Import Procedures in Japan for Food & Beverage Products

SOURCE: ASEAN Promotion Centre on Trade, Investment and Tourism

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# Table of Contents

Preface ................................................................................................................................. 1
Table of Contents .................................................................................................................. 2

## Part 1 Food Import Procedures .................................................................................... 5
1. Food Import Clearance ................................................................................................. 6
2. Japanese Import Regulations ........................................................................................ 9
   - Food Sanitation Law ................................................................................................ 10
   - Plant Protection Law .............................................................................................. 10
   - Domestic Animal Infectious Diseases Control Law ................................................... 10
   - Foreign Exchange and Foreign Trade Law .............................................................. 10
   - Law Concerning Stabilization of Supply, Demand and Prices of Staple Food .......... 11
   - Liquor Tax Law .................................................................................................... 11
   - Salt Business Law ................................................................................................. 11

1) Foods in General – Food Sanitation Law ................................................................. 12
   Prior consultation ....................................................................................................... 13
   Preparation of documents for import notification ...................................................... 13
   Sample Notification Form for Importation of Foods, etc. .......................................... 14
   <Documents to be prepared by importers> ................................................................ 15
   <Documents to be prepared by exporters> ................................................................ 15
   <Documents to be prepared by either exporters or importers (if necessary)> .......... 16
   Import notification ..................................................................................................... 17
   Examination/inspection at a quarantine station ......................................................... 18
   “Specifications and Standards for Food, Food Additives, etc.” prescribed in the Food Sanitation Law ................................................................. 19
   Restrictions on food additives .................................................................................... 21
   Restrictions on residual agricultural chemicals and veterinary drugs in food .......... 23

2) Vegetables, Fruits, Grains – Plant Protection Law .................................................... 24
   Import Inspection Procedures based on the Plant Protection Law ......................... 24
   Preliminary survey – Import inspection classification ................................................. 24
   □ Import-banned items ............................................................................................... 24
   □ Items not subject to quarantine ............................................................................. 25
   □ Items subject to quarantine ................................................................................... 25
   Preparation of import inspection application documents ........................................... 25
   Import inspection application .................................................................................... 25
   Examination/inspection at the Plant Protection Station .......................................... 26
   Rejected items ........................................................................................................... 26

3) Livestock Products – Domestic Animal Infectious Diseases Control Law ................. 27
   Preliminary survey – Import inspection classification ................................................. 27
   Preparation of import inspection application documents ........................................... 28
   Import inspection application .................................................................................... 28
   Examination/inspection at the Animal Quarantine Service ..................................... 29
   Rejected items ........................................................................................................... 29

3. Laws Concerning the Labeling of Foods in Japan ................................................... 30
   1) Food Sanitation Law – Labeling Standards ............................................................. 33
2) Law Concerning Standardization and Proper Labeling of Agricultural and Forestry Products (JAS Law) – Quality Labeling Standards ......................................................... 35
3) Law Concerning Liquor Business Association and Measures for Securing Revenue from Liquor Tax (Liquor Business Association Law) – Liquor Labeling ......................................................... 37
4) Law for Promotion of Effective Utilization of Resources ......................................................... 37

Part 2 Import Procedures by Food Category ................................................................................. 38
1. Fresh and Frozen Vegetables ................................................................................................. 39
   1) Plant Protection Law ............................................................................................................... 40
   2) Food Sanitation Law .............................................................................................................. 43
   3) Considerations for Business Operators .................................................................................. 47
2. Fresh Fruits ............................................................................................................................... 52
   1) Plant Protection Law ............................................................................................................... 53
   2) Food Sanitation Law .............................................................................................................. 55
   3) Considerations for Business Operators .................................................................................. 58
3. Frozen Fish and Shellfish ........................................................................................................ 61
   1) Foreign Exchange and Foreign Trade Law (Cabinet Order Concerning Control of Import Trade) ........................................................................................................................................................................... 62
      □ Import Quota System ............................................................................................................. 62
      □ Paragraph 2 and Paragraph 2-2 Approval System .................................................................. 63
      □ Confirmation System ............................................................................................................. 64
   2) Law Concerning Special Measures to Strengthen the Conservation and Management of Tuna Resources ............................................................................................................................................................................ 65
   3) Food Sanitation Law .............................................................................................................. 66
   4) Considerations for Business Operators .................................................................................. 70
4. Teas and Coffees ......................................................................................................................... 75
   1) Plant Protection Law ............................................................................................................... 76
   2) Food Sanitation Law .............................................................................................................. 77
   3) Considerations for Business Operators .................................................................................. 81
5. Prepared Foods (Canned, Bottled, Retort Foods) ................................................................ 84
   1) Domestic Animal Infectious Diseases Control Law ................................................................. 85
   2) Food Sanitation Law .............................................................................................................. 86
   3) Considerations for Business Operators .................................................................................. 90
6. Confectionery and Snack Foods ............................................................................................. 95
   1) Food Sanitation Law ............................................................................................................... 96
   2) Considerations for Business Operators .................................................................................. 99
7. Soft Drinks ............................................................................................................................... 103
   1) Food Sanitation Law ............................................................................................................... 104
   2) Considerations for Business Operators ..................................................................................108
8. Alcoholic Beverages ............................................................................................................... 114
   1) Food Sanitation Law ............................................................................................................... 115
   2) Considerations for Business Operators ..................................................................................118
List of Official Laboratories in Exporting Countries ................................................................. 123
Part 1 Food Import Procedures
1. Food Import Clearance

Food items imported by sea or air are subject to the following import customs procedure.

**Food Import Clearance**

- Arrival of cargo
- Delivery to bonded area
- Customs clearance
  - Import Declaration
  - Examination/inspection at Customs
  - Payment of customs duty, consumption tax, etc.
  - Import permission
- Collection of cargo
- Sale
  - Regulations concerning food business permits, licenses, notifications and sales activities
  - Regulations concerning food labeling
  - Official system relating to food quality
  - Regulations concerning recycling
Part 1 Food Import Procedures

1. Food Import Clearance

Procedures prior to customs clearance – Import permission based on the Food Sanitation Law, Plant Protection Law, and the Domestic Animal Infectious Diseases Control Law

Goods imported from overseas are regulated by domestic laws such as the Food Sanitation Law and the Plant Protection Law, etc. These regulations are enforced in conjunction with the import authorization system prescribed in the Customs Law.

Food importers must submit a “Notification Form for Importation of Foods, etc.” to a quarantine station of the Ministry of Health, Labour and Welfare to undergo proper examination/inspection procedures in accordance with the Food Sanitation Law, and obtain import permission, prior to customs clearance.

In the case of meat and meat products, fresh vegetables and fruits, a quarantine inspection must first be conducted in accordance with the Domestic Animal Infectious Diseases Control Law or the Plant Protection Law, respectively, and import permission be obtained, before the goods can be processed through subsequent import procedures based on the Food Sanitation Law.

