the provisions of the Food Sanitation Act, and how it was packed and is being stored.

As matters to be surveyed vary by food item, please refer to Appended Table 2 "Basic Guidance for Importers" of the Imported Food Monitoring and Guidance Plan. ^(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 Food 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.

	Major matters to be surveyed
Processed foods	 Item name, product number and JAN code, etc. Name and location of the processor (in English) Name and location of the processing facility (in English) Raw materials (survey places of production and compounding ratios to the extent possible; for items containing additives, names and usage of substances, and for additives subject to specified utilization criteria, the amount used; for items using processed foods as raw materials, whether any non-designated additives are used in said processed foods) For items containing health foods or oriental drugs as raw materials, their scientific names, used parts and purposes of their use Whether the item falls under the category of those using recombinant DNA technology Processing/production methods (concrete methods and conditions for washing, filtration (sterile filtration), disinfection, freezing or refrigeration (including temperature control), and metal detection (X-ray)) Quality of packaging material (quality of materials for the part directly touching the food) Storage methods (at room temperature, refrigerated, or frozen) Usage (for marketing, as raw materials, or other) Methods of cooking, eating, or using
Unprocessed foods	 Item name, product number and JAN code, etc. Name and location of the importer (in English) Name and location of the packager (in English) Details of additives used (if any) Country/region of origin Scientific name and reference materials and photos concerning varieties Whether any additives are used For a food item to be imported to Japan for the first time, the history of use as food at the place of origin and whether it has toxicity Quality of packaging material Storage methods (at room temperature, refrigerated, or frozen) Usage (for marketing, as raw materials, or other) Methods of cooking, eating, or using
Additives	 Name and location of the producer (in English) Name and location of the production facility (in English) Name of substances (chemical names, Japanese name, and English name) Ingredients and their ratios in the case of additive preparations Purpose of use Quality of packaging material Storage methods (at room temperature, refrigerated, or frozen) Specifications

Major Matters to be Surveyed

Checkpoint 1: Standards for Constituents and Production Criteria, etc. of Foods

Under Article 13 of the Food Sanitation Act, standards for constituents and criteria for the methods of producing, processing, cooking, or preserving foods in general are specified. Concrete details are shown in Public Notice of the Ministry of Health, Labour and Welfare No. 370. For items requiring special efforts for ensuring safety (such as soft drinks and processed meat products), standards and criteria are established separately. 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. An importer should check with the producers, etc. regarding the use of any agricultural chemicals and the status of sanitation management at the production stage, and carry out a self-inspection as necessary on the conformity to residue standards for agricultural chemicals and standards for coliforms, etc. to confirm safety.

"Standards and Criteria for Food and Additives, etc."

(Public Notice of the Ministry of Health, Labour and Welfare No.370) - No.1: Structure of Food

No. 1 Food

- A. Standards for constituents for food in general
- B. Criteria for producing, processing, and cooking food in general
- C. Criteria for preserving food in general
- D. 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).

Checkpoint 2: Additives

Additives that can be used in Japan are limited to those designated by the national government, in principle. Exceptionally, only existing additives, natural flavoring agents, and articles that have generally been served for human consumption and are used as additives may be used without obtaining designation. Additives that are not designated cannot be imported or used. For some additives, utilization criteria (maximum limits and food items in which they may be used, etc.) are specified. Therefore, whether such additives are used within permitted ranges need to be checked.

Reference information: MHLW Website: "Food Additives"

https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/syokuten/index_00012.html

Checkpoint 3: Whether Pharmaceutical Ingredients are Contained

In the case of health food or supplements, it is necessary to check whether any ingredient falling under the category of medicine as specified in the Pharmaceuticals and Medical Equipment Act is contained in raw materials. The division between food and medicine is shown in the "Standards on the Scope of Medicine" attached to the MHLW's Notice, "Control of Unapproved Medicine and Unauthorized Medicine," (Yakuhatsu No. 476 of 1971).

During import clearance procedures, an importer may be requested to submit a document by which to confirm the non-applicability of the Pharmaceuticals and Medical Equipment Act. Therefore, the importer should consult, in advance, with the pharmaceutical affairs department of the competent prefectural government with jurisdiction over its business office, and prepare a document recording the details of what the importer has confirmed (when and to whom the importer made inquiries, raw materials in question and handling thereof, etc.).

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.

Webpages 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.

Plant Protection Act — Import of Fruits, Vegetables, Grain, Beans, and Spices, etc.

In order to prevent the entry into Japan of pests that may damage useful plants, plants to be imported must be quarantined under the Plant Protection Act.

All imported plants are subject to quarantine, irrespective of transportation modes of cargoes, personal effects, and articles sent by international mail, etc., or their quantity or usage such as for business or for personal consumption.

Under the Plant Protection Act, plants are categorized into three categories: [i] import-prohibited articles, [ii] articles exempted from import inspection, and [iii] articles subject to import inspection. When any food to be imported is a plant, it is necessary to check, in advance, (a) the category of said plant, (b) whether the importer is exempted from the obligation to attach a phytosanitary certificate issued by a government organization of the exporting country and (c) whether it is possible to obtain a phytosanitary certificate from the exporting country.

Import-Prohibited Articles (Article 7, paragraph (1) of the Plant Protection Act)

- 1. Plants that are sent from areas set forth in Appended Table 2 of the Ordinance for Enforcement of the Plant Protection Act or those sent by way of such areas and which are provided for in said table
- 2. Plants that are sent from areas set forth in Appended Table 2-2 of the Ordinance for Enforcement of the Plant Protection Act or those sent by way of such areas and which are provided for in said table (excluding those satisfying the standards set forth in said table)
- 3. Plants that are provided for in Appended Table 1- 2 of the Ordinance for Enforcement of the Plant Protection Act (excluding those that were grown in areas set forth in said table)
- 4. Live pests subject to plant quarantine

3

- 5. Soil or plants to which soil is attached
- 6. Containers or packages of articles listed in 1. to 5. above

(Source) Plant Protection Station's website "Ban on Imports"

As damage by plant pests varies by country and region, import of the same plants may be permitted in some countries and regions but be prohibited in others. Furthermore, even though a producing country or region is free from plant pests, import of articles that were sent by way of any area sustaining damage by plant pests may be prohibited due to a possibility that pests may have become attached to the articles during the transportation process. In order to check whether the plant to be imported falls under the category of import-prohibited articles, make inquiries to the Plant Protection Station, or use the "Database for Importing Conditions" available on the Plant Protection Station's website to search importing conditions by inputting the country or region and the relevant plant.

■ Reference information: Plant Protection Station's website: "Database for Importing Conditions" https://www.pps.go.jp/eximlist/Pages/exp/conditionE.xhtml

Articles Exempted from Import Inspection (Article 6 of the Imported Plant Quarantine Rules)

- · Processed tea (dried, heated, fermented, or otherwise processed tea); dried hop flowers; dried bamboo shoots
- · Fermented vanilla beans
- \cdot Plants pickled in sulphurous acid, alcohol, acetic acid, sugar, salt, etc.
- Dried apricot, fig, persimmon, Actinidia chinensis, plum, pear, jujube, date, pineapple, banana, papaya, grape, mango, peach, and longan
- · Grained endocarp of Cocos nucifera
- · Dried spices sealed in containers for retail sale

(Note) Processed tea refers to green tea, black tea, oolong tea or other tea (including mate, guava tea, wolfberry tea, Jasmine tea, Hibiscus tea, ginseng tea, herb tea, and persimmon tea) that has been dried, heated, fermented, or otherwise processed (including primary processed tea).

Out of processed foods made of plants, highly processed articles such as processed tea as well as dried spices sealed in bottles or cans, which are free from pests subject to plant quarantine, are exempted from import quarantine. Regarding whether articles to be imported are exempted from import inspection, make inquiries to the Plant Protection Station after preparing the food production flow chart or processing flow chart, or other reference materials by which the plant's name and used parts can be identified.

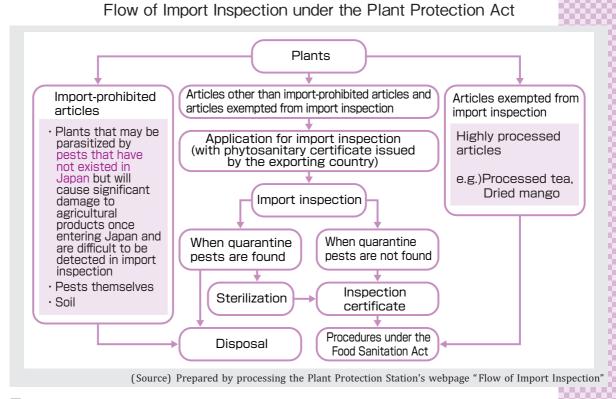
Articles Subject to Import Inspection and Procedures

Plants other than those falling under the categories of import-prohibited articles and articles exempted from import inspection are all subject to import inspection. Foods subject to plant quarantine include fruits (fresh, frozen, and dried), vegetables (fresh, frozen, and dried), grain, beans, green coffee beans, spices, herbs, rapeseed, sesame, plant materials for Chinese medicine.

Prior to importing such articles, it is necessary to obtain a phytosanitary certificate issued by a government organization of the exporting country (there is an exemption provision; see the column below). Without this certificate, no one can import plants from overseas.

In order to receive import inspection, an importer must submit an application for import inspection of plants and import-prohibited articles to the plant protection station that has jurisdiction over the port (airport) where the importer intends to import the relevant plant, together with required documents, such as a phytosanitary certificate issued by a government organization of the exporting country, an invoice, packing list, and air way bill.

When it is confirmed, as a result of the inspection, that the relevant articles do not fall under the category of import- prohibited articles and no pests subject to plant quarantine are found, an inspection certificate will be issued. If any pest is found, the articles are rejected, but even in such cases, if the articles can be sterilized (at the expense of the importer), an inspection certificate may be issued after the sterilization is completed.



