Guide to Import of Apparatuses for Food 2021





Guide to Import of Apparatuses for Food

Tableware, cooking utensils, kitchen electric appliances and the like fall under the category of "apparatus" as defined in the Food Sanitation Act, and when a person intends to import these items for the purpose of marketing or other business purposes, he/she needs to follow procedures for import notification. Sale of such imported apparatuses is subject to regulations similar to those for domestic apparatuses. For some items, labeling requirements or other regulations are established, and acts and labeling matters for their sale via the Internet, etc. are also regulated.

This guidebook has been prepared targeting people who intend to import apparatuses for food for the first time, to outline the import procedures and regulations imposed upon import and sale of such apparatuses and to help lead the way.

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

March 2022

Manufactured Imports and Investment Promotion Organization

Contents -1. Laws concerning Tableware, Cooking Utensils, Kitchen Electric Appliances, etc. 3 2. "Apparatus" Covered under the Food Sanitation Act 3. Overall Flow of Import Procedures for Apparatuses for Food 4. Import Notification to the Quarantine Station 6 Obligation to make an import notification; Apparatuses for which a notification needs to be made; Apparatuses for which notification is not required 6 Procedures for notification; Documents necessary for notification; Notification Form for Importation of Foods, etc. 8 Inspections directed by the quarantine station; Implementation of self-inspections 10 6. Positive List System and Information Sharing for Apparatuses Made of Synthetic Examination and confirmation under other relevant laws and ordinances Tax declaration of tariffs, etc. Tariff rates, Tariff classification, Advance ruling system 23 Three conditions for applying preferential duty rates, Three types of 4. Electrical Appliances and Materials Safety Act

As tableware, cooking utensils, kitchen electric appliances and the like come into direct contact with food when used, they are regulated under the Food Sanitation Act so as to prevent the occurrence of leakage of any toxic or harmful substances that involves a risk to human health. Import of any goods infringing intellectual property rights and misleading representations upon selling goods are prohibited, while regulations on quality labeling are imposed on some items and confirmation of the conformity to technical standards is required for items for which consumer safety needs to be ensured.

Attention should also be paid to regulations on sale via the Internet, etc. and on recycling of containers and packaging of goods.

Law Title B.	Main and deline
Law Title → Reference page	Major regulations on import and sale
Food Sanitation Act → p.4-21	 Notification of import of "apparatus" that comes into direct contact with food Inspections upon import as necessary Prohibition of sale, etc. of toxic or harmful apparatuses Establishment of standards and criteria for apparatuses and prohibition of sale, etc. of apparatuses that do not conform to such standards and criteria
Customs Act → p.22-24	 Determination and payment of customs, customs clearance procedure, ban on the import of goods infringing intellectual property right Ban on the import of goods labeled with false or misleading indications of origin
Household Goods Quality Labeling Act → p.26	Items subject to quality labeling regulations for plastic goods, miscellaneous manufactured goods and electrical appliances and apparatuses shall be sold with labeling indicating prescribed matters.
Act against Unjustifiable Premiums and Misleading Representations → p.27-29	Prohibition of representation misleading people to believe something is better or more favorable than the actual one, and prohibition of false labeling of the country of origin, etc.
Electrical Appliances and Materials Safety Act → p.30	The Law covers specified electrical appliances and materials and other general electrical appliances and materials. (e.g. electrical coffee makers, electrical blenders, electrical refrigerators) · Notification of import business and confirmation of the conformity to technical standards · Conformity assessment of specified electrical appliances and materials · Implementation of self-inspections and preparation and preservation of inspection results · Sale with PSE mark
Consumer Product Safety Act → p.31	Pressure cookers and pressure pans for domestic use are included in "specified products" as defined in said Act and the following are required. Notification of import business and confirmation of the conformity to technical standards Implementation of self-inspections and preparation and preservation of inspection results Sale with PSC mark With regard to "consumer products" as defined in said Act, serious product accidents are to be reported.
Act on Specified Commercial Transactions → p.32	When selling goods by mail order sales (including Internet sales and auctions), the following are required. Indication of prescribed matters in advertisement Prohibition of misleading advertising, etc.
Act on the Promotion of Effective Utilization of Resources → p.33	A mark to distinguish the materials shall be indicated on paper and plastic containers and packaging.
Act on the Promotion of Sorted Collection and Recycling of Containers and Packaging → p.33	When using glass containers, or paper or plastic containers and packaging, recycling charges are to be borne.

(Notes)

- · Major Laws that impose obligations concerning import and sale of goods on business operators
- · Additionally, local governments= ordinances are applied in some cases or industry segments have established voluntary standards or labeling rules.

2 The "Apparatus" Covered under the Food Sanitation Act

Various products are used at a dining table or in a kitchen, but not all of them fall under the category of apparatus as defined in the Food Sanitation Act. The Food Sanitation Act defines the products it covers as follows.

Definition of apparatus (Article 4, paragraph (4) of the Food Sanitation Act)

The term "apparatus" as used in this Act shall mean tableware, kitchen utensils, and other machines, implements, and other articles which are used for collecting, producing, processing, cooking, storing, transporting, displaying, delivering, or consuming food or additives and which come into direct contact with food or additives; provided, however, that this term shall not include machines, implements, and other articles used for harvesting food in agriculture and fisheries.

Whether a product falls under the category of "apparatus" is determined based on whether "it comes into direct contact with food."

For example, a knife comes into direct contact with food and falls under the category of apparatus, while a knife rest does not come into direct contact with food and is not covered by the Act.

This is one concrete example. If you are not sure, please make inquiries at the quarantine station.

Examples of apparatus

Tableware	Cups, dishes, tumblers, chopsticks, spoons, knives, forks, baby bottles, straws, etc.
Kitchen utensils	Kitchen knives, cutting boards, pots, frying pans, bowls, ladles, etc.
Machines and implements, etc. which come into direct contact with food	 For producing, processing and cooking food (conveyers, pipes, hoses, etc. installed in manufacturing facilities; coffee makers, juicers, blenders, slicers, pasta machines, etc.) For storing and transporting food (tanks, bottles, containers, refrigerators, water flasks, cruets and vessels for seasoning, etc.) For displaying and selling food (food trays, baskets, etc.)

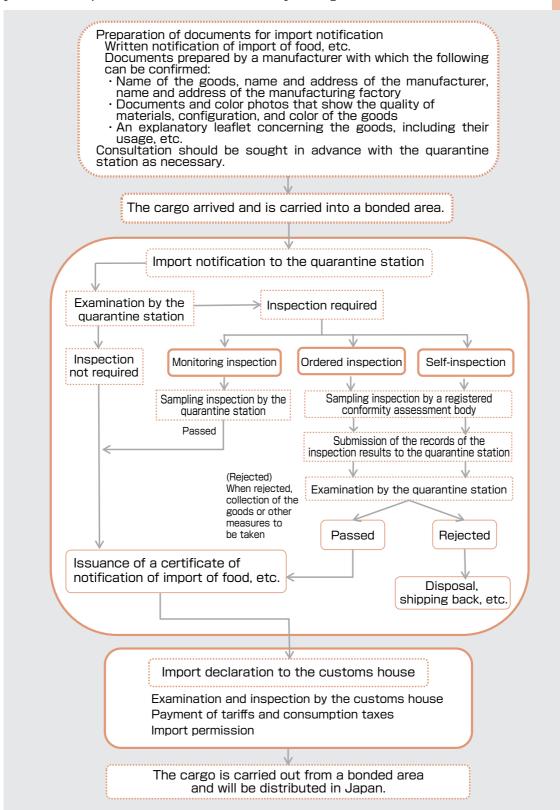
Regulations for ensuring safety of apparatuses

The safety of apparatuses for food is ensured by Article 16 and Article 18 of the Food Sanitation Act.

Article 16 of the Food Sanitation Act (Outline)	Apparatuses which contain or are covered with toxic or harmful substances and involve a risk to human health shall not be produced, imported, or sold, nor be used in business.
Article 18 of the Food Sanitation Act (Outline)	 (1) The Minister of Health, Labour and Welfare may establish standards or criteria for the apparatus to serve for the purpose of marketing or to be used in business and the raw materials thereof. (2) When the standards or criteria have been established, the apparatus which do not conform to such standards shall not be sold, nor be produced or imported for the purpose of marketing, nor be used in business; raw materials which do not conform to such standards shall not be used; and the apparatus shall not be produced by methods that do not conform to such criteria. (3) *Newly established in June 2020 ⇒ See p. 20 · Quality of raw materials (synthetic resin) specified in the Order for Enforcement of the Food Sanitation Act must be substances on the positive list. · However, substances other than those on the positive list may be used if they are not used in parts that come into contact with food and do not move to the food side in amounts that exceed the amount specified as not likely to damage human health (Public Notice of the Ministry of Health, Labour and Welfare No. 195 of 2020: concentration in food 0. 01 mg/kg).

3 Overall Flow of Import Procedures for Apparatuses for Food

A person who intends to import apparatuses for food must prepare documents for import notification under the Food Sanitation Act and make a notification to the quarantine station. When it is judged to be legal as a result of an examination by the quarantine station, a certificate of notification of import of food, etc. is returned to the importer. The importer attaches this certificate of notification upon making an import declaration at customs, and when the import is permitted, he/she will be able to sell the imported goods.



4 Import Notification to the Quarantine Station

An importer who intends to import apparatuses for food for the purpose of marketing or other business purposes is obliged to make a notification under the Food Sanitation Act, from the perspective of ensuring the safety of such apparatuses.

It is not permitted to use for marketing or other purposes any apparatus for food for which import notification has not been made.