Import declaration

Anyone who wishes to import goods into Japan must declare those goods to the Customs Office, by submitting an Import Declaration Form along with other relevant documents. Relevant documents include documents based on which the Customs Office can determine customs duty payment, as well as any permit application forms, in the case of imported goods requiring notification or permission under domestic laws and regulations.

Importers may hire a customs broker to deal with the import declaration on their behalf.

Customs examination/inspection

The Customs Office examines the submitted import declaration documents and, when necessary, inspects the items concerned, to check whether they are consistent with the declaration form and whether they are correctly categorized according to the tariff schedule. Where goods require import permission or approval under laws and regulations other than customs-related laws, such as in the case of food items, the Customs Office is responsible for verifying that all necessary procedures have been completed.

The Customs Office is also responsible for making sure that the goods to be imported do not infringe on trademarks and other intellectual property rights, that they are not among those banned from being imported, such as illegal drugs, and that their country of origin is not falsely indicated.

Payment of customs duty, consumption tax, etc.

Goods that are imported into Japan are in principle subject to the following duty and tax.

- Customs duty: Import price \( \text{price of product itself} + \text{insurance} + \text{freight} \) \( \times \) tariff rate
- Consumption tax: \( \text{Import price} + \text{customs duty} \) \( \times \) 5%
**Import permission and goods collection**

Import permission is granted once the Customs Office confirms that the goods are consistent with the declaration, all necessary procedures have been completed, and customs duties, consumption tax, and (in the case of alcoholic beverages) liquor tax, have been paid.

The goods are stored in a bonded area until the above customs procedure is completed. A bonded area is usually operated by a warehouse company or other such company that has been granted permission by the Chief Customs Officer for providing a convenient facility for temporary storage, business activities such as processing, manufacturing, and exhibiting, and trade promotion of imported or exported goods. After the above customs procedure has been completed and import permission has been issued, importers may claim their goods from the bonded area. This completes the import process.

**Sale**

Those who wish to sell imported food for commercial purposes must fulfill their responsibilities for ensuring food safety, in compliance with the Food Safety Law and the Food Sanitation Law.

Depending on the type of food and sales method, a sales permit may need to be obtained in accordance with the Food Sanitation Law or local governmental regulations, or a liquor sales license, in accordance with the Liquor Tax Law. All businesses are subject to regulations for preventing unfair competition and specified sales practices.

Operators of food selling businesses must also comply with rules and regulations concerning labeling and recycling (see p.30, “3. Laws Concerning the Labeling of Foods in Japan”).
2. Japanese Import Regulations

Food import procedures are carried out in compliance with laws that aim to achieve the following objectives:

- To safeguard human health under the Food Sanitation Law
- To ensure domestic animal and plant safety through plant quarantine (under the Plant Protection Law) and animal quarantine (under the Domestic Animal Infectious Diseases Control Law)
- To maintain harmonious relationships with the international community and domestic industries

Principle laws and regulations that pertain to each food category are as follows:

<table>
<thead>
<tr>
<th>Food Category</th>
<th>Food Sanitation Law</th>
<th>Plant Protection Law</th>
<th>Domestic Animal Infectious Diseases Control Law</th>
<th>Foreign Exchange and Foreign Trade Law</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vegetables and fruits (fresh, frozen, dried)</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□ Items announced in import notices</td>
<td>Note 1</td>
</tr>
<tr>
<td>Meat and meat products</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□ Items announced in import notices</td>
<td>Note 1</td>
</tr>
<tr>
<td>Fishery products (fresh, frozen, chilled, salted)</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□ Items announced in import notices</td>
<td>Note 1</td>
</tr>
<tr>
<td>Tea in general, black tea, and coffee</td>
<td>□</td>
<td>⬕</td>
<td>□</td>
<td>□ Note 2</td>
<td></td>
</tr>
<tr>
<td>Rice</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□ Note 1</td>
<td>Staple Foods Law</td>
</tr>
<tr>
<td>Liquor</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□ Note 1</td>
<td>Liquor Tax Law</td>
</tr>
<tr>
<td>Salt</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□ Note 1</td>
<td>Salt Business Law</td>
</tr>
<tr>
<td>Processed foods (canned, bottled, pre-cooked and frozen)</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□ Note 1</td>
<td>□ Items announced in import notices</td>
</tr>
</tbody>
</table>

Note 1: Inspection is not required for some items depending on how they have been processed. Please enquire at the Plant Protection Station or Animal Quarantine Service in Japan for details.

Note 2: This category also includes dried tea leaves and coffee beans (raw beans). Please enquire at the Plant Protection Station in Japan for details.

Note 3: Canned fruits and other food items that have been sterilized by heating generally do not need to be inspected. However, please enquire at the Plant Protection Station in Japan for details.
Part 1 Food Import Procedures
2. Japanese Import Regulations

**Food Sanitation Law**

The Food Sanitation Law aims to protect public health, by prescribing necessary regulations from the standpoint of preventing health hazards that may be caused by the consumption of foods.

Anyone who wishes to import food items (including such non-food items as containers and packages, tableware, and toys for infants) for the purpose of sale or for other commercial purposes must submit a food import notification to the quarantine station, on each import occasion. (For more information, see “(1) Food Sanitation Law” on p.12)

[Inquiry about the import notification system]
Ministry of Health, Labour and Welfare, Pharmaceutical and Food Safety Bureau, Department of Food Safety, Inspection and Safety Division, Safety for Imported Food Section

**Plant Protection Law**

Food items that are made from plants, such as vegetables, fruits, and tea, are subject to plant quarantine. (For more information, see “(2) Plant Protection Law” on p.24)

The purpose of plant quarantine is to prevent foreign pests from spreading and harming valuable plants in Japan.

[Inquiry about plant quarantine]
Ministry of Agriculture, Forestry and Fisheries, Food Safety and Consumer Affairs Bureau, Plant Protection Division
http://www.maff.go.jp/e/index.html

**Domestic Animal Infectious Diseases Control Law**

Livestock food items and food items containing meat in their raw ingredients are subject to animal quarantine. (For more information, see “(3) Domestic Animal Infectious Diseases Control Law” on p.27)

The purpose of animal quarantine is to prevent pathogenic organisms that may cause infectious disease in livestock from entering Japan and spreading among domestic livestock.

[Inquiry about animal quarantine]
Ministry of Agriculture, Forestry and Fisheries, Food Safety and Consumer Affairs Bureau, Animal Quarantine Division
http://www.maff.go.jp/e/index.html

**Foreign Exchange and Foreign Trade Law**

The central government controls and coordinates foreign trade, as necessary, in accordance with the Foreign Exchange and Foreign Trade Law, to fulfill its responsibilities as a participating member of international conventions and agreements, and to contribute to the sound development of national economy.