 Inquiries: Plant protection station having jurisdiction over the port of importation
 Reference information: Plant Protection Station's website: "Other Languages Menu" https://www.maff.go.jp/pps/j/information/language_top.html

Plants for which the importer is exempted from the obligation to attach a phytosanitary certificate from the exporting country (Article 5-3 of the Enforcement Regulation)

From August 5, 2020, importers who import plants to which harmful plants or animals subject to quarantine are unlikely to adhere were newly required to only undergo an import inspection and were exempted from the obligation to attach a phytosanitary certificate from the exporting country to a written application for import inspection. \circ Dried plants, plants that are dried and compressed, shredded, crushed or smashed

e. g. : Green coffee beans, spices, medicinal ginseng, dried vegetables, and nuts

• Frozen plants: Plants in a completely frozen state through freezing treatment or in a state at - 17. 8°c (0°F) or lower in temperature

Act on Domestic Animal Infectious Diseases Control —Import of Livestock Products

In order to prevent the entry into Japan of domestic animal infectious diseases, the Act on Domestic Animal Infectious Diseases Control specifies targets of animal quarantine (designated quarantine items) and requires import inspection for such livestock animals (including dairy products). Designated quarantine items are subject to animal quarantine irrespective of their quantity or usage such as for business or for personal consumption, or transportation modes of cargoes, personal effects, and articles sent by mail, etc.

When intending to import foods, it is necessary to check, in advance, [i] whether any raw materials derived from designated quarantine items are used, [ii] whether the producing country is a country or region from where import of foods is prohibited, [iii] whether an agreement on Animal Health Requirements has been signed for the relevant foods, and [iv] whether it is possible to obtain a health certificate or veterinary certificate from the exporting country.

Livestock Products Subject to Import Inspection (designated quarantine items: Article 45 of the Ordinance for Enforcement of the Act on Domestic Animal Infectious Diseases Control)

When it is impossible to determine whether import inspection is necessary or not after checking the raw materials and the processing flow, etc. of a food item to be imported, please make inquiries to the animal quarantine service.

(1) Following animals and dead bodies thereof

4

- Cloven-hoofed animals, such as cattle, buffalo, pig, sheep, goat, deer, boar, and llama, as well as horse
- Chicken, quail, pheasant, ostrich, guinea fowl, turkey, and Anseriformes birds such as duck and goose
- · Dogs · Rabbit · Honey bees^(Note)
- (2) Eggs of chicken, quail, pheasant, ostrich, guinea fowl, turkey, and Anseriformes birds
- (3) Bone, meat, fat, blood, skin, coat, feather, horn, hoof, tendon, and organ of the animals mentioned in (1)
- (4) Raw milk, milk, etc. (milk, skim milk, cream, butter, cheese, condensed milk, powdered milk, and other products whose major raw material is milk, but excluding those imported as personal effects (including unaccompanied goods)), semen, fertilized egg, unfertilized egg, feces and urine of the animals mentioned in (1)
- (5) Bone meal, meat meal, meat and bone meal, blood meal, hide powder, feather powder, hoof and horn powder, and organ powder of the animals mentioned in (1)
- (6) Sausage, ham and bacon made from those mentioned in (3)

(Note) Honey is not a designated quarantine item, but comb honey (products in the form of honeycombs) and products containing bee larvae or bees are subject to inspection.

Livestock Products for which Import is Prohibited or Suspended

Regarding virulent domestic animal infectious diseases, out of monitored infectious diseases, which are serious and highly contagious (rinderpest, foot- and- mouth disease, classical swine fever, African Swine Fever, and highly- pathogenic avian influenza, at present), the Act on Domestic Animal Infectious Diseases Control classifies regions for each type of animal according to the level of infection spread and the implementation of epidemic prevention measures and specifies those for which import is prohibited (Article 43 of the Regulation for Enforcement of Act on Domestic Animal Infectious Diseases Control).

It should be noted that there may be cases in which import is temporarily suspended for some animals and livestock products whose import is permitted depending on the circumstances of occurrence of other diseases.

Reference information: Animal Quarantine Service's website: "Import Prohibition Area" https://www.maff.go.jp/aqs/english/news/im_prohibit.html

Import Inspection

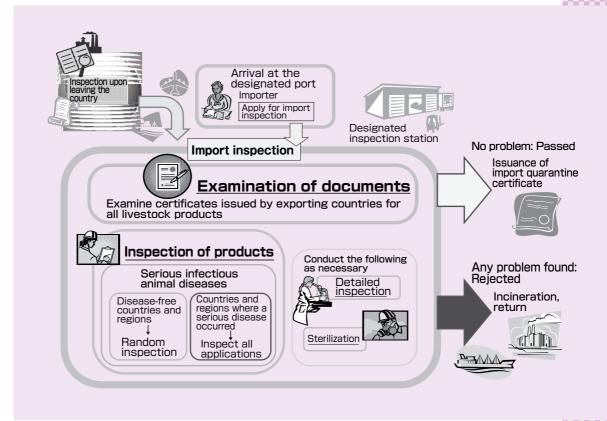
Prior to importing livestock products, it is necessary to obtain a health certificate or veterinary certificate issued by a government organization of the exporting country. Such certificate verifies the results of the inspection conducted in the exporting country based on the Animal Health Requirements agreed upon in advance between the relevant country and Japan. Without such certificate, no one can import livestock products from overseas.

An importer must submit an application for import inspection to the animal quarantine service that has jurisdiction over the port of importation, without delay after the arrival of the relevant designated quarantine item in Japan (in the case of a cargo by ship, by the day preceding the day on which the importer wishes to have the relevant item inspected, in principle), together with required documents, such as a health certificate or veterinary certificate issued by a government organization of the exporting country, an invoice, packing list, air way bill, and IAW (inquiries on inward cargo information), etc. Submission of a product description (raw materials, etc.) and processing flow chart, etc. may also be requested.

Types of designated quarantine items that can be imported are defined for each port and airport. However, articles sent by mail are inspected by post offices that handle customs procedures and are excluded from the restriction on place of import.

An animal quarantine service examines submitted documents and inspects the relevant products, and also conducts a detailed inspection and sterilization as necessary. When it finds that the products have no risk of spreading pathogens of monitored infectious diseases, it issues an import quarantine certificate.

(Note) Import inspection of livestock products is conducted based on the Guidelines for Import Inspection of Livestock Products and other related guidelines (see the List of Notices on the Animal Quarantine Service's Website).



Flow of Import Inspection of Livestock Products

(Source) Ministry of Agriculture, Forestry and Fisheries

- Inquiries: Animal quarantine service having jurisdiction over the port of importation https://www.maff.go.jp/aqs/english/contactus.html
- Reference information: Animal Quarantine Service's website: "What is animal quarantine?" https://www.maff.go.jp/aqs/english/index.html

Quarantine of Dairy Products

In order to build a quarantine system at an international level and deal with contamination risks due to dairy products from countries where foot- and- mouth disease has occurred, dairy products were newly made subject to animal quarantine in November 2017, in addition to raw milk that had already been subject to animal quarantine. Specific coverage is defined by HS codes (see p. 29).

When considering import of dairy products, check the HS code of the relevant product in advance by utilizing the Advance Ruling System or other means to confirm whether the product is subject to animal quarantine.

Procedures for importing dairy products are basically the same as those for importing processed meat products.

When an importer submits an inspection certificate issued by the government organization of the exporting country, and undergoes and passes inspection at an animal quarantine service or a designated inspection station, an import quarantine certificate is issued.

Dairy Products Subject to Animal Quarantine (HS codes)

0401 (milk, cream, etc.); 0402 (milk, cream, etc.); 0403 (butter milk, etc.); 0404 (whey powder, etc.); 0405 (butter, etc.); 0406 (cheese, etc.) 3502. 20, 3502. 90 (milk albumin, etc., products made of raw milk or dairy products) 2309. 10, 2309. 90 (feed and pet food, etc. made of raw milk or dairy products)

Dairy Products Exempted from Animal Quarantine

- Ice cream, modified milk powder for babies, LL milk, fermented milk, lactic acid bacteria beverage, unsweetened condensed milk, unsweetened condensed skim milk, butter oil, and processed cheese
- Products made of dairy products whose HS codes as final products are not included in the coverage of animal quarantine
- e. g., a frozen pizza topped with natural cheese (HS code: 0406) (HS code of the final product: 1905)
- Canned products, bottled products, and retort products (products that are heat sterilized after being packed and can be stored at room temperature for a long period)
- · Dried pet food, etc.
- · Personal effects (including unaccompanied goods)
 - * However, for those to be sold or used for business, those weighing over 10kg, and those for feed, it is preferable to obtain an inspection certificate.
- Dairy products weighing 10kg or less that are for personal consumption and are not to be sold or used for business (excluding those for feed)
 - * Those in small quantity for personal consumption that are imported mainly by international courier service or mail
- Inquiries: Animal quarantine service having jurisdiction over the port of importation https://www.maff.go.jp/aqs/english/contactus.html
- Reference information: Animal Quarantine Service's website "Animal quarantine inspection for dairy products"
 - https://www.maff.go.jp/aqs/topix/dairy_products_en.html

Act on the Protection of Fishery Resources

In order to prevent intrusion of diseases of aquatic animals from overseas, which may cause serious damage to the aquaculture industry in Japan, import approval of the Minister of Agriculture, Forestry and Fisheries is required for the import of aquatic animals specified by the Act on Protection of Fishery Resources. An importer must confirm that the relevant aquatic animal is one for which an agreement on Animal Health Requirements has been signed with the exporting country, and submit an application for import approval together with an inspection certificate issued by a government organization of the exporting country to an animal quarantine service by five days prior to the aquatic animal's arrival in Japan. When no abnormality is found through a document inspection and physical inspection, a certificate of import approval is issued.

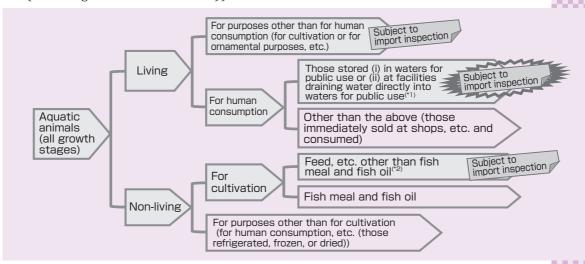
Aquatic Animals Subject to Import Inspection (Article 1-1 of the Regulation for Enforcement of the Act on Protection of Fishery Resources)

Fish	Salmonidae (all species); Cyprinidae (Cyprinus calpio, Carassuis (all species), Hypophthalmichthys nobilis/ Aristichthys nobilis, H. molitrix, Mylopharyngodon piceus, Ctenopharyngodon idella) Cichlidae (Oreochromis niloticus); Sparidae (Pagrus major)						
Crustacea	Penaeidae (all species); Sergestidae (Acetes (all species)); Palaemonidae (all species)						
Shellfish	 Haliotidae (Hariotis diversicolor aquatilis/ supertexta, H. diversicolor diversicolor, H. discus hannai, H. discus discus, H. madaka, H. gigantea) Ostreidae (Crassostrea (all species)); Pectinidae (Mizuhopecten yessoensis) Pyuridae (Halocynthia roretzi) 						

Aquatic Animals Subject to Import Inspection by Usage (Article 1-2 of the Regulation for Enforcement of the Act on Protection of Fishery Resources)

Out of the aquatic animals above, those falling under (i) or (ii) below are subject to import inspection.