Obligation to make an import notification (Article 27 of the Food Sanitation Act)

A person who intends to import food, additives, apparatuses 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 each occasion, pursuant to an Ordinance of the Ministry of Health, Labour and Welfare.

Apparatuses for which a notification needs to be made

As prescribed in Article 27 of the Food Sanitation Act, a notification needs to be made with regard to apparatuses that a person intends to import to "serve for the purpose of marketing or to use in business."

As the term "sales" as prescribed in Article 5 of the Food Sanitation Act includes "delivery other than sales to many and unspecified persons," apparatuses to be delivered for free to many and unspecified persons are also subject to the regulations and a notification needs to be made therefor.

Apparatuses for which notification is not required

Whether notification is required or not is determined in consideration of the objective circumstances, such as the apparatuses' configuration, purpose of use, labeling and other related documents. Notification is not required in principle with regard to the following.

- · Raw materials of apparatuses
- · Apparatuses that do not come into direct contact with food when used in ordinary usage (such as ornaments and figurines)
- The following that have been imported clearly not for the purpose of marketing, or use in business in Japan

For personal use: Limited to such cases where an importer him/herself uses the

apparatuses for home use or where the apparatuses are sent from overseas as a gift or a tourist brings the apparatuses into Japan as

a souvenir or for home use

For experiment and research: Limited to the case where the apparatuses are used for experiment

or research in a testing room or laboratory

For in-house discussions: Limited to the case where the apparatuses are imported for

in-house discussions

For display: Limited to the case where the apparatuses are used solely for

display

(Note) When intending to allow many and unspecified persons to use the apparatuses or to distribute the apparatuses to many and unspecified persons in exhibitions or on other occasions, notification is required in advance

"Written confirmation" to be submitted at the request of customs, etc. in the case where import notification is not required

When an importer makes an import declaration at customs with regard to apparatuses for which import notification is not required, he/she may sometimes be asked to submit a written confirmation that proves that the cargo does not fall under the category that requires import notification under the Food Sanitation Act. The importer must submit two copies of written confirmation (designated form) to the quarantine station to obtain confirmation to the effect that the cargo does not fall under the category that requires import notification.

When the quarantine station finds that notification is not required for the cargo, it affixes a confirmation seal on the written confirmation and returns one of the two copies to the importer. The importer shall submit this to customs.

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

An importer must prepare a written import notification in the designated form and submit it to the quarantine station having jurisdiction over the place of customs clearance of the cargo, together with documents, etc. that show the quality of materials, configuration, and color of the goods, immediately after the arrival of the cargo. (Note)

Due to the need to ensure the effectiveness of disposal orders, etc., an importer who is a non-resident or an Attorney for the Customs Procedures (as defined in Article 95 of the Customs Act: a person who files export and import declarations, witnesses inspections, pays customs duties, etc. on behalf of a person who does not reside in Japan) without an address or residence in Japan may not submit import notifications.

(Note) A notification shall be made after the arrival of the cargo, in principle, but there is the Advance Notification System that allows a person to make a notification in advance, from seven days prior to the planned arrival date. In this case, with regard to cargo that does not require inspection, a certificate of notification is issued promptly before the cargo arrives or after it is carried in. However, if there is any change in the content of the notification after the arrival of the cargo, the importer must report to that effect to the quarantine station to which the importer had made an advance notification.

Documents necessary for notification

Notification Form for Importation of Foods, etc.
Information on how to obtain and complete a notification form is available at websites related to
imported foods of the Ministry of Health, Labour and Welfare or each quarantine station.
MHLW's website: https://www.mhlw.go.jp/content/11130500/000645409.pdf (Japanese)
Documents prepared by a manufacturer (on the manufacturer's letterhead, signed or stamped)
with which the following can be confirmed, of the goods:
· Item name (name and code, etc. of the goods)
· Name and address of the manufacturer, and name and address of the manufacturing factory
· Documents with which the quality of materials (parts that come into contact with food, in
particular), configuration and color pattern can be confirmed.
· Specific usage, product explanatory leaflet
· In the case of components or combination products, a list of components and drawings, such as
a developed figure showing the correlation with the completed product
Product color photographs, catalogs, etc.
Records of self-inspections conducted previously, as needed

Notification methods

Notification may be made by any of the following methods.

- · Request a customs broker^(Note) to submit documents by proxy (necessary documents prepared by the importer)
- · Bring in documents to the counter of the quarantine station
- · Send documents by post
- · Submit documents online by using the Food Automated Import Notification and Inspection Network System (FAINS)

(In this case, you need to register your terminal equipment, etc. with the Ministry of Health, Labour and Welfare in advance.)

- (Note) A customs broker refers to a person who engages in the custom-house business by obtaining permission of the customs director. A customs broker undertakes affairs concerning import declaration (tax filing), etc. in place of an 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/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/yunyu_kanshi/kanshi/index_00004. html
Prior consultation: Offices of Imported Food Consultation ⇒ See p.9

■ Reference information: MHLW Website, "Imported Food Safety" https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/yunyu_kanshi/index_00017.html

(1)Notification Receipt	Nan	ne and address of importer	(Or na	ame o	of imp	orting	corpora	ition ar	nd its addre
Number		(2)Name Address							
(3)Classification of Notification	Prior Notification / General Notification / Planned Import	(Telephone Number)							
(4)Code of Importer		(6)Registration Number							
(5)Name and Code of Country of Production		of Importer Responsible for Food Sanitation							
(7)Name, Address and Code of Manufacturer									
(8)Name, Address and Code of Manufacturing Factory									
(9)Name, Address and Code of Shipper									
(10)Name, Address and Code of Packer									
(11)Name and Code of Port of Loading		(12)Date of Loading		(1	Month)	(Da	y)	(Year)
(13)Name and Code of Port of Discharge		(14)Date of Arrival		(1	Month)	(Da	y)	(Year)
(15)Name and Code of		(16)Date of Storage		(1	Month)	(Da	y)	(Year)
Warehouse		(19)Date of Notification (20)Accident		(1	Month)	(Da	y)	(Year)
(17)Marks and Numbers of Cargo		Brief Explanation (if Yes)	Yes	1	No				
(18)Ship Name or Flight Number of Aircraft		(21)Name and Code of Submitter							
(00)01:	Food / Food Additive / (22) Continuous First /	(20)0	-	_	Т	1 1		<u> </u>	
1 (22)Classification of Cargo	Apparatus / Container-Package/ Toy Import Continue/ Update	(33)Sanitary Certificate Number							
(24)Item Code		(34)If the cargo includes processed food, describe its ingredients							
(25)Description of Article		and their codes. If the cargo includes							
(26)Shipped Volume (Number of Units)		apparatuses, container/packages or							
(27)Shipped Volume (Weight)	kg	toys, describe the raw materials and their codes.							
(28)Usage and its Code		(35)If the cargo includes food with additives,	*2						
(29)Kind of Package and its Code		describe the names and codes of additives. If the cargo includes	*2						
(30)Registration Number 1		manufacturing agents in the additives, describe							
(31)Registration Number 2		the names and codes of additives.							
(32)Registration Number 3		(Additives used as flavoring agents are excluded for either case.)							
(36)If the cargo includes processed food.									
describe the method of manufacturing or processing, and its code.	<u>L</u>				St	amp fo	r Recei	ving N	otification

(Source: MHLW Website)

■ Import consultation service offices at quarantine stations, MHLW (13 locations nationwide as below; ②: 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	_

FAQ

Q Is import notification required even in the case of importing goods 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.

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 to human bodies and is not required to make a notification.

It is not allowed to use any apparatus in business that a person has imported without making a notification, such as selling such apparatus to others or using such apparatus at a restaurant, etc. that he/she operates.

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

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 products that his/her company imports (see "Responsibility of importers" on p. 17).

Q Is import notification required when importing antique tableware?

A When a person imports antique tableware for the purpose of using such tableware in a manner that it comes into direct contact with food, import notification is required. Even in the case where such tableware is one of a kind, it is necessary to confirm that the tableware conforms to the standards and criteria under the Food Sanitation Act in every way.

Notification is not required for decorative plates solely for ornamental use, which look like tableware but have a ribbon or other ornament and are not practically used. However, when an importer makes an import declaration at customs, he/she may sometimes be asked to submit a written confirmation that proves that the cargo does not fall under the category that requires import notification under the Food Sanitation Act (see p. 6).

5 Standards and Criteria for Apparatuses and Inspections

The quarantine station checks the details of the notifications and examines whether the apparatus contains any toxic or harmful substances and whether the apparatus conforms to the standards and criteria under the Food Sanitation Act.

When the quarantine station finds it necessary to conduct 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 the Act, it is shipped back or disposed of and the importer must bear the expenses therefor.

Inspections directed by the quarantine station

Ordered inspection	An inspection that the quarantine station orders to 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 the Law, such as those found to violate the 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,

Implementation of self-inspections

This is also called instructed inspection because it is an inspection in which the quarantine office instructs importers.

Initial inspection upon their first import is mandatory for apparatuses, containers and packaging whose conformity to the standards and criteria under the Food Sanitation Act needs to be confirmed. Inspection expenses are borne by importers.

There are three ways to conduct inspections: Inspections 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 his/her discretion from among the registered conformity assessment bodies listed on the website of the Ministry of Health, Labour and Welfare. Check the websites of each registered conformity assessment body to confirm which matters to be inspected can be performed.

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 for expenses and the number of days required for inspection.

■ Reference information: MHLW Website, "List of Registered Conformity Assessment Bodies" https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/jigyousya/kikan/index.html(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. Matters that may change during transport (bacteria, mycotoxins, etc.) cannot be inspected using advance samples; therefore, this is a more effective method for apparatuses than for food.