The Cabinet Order Concerning Control of Import Trade (Import Order) stipulates specific import control measures, including the Import Notice system (prescribed and announced by the Minister of Economy, Trade and Industry (METI)) and the Import Approval system (requiring the approval of the METI Minister to import specified items). (For more information, see Part 2, “3. Frozen Fish and Shellfish” on p.62)

[Inquiry about trade control]
Ministry of Economy, Trade and Industry, Trade and Economic Cooperation Bureau, Agricultural and Marine Products Office
Law Concerning Stabilization of Supply, Demand and Prices of Staple Food
(Staple Food Law)

The trade in the major cereals of rice, wheat, and barley are directly controlled by the central government, in order to stabilize supply-demand and prices, and a system is in place for the purchase, import, and sale of these staples by the government under the Staple Food Law. Besides the government, however, private companies may also import staple foods, by paying the specified amount and custom duty.

[Inquiry about the staple food system]
Ministry of Agriculture, Forestry and Fisheries, General Food Policy Bureau, Staple Food Department, Grain Trade Division
http://www.maff.go.jp/e/index.html

Liquor Tax Law

The Liquor Tax Law defines liquor as beverages that have an alcoholic content of one percent or more (including powdered substances which can be dissolved to make a drink with an alcoholic content of one percent or more), and requires a license for producing and selling liquor. No one may engage in a liquor-related business without the proper license. (See Part 2, “8. Alcoholic Beverages” on p.122)

[Inquiry about the liquor sales license system]
National Tax Agency, Taxation Department, Liquor Tax and Industry Division
http://www.nta.go.jp/foreign_language/index.htm

Salt Business Law

Salt is a fundamental, non-substitutable commodity that is indispensable to life. Because of this specificity, restrictions are placed on the production, import and sales, and wholesale of salt, in order to ensure stable supplies of quality salt. To engage in a salt import and sales business, registration and notification procedures must be observed, according to the type of salt.

[Inquiry about the salt business system]
Ministry of Finance, Financial Bureau, Coordination Division, Tobacco and Salt Industries Office
http://www.mof.go.jp/english/index.htm
1) Foods in General – Food Sanitation Law

Import Notification Procedures for Foods and Related Products

- Prior consultation
- Preparation of documents for import notification
- Arrival of cargo
- Import notification
- Document examination at a MHLW quarantine station
- Inspection unnecessary
- Issuance of Certificate of Notification
- Customs clearance
- Domestic distribution

Consultation at an imported foods inspection section or imported food pre-import guidance offices at the quarantine station prior to import.

Notification Form for Importation of Foods, etc.
Other documents:
- Document showing raw materials, ingredients, and/or manufacturing methods
- Sanitary (Health) certificate (if necessary)
- Self-inspection Results (if necessary)

Submission of Notification Form for Importation of Foods, etc. to a quarantine station or via online system.

Inspection required
- Quarantine station
- Registered laboratory
- Ordered inspection

Inspection unnecessary
- Monitoring inspection
  - Withdrawal, etc. of items that fail to pass the inspection
  - Rejected
  - Passed
  - Administrative inspection
  - Quarantine station
  - Ordered inspection
  - Registered laboratory

Issuance of Certificate of Notification

Disposal, re-shipment, etc.

(Source: Ministry of Health, Labour and Welfare)
Prior consultation

Imported Foods Inspection Sections in quarantine stations offer consultation on food import procedures to importers in Japan. Quarantine stations that handle a large amount of imported goods have “Pre-import Guidance Offices,” for providing individual guidance (reservation is required).

Prior consultation is particularly recommended to those who are importing a food product that is being imported into Japan for the first time, or are importing health foods or food products that fall in the same category as products that have been associated with food sanitation violations in the past. Before receiving consultation at the quarantine station, however, importers should prepare the after-mentioned documents for import notification and make sure they conform to standards under the Food Sanitation Law.

Note that prior consultation is different from the pre-arrival examination or pre-arrival permit. Importers who desire pre-arrival examination should make use of the Advance Notification System (a system that allows import notification documents to be submitted starting 7 days before the estimated date of the cargo’s arrival).

[Inquiry]
Ministry of Health, Labour and Welfare, quarantine station, imported food pre-import guidance offices

Preparation of documents for import notification

Documents for import notification include the “Notification Form for Importation of Foods, etc.” obtained from the Ministry of Health, Labour and Welfare, a sanitary (health) certificate issued by a governmental agency in the country of export, a list of materials, and manufacturing process schedule. However, the required documents vary according to the category of the item to be imported. Therefore, importers should enquire at the quarantine station, and if necessary, ask the exporter to prepare the necessary documents.

In addition to the above, importers should conduct a self-inspection of required items and prepare to submit the results of the inspection.

When importing health foods or food items that contain Japanese or Chinese herbal medicine, importers should provide the scientific name (Japanese name) of the raw ingredient and clarify what part of the plant is used as an ingredient and its effect, and at the same time confirm with the pharmaceutical department in the local government whether it is subject to the Pharmaceutical Affairs Law. If it is, import procedures for medicine must be taken in compliance with the law, and the item may not be imported as a food item. In the case of health foods and related products, importers must prepare documents that provide details of the steps they have taken to verify that the item does not apply to the Pharmaceutical Affairs Law (verification date, verifying organization, identification of relevant substances and their handling, etc.), and submit them to the quarantine station along with other import notification documents.
### Sample Notification Form for Importation of Foods, etc.

#### Part 1: Food Import Procedures

**2. Japanese Import Regulations**

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### 通知者

**食品等輸入届出書**

| 通知者名 | 厚生労働大臣 藤田
| 通知者連絡番号 | （略）○○○○○○○

### 2. 輸入届出届出者

| 輸入届出届出者コード | 20000
| 通商・貿易コード F E | フランス

#### 3. 製造者名、住所・コード

| 製造者名 | 美味しい食品
| 住所 | 日本東京都○○○○○○○

#### 4. 輸入届出届出者

| 輸入届出届出者コード | 20000
| 通商・貿易コード F E | フランス

#### 5. 日時

| 日時 | 2005年1月1日
| 日付 | 2005年1月1日

#### 6. 保管場所

| 保管場所 | 東京都中央区○○○○○
| 管理者 | 東京都中央区○○○○○

### 7. 通知書の保管

| 通知書の保管状態 | 保管
| 保管場所 | 東京都中央区○○○○○

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### 8. 通知書の受取

| 受取者 | 東京都中央区○○○○○
| 受取者連絡番号 | 03-1234-5678

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### 9. 註

- 食品等輸入届出書
- 輸入届出届出者
- 製造者
- 日時
- 保管場所
- 通知書の保管
- 通知書の受取

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**注意**

この通知は、従来の通知書の紙面の拡張についての、一部の内容として拡張を行っているものであり、拡張を行ったものについては、拡張したことについての、通知書の表示は、拡張に応じて拡張されているものとする。
<Documents to be prepared by importers>

- Notification Form for Importation of Foods, etc.
  Fill out the form, providing all the required information, such as the name and address of the importer, name of the item, name of the product, quantity, weight, country of export, name and address of the manufacturer and place of manufacture, port of loading, and ingredients and materials and manufacturing or processing method of processed foods.