- (i) Living aquatic animals (regarding living aquatic animals for human consumption, limited to those stored in waters for public use or at facilities draining water directly into waters for public use)
- (ii) Non-living aquatic animals (including processed ones and limited to those to be used for cultivation (excluding fish meal and fish oil))



(Note) In the case where living aquatic animals for human consumption (abalone, oysters, prawns, etc., in particular) are stored for a certain period of time after import until the time of shipment, if the water used at the relevant storage facility is discharged into sewers or is drained after sufficient sterilization, those aquatic animals are exempted from import inspection and it is unnecessary to apply for import approval therefor. Therefore, an importer needs to inquire at the Fish and Fishery Products Safety Office in advance.

(Source) Animal Quarantine Service "Notice for Importers of Aquatic Animals"

Inquiries:

5

For *1 and *2 above, whether import approval is required or not

Fish and Fishery Products Safety Office, Animal Products Safety Division, Food Safety and Consumer Affairs Bureau, MAFF: TEL: +81-3-6744-2105

Procedures for applying for import approval

Animal quarantine service having jurisdiction over the port of importation

Reference information: Animal Quarantine Service's website: "Entry into Japan-Aquatic Animals" https://www.maff.go.jp/aqs/english/animal/im_aquatic_animal.html

Import and Labeling of Liquor

In order to import liquor (alcoholic beverage with an alcoholic content of one percent or higher) for the purpose of marketing, it is necessary to obtain a license to sell liquor in advance. When undergoing import clearance procedures, an importer needs to file an import notification under the Food Sanitation Act.

A license to sell liquor is not required when a person running an eating and drinking establishment imports liquor only for the purpose of serving it at his/her bar or restaurant, etc. and does not sell unopened cans or bottles of liquor to customers or other shops. However, as such import falls under the category of import for the purpose of business, an import notification under the Food Sanitation Act is required.

(Note) In the case where it is clear that the purpose of importing liquor is just for personal consumption due to a fact such as that the total amount is 10kg or less, neither a license to sell liquor nor an import notification is required.

License to Sell Liquor under the Liquor Tax Act

The license to sell liquor varies by category depending on whether it is for retail services or wholesale services, the scope of types of liquor the person deals with (all types, beer, foreign liquor, or liquor for export and import, etc.), and sales method (at stores or online). Requirements also differ by category (personnel requirements, locational requirements, business base requirements, and supply and demand adjustment requirements).

Prior to applying for a license, the applicant should make it clear to whom he/she intends to sell what types of liquor in what amount and in what manner, and should consult with a chief examiner of the liquor tax and industry division of a tax office.

For example, a person who intends to import liquor and sell it to liquor distributors must obtain a license to wholesale imported liquor, and a person who intends to retail all kinds of liquor, in principle, to consumers or persons in the entertainment business dealing with liquor, such as those running eating and drinking establishments, must obtain a general license to retail liquor. When selling imported liquor to consumers living in a wide area covering two or more prefectures via the Internet or by sending catalogues, etc., a license to retail liquor by mail is required.

Payment of Liquor Tax

6

Under the Liquor Tax Act, a person who receives imported liquor from a bonded area is considered to be a taxpayer. The importer must pay liquor tax together with duties and consumption taxes upon filing an application for import clearance.

■ Reference information: Japan Customs' Website: "Customs Answer No.3105" https://www.customs.go.jp/english/c-answer_e/kojin/3105_e.htm

Notification of Labeling Method for Liquor

By the time of receiving imported liquor from a bonded area, an importer must affix a label that indicates the matters specified by laws and regulations in accordance with the item category on a conspicuous part of each of the containers in an easily distinguishable manner (Article 86-5 of the Act on Securing of Liquor Tax and on Liquor Business Associations).

Regarding a labeling method, the importer must prepare two copies of written notification of the labeling method and submit one of them to customs having jurisdiction over the relevant bonded area, together with a copy of his/her license to sell liquor, thereby obtaining confirmation on the method from customs. After obtaining the confirmation, the importer must affix labels to liquor containers by the time of transporting them out of the bonded area.

Labeling of liquor must contain the matters specified by the Food Labeling Standards based on the Act on Securing of Liquor Tax and on Liquor Business Associations and the Food Labeling Act. Required matters common to the both laws may be indicated once, but other matters need to be indicated based on the relevant law, respectively. See the National Tax Agency's "Q&A on Labeling of Liquor under the Food Labeling Act" for the details of the changes

⁽Note) Under the Food Labeling Act, liquor packed in containers to be sold to consumers falls under the category of processed food for general consumers.

Example of Labeling Labeling of Wine

品目	果実酒
内容量	750ml
アルコール分	13度
添加物	酸化防止剤(亜硫酸塩)
原産国名	フランス
輸入者及び引取先	株式会社〇〇
	東京都港区〇〇町3-1-3
20歳未満の者の飲酒に	は法律で禁止されています

Labeling of Whiskey

品目	ウイスキー
原材料名	モルト、グレーン
アルコール分	43度
内容量	750ml
原産地名	スコットランド
輸 入 者	○○株式会社
	東京都新宿区〇〇町〇一〇
引取先	横浜市中区〇〇町〇一〇
飲酒は、20歳に	なってから。

Inquiries: Customs having jurisdiction over the place to receive imported liquor



Tax rates are to be revised in stages.

Through the FY2017 Tax Reform, the structure of tax rates for liquors was significantly revised from the perspective of restoring tax burden fairness between different types of liquors. Tax rate revision is to be enforced on October 1, 2020, but a sufficient transitional period up to October 1, 2026, is set and the revision is to be implemented in stages. For example, the basic tax rate for fermented liquors is uniformly set at 100,000 yen/kl with the aim of eliminating the tax rate difference between wine and refined sake. Therefore, the tax rate for wine is to be raised in stages.

	Oct. 1, 2020	Oct. 1, 2023	Oct. 1, 2026					
Beer-like liquors	200,000円/kl	181,000円/kl						
Low-malt beer (malt rate: 25% or more but less than 50%)	167,125円/kl	155,000円/kl						
Low-malt beer (malt rate: less than 25%)	134,250円/kl	- 134.250円/kl	- 155,000円/kl					
Other beer-like liquors (new genre)	108,000円/kl	134,230mj/ Ke						
Other beer-like liquors (other than new genre)	80,000円/kl	80,000円/kl	100,000円/kl					
Fermented liquors	120,000円/kl							
Refined sake	110,000円/kl	100,000円/kl	100,000円/ke					
Wine	90,000円/kl							
Mixed liquors (alcohol content: less than 21%)			200,000円/kl					
Distilled liquors with a low alcohol content	80,000円/kl	80,000円/kl	100,000円/kl					
(Source) Ministry of Finance's Website, "FY2017 Tax Reform (Main Points) - Liquor Tax Reform"								

Import of Rice and Wheat, Salt, Sugar and Starch, Dairy Products, Fisheries Products, and Articles Covered by the CITES

Import and sale of rice and wheat, salt, sugar and starch, and some dairy products are regulated by respective laws and regulations for such purposes as securing their stable supply to the general public, stabilizing their prices, and ensuring stable management of domestic producers, and prescribed procedures need to be followed.

When intending to import fisheries products designated for the government's import controls under the Foreign Exchange and Foreign Trade Act or articles covered by the CITES (Convention on International Trade in Endangered Species of Wild Fauna and Flora), it is necessary to take procedures to obtain import permits or approval, etc.

In order to ensure proper import and export and domestic distribution regarding illegally captured or gathered aquatic animals and plants, prescribed procedures for importing and selling designated aquatic animals and plants need to be followed.

1 Act on Stabilization of Supply, Demand and Prices for Staple Food

Major Items (Article 1 of the Order for Enforcement of the Act on Stabilization of Supply, Demand and Prices for Staple Food)

- Rice, wheat, (wheat, barley, and naked barley), maslin, and triticale
- · Rice flour, wheat flour, barley flour, and naked barley flour
- · Ground rice, wheat, barley, and naked barley groats and meal thereof
- \cdot Wheat starch
- Rice cake, dumplings, and other similar prepared foodstuffs made of rice (excluding those for baby food or dietary cures, or those with a rice content of 30% or less of the total weight)
- Grained rice already heated or otherwise cooked (excluding those with a rice content of 30% or less of the total weight)
- Other processed or prepared foodstuffs made of rice, wheat, barley, naked barley, maslin, or triticale that are designated by the Minister of Agriculture, Forestry and Fisheries

Import Levy on Rice and Wheat, etc.

When importing rice, etc. for commercial use, an importer is obliged to pay an import levy under the Act on Stabilization of Supply, Demand and Prices for Staple Food.

A person who intends to import rice for marketing must fill in an import levy payment form and submit it to the relevant regional agricultural administration office, together with documents by which the item name and quantity can be confirmed (such as an invoice, B/L, packing list, or written contract). When no deficiency is found as a result of an examination, [i] a payment notice is issued and [ii] a copy of the import levy payment form is returned. The person must bring the payment notice [i] to a financial institution and pay the import levy on rice, etc. (292 yen/kg), and upon undergoing import clearance procedures, he/she must submit the receipt of the import levy and the copy of the import levy payment form [ii] to customs and pay duties (temporary duty rate: 49 yen/kg) and consumption taxes.

When importing wheat, etc. for commercial use, an importer is also obliged to pay an import levy under the Act on Stabilization of Supply, Demand and Prices for Staple Food.

(Note) Since April 2016, procedures can be undertaken through electronic applications.

Report of the Import Quantity of Rice

When importing rice, it is necessary to report the import quantity to the relevant regional agricultural administration office in advance.

Import of Processed or Prepared Products Made of Rice or Wheat

When importing any products subject to an import levy, it is required to pay a levy and duties as in the case of importing rice. Regarding whether products to be imported are subject to an import levy, make inquiries to customs where the importer intends to make an import declaration after preparing reference materials that show the blending ratio of rice and wheat, etc.