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

Conduct preliminary survey Survey of cargo to be imported = Raw materials (quality of material), manufacturing method, etc. (2) Setting matters to be inspected **Importer** *Please use Quarantine Station Consultation Room. Confirmation of number of inspection samples *Consult with registered conformity assessment body Deliver inspection samples and related documents Attachment of invoice and B/L (2) Enclosure of sample information documents · Product name, product code, JAN code, manufacturer name, catalog, photograph, Manufacturer · 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 conformity Conduct inspection Issuance of report of inspection results assessment body Submit written notification for importation of foods, etc. and attach report of **Importer** inspection results

(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. In this case, matters that may change during transport (bacteria, mycotoxins, etc.) cannot be exempted at the time of importing a cargo; therefore, this is a more effective method for apparatuses than for food.

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

- 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.
- · 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.)

Quality of materials, color and pattern, etc. (limited to apparatuses, containers, packaging, and toys)

Depth, capacity, and type of cooking apparatus (limited to apparatuses and containers/packaging made of glass, porcelain or enamel)

Color photos (limited to apparatuses, containers, packaging, and toys)

(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, "List of Foreign Official Laboratories" https://www.mhlw.go.jp/english/topics/importedfoods/1-10.html

Standards and criteria for apparatuses, containers and packaging

Standards and criteria for apparatuses are defined in Section 3 of the Standards and Criteria for Food and Food Additives, etc. (Public Notice No. 370).

Section 3 Apparatuses, Containers and Packaging

- A. Standards for apparatuses or containers/packaging, or their raw materials in general
- D. Standards for apparatuses or containers/packaging, or their raw materials by quality
 - 1. Apparatuses or containers/packaging made of glass, porcelain or enamel
 - 2. Apparatuses or containers/packaging made of synthetic resin
 - 3. Apparatuses or containers/packaging made of rubber
- E. Standards for apparatuses or containers/packaging by usage
 - 3. Apparatuses used for manufacturing ice confectionery
 - 4. Vending machines for food (limited to such machines that have a structure wherein components come into direct contact with food) and apparatuses used for selling food by using such vending machines
- F. Criteria for manufacturing for apparatuses or containers/packaging

(Notes)

• The above are titles relating to apparatuses extracted from Public Notice No. 370. The text of the public notice is available on the MHLW Website.

https://www.mhlw.go.jp/content/000757879.pdf (Japanese)

https://www.mhlw.go.jp/english/topics/foodsafety/containers/dl/04.pdf (English)

In Article 4, paragraph (5) of the Food Sanitation Act, the term "containers and packaging" is defined as "articles which contain or wrap food or additives and are offered 'as is' when delivering food or additives." Specifically, the term refers to bottles, cans, boxes, bags, wrapping paper, plastic wrap, plastic trays, etc. that contain or wrap food. Standards and criteria similar to those for apparatuses are established for containers and packaging so as to prevent the occurrence of leakage of any toxic or harmful substances that involves a risk to human health.

Standards for raw materials in general (i), standards for raw materials by quality (ii) and criteria for manufacturing (iii) are outlined below.

(i) Standards for raw materials in general

Standards are established for each of the raw materials of apparatuses, such as metal and used paper.

		erials of apparatuses, such as metal and used paper.
Raw material	Type	Standards
Metal	Apparatuses	Do not have a structure that involves a risk that copper, lead or alloys thereof might be scraped off
	Tin for plating used for parts that come into contact with food	Lead: 0.1% or less
	Metal used for manufacturing or repairing parts of the apparatuses or containers/packaging that come into contact with food	Lead: 0.1% or less Antimony: Less than 5%
	Solder used for manufacturing or repairing parts of the apparatuses or containers/packaging that come into contact with food	Lead: 0.2% or less
	Electrodes of apparatuses with a device to directly pass current through food	Limited to iron, aluminum, platinum or titanium (however, when the current through food is minute, stainless steel may be used)
Raw materials in general	Apparatuses or containers/packaging	Coloring: For chemically-synthesized compounds, those listed in Appended Table 1 of the Ordinance for Enforcement of the Food Sanitation Act (excluding cases where there is no risk that coloring might flow out or transude into food)
Paper (including paper board) (revised on March 12, 2013)	Apparatuses or containers/packaging used for usages wherein water or oil in the paper increases significantly or for usages with lengthy heating	Used paper must not be used as raw materials (excluding cases where used paper is processed so that toxic substances in the paper might not flow out or transude into food).
Synthetic resin (quality of raw materials specified in Article 1 of the Order for Enforcement of the Food Sanitation Act) (revised on April 28, 2020)	Apparatuses or containers/packaging ⇒ See p.20	Appended Table 1 shows the permitted contained amount in apparatus, containers and packaging manufactured using said raw materials, or the amount (content) permitted to flow out or transude into food from apparatuses, containers or packaging. However, this excludes cases where it is used as coloring. (The rest is omitted.)

(ii) Standards for raw materials by quality

With regard to apparatuses and containers/packaging made of glass, porcelain or enamel, the permissible amount of cadmium and lead is defined for elution tests.

[Apparatuses and containers/packaging made of glass]

		Type			Elution test						
	Туре		Tested item	Conditions	Solution	Standards					
	Cool	king apparatus	Cadmium			$0.05 \mu \mathrm{g/ml}$ or less					
Tho	000	King apparatus	Lead			0.5μg/ml or less					
Those whose more when		Capacity: Less than 600ml	Cadmium			0.5μg/ml or less					
	0	0	0	0	Capacity. Less than outfill	Lead			1.5µg/ml or less		
depth is 2.5cm or filled with liquid	Other ap		Cadmium	At normal temperature (dark place), for 24 hours	4% acetic acid	$0.25 \mu \mathrm{g/ml}$ or less					
2.5cm h liquid	apparatus		Lead			0.75μg/ml or less					
d Or	S	S	S	ั้ง	S	S	তি Capacity: 3L or more	Cadmium			0.25 µg/ml or less
		Capacity: 3L or more	Lead			0.5μg/ml or less					
	Those that cannot be filled with liquid or whose depth is less than 2.5cm when filled with liquid		Cadmium			0.7μg/cm ² or less					
			Lead			8μg/cm² or less					

[Apparatuses and containers/packaging made of porcelain]

		Type			Elution test							
	туре		Tested item	Conditions	Solution	Standards						
	Cool	king apparatus	Cadmium			0.05 µg/ml or less						
Tho	000	Kirig apparatus	Lead			0.5μg/ml or less						
Those whose more when		Capacity: Loca than 1 11	Cadmium			0.5μg/ml or less						
	0	0	0	Capacity: Less than 1.1L	Lead			2μg/ml or less				
depth is 2.5cm or filled with liquid	ther ap	Capacity: 1.1L or more but less than 3L	Cadmium	At normal temperature (dark place), for 24 hours	4% acetic acid	$0.25 \mu \mathrm{g/ml}$ or less						
2.5cm h liquic	paratu		Lead			1μg/ml or less						
_ Q	S	S	S	S	ß	S	S	ত Capacity: 3L or more	Cadmium			$0.25 \mu \mathrm{g/ml}$ or less
		Capacity: 3L or more	Lead			0.5 µg/ml or less						
	Those that cannot be filled with liquid or whose depth is less than 2.5cm when filled with liquid		Cadmium			0.7μg/cm ² or less						
			Lead			8μg/cm²or less						

(Note) Cooking apparatus refers to an apparatus mainly used for cooking with direct heat, oven, microwave, etc. An apparatus that is not for cooking but for merely warming cold food is not considered to fall under the category of cooking apparatus and is treated as such, even if it carries a "microwave safe" label.

[Apparatuses and containers/packaging made of enamel]

Type -			i i	Elution test		
		Tested item	Conditions	Solution	Standards	
Those that	Cooking apparatus		Cadmium			$0.5 \mu \mathrm{g/cm^2}$ or less
cannot be filled with liquid or whose depth is			Lead			1μg/cm² or less
less than 2.5cm when filled with	Oth	er	Cadmium			$0.7 \mu \mathrm{g/cm^2}$ or less
liquid	apparatus		Lead	At normal temperature	4% acetic	8μg/cm² or less
	Capacity:		Cadmium			$0.5 \mu \mathrm{g/cm^2}$ or less
	3L o	r more	Lead	(dark place), for 24 hours	acid	1μg/cm² or less
Those whose depth is 2.5cm or	epth is 2.5cm or ore when filled the liquid		Cadmium			$0.07 \mu \mathrm{g/ml}$ or less
more when filled with liquid					$0.4 \mu \mathrm{g/ml}$ or less	
	Less than	Other	Cadmium			$0.07 \mu \mathrm{g/ml}$ or less
	an 3L	apparatus	Lead			$0.8 \mu \mathrm{g/ml}$ or less

[Apparatuses or containers/packaging made of synthetic resin]

As the general standards, the permissible amount of cadmium and lead for material tests and that of heavy metal and consumption of potassium permanganate ($KMnO_4$) for elution tests are defined. Furthermore, standards are defined respectively for 13 types of resin.