[Where to obtain the form]
Ministry of Health, Labour and Welfare
http://www.mhlw.go.jp/english/topics/importedfoods/1-3.html

<Documents to be prepared by exporters>

<table>
<thead>
<tr>
<th>Meat and meat products</th>
<th>Sanitary (health) certificate issued by a governmental agency in the country of export</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swellfish</td>
<td>Sanitary (health) certificate issued by a governmental agency in the country of export, which provides information on the fish species and the sea area of the catch, and proves that the fish has been processed in a sanitary manner</td>
</tr>
</tbody>
</table>
| Processed foods        | List of materials specifically showing the scientific names of all raw ingredients (food ingredients) and additives used, prepared and issued by the manufacturing company and bearing the name of the company (a Japanese translation thereof, in cases where the original document is written in a language other than English)  
  Schedule showing the complete manufacturing process from the raw ingredients to the end product, including sterilization temperatures and time, prepared and issued by and bearing the name of the manufacturing company and signed by the person in charge (a Japanese translation thereof, in cases where the original document is written in a language other than English)  
  Description of the product (a Japanese translation thereof, in cases where the original document is written in a language other than English)  
  Name and address of the manufacturer and place of manufacture in the country of export  
  Document showing the name of the product  
  If a food item includes beef or beef-derived substances among its raw ingredients, a written document showing the country in which the cattle were nurtured, slaughtered and processed, and the parts of the cattle used as raw ingredients |
| Others                 | Depending on the food category (cheese, mushroom, tomato, flatfish, eel, health foods, etc.) and country of export, a sanitary (health) certificate, self-inspection results, or other confirmation documents must be submitted. Check the list of foods requiring inspection, or enquire at the quarantine station. |
<Documents to be prepared by either exporters or importers (if necessary)>  

- **Self-inspection results**

  If goods that arrive in Japan are rejected after food sanitation inspection, importers suffer enormous financial damage, including the cost of disposal or re-shipment. Therefore, importers are highly recommended to conduct a self-inspection of relevant inspection items in advance (for a fee), to confirm that the food item they wish to import complies with the Food Sanitation Law, with respect to ingredients, agricultural chemical and veterinary drug residues, and the use of food additives.

  When applying for self-inspection in Japan, importers need to present a sufficient number of samples obtained from the exporter and request inspection at a laboratory registered with the Ministry of Health, Labour and Welfare. If the inspection results issued by the laboratory show that the food item conforms to the standards prescribed in the Food Sanitation Law, the importer may proceed with subsequent import procedures.

  The inspection results are valid for about a year, so importers should keep it on hand for that duration. By submitting a copy of the report along with the import notification form, the inspected items can be exempt from inspection, and the import process be expedited. In this case, it is extremely important that the quality of the imported food item is consistent with the sample that passed the self-inspection. Therefore, importers should make sure that the names of the importer, manufacturer and place of manufacture, the name of the product, the raw materials and additives, and the processing/manufacturing methods are the same on both the inspection results and the notification form.

  Importers may also request a self-inspection at a facility in the country of export included on the list of official laboratories authorized by the Ministry of Health, Labour and Welfare. Inspection results issued by such authorized facilities are equally effective as those issued by Japanese laboratories registered with the ministry. Note that in both cases, it is essential that the quality of the imported food item is consistent with the sample that passed the self-inspection.

[Inquiry about inspection facilities]  
Ministry of Health, Labour and Welfare <List of official laboratories authorized by MHLW>  
Note) In the ASEAN countries, there are official laboratories authorized by MHLW in Indonesia, Singapore, Thailand, and the Philippines. (See p.123)
Import notification

Under the Food Sanitation Law, importers of foods or related products (including non-food items such as food containers and packages, tableware, and toys for infants) for the purpose of sale or for other commercial purposes (including foods to be provided free to the general public or offered for tasting purposes at exhibitions or public events) are required to submit an import notification to the quarantine station, on each import occasion. Food items that are not properly notified may not be commercially sold or used in Japan.

Systems for simplifying and expediting import notification procedures are also available. Please enquire at a MHLW quarantine station for details.

<table>
<thead>
<tr>
<th>Date of submission</th>
<th>During the period starting 7 days before the estimated date of the cargo’s arrival and until the time the goods are stored in the bonded area (or after animal or plant quarantine inspection, in some cases)</th>
</tr>
</thead>
</table>
| Submission         | (1) Submission of written documents  
Importers should submit the necessary documents to the food import notification section at the quarantine station having jurisdiction over the area where the relevant goods are to be cleared through customs. Enquire with the quarantine station concerning open hours.  
(2) Online submission using FAINS (Food Automated Import Notification and Inspection Network System)  
To use the system, importers need to register their communications equipment with the Ministry of Health, Labour and Welfare, in advance. |
| Fee                | Free of charge. However, bear in mind that importers will be charged an inspection fee and transportation fee if they receive an inspection order or require inspection guidance. |

[Inquiry]
MHLW quarantine stations having jurisdiction over ports of entry <Food import notification sections>
http://www.mhlw.go.jp/english/topics/importedfoods/1-2.html

<Items not subject to import notification>

The food items given below are exempt from import notification requirements. However, if at the import declaration stage, importers are required to prove that the exemption applies to their goods, they must submit two copies of the Confirmation Application Form to the quarantine station and receive verification that the goods concerned do not in fact require import notification.

- Food items specified in Table 6-2 of the Food Sanitation Law Enforcement Regulations  
  Raw salt, copra, raw materials derived from animals or plants and used in the manufacture of edible fats and oils, raw sugar, crude alcohol, molasses, malt, hop
- Foods and related products which are clearly not intended for sale or commercial use in Japan  
  - Foods and related products intended for use by individuals, for research/tests, and internal consideration by companies (less than 10 kg, as a rule)  
  - Foods and related products intended for display purposes (where they are to be displayed simply as a sample, and not to be sold or distributed)  
  - Imported foods and related products that will obviously be re-exported in their entirety
Examination/inspection at a quarantine station

At the quarantine station where the import notification is submitted, food sanitation inspectors examine the submitted documents and perform a spot inspection as necessary, to check whether the item concerned complies with the Food Sanitation Law. Items that pass the document examination and spot inspection are issued a certificate of notification, which allows the importer to proceed with subsequent customs procedures.

Items that fail to pass the import inspection (for violating the Food Sanitation Law) are most commonly rejected on the basis of Article 11 of the Law, which prescribes standards concerning agricultural chemical residues, bacterial contamination of frozen foods, and the use of food additives. In fact, violation of Article 11 accounts for more than 70% of the total number of violations. The next most common grounds for rejection are Article 6, relating to contamination by poisonous or harmful substances such as aflatoxin, followed by Article 10, on the use of undesignated additives (cited from “FY2007 Results of Monitoring Guidance based on the Imported Food Monitoring and Guidance Plan”).

Foods and food products that are rejected cannot be imported into Japan. They are disposed of, re-shipped to the country of export, or otherwise processed, principally at the expense of the importer. Therefore, importers should confirm in advance whether the item they wish to import conforms to standards prescribed in Japan’s Food Sanitation Law.