2 Salt Industry Act

The Salt Industry Act defines salt as solids with a sodium chloride content of 40% or more. A person who imports and sells salt needs to be registered as a specified wholesaler of salt by the director-general of customs. When importing and selling only salt that has a special usage and property and which is specified by Ordinance of the Ministry of Finance (Article 4 of the Ordinance for Enforcement of the Salt Industry Act), an importer needs to file a notification as a specified wholesaler of special- use Salt to the director-general of customs.

Regarding whether products to be imported fall under the category of salt, for which registration is required, or the category of salt for special purposes, for which a notification is required, or whether they are not covered by the Salt Industry Act, make inquiries to the customs where the importer intends to make an import declaration after preparing reference materials on the production method, ingredients, usage, and samples, etc.

■ Inquiries: General examination officers or special examination officers of administrative affairs departments of respective customs

3 Act on Price Adjustment of Sugar and Starch

Regarding sugar and starch, a price adjustment system has been introduced, under which subsidies mainly financed by funds collected from cheap imported goods are granted to producers and processors of domestic products to compensate the amount of difference between their sales price and processing and production costs.

As the TPP Agreement came into force on December 30, 2018, imported sweetened preparations (cocoa preparations, coffee preparations, etc. with a sugar content of 50% or more) were newly included in the coverage of the price adjustment system.

When importing sugar, starch, and sweetened preparations, a person making an import declaration must conclude a transaction agreement in writing with the Agriculture & Livestock Industries Corporation in advance and is obliged to pay the amount of difference in sales and purchases as adjustment funds to the Corporation.

Regarding whether products to be imported are subject to transactions, make inquiries to the customs where the importer intends to make an import declaration after preparing reference materials on the production method, ingredient ratios, property, usage, and samples, etc. When the importer seeks responses that will be respected in an examination of import declaration, it is recommendable to utilize the Advance Ruling System (see p. 29).

4 Act on Stabilization of Livestock Farming

Designated dairy products, etc. specified by said Act (butter, powdered skim milk, whey and modified whey, dairy spread, butter oil, etc.) are imported by the national government through state trading, and also by general importers who pay the amount of money equivalent to duties as specified for persons out of the state trading framework. Prior to making an import declaration, a general importer must [i] register him/herself with the Agriculture & Livestock Industries Corporation, [ii] submit an application for selling and buy-back, and [iii] provide a deposit equivalent to the amount legally specified, thereby obtaining the issuance of a written consent for purchasing and sell-back.

Regarding whether products to be imported fall under the category of designated dairy products, etc., make inquiries to the customs where the importer intends to make an import declaration after preparing reference materials on production method, ingredient ratios, property, usage, and samples, etc. When the importer seeks responses that will be respected in an examination of import declaration, it is recommendable to utilize the Advance Ruling System (see p. 29).

5 Foreign Exchange and Foreign Trade Act

The Foreign Exchange and Foreign Trade Act aims to enable the proper development of foreign transactions and the maintenance of peace and security in Japan and in the international community through the minimum necessary control or coordination of foreign transactions. Concrete control methods are specified in the Import Trade Control Order and the Public Announcement on Import, etc. When importing specified goods or goods whose place of origin or place of shipment is any of the specified countries or regions, the permission and approval of the Minister of Economy, Trade and Industry needs to be obtained. There are five systems as follows to enhance the effectiveness of the regulatory purposes.

System	Outline	Major targets
Import quota	System to allocate import quotas to importers, etc. based on the quantity or value of the goods to be imported based on domestic demand, etc. [quanti- tative restrictions]	Herring, cod, yellowtail, and other fish caught in adjacent waters; scal- lop; squid; edible seaweed; and pre- pared foodstuffs made of seaweed, etc.
Approval under item (ii)	System to require approval for import from a specified place of origin or place of shipment [restrictions on specific regions]	Salmon and trout whose place of origin or place of shipment is China, North Korea, or Taiwan, and pre- pared foodstuffs made thereof, etc.
Approval under item (ii)-2	System to require approval for import of specified goods irrespective of their place of origin or place of shipment [restrictions on all regions]	Fauna and flora listed in Appendix I of the CITES and derivatives thereof
Prior confirma- tion	System under which an importer who has obtained prior confirmation by the Minister of Economy, Trade and Industry, etc. is permitted to import specified goods without approval	Frozen tuna, Antarctic toothfish, and frozen crab; fauna and flora listed in Appendices II and III of the CITES and derivatives thereof, etc.
Confirmation upon customs clearance	System under which an importer who submits documents specified upon undergoing import clear- ance procedures to customs is permitted to import specified goods without approval	Fresh or chilled tuna and crab: fauna and flora listed in Appendices II and III of the CITES and derivatives thereof, etc.

Inquiries: Agricultural and Marine Products Office, Trade Control Department,

Trade and Economic Cooperation Bureau, METI: Tel: +81-3-3501-0532

Reference information: METI website: "Trade Control"

https://www.meti.go.jp/english/policy/external_economy/trade_control/index.html

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 or a certificate of prior-confirmation 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 vary by classification of Appendices and place of origin or place of shipment of the relevant fauna and flora.

 $^{\circ}$ Those listed in Appendix I (trade for commercial purposes is prohibited in principle)

⇒ For artificially propagated ones, application for import approval to the Ministry of Economy, Trade and Industry
 ○ Those that are listed in Appendices II and III and are designated in 7, (2), (3) or (4) of Public Announcement on Import III
 ⇒ Application for prior confirmation to the Ministry of Economy, Trade and Industry
 ○ Those that are listed in Appendices II and III and are designated in 8, (3) or (4) of Public Announcement on Import III

 $^{\circ}$ Those that are listed in Appendices II and III and are designated in 8, (3) or (4) of Public Announcement on Import III \Rightarrow Confirmation upon customs clearance (An application under the Foreign Exchange and Foreign Trade Act is not

required. An importer must submit a CITES export permit to the customs upon making an import declaration.) 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 such foods or Chinese medicine as crocodiles, caviar, musk, Saussureae costus, and American ginseng, etc.

■ Inquiries: Licensing Group, Office of Trade Licensing for Wild Animal and Plants, Trade Control Department, Trade and Economic Cooperation Bureau, METI: Tel: +81-3-3501-1723

6 Act on Proper Domestic Distribution of Aquatic Animals and Plants

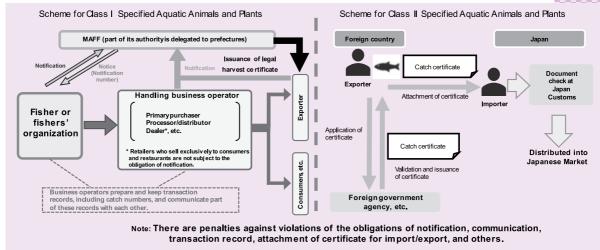
In order to prevent the mixing of illegally captured or gathered aquatic animals and plants in the distribution process and the inflow of aquatic animals and plants captured or gathered through illegal, unreported and unregulated (IUU) fishing, the Act on Ensuring the Proper Domestic Distribution and Importation of Specified Aquatic Animals and Plants was promulgated and was enforced in December 2022.

Coverage and Obligations under the Proper Domestic Distribution System for Aquatic Animals and Plants

Class I aquatic animals and plants are defined as aquatic animals and plants that are recognized to be under significant risk of illegal and excessive capture or gathering in Japan and are recognized to be particularly in need for conservation and management, and class II aquatic animals and plants are defined as aquatic animals and plants that are recognized to be in need for measures to regulate the import thereof by reasons that they are recognized to be under significant risk of illegal capture or gathering by foreign fishing vessels. Regulations are imposed on these aquatic animals and plants by designating their species.

	Fish species	Obligations
Class I aquatic animals and plants	Abalone and sea cu- cumber (including their processed products) (Note) The Act will become applicable to glass eels from December 2025.	 The following obligations are imposed on capturers or gatherers and business operators engaging in import, processing and wholesale, etc. of class I aquatic animals and plants. (i) Notification to administrative organs (Electronic filing using eMAFF (Ministry of Agriculture, Forestry and Fisheries' filing services)) (ii) Communication of a catch number or a lot number upon a transaction In the case of imported or cultured aquatic animals and plants, communication of that fact A commercial exporter must attach a legal harvest certificate upon export.
Class II aquatic animals and plants	Squid and cuttle- fish, Pacific saury, mackerel and sar- dine (including their processed prod- ucts)	 A catch certificate issued by a government organization of the relevant foreign state (flag state) must be attached upon import. When an aquatic animal or plant processed in a third state other than the flag state is imported, a processing statement issued by a government organization of the third state (place of processing) must also be attached upon import.

Outline of the System



(Source) Japan Fisheries Agency White Paper "FY2021 Trends in Fisheries, FY2022 Fisheries Policy"

■Reference information: Fisheries Agency Website: "Act on Ensuring the Proper Domestic Distribution and Importation of Specified Aquatic Animals and Plants": https://www.jfa.maff.go.jp/220614.html

Customs Clearance Procedures

When importing cargoes from abroad that arrived in Japan, the importer must make an import (tax) declaration to the director- general of the customs that has the jurisdiction over the bonded area where the relevant cargoes are stored, in principle. The customs that received the import declaration examines documents and inspects cargoes as necessary, confirms the payment of duties, etc., and permits the import of the cargoes. This series of procedures is called customs clearance. Only after going through customs clearance procedures, cargoes are permitted to be distributed in Japan.

Required customs clearance procedures differ by import method (general cargoes, articles sent by international mail, or international courier service) or when hand baggage is used upon entry. In any case, an importer is not permitted to import items that require permission or approval under other relevant laws and ordinances, unless he/she gets confirmation from the customs by proving that he/she has obtained the required permission or approval.

(Note) A bonded area refers to a place where cargoes from abroad may be stored temporarily without paying duties and consumption taxes.

Examination and Confirmation under Other Relevant Laws and Ordinances

Other relevant laws and ordinances are those set forth in Article 70 of the Customs Act, meaning laws and ordinances other than those relating to customs duties that provide for permission and approval, etc. for the import and export of goods. The Food Sanitation Act, Plant Protection Act, Act on Domestic Animal Infectious Diseases Control, and Foreign Exchange and Foreign Trade Act, etc. are included in other relevant laws and ordinances. An importer presents such documents as a certificate of import notification, inspection certificate, or certificate of approval in customs clearance procedures and undergoes examinations as to whether conditions under other relevant laws and regulations are satisfied.

Tax Declaration and Payment of Duties

Taxes, such as duties and consumption taxes (or liquor tax in the case of liquor), are imposed on imported goods. It should be noted that even in the case of duty-free goods, consumption taxes, etc. are imposed.