		Elution test				
Type	Material test	Tested item	Conditions	Solution	Standards	
Synthetic resin in general	●Cadmium:100 µg/g or	Heavy metal	At 60°C, for 30 minutes*1	4% acetic acid	$1\mu \mathrm{g/ml}$ or less	
(general standards)	less ●Lead:100 µg/g or less	Lead: $100 \mu \mathrm{g/g}$ or less Consumption of KMnO ₄ * 2 30 minutes 3		Water	10μg/ml or less	
		Phenol	At 60°C, for 30 minutes*1	Water	5μg/ml	
		Formaldehyde	30 minutes*1	vvatei	Negative	
Phenol resin, melamine resin			At 25°C, for one hour	Heptane*3		
or urea resin		Evaporation residue	At 60°C, for 30 minutes	20% ethanol* ⁴	30 µg/ml	
			At 60°C, for	Water*5		
			30 minutes *1	4% acetic acid*6		
		Formaldehyde	At 60°C, for 30 minutes*1	Water	Negative	
Those using		Evaporation residue	At 25°C, for one hour	Heptane*3		
formaldehyde as raw materials			At 60°C, for 30 minutes	20% ethanol* ⁴	30 <i>μ</i> g/ml	
			At 60°C, for	Water*5		
			30 minutes *1	4% acetic acid*6		
	●Dibutyltin compounds:50 µg/g		At 25°C, for one hour	Heptane*3	150 µg/ml or less	
Polyvinyl chloride	or less (in the form of dibutyltin dichloride)	Evaporation	At 60°C, for 30 minutes	20% ethanol* ⁴		
(PVC)	Ocresol phosphoric acid ester: Img/g or less	residue	At 60°C, for	Water*5	30 µg/ml or less	
	●Vinyl chloride: 1 µg/g or less		At 60°C, for 30 minutes*1	4% acetic acid*6		

Typo	Motorial toot	Elution test			
Type	Material test	Tested item	Conditions	Solution	Standards
Polyethylene (PE) and		E	At 25°C, for one hour	Heptane*3	30 µg/ml or less (for specimens used at 100°C or lower temperature, 150 µg/ml or less)
polypropylene (PP)		Evaporation residue	At 60°C, for 30 minutes	20% ethanol* ⁴	
			At 60℃, fọr	Water*5	30μg/ml or less
			30 minutes*1	4% acetic acid*6	
	 Volatile substance (total of styrene, toluene, ethyl benzene, isopropyl 		At 25°C, for one hour	Heptane*3	240 μg/ml or less
Polystyrene(PS)	benzene and propyl benzene): 5mg/g or less; expanded	Evaporation	At 60°C, for 30 minutes	20% ethanol* ⁴	
	polystyrene (limited to those using boiling water): 2mg/g or less; styrene and	residue	At 60°C, for	Water*5	30μg/ml or less
	ethyl benzene: 1mg/g or less, respectively	30 minu	30 minutes*1	4% acetic acid*6	
	●Barium: 100 µg/g or less ●Vinylidene chloride: 6 µg/g or less	Evaporation residue	At 25°C, for one hour	Heptane*3	30μg/ml or less
Polyvinylidene chloride (PVDC)			At 60°C, for 30 minutes	20% ethanol* ⁴	
Cilionae (FVDC)			At 60℃, for	Water*5	
			At 60°C, for 30 minutes*1	4% acetic acid*6	
		Antimony	At 60°C, for 30 minutes*1	4% acetic acid	$0.05 \mu \text{g/ml}$ or less
		Germanium Evaporation residue	At 25°C, for		0.1μg/ml or less
Polyethylene terephthalate			one hour At 60°C, for	Heptane*3	30μg/ml or less
(PET)			30 minutes eth	ethanol*4	
			At 60°C, for	Water*5 4% acetic	
			30 minutes*1	acid*6	
		Methyl methacrylate	At 60°C, for 30 minutes	20% ethanol	15μg/ml or less
Polymethylmethacrylate			At 25°C, for one hour	Heptane*3	30μg/ml or less
(PMMA)		Evaporation residue	At 60°C, for 30 minutes	20% ethanol* ⁴	
		1 - 3 - 3 - 3 - 3 - 3 - 3 - 3 - 3 - 3 -	At 60°C, for 30 minutes*1	Water*5	-
				4% acetic acid*6	
		Caprolactam	At 60°C, for 30 minutes	20% ethanol	15μg/ml or less
Nylon (PA)		Evaporation residue	At 25°C, for one hour	Heptane*3	
			At 60°C, for 30 minutes At 60°C, for	20% ethanol* ⁴	30μg/ml or less
				Water*5	
			30 minutes*1	4% acetic acid ^{*6}	

Typo	Material test		Elut	ion test	
Type	iviateriai test	Tested item	Conditions	Solution	Standards
			At 25°C, for one hour	Heptane*3	$120\mu\mathrm{g/ml}$ or less
Polymethylpentene (PMP)		Evaporation residue	At 60°C, for 30 minutes	20% ethanol* ⁴	00
			At 60°C, for	Water*5	30μg/ml or less
			30 minutes*1	4% acetic acid*6	
		Bisphenol-A	At 25°C, for one hour	Heptane*3	
	Bisphenol-A (containing phenol	(containing phenol and	At 60°C, for 30 minutes	20% ethanol* ⁴	2.5µg/ml or less
	and p-t-butylphenol): $500 \mu g/g$ or less	p-t-butylphenol)	At 60°C, for	Water*5	
Polycarbonate	Diphenyl carbonate:		30 minutes*1	4% acetic acid*6	
(PC)	500 µg/g or less ●Amines (triethylamine and		At 25°C, for one hour	Heptane*3	
	tributylamine): 1 µg/g or less	Evaporation residue	At 60°C, for 30 minutes	20% ethanol* ⁴	30μg/ml or less
	,, 5 5 5 5 5 5		At 60°C , for	Water*5	
			30 minutes*1	4% acetic acid*6	
		Evaporation residue	At 25°C, for one hour	Heptane*3	30μg/ml or less
Polyvinyl alcohol (PVA)			At 60°C, for 30 minutes	20% ethanol* ⁴	
			At 60°C, for	Water*5	
			30 minutes*1	4% acetic acid*6	
		Total lactic acid	At 60°C, for 30 minutes*1	Water	30μg/ml or less
Polylactic acid		Evaporation residue	At 25°C, for one hour	Heptane*3	30μg/ml or less
(PLA)			At 60°C, for 30 minutes	20% ethanol* ⁴	
			At 60℃, for	Water*5	
			30 minutes*1	4% acetic acid*6	
		Germanium	At 60°C, for 30 minutes*1	4% acetic acid	$0.1 \mu \mathrm{g/ml}$ or less
Polyethylene naphthalate (PEN)		Evaporation residue	At 25°C, for one hour	Heptane*3	
			At 60°C, for 30 minutes	20% ethanol* ⁴	$30 \mu \mathrm{g/ml}$ or less
			At 60°C, for 30 minutes*1	Water*5	
				4% acetic acid*6	

Responsibility of importers

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 apparatuses, etc., and for that purpose, he/she shall endeavor to

(i) obtain knowledge and technologies concerning food sanitation, (ii) ensure the safety of raw materials to be used, (iii) conduct self-inspections, and (iv) take other necessary measures.

An importer must confirm by him/herself the safety of the apparatuses he/she imports, including that such apparatuses conform to the Food Sanitation Act.

An importer is also required to endeavor to preserve records, such as written import notifications, customs releases and ledgers for receipt and delivery of goods, and to take necessary measures properly and promptly in the event of any hazard, such as offering the relevant records to the national government and prefectural governments, etc.

[Apparatuses or containers/packaging made of rubber]

The permissible amount of cadmium and lead for material tests and that of phenol, formaldehyde, zinc, heavy metal, and evaporation residue for elution tests are defined.

Type	Motorial toot		Elut	ion test	
Type	Material test	Tested item	Conditions	Solution	Standards
		Phenol		Water	5μg/ml or less
		Formaldehyde			Negative
Apparatuses or	●Cadmium:100µg/g	Zinc		4% acetic acid	$15\mu g/ml$ or less
containers/ packaging made	or less ●Lead:100 µg/g or less ●2-Mercaptoimidazoline (limited to those containing chlorine): Negative	Heavy metal	At 60° C, for 30 minutes^{*1}		$1 \mu g/ml$ or less (in the form of lead)
of rubber (excluding baby		Evaporation residue	At 60°C, for 30 minutes	Water*5,*7	60μg/ml or less
bottles)				4% acetic acid*6	
		rodiado		20% ethanol* ^{3,*4}	
	●Cadmium:10µg/g or less ●Lead:10µg/g or less	Phenol	At 40°C , for 24 hours	Water	$5\mu \text{g/ml}$ or less
		Formaldehyde			Negative
Parts of baby		Zinc			$1\mu g/ml$ or less
bottles made of rubber		Heavy metal		4% acetic acid	$1 \mu g/ml$ or less (in the form of lead)
		Evaporation residue		Water	40μg/ml or less

- *1 When the temperature at which the relevant apparatus, etc. is used is over 100°C, at 95°C for 30 minutes
- *2 Excluding phenol resin, melamine resin and urea resin
- *3 Applicable to fat and fatty substances
- *4 Applicable to liquor
- *5 Applicable to food whose pH exceeds 5
- *6 Applicable to food whose pH is 5 or less
- *7 Applicable to apparatuses

(iii) Criteria for manufacturing apparatuses and containers/packaging

Type	Criteria
Apparatuses and containers/packaging made of copper or copper alloy	Limited to those for which the whole parts that come into contact with food are tinned, silver-plated or otherwise treated so as to prevent food sanitation hazards (excluding those that have unique luster and are not rusty)
Apparatuses and containers/packaging in general	Coloring: When using chemically-synthesized compounds, those listed in Appended Table 1 of the Ordinance for Enforcement of the Food Sanitation Act (excluding cases where such coloring is used by being blended with glaze, glass or enamel or in another way that poses no risk of being mixed with food)
Containers/packaging for ice confectionery made of paper, wood shavings or metal foil	Limited to those sterilized after being manufactured
Apparatuses and containers/packaging in general	Spine of specific cattle must not be used. However, this does not apply when any of the following is used as a raw material. (1) Fat derived from the spine of specific cattle, which has been hydrolyzed, saponified or transesterified under high temperature and high pressure (2) Spine manufactured from specific cattle aged 30 months or less, which has been degreased, decalcified with acid, treated with acid or alkali, filtered, and heat sterilized at 138°C or more for four seconds or more, or has received treatment equivalent or superior to such treatment to reduce infectivity.