<Main points of examination>

- Does the manufacturing method conform to the manufacturing standards prescribed in the Food Sanitation Law?
- Is the use of additives within the allowable limit?
- Does the item contain any poisonous or harmful substances?
- Does the manufacturer or place of manufacture have a history of any sanitation violations in the past?

<Cases where inspection is required>

- The item has been designated as a target for ordered inspection
- The item has been targeted for monitoring inspection
- The item is being imported to Japan for the first time
- A sanitation problem may have occurred as a result of an accident occurring during transportation
- Safety of the item needs to be confirmed by inspection, for other reasons
“Specifications and Standards for Food, Food Additives, etc.” prescribed in the Food Sanitation Law

All food items distributed in Japan are subject to the Food Sanitation Law. Unless they conform to “Specifications and Standards for Food, Food Additives, etc.” stipulated by the Law, they are prohibited from production, import, and sale in Japan.

“Specifications and Standards for Food, Food Additives, etc.” are divided into 5 categories: foods, additives, implements and containers/packages, toys (for infants), and detergents (for vegetables, fruits, and crockery). The food category includes standards for food in general and those for specific items such as soft drinks and frozen foods.

Compositional Specifications for Foods in General stipulate, for example, that foods, in principle, shall not contain antibacterial or antibiotic substances, and that genetically-modified foods must be subject to food safety inspection. They also contain provisions concerning the Positive List System (see p.23) for residues of agricultural chemicals and veterinary drugs in foods. Standards for Manufacturing, Processing, and Preparation of Foods in General stipulate, for example, that in the case of production, foods shall not be irradiated; that whole chicken eggs in shells for use in the production process must be edible eggs; and that fish and shellfish for raw consumption shall be properly washed with potable water to remove any substances that may contaminate the product. Preservation Standards for Foods in General stipulate, for example, that antibacterial substances shall not be used to preserve foods, and that foods shall not be irradiated.

Some food items are subject to separate requirements regarding specifications of composition (such as heavy metals, bacteria count, and chemical substances); standards of manufacturing, processing, using, and preparation (mainly related to sterilization methods and time, types of containers, quality of materials, water used in the production process, treatment and freshness of raw materials, machinery used in the production process, and methods of cleaning and sterilizing implements); and preservation standards (preservation temperature during storage, transport, and marketing processes, type and structure of containers, etc.).

Food items with separately-defined specifications/standards

<table>
<thead>
<tr>
<th></th>
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<th>1</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Soft drinks</td>
<td>12</td>
<td>Fish paste products</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Powdered soft drinks</td>
<td>13</td>
<td>Salmon roe, salted salmon roe, cod roe</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Ice</td>
<td>14</td>
<td>Boiled octopus</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Flavored ices</td>
<td>15</td>
<td>Boiled crab</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Meat, including whale meat (excl. frozen whale meat intended for raw consumption)</td>
<td>16</td>
<td>Agar</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Poultry eggs</td>
<td>17</td>
<td>Grains, beans and vegetables</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Blood, blood cells and plasma</td>
<td>18</td>
<td>Raw bean jam</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Meat products</td>
<td>19</td>
<td>Foods sterilized by pressure-heating and packed in containers/packages</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Whale meat products</td>
<td>20</td>
<td>Tofu</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Fresh fish and shellfish intended for raw consumption (excl. oysters intended for raw consumption)</td>
<td>21</td>
<td>Instant noodles</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Oysters for raw consumption</td>
<td>22</td>
<td>Frozen foods</td>
<td></td>
</tr>
</tbody>
</table>

Milk, dairy products, and other products made of milk and dairy products require strict sanitary management, and are regulated by the Ministerial Ordinance on Milk and Milk Products Concerning Compositional Standards (Ordinance on Milk and Milk Products), aside from other regulations for foods in general.
[Information on “Specifications and Standards for Food, Food Additives, etc.”]
Japan External Trade Organization (JETRO), <Webpage on standards and regulations>
http://www.jetro.go.jp/en/reports/regulations/

[Inquiry about standards prescribed in the Food Sanitation Law]
Ministry of Health, Labour and Welfare, Pharmaceutical and Food Safety Bureau, Department of Food Safety, Specification Examination Section
## Restrictions on food additives

The Food Sanitation Law defines food additives as “substances to be used in or on food, in the process of the manufacturing of food or for the purpose of processing or preserving food, by adding, mixing, infiltrating, or other means.”

### Types of food additives allowed to be used in Japan

(as of July 2008)

<table>
<thead>
<tr>
<th>Type of Food Additives</th>
<th>Details</th>
</tr>
</thead>
</table>
| **Designated food additives**<br>377 items | Food additives designated by the Minister of Health, Labour and Welfare based on Article 10 of the Food Sanitation Law, and listed in Annexed Table 1 in the Food Sanitation Law Enforcement Regulations.  
- The Japan Food Chemical Research Foundation [List of designated food additives](http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/e-foodadditives) |
| **Existing food additives (natural additives)**<br>419 items | Food additives that were already widely used in food long before the Food Sanitation Law was amended in 1995 to include not only chemically synthesized substances but also natural additives. These additives, which are listed on the List of Existing Food Additives, are approved for continuous use and sale, and are exempted from the provisions of Article 10 of the Food Sanitation Law.  
- The Japan Food Chemical Research Foundation [List of existing food additives](http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/e-foodadditives) |
| **Natural food additives**<br>Approx. 600 items | Plant and animal-derived natural substances that are intended for use as flavoring for food, and are generally used in small amounts (e.g., vanilla essence, crab essence).  
- The Japan Food Chemical Research Foundation [List of natural food additives](http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/e-foodadditives) |
| **General food additives** | Items that are generally provided for eating or drinking as foods and which are used as food additives (e.g., strawberry juice, agar).  
- The Japan Food Chemical Research Foundation [List of food additives generally provided for eating or drinking as foods and which are used as food additives](http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/e-foodadditives) |

(Source: Ministry of Health, Labour and Welfare)

### Designation of food additives

As a rule, only food additives designated by the Minister of Health, Labour and Welfare may be manufactured, imported, used, or sold as additives, with the exception of existing food additives, natural food additives, and general food additives.

### Standards for food additives

Food additives are subject to various standards as appropriate, including specifications of composition which specify purity and properties and usage standards specifying how much of each additive may be used in what types of foods. Some food additives that are legally approved in their countries of export may not be permitted in Japan. Additionally, some additives that bear the same name may in fact be two different additives based on different composition specifications or usage standards. Therefore, importers need to make sure the item they wish to import conforms to Japanese standards prior to their importation, and bear in mind that items that do not comply with Japanese specifications and standards may not be imported into Japan.
Labeling standards for food additives

In principle, all food additives used in food are subject to labeling requirements. Labels must indicate the name of the substance and, in the case of additives used as preservatives or sweeteners, their intended purpose. Food items that do not conform to labeling standards may not be sold in Japan.