When importing a general cargo, an article sent by international mail for which the taxation amount exceeds 200, 000 yen, or hand baggage for which the total of taxation amounts exceeds 300, 000 yen, the importer needs to submit a written import (tax) declaration by entering therein the information relating to the payment of duties, such as item names and quantities (determination of customs duties under the self-assessment system). An import declaration is to be made by a person who intends to import a cargo, but such person may ask a customs broker to undertake procedures by proxy. In the case of international courier service, a courier makes an import declaration by proxy.

On the other hand, in the case of an import declaration for personal effects/unaccompanied goods upon entering Japan and in the case of articles sent by international mail for which the taxation amount does not exceed 200,000 yen, the amount calculated by the customs should be paid as duties (determination of customs duties under the official assessment system).

Hakodate Customs	TEL:+81-138-40-4261	hkd-gyomu-sodan@customs.go.jp
Tokyo Customs	TEL:+81-3-3529-0700	tyo-gyomu-sodankan@customs.go.jp
Yokohama Customs	TEL:+81-45-212-6000	yok-sodan@customs.go.jp
Nagoya Customs	TEL:+81-52-654-4100	nagoya-gyomu-sodankan@customs.go.jp
Osaka Customs	TEL:+81-6-6576-3001	osaka-sodan@customs.go.jp
Kobe Customs	TEL:+81-78-333-3100	kobe-sodan@customs.go.jp
Moji Customs	TEL:+81-50-3530-8372	moji-sodankan@customs.go.jp
Nagasaki Customs	TEL:+81-95-828-8619	nagasaki-sodan@customs.go.jp
Okinawa Regional Customs	TEL:+81-98-863-0099	oki-9a-sodan@customs.go.jp

■ Inquiries Concerning Customs Procedures (Contact Points for Major Customs Counselors)

Reference information: Japan Customs' website: https://www.customs.go.jp/english/index.htm

Customs System

When importing goods, the following taxes are basically imposed: Duty: Customs value (CIF price + Miscellaneous additions^(Note)) × Duty rate Consumption tax: (Taxable price + Duty) × Consumption tax rate

(Note) · Customs value: Value that serves as the standard when calculating duty amounts
 · Miscellaneous additions: Expenses relating to transport to the port of importation, license fees, expenses for members offered for free, etc.

Duty Rates

9

Duty rates are determined for each item categorized under the Customs Tariff Act. There are various duty rates depending on item category and country of origin, such as the general duty rates, temporary duty rates (duty rates determined by amending the general duty rates depending on domestic and overseas economic conditions), preferential duty rates (duty rates applied to goods imported from developing countries), WTO duty rates (duty rates determined by the WTO), and EPA duty rates (duty rates determined among EPA member countries), and the lowest duty rate applicable to the relevant exporting country is applied basically. However, in order to receive the application of preferential duty rates or EPA duty rates, the rules of origin must be satisfied.

Japan's Tariff Schedule is available on the Japan Customs'website (https://www.customs.go.jp/ english/tariff/index.htm). If it is difficult to find applicable duty rates, the Advance Ruling System may be utilized to make an inquiry about duty classification.

Additionally, simplified duty rates are also established for goods brought in with people entering Japan, as well as general cargoes (including international courier services) and international mails, for which the total customs value is 200, 000 yen or less, for easy calculation of duty amounts.

Duty Classification (HS Classification)

Japan's Tariff Schedule is a list aiming to systematically classify all commodities based on the international "HS Convention." Nine-digit codes, adding Japan's original three-digit codes to the globally harmonized six-digit codes (HS codes), are set for all commodities. Identifying applicable codes for imported products in the Tariff Schedule is referred to as duty classification or HS classification.

Chapter	Heading	Sub-heading	Duty subdivision / Statistics subdivision
09	0902	0902.30	0902.30-010
Coffee, tea, mate tea, and spices	Теа	Black tea and partially fermented tea (limited to such tea directly packed whose net weight is 3kg or less)	Black tea

Example of Classification of an Item (black tea directly packed whose net weight is 3kg or less (0902. 30-010))

Advance Ruling System

The Advance Ruling System is a system under which a person can make an inquiry about the duty classification (duty code), duty rate, certification of origin, customs valuation, etc. of goods prior to importation and receive a response from customs. Under this system, inquiries are to be made in writing and responses are to be given in writing, in principle.

When a person makes an inquiry in writing, a written response (valid for three years) is issued. If the person attaches the written response upon making an import declaration, its content is to be respected in customs examinations. Inquiries may also be made orally (by phone or at customs counters) or by email, but the content of oral responses is merely treated as reference information and is not respected in examinations of import declarations.

Inquiries: Customs counselors and customs appraiser departments, etc. of respective customs

Reference information: Japan Customs' website: "Advance Ruling System"

https://www.customs.go.jp/english/advance/index.htm

Three Conditions for Applying Preferential Duty Rates (GSP Duty Rates and EPA Duty Rates)

Preferential duty rates are lower rates only applicable to products from specific countries or regions. There are GSP duty rates and EPA duty rates.

GSP (Generalized System of Preferences) duty rates: Applied to developing countries and regions (Note) Products of least developed countries (LDC) are almost duty-free (special preferential tariff system).

EPA (Economic Partnership Agreement) duty rates: Applied to EPA partner countries

For applying preferential duty rates (GSP duty rates or EPA duty rates), the following three conditions must all be satisfied.

- (i) Preferential duty rates (GSP duty rates, EPA duty rates, or special preferential duty rates) have been set for goods to be imported.
- (ii) Produced goods are acknowledged as those that originated from the exporting country or region (=satisfaction of the rules of origin criteria).
- (iii) An importer proves and reports to customs that the relevant goods satisfy both the rules of origin criteria and the consignment conditions (=procedures for proving the place of origin)
 - (Note) The rules of origin criteria, which provide for the criteria for acknowledging goods as those that originated from relevant exporting countries or regions; the consignment conditions, which provide for the conditions that must be satisfied for transporting goods to Japan; and the procedures for proving the place of origin, which provide for procedures for applying for preferential duty rates, are collectively referred to as the "rules of origin."

Three Types of Procedures for Proving the Place of Origin

In order to receive the application of preferential duty rates, an importer needs to prove that the relevant goods originated from the exporting country or region. An importer should confirm the details of the procedures adopted for the preferential duty rates to be applied, in advance, and prepare the required documents. However, when the total customs value is 200, 000 yen or less, and when the goods are found to evidently originate from the relevant country or region, preferential duty rates can be applied through simple procedures (presentation of an invoice, purchase price receipt, etc.).

Third-party certification system	An importer submits a certificate of origin, which was issued at the request of an exporter by a certificate issuing authority such as a chamber of commerce, to customs of the importing country.	 Generalized System of Preferences Following EPAs Japan-Singapore, Japan-Mexico, Japan-Malaysia, Japan-Chili, Japan-Thailand, Japan-Indonesia, Japan-Brunei, Japan-ASEAN, Japan-Philippines, Japan-Switzerland, Japan-Vietnam, Japan-India, Japan-Peru, Japan-Mongolia, Japan-Australia, RCEP
Self-certification system	An importer, exporter, or producer prepares a statement on origin, and an importer submits it to customs of the importing country. When making an import declaration, it is necessary to submit documents to prove that the goods originated from the exporting country or region (a detailed statement, written contract, price list, food production flow chart, etc.).	TPP 11, Japan-EU EPA, Japan-US Trade Agreement. Japan-UK EPA, Japan-Australia EPA, RCEP
Approved exporter self-certification system	An importer submits a declaration of origin, which was prepared by an exporter approved by the government of the exporting country, to customs of the importing country.	Japan-Switzerland EPA, Japan-Peru EPA, Japan-Mexico EPA, RCEP

Inquiries: Place of origin examiners of respective customs

Reference information: Japan Customs' website: "Rules of Origin"

https://www.customs.go.jp/roo/english/index.htm

Utilize the Advance Ruling System in writing for certification of origin.

The Advance Ruling System, under which an importer can make an inquiry and receive a response in writing from customs, is useful for confirming in advance whether GSP duty rates or EPA duty rates may be applicable for goods to be imported.

<Advantage of the Advance Ruling System in writing>

- \cdot Responses in writing from customs are respected in customs examinations for three years.
- Handling of places of origin and applicability of preferential duty rates can be confirmed in advance, which is helpful for cost calculation, etc.
- · Certification of origin is conducted smoothly in customs examinations and goods can be accepted earlier.

Tariff Quota System

The Tariff Quota System is a system to ensure the supply of imported goods to demanders at low prices by applying lower duty rates (primary duty rates) to imports of specific items up to a certain quantity, while applying relatively high duty rates (secondary duty rates) to imports exceeding said certain quantity. Targeted items have been added or deleted depending on changes in circumstances surrounding domestic industries. The following are covered under this system in FY2022.

Items Covered by the Tariff Quota System (only foods)

(as of April 1, 2022)

Corn (as raw materials for corn starch, etc.); Natural cheese (as raw materials for processed cheese); Malt; Sugar-free cocoa preparations (for producing chocolate); Tomato puree and paste (for producing tomato ketchup and sauce); Canned pineapple; other dairy products; Powdered skim milk; Sugar-free condensed milk; Whey, etc.; Butter and butter oil; Miscellaneous beans; Starch, inulin, and starch preparations; Peanuts; Konnyaku imo; Prepared edible fat

An importer who seeks the application of a primary duty rate must prepare application documents in accordance with the Tariff Quota Notice, which is publicized by the Ministry of Agriculture, Forestry and Fisheries in April every year, and submit them to the responsible department to obtain a tariff quota certificate. The importer must submit this certificate to customs upon making an import declaration.

Apart from this general framework, there is another tariff quota system under EPAs which covers 12 countries and two regions in FY2022. Covered items and procedures are available on the MAFF website.

Countries Covered by the Tariff Quota System under EPAs

(1) Mexico (2) Malaysia (3) Chile (4) Thailand (5) Indonesia (6) the Philippines (7) Switzerland
(8) Vietnam (9) Peru (10) Australia (11) Mongolia (12) CPTPP (13) the EU (14) U. S. A

■ Inquiries: International Economic Affairs Division, Export and International Affairs Bureau, MAFF: TEL:+81-3-6744-7165

Import of goods with a label falsifying the place of origin or misleading consumers is not permitted.