FAQ

- We are going to import porcelain coffee cups. What standards and criteria for apparatuses are applicable?
- A) As lead (Pb) and cadmium (Cd), which are used for glazing or painting porcelain tableware, may harm human health when ingested in large amounts, their elution is regulated.

Apparatuses and containers/packaging made of porcelain are classified into two by depth and those with a certain depth are further categorized into those for cooking and those for other purposes. Those for other purposes are classified into three by capacity.

Porcelain coffee cups fall under the categories of "those whose depth is 2. 5cm or more when filled with liquid," "other apparatus," and those with capacity of "less than 1. 1L." Therefore, they need to conform to the standards that contained cadmium and lead are 0. 5μ g/ml or less and 2μ g/ml or less, respectively. Basically, parts that come into direct contact with food (the inside of the tableware) are subject to the regulations, and the elution of cadmium and lead from the outside, which does not come into contact with food, is not regulated.

Even if tableware is made of the same materials and falls under the same category, when parts that come into contact with food are different in color, inspections are required separately for each color

For details, please make inquiries at the quarantine station or registered conformity assessment body after preparing materials with which the quality of materials, configuration and color of the apparatuses can be confirmed.

- When we import the same goods repeatedly, do we need to submit inspection records every time?
- A You can utilize the System of Continuous Import of Same Items.

When you repeatedly import the same apparatuses or containers/packaging (the manufacturing factory, quality of materials, color and manufacturing method are the same), you may submit a copy of the initial written import notification and a copy of the inspection records, and then, inspections upon import are to be exempted indefinitely for the items stated in said inspection records. However, where inspection methods or standard values, etc. have been altered due to legal changes, you need to undergo self-inspections anew.

- When we import tableware and cooking utensils, etc., what are the most common violations?
- A) When importing tableware and cooking utensils, most violations are due to non-conformity with the standards by material.

Specific content, including the name of products in actual violation, the name of manufacturers, the country of origin, non-conforming content, the name of the importer, and the status of measures, etc. are posted on the website of the Ministry of Health, Labour and Welfare.

Cases of violation of apparatus at the time of import (partial excerpt from 2016)

Product name	Country of origin	Details of nonconformity	Cause
Gold-plated brass apparatus	Italy	Non-compliance with standards by material (Lead 1.8% detected)	
Tableware (made of porcelain): Dish	Vietnam	Non-compliance with standards by material (Lead 14 μ g/ml detected)	Insufficient prior confirmation
Other apparatus (made of enamel): Cocotte oval lid	France	Non-compliance with standards by material (Cadmium $0.6\mu\mathrm{g/cm^2}$ detected)	
Tableware (made of melamine resin): Mug	China	Non-compliance with standards by material (Evaporation residue (4% acetic acid) 45 μ g/ml detected)	Insufficient control of molding process
Other apparatus (made of polyethylene): Freezer bag	China	Non-compliance with standards by material (Lead 430 $\mu\mathrm{g/g}$ detected)	Insufficient control of colorant use
Tableware (made of polypropylene): Spoon	Vietnam	Non-compliance with standards by material (Cadmium 110 μ g/g detected)	Detection due to colorant
Kitchen utensils (made of nylon): Scraper	France	Non-compliance with standards by material (Caprolactam 17 μ g/ml detected)	Insufficient recognition of the Food Sanitation Act
Other apparatus (made of rubber): Food gloves	Malaysia	Non-compliance with standards by material (Zink nonconformity)	Insufficient surface washing

6 Positive List System and Information Sharing for Apparatuses Made of Synthetic Resin

Use of all substances was allowed, in principle, for apparatuses, containers and packaging in Japan under the negative list system, which restricts the use of substances specified by the government. However, it was impossible to immediately regulate the use of substances that were banned in other countries without setting standards and criteria.

Therefore, the positive list system was introduced to allow the use of only substances that have been assessed for safety in apparatuses, containers and packaging, and came into effect for synthetic resin apparatuses, containers and packaging on June 1, 2020.

Materials other than synthetic resins will also be covered by the positive list system and be added in the future.

The existing negative list system will continue to operate, which means that synthetic resins will be subject to both the regulations of the negative list system and the positive list system.

Positive list system (Newly established by Article 18, Paragraph 3 of the Food Sanitation Act \Rightarrow See p. 4)

The positive list system, in principle, has regulations that prohibit the use of all substances, stipulate which substances are permitted to be used, and allow the use of only substances guaranteed to be safe.

In addition to the United States, the European Union, China and others introducing this system, Asian countries such as South Korea and Thailand are also considering its introduction.

Scope of application (Article 1 of the Order for Enforcement of the Food Sanitation Act, Enforcement Notice: Environmental Health and Food Safety No. 1107-1)

- OThis system applies to synthetic resin. Excludes rubber (elastic material without thermoplasticity).
- OThis system also applies to synthetic resin that has formed on the food contact surface with other materials.

Examples: Milk cartons with synthetic resin sheets, metal cans with synthetic resin coating

Classification of synthetic resins (Outline)

	Thermoplastic	Non-thermoplastic	
Plastic	Thermoplastic resin Ex.) Polyethylene, Polystyrene	Thermosetting resin Ex.) Melamine resin, Phenol resin	
Elastomer	Thermoplastic elastomer Ex.) Polystyrene elastomer, Styrene block copolymer	Rubber (thermosetting elastomer) Ex.) Butadiene rubber, Nitrile rubber	

(Source) MHLW

Substances controlled under the positive list system (Public Notice No. 370, Paragraph 3-A: Raw Materials General Standard 8)

- OSubstances subject to the positive list system are listed in "Table 1: Base Polymers" and "Table 2: Additives and Coating Materials" in Appended Table 1 of the "Standards and Criteria for Food and Additives, etc." (Public Notice of the Ministry of Health, Labour and Welfare No. 370, promulgated on April 28, 2020).
- OBase polymers and additives are substances used with the intention of remaining in the final product.
- OSubstances that are not intended to remain in the final product are controlled using the existing negative list system.

Examples: Catalysts and polymerization aids used in monomer polymerization reactions, raw materials for base polymers

What is synthetic resin?

Synthetic resin: Polymer obtained through the polymerization (repeated bonding) of monomers with added additives. **Monomer**: Low molecular weight compound, such as ethylene or propylene, that is the smallest unit to constitute a polymer. **Polymer**: High molecular weight compound made by polymerizing thousands to hundreds of thousands of monomers. **Base polymer**: Polymer that forms the basic structure of a synthetic resin.

Additive: Chemical substance added to polymers to impart physical or chemical strength, properties, or functions to the synthetic resin.

(Source) Prepared from Food Safety Commission of Japan and Ministry of Health, Labour and Welfare documents

Positive list regulations and key points to confirm conformity

- O"Table 1: Base Polymers" consists of three lists: (1) base polymers (plastics), (2) base polymers (coating resins), and (3) monomers that can be polymerized in only trace amounts to base polymers (minor monomers).
- OThe usable food and maximum usable temperature are specified for the base polymers in Table 1 (1) and (2).
 - Confirmation points \Rightarrow (i) Is the product's synthetic resin in the list of base polymers?
 - (ii) Are the product's usage conditions within the scope of the usable food and maximum usable temperature?
- OWhen using minor monomers in Table 1 (3) as components, the base polymer must comprise more than 98% of components.
- OBase polymers are classified into seven categories based on their characteristics (physicochemical properties) and actual use, and the usage limits (percentage by total weight of synthetic resin, including base polymers and additives) in "Table 2: Additives, etc." are specified by category.
 - Confirmation points \Rightarrow (i) Is the synthetic resin additive listed in Table 2?
 - (ii) Can the additive be used for the base polymer resin category? Is it within the usage limit?

Two responses required of importers

- (1) Confirmation that the product is manufactured using raw materials conforming with the positive list system, and explanation during import clearance
- · Obtain information from the exporter (manufacturer of apparatuses, containers and packaging, and raw material manufacturers) on the composition, ingredients, content (%), and usage conditions, etc. of the synthetic resins, and check them against the positive list to <u>confirm conformity</u>. In this case, rather than the disclosure of the type and amount of individual substances in the synthetic resin, the confirmation of information that can show conformance to the list is requested.
- For checking against the list, it is convenient to provide the exporter with the Appended Table 1, Table 1 Reference List and the Appended Table 1, Table 2 Reference List, both of which are posted on the MHLW website and have the Japanese, English, and CAS for the positive list.
- · During import clearance, it is necessary to prepare information and documents that can explain to the quarantine station the conformity with the positive list system.
 - (i) Information identifying the imported product
 - (ii) Information confirming manufacture using raw materials conforming with the positive list system
 - (iii) Documents confirming the content of (i) and (ii)
- (2) Information sharing among business operators (Article 50-4 of the Food Sanitation Act, Article 66-6 of the Ordinance for Enforcement of the Food Sanitation Act)

When selling imported synthetic resin apparatuses, containers and packaging, it is now mandatory to explain the content confirmed in (1) above to the customer (business operator handling the product). There are no specific rules concerning the method of information sharing. However, it is required to have documents (specifications at contracting, quality assurance certificate at receipt, confirmation certificate from industry group, documents verifying conformity, etc.) that can be confirmed later by recording and storing information at the business operator.