[Information on food additives]
Ministry of Health, Labour and Welfare <Sector policy—webpage on food additives>
Part 1 Food Import Procedures
2. Japanese Import Regulations

Restrictions on residual agricultural chemicals and veterinary drugs in food

In Japan, residues of agricultural chemicals and veterinary drugs (drugs used to prevent and treat diseases in livestock, such as cows and pigs, poultry, and fish and shellfish) in food are regulated according to the Positive List System.

Under this system, a maximum residue limit (MRL) is set for all agricultural chemicals and veterinary drugs in food, in principle. Food items containing residual agricultural chemicals or veterinary drugs in amounts exceeding their limit are prohibited from being imported or sold in Japan.

A uniform limit of 0.01 ppm is applied to agricultural chemicals and veterinary drugs for which maximum residue limits have not been established, either inside or outside of Japan. The 0.01 ppm uniform limit is considered the level that is unlikely to pose a risk to human health, and also applies to processed foods that are not subject to separately defined standards.

Positive List System for Agricultural Chemicals and Veterinary Drugs

(Source: Ministry of Health, Labour and Welfare)

[Information on residual agricultural chemicals and veterinary drugs]
The Japan Food Chemical Research Foundation < Positive List System for agricultural chemical residues in foods>
http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/MRLs-p
2) Vegetables, Fruits, Grains – Plant Protection Law

Import Inspection Procedures based on the Plant Protection Law

(Source: Plant Protection Station)

Preliminary survey – Import inspection classification
Imported plants and plant products are subject to plant quarantine under the Plant Protection Law, to prevent agricultural pests that may infest plants and plant products from spreading and damaging valuable plants in Japan.

All plants and plant products are classified into three categories: items subject to quarantine, items not subject to quarantine, and import-banned items. Importers who wish to import food items that are a type of plant, such as vegetable, fruit, or tea, should confirm to which classification the items correspond.

- Import-banned items
The following items may not be imported.
- Any plants and plant products that have soil attached to them
- Plants that serve as host for pests that have not been introduced to Japan and could cause serious damage to agricultural crops if introduced, but are difficult to discover in an import inspection. These plants are prohibited from being imported, in principle.

Since the outbreak of pests depends on country/region, the same plant may be subject to different import requirements. The website of the Plant Protection Station provides a database on conditions for import/export, which can be used to search for import requirements according to country of export and plant types.

Import-banned items may be imported if they are to be used for research, display, or other such limited purposes, with the approval of the Minister of Agriculture, Forestry and Fisheries, provided they satisfy certain conditions. They may also be imported if importer can prove that measures have been taken to...
prevent the spreading of pests, such as proof of disinfecting technology or proof that no outbreak of pests has occurred in the region of origin, and that those measures satisfy the standards for disinfection prescribed by the Minister of Agriculture, Forestry and Fisheries. For more information, please enquire with the Plant Protection Station.

[Information on import-banned items]
Plant Protection Station < Plant Protection Law Enforcement Regulations, Annexed Table 2>
http://www.pps.go.jp/english/law/list2-(080911-).html

- **Items not subject to quarantine**
  Some plants that would normally be subject to quarantine may be exempt from import inspection depending on how they are processed or packaged. For instance, the following items are not subject to quarantine: agricultural products preserved in salt, sugar or vinegar; processed tea; roasted or otherwise processed nuts; designated dried fruits; dried spices canned, bottled, or otherwise packed for retail sale. For more information, please enquire with the Plant Protection Station.

- **Items subject to quarantine**
  All plants and plant products other than import-banned items and items not subject to quarantine must be inspected, and must conform to import inspection requirements.

  Article 2 of the Plant Protection Law provides a definition of plants. According to the definition, some typical food items that are subject to quarantine include the following: fruits (fresh, frozen, and dried), vegetables (fresh, frozen, and dried), nuts, grains, beans, coffee beans (raw beans), spices, rape seeds, sesame seeds, and herbal medicine materials derived from plants. Note that mushrooms, such as matsutake and shiitake mushrooms, are classified as fungi and are not subject to quarantine, as they do not fit the definition of plants as defined under the Plant Protection Law.

**Preparation of import inspection application documents**
To apply for plant import inspection, importers must submit the designated “Plant or import-banned item import inspection application form” and a phytosanitary certificate issued by a governmental agency in the country of export.

<Documents to be prepared by importers>
- “Plant or import-banned item import inspection application form”

<Documents to be prepared by exporters>
- A phytosanitary certificate issued by a governmental agency in the country of export
  Prior to importation, plants and plant products must be inspected by a plant quarantine station in the country of export. Items that pass the inspection are issued a phytosanitary certificate in the format stipulated by the International Plant Protection Convention.
- Exporters may also be required to present a bill of lading (B/L), invoice, packing list, air waybill, or other relevant documents.

**Import inspection application**
When importing items subject to quarantine, importers must submit the “Plant or import-banned item import inspection application form” to the Plant Protection Station having jurisdiction over the port of entry. Applications are accepted starting 7 days before the estimated date of the cargo’s arrival. Results of the
application and inspection can be received using the PQ-NETWORK (Plant Quarantine Network), an electronic processing system for imported plant inspection.

Plant quarantine is conducted at certain ports and airports only, so importers should be careful when selecting a port of entry.

[Inquiry]
Plant Protection Stations having jurisdiction over ports of entry

Examination/inspection at the Plant Protection Station
At the Plant Protection Station, the plant or plant product to be imported is sampled in amounts appropriate to each plant type and checked for any quarantine pests and soil contamination.

A plant quarantine certificate is issued if no quarantine pests or soil are detected from the item, and the item may be processed through subsequent procedures based on the Food Sanitation Law. Even if pests or soil are found, a certificate may still be issued, after the item has been properly disinfected.

<Main points of examination>
- Has the inspection application form been properly filled out and the necessary documents attached?
- Does the item fall under the import-banned category?
- Have any soil and quarantine pests been detected from the item in a spot inspection?

Rejected items
If quarantine pests are detected from an item, the item is ordered to be “disinfected (disposed of).” Importers may choose to either disinfect (where disinfection methods exist), dispose of, or re-ship the item to the country of export.

Importers are legally required to do the disinfecting themselves, at their own expense. If they do not have the necessary disinfecting technology and equipment, they may outsource the task to private services.