The term "place of origin" generally refers to a country or region where the relevant cargo was actually produced or processed. When any label falsifying the place of origin or misleading consumers is affixed directly to an imported cargo or indirectly to a container or packaging of an imported cargo, regulations under Article 71 of the Customs Act are applied and the import is not permitted by customs. In such cases, the import is permitted if any of the measures including the deletion or correction of the false or misleading labeling or reshipment are taken.

For ensuring smooth customs clearance procedures, pay attention to proper labeling of the place of origin in advance.

10 Labeling of Food

Labeling provides significant information to enable consumers to understand the details when selecting and purchasing food items and helps them learn preservation methods and usage thereof. In the event of an accident, it can also be an aid in ensuring prompt and proper administrative action such as seeking accountability or recalling relevant items.

Labeling under the Food Labeling Act is required for all food items to be sold to consumers, etc. Additionally, there are the Measurement Act, which provides for proper measurement and labeling, the Act against Unjustifiable Premiums and Misleading Representations, which prohibits misrepresentations concerning quality and other matters, the Health Promotion Act, which prohibits false or deceptive advertising concerning the effects of promoting and maintaining good health, the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics, which regulates pharmaceuticals to prevent confusion with food, the Act on Record of Transaction Information and Dissemination of Origin Information of Rice, which aims to secure proper and smooth distribution of rice, and the JAS Act, which regulates standards and labeling of organic food.

1 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 Act 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.

The Food Labeling Standards categorizes food items into three, i. e., processed foods, perishable foods, and additives, and provides for overall mandatory labeling, voluntary labeling, labeling methods, prohibited matters in labeling, with regard to business operators dealing with food for general consumers, business operators dealing with food for business use, and distributors other than those engaged in food-related business, for each of the three food categories.

Reference information: Consumer Affairs Agency's website: "Food Labeling" https://www.caa.go.jp/en/policy/food_labeling/

List of Provisions of the Food Labeling Standards

			1000					
Chap	ter I Ge	eneral Provi	isions					
		Article 1	Scope of application (restaurants, etc. (excluding some) are not covered)					
		Article 2	Definition of terms					
Chap	ter II Pi	rocessed F	oods					
			Overall mandatory labeling					
	ស្	Article 3	Paragraph (1) Labeling common to all types of food (item name, names of raw materials, preservatio methods, etc.)					
ess	consumers		Paragraph (2) Labeling common to certain types of food (allergen, genetic modification, etc.) Paragraph (3) Omission of labeling (exceptions of paragraphs (1) and (2))					
ISI	log	Article 4	Individual mandatory labeling (individual standards under the former JAS Act; jam, and dairy products, etc.					
in food-related business	general (Article 5	Special provisions on mandatory labeling (special provisions concerning liquor, those concerning local sellin, and gratuitous conveyance)					
elat	ger	Article 6	Recommended labeling (saturated fatty acid, food fiber)					
d-re	For	Article 7	oluntary labeling (labeling emphasizing characteristic raw materials and nutrition, etc.)					
Į00		Article 8	Labeling methods, etc. (formats, font sizes, etc.)					
.⊆		Article 9	Prohibited matters in labeling (overall prohibited matters, prohibited matters for individual food items)					
engaged			Mandatory labeling					
с С	e	Antiple 10	Paragraphs (1) and (2) Overall mandatory labeling and individual mandatory labeling					
en	esu s	Article 10	Paragraph (3) Exceptions for labeling methods					
SUC	e so		Paragraph (4) Omission of labeling					
Persons	business	Article 11	Special provisions on mandatory labeling (special provisions concerning liquor, those concerning food for dining out, local selling, and gratuitous conveyance, etc.)					
	For	Article 12	Voluntary labeling (labeling of characteristic raw materials and nutrients, etc.)					
		Article 13	Labeling methods, etc. (matters that can be stated on containers and packaging or in invoices, etc.)					
		Article 14	Prohibited matters in labeling (mutatis mutandis application of Article 9, paragraph (1))					
		Article 15	Mandatory labeling matters (item name, preservation methods, use-by date, etc.)					
)ther listrik	outors	Article 16	Labeling methods, etc.					
notric		Article 17 Prohibited matters in labeling (mutatis mutandis application of Article 9, paragraph (1))						
Chap	ter III P	erishable f	pods					
		Article 18	Overall mandatory labeling (item name, place of origin, genetic modification, etc.)					
ted	<u></u> 0	Article 19	Individual mandatory labeling (brown rice and polished rice, meat, milk, globefish (fugu), etc.)					
engaged in food-related business	For general consumers	Article 20	Special provisions on mandatory labeling (special provisions concerning local selling, gratuitous conve ance, and food without containers or packaging, etc.)					
poq	on suc	Article 21	Voluntary labeling (labeling of nutrients, labeling emphasizing nutrition, etc.)					
sss of the	шö	Article 22	Labeling methods, etc. (media, font sizes, etc.)					
ed		Article 23	Prohibited matters in labeling (overall prohibited matters, prohibited matters for individual food items)					
bug		Article 24	Mandatory labeling (item name, place of origin, etc.)					
ene	business use	Article 25	Special provisions on mandatory labeling (special provisions concerning food for dining out, local selling gratuitous conveyance, and food without containers or packaging, etc.)					
SODS	busir use		Voluntary labeling (labeling of nutrients)					
Lei	For		Labeling methods, etc. (matters that can be stated on containers and packaging or in invoices, etc.)					
		Article 28	Prohibited matters in labeling (mutatis mutandis application of Article 23, paragraph (1))					
)+l= =		Article 29	Mandatory labeling (item name, genetic modification, etc.)					
)ther listrit	outors	Article 30	Labeling methods, etc.					
		Article 31	Prohibited matters in labeling (mutatis mutandis application of Article 23, paragraph (1))					
Chap	ter IV A	Additives						
		Article 32	Mandatory labeling (item name, the fact of being additives, use-by date, etc.)					
Perso	ns zed in	Article 33	Special provisions on mandatory labeling (special provisions concerning gratuitous conveyance)					
engag food- relate busin	d	Article 34	Voluntary labeling (labeling of nutrients)					
	ess	Article 35	Labeling methods, etc. (formats, font sizes, etc.)					
		Article 36	Prohibited matters in labeling					
		Article 37	Mandatory labeling (item name, the fact of being additives, use-by date, etc.)					
Dther Iistrik	outors	Article 38	Labeling methods, etc. (formats, font sizes, etc.)					
		Article 39	Prohibited matters in labeling (mutatis mutandis application of Article 36)					
		liacellance	us Provisions					
Chap	ter V N	liscellaneo						
Chap	ter V N		Labeling alert regarding beef to be eaten raw					

Mandatory Labeling Concerning Quality and Sanitation

When selling processed foods in a container and packaging that are marketed for general consumers (such as those listed in Appended Table 1 of the Food Labeling Standards), labeling should be made accurately in Japanese using terms that are easy to read and understand, presenting such information as the item name, names of raw materials, additives, and net contents in the prescribed form at a place easily visible without opening the container or packaging.

Item name	Generic term, not a product name	
Names of raw materials	Describe the names of used raw materials in accordance with the descending order of the proportion in weight among all raw materials. Allergens: Seven items such as eggs and flour must be indicated. Genetically modified foods: Regarding the covered 33 processed foods, if an item contains any genetically modified agricultural products or agricultural products without separating genetically modified ones, that fact must be indicated.	
Additives	Describe the names of used additives in accordance with the descending order of the proportion in weight among all additives. Information on additives may be indicated in the column for names of raw materials by clearly separating it from that on raw materials. Allergens: Seven items such as eggs and flour must be indicated.	
Net contents	Weight (g or kg), volume (ml or I), or quantity (number, etc.)	
Best-before date	Describe in the order of year, month and day. Regarding processed foods for which the period from the production date to the best-before date is over three months, only the year and month may suffice.	
Preservation method	Specifically describe the conditions for preservation until the indicated use-by date or best-before date. Descriptions here are not matters to note after opening.	
Name of the country of origin	For imported processed foods, the name of the country of origin must not be omitted.	
Importer	When a person engaged in food-related business that assumes responsibility for the content of labeling is an importer, the column title should be "Importer." Describe the importer's address (location of the office) and name (the individual's name when the importer is an individual, and the corporation's name when the importer is a corporation; it is not acceptable to only state the shop name.)	

Basic Labeling Matters for Processed Foods for General Consumers

(Note) In addition to basic labeling matters common to all processed foods, individual mandatory labeling (Article 4, Appended Table 19 of the Food Labeling Act) and labeling methods (Appended Table 20) are prescribed for some foods.

Recall Information Notification System for Food and Other Products – Introduction of obligation to notify recall information –

Since June 2021, a business operator who commenced a recall of food items has come to be obliged to file a notification to that effect to the public administration without delay. This system aims to enable the national government to surely ascertain recall information for food and other products and publicize it in the form of a list to provide information to customers, thereby preventing the occurrence of health damage caused by such food and other products. A notification is to be filed online using the Food Business Application System for licenses, export certifications, and report of food recalls.

< Recalls that need to be reported >

Food Sanitation Act: Recall of foods that violate or are highly likely to violate the Food Sanitation Act, such as those contaminated with Bacillus coli and those containing hard foreign substances (glass pieces, plastic, etc.)

Food Labeling Act: Recall of foods for which labeling to ensure food safety is not made in accordance with the Food Labeling Standards, such as those lacking labeling on allergens or best- before date and those with incorrect labeling

Obligation to Make Labeling for Nutrients

The Food Labeling Standards based on the Food Labeling Act require labeling of the contained amounts of energy, protein, fat, carbohydrate, and sodium (in sodium chloride equivalent) for processed foods in a container and packaging that are marketed for general consumers, in principle.

When emphasizing the contained amounts of some nutrient ingredients and energy, such as low calorie content or salt reduction, their contents need to satisfy certain standards.

[Example of labeling for nutrients]

栄養成分表示				
1包装(2個)当たり				
熱量	483kcal			
たんぱく質	17.2g			
脂質	22.7g			
炭水化物	52.0g			
食塩相当量	3.6g			

(Note) There are items for which labeling for nutrients can be omitted (e. g., liquors, coffee beans, spices, etc. whose contributions as nutrient sources are small, and items sold by small businesses that are exempted from the obligation to pay consumer taxes) and items for which labeling for nutrients is not required (e. g., when transferring certain items to many or unspecified persons).

Inquiries: Regarding the Food Labeling Act as a whole

Food Labeling Division, Consumer Affairs Agency: TEL: +81-3-3507-8800 (main)

2 Commodity Quantity System under the Measurement Act

The Measurement Act requires that business operators make efforts to ensure accurate measurement in transactions of commodities based on statutory measurement units.