■ Reference information: MHLW Website,

"The Positive List System for Food Utensils, Containers, and Packaging" https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/kigu/index_00003.html

7 Customs Clearance Procedures

An importer of cargoes shall make an import (tax) declaration at the competent customs office after discharging cargoes from abroad and carrying them into a bonded area. (Note) The customs house that received the import declaration examines documents and inspects cargoes as necessary, confirms the payment of tariffs, and permits the import of the cargoes. A series of these 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, but 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 relevant customs house by proving that he/she has obtained the required permission or approval.

In addition, it should be noted that when false or misleading representations of origin are directly indicated on imported goods themselves, or when indirectly indicated on the containers or packaging of the imported goods, customs will not permit their importation in accordance with Article 71 of the Customs Act.

■ Reference information: Japan Customs' website,

"False Labeling, etc. of Country of Origin" (Japanese)

https://www.customs.go.jp/zeikan/seido/origin/index.htm

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

Examination and confirmation under other relevant laws and ordinances

Other relevant laws and ordinances as set forth in Article 70 of the Customs Act mean 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 is included in other relevant laws and ordinances. An importer shall present a copy of the written import notification on which a seal is affixed to prove the notification (certificate of notification) and undergo examinations as to whether conditions under other relevant laws and ordinances are satisfied.

■ Reference information: Japan Customs' website,

"Outline of other relevant laws and ordinances referred to by Customs" https://www.customs.go.jp/english/c-answer_e/imtsukan/1801_e.htm

Tax declaration of tariffs, etc.

Taxes, such as tariffs and consumption taxes, are imposed on imported goods. It should be noted that even in the case of duty-free goods, consumption taxes are imposed.

The person who pays tariffs is the importer of the relevant cargoes, in principle, and is ordinarily the consignee of the invoice. In practice, a customs broker often takes customs clearance procedures by proxy and temporarily pays tariffs, etc. for the importer, and later charges the importer said expenses and fees integrally after delivering the cargoes.

■ Where to make inquiries concerning customs clearance procedures ■ Reference information: Japan Customs' website: https://www.customs.go.jp/english/

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
Narita Branch Customs	TEL:+81-476-34-2128	
Tokyo Overseas Mail Sub-branch Customs	TEL:+81-3-5665-3755	
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-koho@customs.go.jp

Customs System

When importing goods, the following taxes are basically imposed:

- · Tariff: Customs value (CIF price + Miscellaneous additions) (Note) x Tariff rate
- Consumption tax: (Taxable price + Tariff) × Consumption tax rate

(Notes) · Customs value: Standard value used to calculate the amount of customs duties

· Miscellaneous additions: Expenses relating to transport to the port of import, license fees, expenses for members offered for free, etc.

Tariff rates

Tariff rates are determined for each item categorized under the Customs Tariff Act. Tariff rates include the general tariff rates, temporary tariff rates (tariff rates determined by amending the general tariff rates depending on domestic and overseas economic conditions), preferential tariff rates (tariff rates applied to goods imported from developing countries), WTO bound rates (tariff rates determined by the WTO), or EPA tariff rates (tariff rates determined among EPA member countries). Basically, the lowest among the tariff rates applying to said importing country is applied. However, the rules of the country of origin must be satisfied in order to apply the preferential tariff rates and EPA tariff rates. Japan's Tariff Schedule is available on the Website of Japan Customs.

(https://www.customs.go.jp/english/tariff/index.htm).

If you are not sure about applicable tariff rates, you can utilize the Advance Classification Ruling System of Japan Customs and make an inquiry about tariff classification.

Additionally, simplified tariff 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 tariff amounts.

Tariff classification (HS classification)

The Customs Tariff Schedules of Japan are based on an international convention commonly called the HS Convention, which is an itemized list for systematically classifying various goods. It uses a nine-digit code comprising a three-digit number unique to Japan and a six-digit code (HS number, HS code) used worldwide. The task of assigning the appropriate code to imported goods is called tariff classification or HS classification.

Examples of item classification (for lead stemmed glassware)

Chapter	Heading	Sub-heading	Duty subdivision/ Statistics subdivision
70	7013	7013. 22	7013. 22- 000
Glass and glassware	Glassware of a kind used for table, kitchen, toilet, office, indoor decoration or similar purposes (other than that of heading 70. 10 or 70. 18).	Stemware drinking glasses, other than of glass-ceramics : Of lead crystal	Stemware drinking glasses, other than of glass-ceramics : Of lead crystal

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 importation and receive a response from customs. Under this system, inquiries are to be 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.	Adopted for the GSP and all EPAs except for TPP11 and the Japan-EU EPA
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.).	Adopted for TPP11, the Japan- EU EPA, and the Japan- Australia EPA (also adopting the third- party certification sys- tem)
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.	Adopted for the Japan- Switzerland EPA, the Japan- Peru EPA, and the Japan- Mexico EPA (all adopting the third-party certification sys- tem)

- 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 >
- · 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.

9 Other Laws that Need to be Noted

When importing apparatuses for food, attention also needs to be paid to articles in fringing intellectual property right (infringing products, etc.).

Depending on the prefecture, it is required to notify the public health center with jurisdiction over the location of the main office when importing food, additives, apparatuses, containers and packaging as stipulated in the Food Sanitation Act (ex.: Shiga and Ibaraki prefectures).

Sale of some items may be subject to regulations concerning labeling or conformity to technical standards, etc. based on domestic laws. Furthermore, when selling goods by mail order sales or Internet sales, the Act on Specified Commercial Transactions must be observed.

Also with regard to containers and packaging of goods, indication of a reference mark is necessary for some materials under the Act on the Promotion of Effective Utilization of Resources.

1. Import restriction for articles infringing intellectual property rights

The Customs Act specifies, as cargoes that must not be imported, articles infringing any of the patent right, utility model right, design right, trademark right or copyright, and articles involved in any act of unfair competition prescribed in Article 2, paragraph $(1)(i) \sim (iii)$ of the Unfair Competition Prevention Act (act of creating confusion with another person's goods or business, act of illegally using another person's famous indication and act of imitating the configuration of another person's goods).

These articles infringing intellectual property rights include goods to which a registered trademark, etc. is attached without obtaining a license from the intellectual property right holder, goods illegally copying brand-name products, and fake character goods. These are generally called infringing products against authentic products. It is prohibited to import any infringing products and importers may be punished according to the circumstances.

Intellectual property to be noted when dealing with apparatuses for food

When importing and selling tableware, pots or pans, and cooking utensils, etc., it is necessary to check any risks of infringing intellectual property rights multilaterally, such as whether the name has not been registered as a trademark, whether the design has not been registered as a new design, or whether the function has not been registered as a utility model already in Japan.

First, it is necessary to check whether the relevant goods contain any intellectual property rights that are protected in Japan. If the goods contain any intellectual property rights protected in Japan, import of said goods without obtaining a license from the right holder falls under the category of parallel import. Then, the importer should check the requirements for parallel import that does not infringe the right for each of the relevant intellectual property rights and consider whether the goods he/she intends to import satisfy those requirements. Even if import of said goods does not fall under the category of parallel import, attention needs to be paid to the possibility of falling under an act of unfair competition under the Unfair Competition Prevention Act.

If a person imports and sells any goods infringing intellectual property rights, he/she may be subject to a demand for an injunction against import and domestic sale of the goods and be held liable for compensation of damages to the right holder. Furthermore, if criminality is found, he/she may face a criminal charge.

OBrand

When said goods are under parallel import brand, it is necessary not only to ensure that goods to be imported are authentic products but also to pay attention to whether their quality and trademark right holder are identical to those of goods already being distributed in Japan. In addition, when the said brand name, etc. is identical or similar in scope to the registered trademark of another company in Japan, it is not possible in principle to use that foreign brand in Japan.

ODesign and configuration

Design rights may have been established for some cups or other tableware, pots or pans, and cooking utensils.

If a person sells goods that completely imitate the configuration of certain goods already being sold in Japan, he/she may be subject to a demand for an injunction filed by a prior seller in Japan alleging that such sale falls under the act of imitating the configuration of another person's goods as prescribed in the Unfair Competition Prevention Act.

2. Labeling under the Household Goods Quality Labeling Act

The Household Goods Quality Labeling Act designates household goods that require quality labeling and specifies matters to be indicated for each item and matters to be complied with when labeling, with the aim of ensuring that proper information on the quality, etc. of goods is provided to consumers. When a person sells designated items to consumers, he/she must affix prescribed labeling even if they are imported items.

Specific labeling for apparatuses for food and related products is provided in the Quality Labeling Regulations for Plastic Goods, the Quality Labeling Regulations for Miscellaneous Manufactured Goods and the Quality Labeling Regulations for Electrical Appliances and Apparatuses.

Labeling should be affixed by a business operator that has a service office in Japan (any of the importer, seller or labeling contractor ^(Note)).

(Note) A labeling contractor refers to a person who has been commissioned by a manufacturer (importer) or a seller.

Items requiring quality labeling (extracted those relating to apparatuses for food)

The following apparatuses and related products are designated as items requiring quality labeling. Goods for professional use or goods not for sale are excluded, but quality labeling is necessary for goods that may be sold to general consumers.