A plant quarantine certificate will be issued if, after disinfection, the plant protection officer confirms that all quarantine pests have been exterminated or removed.
3) Livestock Products – Domestic Animal Infectious Diseases Control Law

Import Inspection Procedures for Livestock Products based on the Domestic Animal Infectious Diseases Control Law

**Preliminary survey – Import inspection classification**

Animals and livestock products for import into Japan must be inspected under the Domestic Animal Infectious Diseases Control Law, to prevent pathogenic organisms that can cause infectious diseases in livestock from entering Japan and spreading among domestic livestock. Livestock products that are subject to quarantine procedures are classified as “designated quarantine items,” and include the following:

- Meat, bones, fat, organs, milk, etc. of cloven-hoofed animals (cows, pigs, sheep, goats, deer), horses, dogs, and rabbits
- Meat and eggs of poultry (chickens, ducks, turkeys, quails, and geese)
- Sausages, ham, and bacon made from the meat of designated quarantine items

Designated quarantine items must first be inspected at a governmental agency in the country of export and issued a health (veterinary) certificate, which is needed for import application. Items to be inspected in the country of export and provided on the certificate are predetermined as “domestic animal sanitation requirements” in a prior agreement between the country of export and Japan. Products from countries that have no agreement with Japan may not be imported. Additionally, meat and livestock products for import into Japan may only be handled by facilities authorized by Japan or the country of export. Meat and livestock products handled by undesignated facilities are prohibited from being imported into Japan.
Among the ASEAN countries, Thailand and Malaysia have an agreement with Japan on domestic animal sanitation requirements regarding such livestock products as the meat of cloven-hoofed animals (cows, pigs, sheep, goats, deer, etc.) (as of Sept. 30, 2008). Singapore, the Philippines, and Thailand have an agreement with Japan on domestic animal sanitation requirements regarding such livestock products as poultry meat (chickens, quails, ostriches, turkeys, ducks, geese, etc.) (as of Sept. 30, 2008).

Note that the export and import of livestock products may be temporarily suspended in the event of an outbreak of infectious diseases among livestock, such as bird flu.

Some livestock products may be exempt from animal quarantine inspection, depending on their processing method (e.g., canned meat, pidan eggs, boiled eggs, lard, butter, cheese, etc.). The major grounds for exempting a livestock product from animal quarantine inspection are based on whether the product has been thoroughly sterilized by heating to allow long shelf-life, determined by its materials, processing method, and condition of its container. For example, pre-cooked retort foods containing meat are not subject to quarantine inspection, as long as they conform to standards for retort foods prescribed by the Japan’s Food Sanitation Law.

Importers of livestock products which may be exempt from animal quarantine inspection must submit a list of materials and a manufacturing process schedule along with the import inspection application form and a health (veterinary) certificate issued by a governmental agency in the country of export to the Animal Quarantine Service, so that the Quarantine Service can confirm whether or not the product can indeed be exempted from inspection.

Importers should therefore check with the Animal Quarantine Service concerning the latest information on animal quarantine and whether or not the livestock product they wish to import is subject to quarantine inspection.

**Preparation of import inspection application documents**

To import livestock products, importers must submit the designated import inspection application form and a health (veterinary) certificate issued by a governmental agency in the country of export (an organization equivalent to the Animal Quarantine Service in Japan).

**<Documents to be prepared by importers>**

- Import inspection application form
  
  [Where to obtain the application form]
  
  Animal Quarantine Service
  

**<Document to be prepared by exporters>**

- Health (veterinary) certificate issued by a governmental agency in the country of export
  
  Prior to export, livestock products must be inspected by an animal quarantine institution in the country of export. Items to be inspected and provided on the health (veterinary) certificate are predetermined as “domestic animal sanitation requirements” in a prior agreement between the country of export and Japan.
- Exporters may also be required to present a bill of lading (B/L), invoice, packing list, air waybill, manufacturing process schedule, list of materials and ingredients or other relevant documents.

**Import inspection application**

When importing designated quarantine items, importers must submit an import inspection application form, a health (veterinary) certificate issued by a governmental agency in the country of export, and other relevant documents to the Animal Quarantine Service having jurisdiction over the port of entry (in principle,
by the day prior to the desired day of inspection). Importers may apply and receive results of the inspection online, via ANIPAS (Animal Inspection Procedure Automated System), an electronic processing system for animal quarantine inspection.

Animal quarantine is only conducted at certain ports and airports, so importers/exporters should be careful when selecting a port of entry.

**[Inquiry]**
Animal Quarantine Service having jurisdiction over ports of entry

**Examination/inspection at the Animal Quarantine Service**

At the Animal Quarantine Service, an animal quarantine officer examines the submitted documents and inspects the livestock product concerned. After conducting a detailed inspection and taking disinfection measures as necessary, an import quarantine certificate is issued if the product is verified as being free of pathogenic organisms that could cause infectious diseases among livestock in Japan, and the product may be processed through subsequent procedures based on the Food Sanitation Law.

**<Main points of examination>**

- Has the inspection application form been properly filled out and the necessary documents attached?
- Does the product fall under the import-banned category, or does it satisfy domestic animal sanitation requirements?
- Has the safety of the product been confirmed in terms of infectious diseases, in a spot inspection?

**Rejected items**

As a result of inspection, products prohibited from being imported even if disinfected must be incinerated, buried, or returned to the country of export, as instructed by the animal quarantine officer.
## Part 1 Food Import Procedures

### 3. Laws Concerning the Labeling of Foods in Japan

#### Principal Laws and Regulations Related to Food Labeling

<table>
<thead>
<tr>
<th>Name</th>
<th>Competent authority</th>
<th>Purpose</th>
<th>Scope of application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food Sanitation Law</td>
<td>Ministry of Health, Labour and Welfare Pharmaceutical and Food Safety Bureau, Department of Food Safety <a href="http://www.mhlw.go.jp/english/index.html">http://www.mhlw.go.jp/english/index.html</a></td>
<td>Aims to protect public health by preventing health hazards occurring from the consumption of food</td>
<td>Processed foods in containers or packages (incl. certain fresh foods)</td>
</tr>
<tr>
<td>Law Concerning Standardization and Proper Labeling of Agricultural and Forestry Products (JAS Law)</td>
<td>Ministry of Agriculture, Forestry and Fisheries Food Safety and Consumer Affairs Bureau, Standards and Labeling Division <a href="http://www.maff.go.jp/e/index.html">http://www.maff.go.jp/e/index.html</a></td>
<td>(Quality display standards) Aims to ensure proper labeling of quality, to facilitate product selection</td>
<td>Fresh foods, processed foods, brown and milled rice&lt;br&gt; This law originally applied to foods intended for consumer sale, but was revised on April 1, 2008 to include foods intended for business transactions.</td>
</tr>
<tr>
<td>Health Promotion Law</td>
<td>Ministry of Health, Labour and Welfare Pharmaceutical and Food Safety Bureau, Standards and Evaluation Division, Newly Developed Food and Health Measure Section <a href="http://www.mhlw.go.jp/english/index.html">http://www.mhlw.go.jp/english/index.html</a></td>
<td>(Nutrition display standards) To provide accurate information on nutrient components</td>
<td>Processed foods and chicken eggs that bear nutritional labeling</td>
</tr>
<tr>
<td>Fair Competition Codes (Voluntary rules of the food industry)</td>
<td>Federation of Fair Trade Conferences <a href="http://www.jftc.go.jp/e-page/index.html">http://www.jftc.go.jp/e-page/index.html</a></td>
<td>To assure fair competition and protection of consumer interests</td>
<td>Prevention of fraudulent and misleading labeling</td>
</tr>
<tr>
<td>Local government ordinances</td>
<td>Relevant authorities in prefectoral and municipal governments</td>
<td>To promote proper labeling of quality in regard to products unregulated by other laws</td>
<td>(In the case of Tokyo) Pre-cooked frozen foods, kamaboko (fish-paste cake), honey, cut vegetables and fruits</td>
</tr>
</tbody>
</table>
Food labels are important sources of information that allow consumers to select and purchase food products based on an accurate understanding of the contents and the methods of preservation and usage. In the event of a food-related accident, food labels also provide information helpful to pursuing the issue of responsibility, as well as to taking prompt and proper action for recalling the relevant products and other administrative measures.