When the relevant food falls under the category of specified commodities under the Measurement Act (consumer life products that are ordinarily traded in mass or volume, for which consumers need to confirm their quantity when making a reasonable choice), a person who sells the food by sealing it up in a container by weight must measure the quantity of said food within the measurement error level specified by said Act (the "quantity tolerance").

For certain types of specified commodities, persons who sell such commodities by sealing them up in containers by weight must measure their quantity within the quantity tolerance and affix labeling to show the net contents and name and address of a person responsible for the content of the labeling. Inquiries: Metrology Policy Office.

Industrial Science, Technology and Environment Policy Bureau, METI TEL: +81-3-3501-1688

3 Misleading Representations under the Act against Unjustifiable Premiums and Misleading Representations

The Act against Unjustifiable Premiums and Misleading Representations aims to protect the interest of general consumers by ensuring that they can make voluntary and reasonable choices in transactions of goods or services. Business operators are basically free to use any expressions in their advertising and marketing activities to demonstrate appeal of their goods or services to customers, but misleading representations are prohibited.

The term "representations" here means not only those on products themselves (including their containers and packaging, etc.) but also those in stores and advertisements using such media as leaflets, newspapers, magazines, TVs, and the Internet. The term is defined specifically by a public notice.

Representations that may mislead consumers into believing that the quality, standards, content, etc. of a good or service are significantly better than they actually are (misrepresentations concerning quality), those that may mislead consumers into believing that the price or other transaction conditions are significantly advantageous (misrepresentations concerning transaction conditions), those that may mislead consumers regarding the country of origin, and bait- and- switch advertising, etc. are all misleading representations. When a violation of the Act against Unjustifiable Premiums and Misleading Representations is suspected, the Consumer Affairs Agency and relevant prefectures collect related materials, request reports from the business operators, or otherwise carry out an investigation. If any act suspected to be in violation of the Act is found as a result of the investigation, guidance: such as the improvement of the representations, is given, and violating acts are subject to an order to take measures.

Labeling of Country of Origin

The Act against Unjustifiable Premiums and Misleading Representations prohibits misleading representations concerning the country of origin of goods. The term "country of origin" means a country where an act resulting in a substantial change in the content of the goods^(Note) was performed. Regarding goods made in foreign countries, the following representations that make it difficult for consumers to understand that the goods were actually produced in the country of origin are considered to be misleading representations:

- (i) Name of a country or a place, or a national flag, etc. irrelevant to the country of origin
- (ii) Name of a business operator or a designer or trademark of a country other than the country of origin
- (iii) The entirety or the major part of the character representation is in the Japanese language
- (Note) An act resulting in a substantial change does not include such acts as affixing a label or other indication to goods, packing goods in a container or wrapping goods, simply assorting or mixing multiple goods, or assembling simple parts.

False or Exaggerated Advertisements and Misleading Representations of Health Food

Careful attention is required for representations and advertisements of health food, as they may conflict with the provisions of the Health Promotion Act, which prohibits false or exaggerated representations regarding products' effects and functions relating to the maintenance or promotion of good health, or with the provisions of the Act against Unjustifiable Premiums and Misleading Representations, which prohibits misrepresentations concerning quality. The Consumer Affairs Agency presents basic concepts of legal regulations, examples of violations, and concrete examples of representations and advertisements that may cause problems in its notice titled "Matters to Note with Regard to Health Food under the Act against Unjustifiable Premiums and Misleading Representations and the Health Promotion Act" (June 30, 2016, and partially revised in December 5, 2022).

Advertisements Concerning Online Consumer Transactions

Attention should be paid to advertisements for Internet sales to general consumers as they may not only be problematic in their expressions themselves but may mislead consumers in their selection and ordering of goods, leading to the expansion of consumer damage as a result.

The Consumer Affairs Agency publicized a notice titled "Problems and Matters to Note with Regard to Online Consumer Transactions under the Act against Unjustifiable Premiums and Misleading Representations" (publicized on October 28, 2011, and partially revised in June 2022).

Business Operators' Development of Labeling Management System and the Administrative Monetary Penalty System

In order to prevent the inducement of customers by means of unjustifiable premiums and misleading representations, business operators are obliged to establish necessary systems and take other necessary measures to properly manage matters relating to premiums and representations (Article 26, paragraph (1) of the Act).

Regarding matters necessary for properly and effectively fulfilling this obligation, the Guidelines for Measures to be Taken by Business Operators for Managing the Provision of Premiums and Labeling of Goods (Notice of the Cabinet Office No. 276 of November 2014; amended in June 2022) were presented, and business operators are required to develop a management system commensurate with their business size and type of business while referring to the Guidelines.

Furthermore, with the aim of preventing violations, the administrative monetary penalty system was introduced to impose an economic disadvantage on business operators that made misleading representations (representations that cause misperception regarding being significantly superior or significantly more advantageous) after granting an opportunity for explanation.

■ Inquiries: Guidance Office, Representation Division, Consumer Affairs Agency TEL: +81-3-3507-8800 (main)

Are there reasonable grounds for the labeling? - Regulations on undemonstrated advertisements

When a misrepresentation concerning quality is suspected with regard to the effects and efficacy of goods, the Consumer Affairs Agency may request the relevant business operator to submit materials showing reasonable grounds for the labeling.

When the business operator 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.

- Deadline for the submission of documents
- By the elapse of 15 days from the day on which the Secretary General 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 a justifiable ground))

 \circ Criteria for reasonable grounds – need to satisfy both of the following requirements

- 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.

4 Act on Record of Transaction Information and Dissemination of Origin Information of Rice (Rice Traceability Act)

The Act on Record of Transaction Information and Dissemination of Origin Information of Rice was established with the aim of identifying a distribution route based on preserved records in the event of an accident regarding rice, etc., thereby preventing food whose safety is not guaranteed from being distributed, and ensuring proper labeling and proper and smooth distribution of safe rice.

Rice (brown rice, polished rice, and crushed rice), rice flour, rice flour preparations, rice confectionery dough, cooked rice, refined sake, sweet cooking rice wine, and other processed rice foods are covered by the Rice Traceability System. Busines operators selling, importing, processing, producing, or supplying these items are obliged to [i] prepare and preserve transaction records, etc. and [ii] provide information on places of production.

■ Inquiries: Food Labeling Division, Consumer Affairs Agency: TEL: +81-3-3507-8800 (main)

5 Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics

(Note) Abbreviated as the "Pharmaceuticals and Medical Devices Act"

In order to prevent health damage, etc. of consumers that may be caused by distribution of food confusable with pharmaceuticals, this Act strictly classifies pharmaceuticals and food and regulates them separately (refer to the notice of the Ministry of Health, Labour and Welfare, "Standards Concerning the Scope of Pharmaceuticals," for the classification of food and pharmaceuticals; see p. 15).

The Pharmaceuticals and Medical Devices Act defines pharmaceuticals as those intended to be used for the diagnosis, treatment, or prevention of diseases and to affect the structure and functions of the body, and regulates them under various approval and authorization systems for ensuring their quality, effectiveness, and safety. For example, food emphasizing pharmaceutical effects and efficacy, such as being effective against cancer or high blood pressure, or food emphasizing a slimming effect that contains a laxative agent, anorectic agent, or other pharmaceutical ingredients are subject to administrative guidance and control as unapproved or unauthorized drugs.

Labeling indicating pharmaceutical effects, efficacy, or functions is not permitted for general food.

In Japan, the System for Food with Health Claims has been adopted, under which functions of food may be indicated. It should be noted that the Food Labeling Act prohibits the use of any name confusable with food with health claims or the use of any term indicating functions of nutrients or expected achievement of specific health purposes in labeling for other general food.

Pharmaceuticals (including quasi-pharmaceutical products and regenerative medicine)					
	Food with health claims (functions may be indicated) Foo func clai	Food for specified health uses	Food that contains ingredients with health functions that affect physiological functions, etc. of the body to which labeling indicating expected achievement of specific health purposes is affixed	Business operators 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	
Food (pharmaceutical expressions are not permitted)		Food with function claims	Food with labeling targeting people free from diseases to imply that functional ingredients are expected to improve and maintain good health	Based on the rules specified by the national government, business operators 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	
		Food with nutrient function claims	For food that conforms with the standards and criteria specified by the national government, functions of the nutrient ingredients may be indicated.	Business operators do not need to file an application for authorization or make reports to the Consumer Affairs Agency.	
	General foo	d	Functions may not be indica	ited.	

Classification of Orally-Ingested Goods

6 Organic JAS Standards Based on the Act on Japanese Agricultural Standards (JAS Act)

The JAS Act specifies the mechanism of certification of organic food by a third party. JAS standards are established for organic plants, organic processed foods (categorized into organic processed foods of plant origin, organic processed foods of animal origin, and organic processed foods of plant and animal origin), and organic livestock products, and such food for which the processing or producing method is authorized is permitted to be distributed with an organic JAS mark.

Organic plants, organic processed foods, and organic livestock products are designated as specified agricultural and forestry products for which it is especially necessary to ensure proper labeling concerning their item names, because confusion in labeling is observed for these products and improper labeling may significantly hinder consumers' ability to make correct selections. Accordingly, labeling using such terms as "有機" or " $\pi - \pi = \gamma \rho$ " (meaning "organic") or any other terms which might cause confusion is not permitted for food items other than those that satisfy organic JAS standards and to which certified business operators affix the organic JAS mark.

Organic liquor had not been covered by the JAS system, but the Act on Japanese Agricultural Standards was amended and business operators that intend to label liquor using such terms as "有機" or "オーガニック" came to be also required to obtain JAS certification for organic processed foods and affix the organic JAS mark from October 1, 2022.

(The Labelling Standards for Organic Liquor under the jurisdiction of the National Tax Agency was repealed on October 1, 2022, but the former standards continue to apply until September 30, 2025, as transitional measures.)

	Organic JAS standards	Labeling regulations under the JAS Act	Method of affixing organic JAS mark to imported products	
Or	ganic plants		(i) A certified importer in Japan imports organic plants,	
sed foods	Organic processed foods of plant origin	Specified agricultural and forestry products Organic JAS mark is indispensable for labeling as organic food	organic processed foods, and organic livestock proc ucts that were produced in a country for which Japan has recognized the organic equivalency, and distrib- utes those imports after affixing the organic JAS mark (For affixing the organic JAS mark, a certificate issued by a government organization of the exporting countr or a copy thereof needs to be attached.) (ii) An importer imports organic food items that an overseas business operator having JAS certification	
proces	Organic processed foods of animal origin			
Organic	Organic processed foods of plant and animal origin		for organic processed foods produced and affixed the organic JAS mark, and distributes those imports (as such products were already certified as being organic under the JAS system, they may also be imported by	
Organic livestock products			importers other than certified importers).	