Plastic goods

Baskets; trays; water flasks; apparatuses for meals, table apparatuses and kitchen apparatuses (refuse containers and other bins; dishpans; water flasks for refrigerators; sealed containers for drinks and containers using refrigerant, etc.; containers for which indication of capacity is not required, such as dishes, bowls, glasses, sealed containers for food, lunch boxes, colanders, chopstick stands, bread cases; cutting boards; ice making apparatuses; apparatuses for meals); polyethylene film bags or polypropylene film bags

Miscellaneous manufactured goods

Thermos bottles; apparatuses for meals, table apparatuses and kitchen apparatuses coated with lacquer or cashew nut resin paint (made of wood or synthetic resin); apparatuses for meals, table apparatuses and kitchen apparatuses made of reinforced glass; apparatuses for meals, table apparatuses and kitchen apparatuses made of borosilicate glass or glass ceramics; aluminum foil (for meals, or for table or kitchen); baby bottles; pots; kettles; water purifiers; apparatuses for meals, table apparatuses and kitchen apparatuses made of synthetic rubber (including silicone rubber)

Electrical appliances and apparatuses

Vacuum bottle rice cookers; refrigerators; electric juicers, blenders and juicer-mixers; electric pots; roasters; microwave ovens; hot plates; coffee makers

Matters to be indicated and labeling methods

Please refer to the website of the Consumer Affairs Agency for the matters to be indicated and labeling methods for each item.

Sizes of labeling or characters to be used are not specified, but labeling should be affixed in a place easily viewable for consumers. The content should be indicated in Japanese.

Inquiries:

Representation Division, Consumer Affairs Agency: TEL: +81-3-3507-8800

Product Safety Division, Industrial and Product Safety Policy Group, METI: +81-3-3501-4707

■Reference information: Website of the Consumer Affairs Agency,

"Brochure of Household Goods Quality Labeling Act"

https://www.caa.go.jp/policies/policy/representation/household_goods/pamphlet/pdf/pamphlet_03_0001.pdf

(Examples of labeling)

Synthetic rubber apparatus: kitchen containers, etc. (When not altered by terpenes or fats, designed to be cold resistant for freezers, and does not use refrigerants)

使用材料 シリコーンゴム 耐熱温度 220°C 耐冷温度 -60°C 量 3.06 取扱い上の注意 ○火のそばに置かない旨 ○電子レンジを使用する際の注意事項 ○オーブンを使用する際の注意事項 ○臭い移りに関する旨 ○変色に関する旨 〇〇××株式会社 東京都千代田区〇〇町××番地 TEL 03-9999-9999

Pot

表面加工 内面 ふっ素樹脂塗膜加工 外面 (底面を除く)焼付け塗装 材料の種類 本体 アルミニウム合金 はり底 ステンレス鋼(クロム18%)

(底の厚さ 2.3mm (はり底を含む))

寸法 23cm 満水容量 2.0L

- 取扱い上の注意 ・空だきをしない旨
 - ・使用後はよく洗って乾燥させる旨
 - ・取っ手又は握りの部分が熱くなる場合がある旨
 - ・縁まで水等を満たした状態で使用しない旨
 - ・スチールたわし、磨き粉等を使用しない旨
 - ・こげつき等を落とす際は金属製の固いものを使用しない旨
 - ・酸性又はアルカリ性のものの使用は避ける旨
 - ・天ぷら等の料理に際しては、油温を200℃以上に上昇させない旨
 - ・急激な衝撃を与えたり、空だきをした場合に水等をかけて急冷しない旨
 - ・ストーブの上で使用しない旨

○○××株式会社 東京都千代田区○○町××番地 TEL 03-9999-9999

3. Act against Unjustifiable Premiums and Misleading Representations

The Act against Unjustifiable Premiums and Misleading Representations prohibits misleading representations and provision of excessive premiums by business operators so that consumers can properly select goods and services.

There have been many cases of misleading food representation, etc. since 2013, and this has shaken the safety and confidence of consumers. In response, the Act against Unjustifiable Premiums and Misleading Representations was amended to stipulate the necessary measures to be taken by business operators, to grant prefectural governors the authority to order measures, etc., and to delegate investigation authority to the minister in charge of the business, all of which strengthens the administrative monitoring and guidance system. Furthermore, business operators should note the risks of violating the Premiums and Representations Act, due to the increased penalties with the introduction of the surcharge system in the Act against Unjustifiable Premiums and Misleading Representation.

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

ODeadline 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))

- \bigcirc 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 body, or specialized organization)
- 2. Effects and efficacy in the labeling appropriately correspond to demonstrated facts.

Outline of the Act against Unjustifiable Premiums and Misleading Representations

Purpose: Protecting the interests of general consumers



Prohibition of unjust inducement of customers

Prohibition of misleading representations

What are Representations?: An advertisement or any other representations that a business operator makes with respect to the substance of goods or services, or the trade terms

Examples: Flyers, brochures, instructions, containers (labels), posters, signboards, advertisements in newspapers or magazines, Internet advertisements and emails, TV commercials, direct mails

Prohibition of misrepresentation concerning quality

Misleading representations of the quality, standard or any other particulars relating to the content of goods or services

(1) Any representation where the content is portrayed to general consumers as being significantly superior to the actual content

- (2) Any representation where the content is portrayed to general consumers as being, contrary to fact, significantly superior to those of competing business operators
- Prohibition of misrepresentation concerning transaction conditions

Misleading representations on price or any other trade terms of goods or services (1) Any representation by which trade terms could be misunderstood by general consumers to be significantly more advantageous to the other party in a transaction than the actual goods or service

- (2) Any representation by which trade terms could be misunderstood by general consumers to be significantly more advantageous to the other party in a transaction than those of competing business operators
- Any representation by which any particulars relating to transactions of goods or services is likely to be misunderstood by general consumers and which is designated by the Prime Minister
 Misleading representations concerning place of origin, etc.

Prohibition of provision of excessive premiums

What are Premiums?: Any article, money, or other source of economic gain given to another party, in connection with a transaction involving goods or services

- Restrictions on the provision of premiums in general giveaways (maximum amount and total value)
 Restricts the provision of premiums to the users of goods and services based on chance in lotteries, etc., or superior capabilities in specific acts, etc.
- Restrictions on the provision of premiums in joint giveaways (maximum amount and total value)
 Restricts giveaways conducted jointly among industry competitors within a shopping district or a certain area
- Restrictions on the provision of premiums accompanying products (maximum amount) Restricts premiums provided to all product purchasers and store visitors

(Source) Website of the Consumer Affairs Agency

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 entity 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.

Representations in internet sales

For representations in Internet sales to consumers, it is necessary that important information concerning product content and the terms and conditions of transactions be provided appropriately to consumers, as lack of such can easily lead to misunderstanding by consumers when selecting products and making orders, resulting in increased damage to consumers.

Please refer to "Problems and Matters to Note with Regard to Representations in Business-to-Consumer E-Commerce under the Act against Unjustifiable Premiums and Misleading Representations" (March 2003) and "Problems and Matters to Note with Regard to Online Consumer Transactions under the Act against Unjustifiable Premiums and Misleading Representations" (October 2011) published by the Consumer Affairs Agency.

■ Reference information: Website of the Consumer Affairs Agency,

"Problems and Matters to Note with Regard to Representations in Business-to-Consumer E-Commerce under the Act against Unjustifiable Premiums and Misleading Representations" (Japanese)

https://www.caa.go.jp/policies/policy/representation/fair_labeling/guideline/pdf/100121premiums_38.pdf

Obligation of business operators to introduce representation management systems, etc.

In December 2014, the Act against Unjustifiable Premiums and Misleading Representations was amended to strengthen the compliance of business operators, and required business operators to establish a system to properly manage representations, etc. and take other necessary measures (Article 7). Failure to take necessary measures may result in guidance, advice, recommendations, or public announcements.

The Cabinet Office issued the "Guidelines on Measures on Provision of Premiums and Representation that Business Operators Must Take" (Cabinet Notice Ordinance No. 276) in November 2014, and business operators that provide representations for consumers are required to take necessary measures in line with these guidelines depending on their size, business type, and handled product content. Please refer to the specific examples of measures shown in the attachment.

■Inquiries: Advance consultation by business operators regarding the Act against Unjustifiable Premiums and Misleading Representations

Advisory Unit, Representation Division, Consumer Affairs Agency TEL: +81-3-3507-8800 (main) Prefectural division in charge of the Act against Unjustifiable Premiums and Misleading Representations

■ Reference information: Website of the Consumer Affairs Agency,

"Establishing Trusted Representation"

https://www.caa.go.jp/en/policy/representation/

Violations of the Act against Unjustifiable Premiums and Misleading Representations will result in cease-and-desist orders and surcharge payment orders

When there is a suspected violation of the Act against Unjustifiable Premiums and Misleading Representations, the Consumer Affairs Agency or the prefectural government will investigate by collecting relevant documents and questioning the business operator. As a result of the investigation, if the business operator is found to be in violation, after being given an opportunity to justify themselves, a cease-and-desist order will be issued, ordering the business operator to inform the general public of the violation, to take measures to prevent recurrence, and not to repeat the violation in the future. In addition, after giving the business operator an opportunity to justify themselves, a surcharge payment order imposing a monetary sanction will be issued to business operators who have committed violations that are subject to a surcharge.

Recent cases when a cease-and-desist order was issued for food apparatuses include "misrepresentation regarding the number of pot-type water purifier cartridges" (2018), "misrepresentation regarding the surface treatment processing of frying pans" (2016), and "misrepresentation regarding the fermentation treatment effect of pickle containers" (2013).

Even when no violation is found, administrative guidance will be given for a potential violation. Therefore, it should be noted whether product advertising and labeling in general are not misleading representations.

4. Electrical Appliances and Materials Safety Act

When Selling Electrical Appliances and Materials –

With the aim of preventing hazards and damages resulting from electrical appliances and materials, the Electrical Appliances and Materials Safety Act designates 457 items and regulates import and sale thereof. Most products used in general households, etc. with a 100V or 200V AC power supply fall under electrical appliances and materials.

PSE Mark (other than specified electrical appliances and materials)



An import business operator of electrical appliances and materials must make a notification of his/her business in accordance with the classification of the electrical appliances and materials as specified by the Ordinance of the Ministry of Economy, Trade and Industry, within 30 days from the day on which he/she

commenced the business, to the Minister of Economy, Trade and Industry or the Director of the competent Regional Bureau of Economy, Trade and Industry. Notification should be made for classification by product type^(Note) of the electrical appliances and materials to be imported. The business operator is also obliged to ensure that the relevant electrical appliances and materials comply with the technical standards, conduct self-inspections, compile and preserve the results thereof, and affix the PSE Mark or other prescribed labeling to the relevant electrical appliances and materials. Furthermore, with regard to specified electrical appliances and materials (electrical appliances and materials that are particularly likely to cause hazards), it is necessary to undergo conformity assessment by a registered conformity assessment body and retain the certificate.

It is not permitted to sell or display, for the purpose of marketing, any items falling under the category of electrical appliances and materials without affixing the PSE Mark or other prescribed labeling thereto.

(Note) Classification by product type refers to each of the combinations of elements (characteristics) of items listed by category of electrical appliances and materials, and is specified in Appended Table 2 of Article 4 of the Ordinance for Enforcement of the Electrical Appliances and Materials Safety Act.

< Examples of applicable items >

 $* Battery-operated \ appliances \ are \ not \ included.$

Bodies of the equipment charged with detachable AC adapters are not included.

■ Inquiries: Regional Bureau of Economy, Trade and Industry with jurisdiction over the business office of the importer

Product Safety Division, Ministry of Economy, Trade and Industry	TEL:+81-3-3501-4707
Product Safety Office, Hokkaido Bureau of Economy, Trade and Industry	TEL:+81-11-709-1792
Product Safety Office, Tohoku Bureau of Economy, Trade and Industry	TEL:+81-22-221-4918
Product Safety Office, Kanto Bureau of Economy, Trade and Industry	TEL:+81-48-600-0409
Product Safety Office, Chubu Bureau of Economy, Trade and Industry	TEL:+81-52-951-0576
Product Safety Office, Kinki Bureau of Economy, Trade and Industry	TEL:+81-6-6966-6098
Product Safety Office, Chugoku Bureau of Economy, Trade and Industry	TEL:+81-82-224-5671
Product Safety Office, Shikoku Bureau of Economy, Trade and Industry	TEL:+81-87-811-8526
Product Safety Office, Kyushu Bureau of Economy, Trade and Industry	TEL:+81-92-482-5523
Commerce and Trade Division, Okinawa General Bureau	TEL:+81-98-866-1731

■ Reference information: METI Website, "Electrical Appliance and Material Safety Act" https://www.meti.go.jp/english/policy/economy/consumer/pse/index.html

5. Consumer Product Safety Act

The Consumer Product Safety Act aims to ensure the safety of products that are used by general consumers for their routine everyday activities but for which safety regulations are not specifically established under other laws and regulations (consumer products).

Regulations for specified products

Products that are deemed as being highly likely to cause danger particularly to the lives or bodies of general consumers are designated as "specified products" and regulations are established with regard to their safety. Out of apparatuses for food, pressure cookers and pressure pans for domestic use are designated as specified products.

Prior to the commencement of business, a business operator who imports specified products must make a notification of his/her business to the Minister

of Economy, Trade and Industry or the Director of the competent Regional Bureau of Economy, Trade and Industry. (Note) The business operator is also obliged to ensure that the relevant specified products conform to the technical requirements, conduct self-inspections, compile and preserve the results thereof, and affix the PSC Mark or other prescribed labeling to the relevant specified products.

It is not permitted to sell or display, for the purpose of marketing, any items falling under the category of specified products without affixing the PSC Mark or other prescribed labeling thereto.

(Note) Upon making a notification, a business operator is required to become insured under a liability insurance policy.

■Inquiries:

Product Safety Division, Industrial and Product Safety Policy Group, METI TEL: +81-3-3501-4707

System for report and publication of product accident information

The Consumer Product Safety Act obliges business operators who import consumer products (Note) to report any serious product accident to the Consumer Affairs Agency within 10 days from the day on which they become aware of the occurrence of the accident.

The scope of the accidents to be reported covers death, a serious wound or disease (requiring treatment for 30 days or longer), residual disability, carbon monoxide poisoning, and fire (confirmed by the fire department). Accidents other than those apparently not caused by a defect in the consumer products are considered to be product accidents. In other words, even an accident that seems to have been caused by improper use by a consumer falls under the category of product accidents, as long as there are any factors that induce such improper use (inadequate precautions, etc.), and the relevant business operator needs to report the accident.

The details of the reported accidents are immediately publicized to general consumers. Additionally, import business operators must examine the causes of the accidents and endeavor to take proper measures such as voluntary recall of the relevant products, as necessary, to prevent the recurrence of similar accidents.

(Note) Products for professional use may also be included in consumer products if general consumers can purchase the do-it-yourself stores or other stores for the purpose of using them at home.

PSC Mark (specified products)



With regard to product accidents other than serious ones, the National Institute of Technology and Evaluation (NITE) collects information under its Accident Information Collection System.

■ Reference information: Website of the Consumer Affairs Agency, "Consumer safety" https://www.caa.go.jp/en/policy/consumer_safety/

SG Mark

The Consumer Product Safety Association has established the SG Standards necessary for ensuring the safety of some consumer products that may cause risks depending on their structure or materials, and permits business operators to affix the SG Mark to products that are certified to conform to the SG Standards. This is a voluntary system but household pressure pots and pressure cooking pots, metal pots, saucepans made of aluminum plate, cookware for IH heaters, cooking oil filters, ice crushers and



can openers are designated as applicable kitchen utensils under this system, providing a good indication for consumers and distributors for selecting goods.

With bodily injury liability coverage up to 100 million yen, the SG Mark guarantees compensation in the event of an accident causing injury or death involving a product with the Mark, based on a neutral and fair judgment by the Consumer Product Safety Association.

■Inquiries: Consumer Product Safety Association: TEL: +81-3-5808-3302 https://www.sg-mark.org/

6. Act on Specified Commercial Transactions

- When Conducting Mail Order Sales, Internet Sales, Door-to-Door Sales, etc. -

Sale of goods to general consumers by mail order sales, Internet sales, door-to-door sales, etc. is subject to regulations under the Act on Specified Commercial Transactions. Said Act specifies regulations for seven types of transactions, such as mail order sales, door-to-door sales and telemarketing sales, with the aim of preventing illegal and malicious solicitation by business operators and protecting the interests of consumers.

Said Act requires business operators who conduct mail order sales or Internet sales to indicate matters necessary for advertisement (name, address and telephone number of the business operator, selling price and shipment charge, method and time to pay charges, existence or non-existence of a product return clause, etc.), and prohibits misleading advertising and an act of causing a customer to make an application for a contract against his/her will. Any individuals, not limited to business operators, who conduct Internet sales and auctions are also subject to regulations under certain conditions. Cases where sellers in foreign countries sell goods online to people residing in Japan are also regulated under the Act on Specified Commercial Transactions.

■ Reference information: Website of the Consumer Affairs Agency, "Act on Specified Commercial Transactions Guide" https://www.no-trouble.caa.go.jp/foreignlanguage/

7. Acts Relating to Recycling

Labeling for distinguishing the materials for containers and packaging

The Act on the Promotion of Effective Utilization of Resources requires business operators to affix a reference mark for sorted collection to containers and packaging made of paper or plastic. Imported goods are no exception, and where a business operator who imports and sells goods indicates any of the materials or structure of containers or packaging or the use of a trademark, a reference mark needs to be affixed in the same manner

(Examples)





as in the case of domestic products. Even in the case where there is no such indication, if any indications in Japanese are printed, labeled or stamped on the surface of the container or packaging, a reference mark must be affixed.

■ Reference information: METI Website,

"Identification is Requested by Law on Plastics Containers and Packaging, and on Paper Containers and Packaging"

https://www.meti.go.jp/policy/recycle/main/english/pamphlets/pdf/mark_Indication_e.pdf

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

Under the Act on the Promotion of Sorted Collection and Recycling of Containers and Packaging, business operators who import and sell goods that use glass containers or containers or packaging made of paper or plastic are obliged to recycle used containers and packaging. However, small business operators defined in the Small and Medium-sized Enterprise Basic Act whose sales amount is below a certain level are exempted from the obligation to recycle goods.

■ Reference information: METI Website, "3R Policies" https://www.meti.go.jp/english/policy/energy_environment/3r/index.html

[Notes when using this guidebook]

- The contents were prepared in January 2021. Please note that there may be subsequent amendments.
- This guidebook is a revision of the Guide to Import of Apparatuses for Food 2014 published in October 2014.
- O Main revisions
 - · Amendment of standards and criteria in accordance with the Revision of the Food Sanitation Act (p. 13)
 - · Introduction of positive list system for apparatuses made of synthetic resin, and mandated information sharing among business operators. (p. 20-21)
 - · Addition of three methods of self-inspection (p. 10-11)
 - · Addition of HS classification (p. 23)
 - · Addition of three conditions for applying preferential tariff rates (general preferential and EPA) and three types of country of origin procedures (p. 24).

This guide was created with the support of a FY2021 Promotion Project Expenditure Grant from the Foundation for International Trade and Industrial Co-operation.



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 2022

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.