(Note) • Organic processed foods of animal origin, organic processed foods of plant and animal origin, and organic livestock products were newly designated as specified agricultural and forestry products on July 16, 2020.
 • Countries, etc. for which Japan has recognized the organic equivalency (as of April 2021)

EU (27 countries), United Kingdom, Australia, United States, Switzerland, Argentina, New Zealand, Canada, Taiwan (However, for EU, United Kingdom, Argentina, New Zealand, and Taiwan, limited to organic plants and organic processed foods of plant origin)

Inquiries: Standards and Conformity Assessment Policy Office, Food Manufacture Affairs Division, New Business and Food Industry Department, Minister's Secretariat, MAFF

Tel:+81-3-6744-2098

Email:jas_soudan@maff.go.jp

Reference information: MAFF Website: "Organic JAS"

https://www.maff.go.jp/e/policies/standard/specific/organic_JAS.html

11 Laws that Need to be Noted in Marketing

1 Major Regulations Concerning Permits, Notifications, Licenses, etc. Relating to Food Business

When business operators engage in food-related business or marketing, different types of permits, notifications, licenses, or registrations, etc. are required depending on their business modes and the types of food they deal with.

Some local governments require business operators commencing import of food, etc. or business offices engaging in food import business to make notifications under their own Ordinances (e. g. Shiga prefecture and Ibaraki prefecture).

(i) Business Permit and Notification under the Food Sanitation Act and Implementation of HACCP-based Food Hygiene Control

Since June 2021, all food business operators, in principle, have come to be obliged to implement HACCP-based food hygiene control. Accordingly, for businesses that do not fall under licensed businesses or businesses not requiring notification, business notifications need to be filed with public health centers so that public health centers can ascertain business operators subject to obligation to implement HACCP-based food hygiene control.

When it is difficult to determine whether the business content is subject to a permit or notification obligation, please make inquiries with the public health center having the jurisdiction over the location of the business facilities. An application for a permit and a notification are to be filed using the Food Business Application System for licenses, export certifications, and report of food recalls. (Note) For HACCP-based food hygiene control, see the Ministry of Health, Labour and Welfare's webpage "HACCP."

Risk		System	Outline	Subjects	What business operators must do
High		Business permit (Article 54 to Article 55, paragraph (1) of the Act)	standards and criteria, and past incidents of food poison- ing, etc., a person engaging in any of the prescribed types	32 types of business, includ- ing the manufacturing and cooking businesses, and the sales business involving pro- cessing (Article 35 of the Order for Enforcement of the Food Sanitation Act)	 Appoint a food sanitation manager Implement HACCP-based
Influence on public health		Business notifica- tion (Article 57 of the Act)	fall under licensed busi- nesses or businesses not requiring notification, busi- ness notifications need to be filed with competent public health centers can ascertain business operators subject to obligation to implement	Labour and Welfare's notice "Setting of Types of Business Subject to Notification Obligation" (YakuSeiShokuKan	 OAppoint a food sanitation manager OImplement HACCP-based food hygiene control A notification is necessary when changing or discontinuing a business. There are no requirements concerning facilities and equipment. Notification fees are not required. As a notification does not have a validity period, renewal is unnecessary.
		Not subject to noti- fication obligation	For businesses that have little impact on public health, neither a business permit nor a notification is necessary.	Business of importing food or additives, business of trans- porting and storing food or additives (excluding food freezing or refrigeration busi- ness), and business of sell- ing packed food that can be kept at room temperature (e.g.: manufactured/pro- cessed and packed food, such as confectioneries, soft drinks, liquor, and tea) (Article 35-2 of the Order for Enforcement of the Food Sanitation Act)	operator, but HACCP - based food hygiene control is

Business Permit System and Business Notification System

(Source) Prepared based on the materials posted on the Ministry of Health, Labour and Welfare's webpage "Information on Business Regulations"

Inquiries: Public health center having the jurisdiction over the location of the business facilities

(ii) Liquor Tax Act and Act on Securing of Liquor Tax and on Liquor Business Associations – Liquor Sales License and Liquor Sales Manager System

A person who intends to engage in the wholesale or retail of liquor in Japan needs to obtain a liquor sales license. Required liquor sales license varies depending on the intended buyer.

Under the Act on Securing of Liquor Tax and on Liquor Business Associations, the Liquor Sales Manager System is operated with the aim of preventing drinking by persons who are underage of 20 and ensuring proper management of liquor sales including recycling of containers. Liquor retailers must assign a liquor sales manager at each sales location before commencing the business and submit a written notification of the assignment of the liquor sales manager to the competent tax office within two weeks after the assignment.

(iii) Act on Stabilization of Supply, Demand and Prices for Staple Food – Rice Retailers Notification System (Staple Food Control Act)

A person who intends to start shipping or retailing rice must submit a written notification of the start of the business to the regional agricultural administration office having jurisdiction over the location of the major business office in advance based on the Act on Stabilization of Supply, Demand and Prices for Staple Food (excluding small scale businesses handling less than 20 tons on a polished rice basis).

(iv) Salt Industry Act – Registration as Salt Wholesaler

A person who intends to engage in the salt wholesale business (excluding those intending to engage in the wholesale of only salt for special purposes or specially-made salt) needs to be registered by the director-general of a local finance (branch) bureau.

Registration is not required for salt retail business. Salt may be retailed freely.

2 Act on Specified Commercial Transactions —When Engaging in Online Mail Order Business—

A person engaging in online mail order business, etc. to sell goods to general consumers is subject to regulations under the Act on Specified Commercial Transactions. The Act on Specified Commercial Transactions specifies regulations for seven types of transactions including mail-order sales, door- to- door sales, and telemarketing in order to prevent illegal or malicious solicitation by business operators and to protect consumer interest.

Regarding operators engaging in online mail-order business, matters to be indicated in advertisements (name, address and telephone number of the business operator; prices and shipping charges; payment method and deadline; whether or not to be returnable, etc.) are specified, and misleading advertising and solicitation against customers' intention are prohibited.

Those engaging in Internet auction business: both corporations and individuals are also subject to regulations under certain conditions.

Reference information: Consumer Affairs Agency's website "Act on Specified Commercial Transactions Guide" https://www.no-trouble.caa.go.jp/foreignlanguage/

3 Recycling-related Laws

Identification Marks for Containers and Packaging

The Act on the Promotion of Effective Utilization of Resources requires business operators to affix identification marks to containers and packaging in order to help consumers sort out garbage and facilitate sorted collection of garbage by local communities.

Imported goods are also subject to this regulation, and when an importer designates the materials or structure of a container and/or packaging or instructs the use of its own trademark, identification marks need to be affixed in the same manner as in the case of domestic goods. Even without such designation or instruction, if Japanese indication is printed, labeled, or stamped on the surface of a container and/or packaging, identification marks are required.

Products Requiring Designated Identification Marks for Promoting Sorted Collection



free paper cartons for beverages excluding PET bottles for beverages, liquor, and specified flavoring materials



PET bottles for beverages, liquor, and specified flavoring materials

(excluding those) with a capacity less than 150ml/

Recycling Obligation under the Act on the Promotion of Sorted Collection and Recycling of Containers and Packaging

The Act on the Promotion of Sorted Collection and Recycling of Containers and Packaging requires an importer of goods using glass containers, paper containers and packaging, or plastic containers and packaging to recycle such containers and packaging. However, small-scale entrepreneurs prescribed in the Small and Medium Sized Enterprise Basic Act whose sales amount is below a certain level are exempted from the recycling obligation.

Reference information: METI Website: "3R Policies"

https://www.meti.go.jp/english/policy/energy_environment/3r/index.html

[Notes upon using this Guide]

 \odot The contents are as of October 2022. Please note that there may be legal amendments thereafter.

 \odot This is the revised version of the Guide to Food Import 2019 issued in March 2019.

< Major revisions >

- \bigcirc Amendment of the Food Sanitation Act
- For importing milk, dairy products, pufferfish, and oysters to be eaten raw, an importer is newly obliged to attach a sanitary certificate.
- · The operation of the Recall Information Notification System for Food and Other Products was commenced.
- Upon the introduction of the HACCP- based food hygiene control system, the business permit system was reviewed and the business notification system was newly established.
- O The scope of plants that are exempted from the obligation to attach a phytosanitary certificate upon plant quarantine was expanded.
- Import and export regulations for aquatic animals and plants were introduced under the Act on Proper Domestic Distribution of Aquatic Animals and Plants (enforced on December 1, 2022)
- \bigcirc Amendment of the Act on Japanese Agricultural Standards
- For labeling livestock products and livestock processed foods using such terms as "有機" or "オーガニック," it is required to obtain JAS certification for organic processed foods and affix the organic JAS mark (enforced on July 16, 2020).
- Since October 1, 2025, business operators that intend to label liquor using such terms as "有機" or "オーガニック" will also be required to obtain JAS certification for organic processed foods and affix the organic JAS mark. Accordingly, the Labelling Standards for Organic Liquor (National Tax Agency Notice No. 7 of 2000) was repealed on October 1, 2022.



Issued by Manufactured Imports and Investment Promotion Organization (MIPRO)

6th floor, World Import Mart Bldg. 3-1-3, Higashi-Ikebukuro, Toshima-ku, Tokyo 170-8630, Japan TEL: +81-3-3971-6571 URL https://www.mipro.or.jp

March 2024 Unauthorized copying of the contents of this guidebook is strictly prohibited.

<Notes>

• The translations of the Japanese laws, regulations, announces, notices and guidelines provided in this booklet are not for official use. Only the original Japanese texts of laws and regulations have legal effect in Japan. The translations are to be used solely as reference material to aid in the understanding of Japanese laws and regulations.

• Although MIPRO has made every effort to provide as accurate information as possible in this booklet based on the latest information available at the time of preparation, MIPRO shall not be held responsible for the accuracy, reliability or currency of the legislative materials provided in this booklet, or for any consequence resulting from use of the information in this booklet. For all purposes of interpreting and applying law to any legal issue or dispute, readers should consult the original Japanese texts published in the Official Gazette.