All food products sold in Japan must bear labels that provide the information required by laws and regulations or relevant local government ordinances, in Japanese, according to the specified method.

Food labeling is mainly governed by two laws in Japan. One is the Food Sanitation Law, which prescribes food labeling standards from the standpoint of public health. The other is the Law Concerning Standardization and Proper Labeling of Agricultural and Forestry Products (JAS Law), which aims to promote proper labeling of food quality.

In addition to the above, food labeling is subject to a number of other laws and regulations, including the following: the Measurement Law, which stipulates proper measurement practices; the Health Promotion Law, which promotes proper labeling of nutritional information; the Law Against Unjustifiable Premiums and Misleading Representations, which aims to prevent fraudulent and misleading labeling; and local government ordinances concerning labeling. Importers must comply with all of the above laws and regulations related to labeling.

Food products that do not bear proper labels may not be sold, displayed for selling purposes, or otherwise used for commercial purposes.

Business operators might also abide by a Fair Competition Code, which provides industry-wide rules regarding labeling practices. Such codes are approved by the Japan Fair Trade Commission based on the Law Against Unjustifiable Premiums and Misleading Representations, but since they are independently established at the initiative of industrial circles, the rules apply only to voluntary business operators.

In regard to food containers and packages, the Law for the Promotion of Effective Utilization of Resources requires proper identification of container and package materials.
Labeling of health foods

In Japan, there is no legal definition of “health foods”; it loosely refers to foods that are sold and used as items that generally promote health. Health foods that satisfy governmental standards regarding safety, effectiveness, and labeling are institutionalized as “foods with health claims.” All other “health foods” are treated as general foods, and must comply with labeling requirements established under the Food Sanitation Law, JAS Law, and the Health Promotion Law.

The Pharmaceutical Affairs Law and Health Promotion Law prohibit the use of certain expressions in labeling and advertisements that business operators voluntarily employ for sales purposes.

<Major matters prohibited in voluntary labeling and advertisements>

- Claims of medical effect/efficacy (Pharmaceutical Affairs Law)
  Example of unsuitable expression:
  Expressions such as “for people who suffer allergy symptoms,” “relieves fatigue,” “for perpetual youth and longevity,” etc.

- Claims of medical dosage regimen (Pharmaceutical Affairs Law)
  Example of unsuitable expression:
  Instructions such as “Take 3 times a day before meals,” etc.

- Fraudulent and extravagant labeling and advertisements relating to preservation/promotion of health (Health Promotion Law)
  Example of unsuitable expression:
  Descriptions such as: “This is a diet food product made solely using ingredients approved as food by the Ministry of Health, Labour and Welfare”

- Labeling and advertisements that give false impression of superiority (Law Against Unjustifiable Premiums and Misleading Representations)
  Example of unsuitable expression:
  Expressions such as “amazing power,” “No. 1 product for beautiful skin,” etc.

[Inquiry concerning labeling regulations for health foods]
Pharmaceutical section in prefectoral governments
1) Food Sanitation Law – Labeling Standards

Food products that do not bear proper labels that conform to labeling standards prescribed in the Food Sanitation Law may not be sold, displayed for selling purposes, or otherwise used for commercial purposes. Specific labeling standards are provided for (i) food items specified in the Enforcement Regulations of the Food Sanitation Law and (ii) milk and dairy products (items specified in the Ministerial Ordinance Concerning Compositional Standards, etc. for Milk and Milk Products).

The Food Sanitation Law also establishes labeling requirements for additives, allergenic substances, and genetically modified foods.

Labels must be legibly and accurately written in Japanese and affixed where they are readily visible without opening the container/package. They should not contain fraudulent or extravagant expressions that may pose a hazard to public health.

**Main items to be provided on labels**

- Name
- Additives used (as a rule, include all additives used and additives contained in the ingredients)
- “Use-by date” (the date (Year/month/day) within which, under the specified storage conditions, the product will not pose a health risk due to rotting, deterioration, or other degradation of quality) or “Best-before date” (the date (Year/month/day) that signifies the date until which, under the specified storage conditions, the product may fully retain all its expected qualities)
- Storage instructions
- Name and address of manufacturer (retailer or importer)
- Whether the product contains allergenic substances
- Whether the product is a genetically modified food item
- Whether the product is a food item with health claims

**[Inquiry]**

Public health department having jurisdiction over the address of the relevant business
### Food items subject to labeling standards under the Enforcement Regulations of the Food Sanitation Law

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1</td>
<td>Margarine</td>
</tr>
<tr>
<td>2</td>
<td>Alcoholic beverages</td>
</tr>
<tr>
<td>3</td>
<td>Soft drinks</td>
</tr>
<tr>
<td></td>
<td>Frozen fruit juice, fruit juice for use as an ingredient, mineral water, other soft drinks</td>
</tr>
<tr>
<td>4</td>
<td>Meat products</td>
</tr>
<tr>
<td></td>
<td>Dried meat products, non heat-treated meat products, designated heat-treated meat products, heat-treated meat products</td>
</tr>
<tr>
<td>5</td>
<td>Fish ham, fish sausage, whale bacon</td>
</tr>
<tr>
<td>6</td>
<td>Beans containing cyanide</td>
</tr>
<tr>
<td>7</td>
<td>Frozen foods</td>
</tr>
<tr>
<td></td>
<td>Filleted fresh fish and shucked shellfish (excl. fresh oysters)</td>
</tr>
<tr>
<td></td>
<td>Other frozen foods</td>
</tr>
<tr>
<td>8</td>
<td>Irradiated foods</td>
</tr>
<tr>
<td>9</td>
<td>Food sterilized by pressure-heating and packed in containers/packages</td>
</tr>
<tr>
<td>10</td>
<td>Chicken eggs</td>
</tr>
<tr>
<td></td>
<td>Chicken eggs in shells, chicken egg liquids</td>
</tr>
<tr>
<td>11</td>
<td>Foods packed in containers/packages (excl. items 1-9) and listed on the right</td>
</tr>
<tr>
<td></td>
<td>(1) Meat</td>
</tr>
<tr>
<td></td>
<td>Fresh oysters for raw consumption</td>
</tr>
<tr>
<td></td>
<td>Fresh oysters (those other than for raw consumption)</td>
</tr>
<tr>
<td></td>
<td>Fish paste products</td>
</tr>
<tr>
<td></td>
<td>Instant noodles</td>
</tr>
<tr>
<td></td>
<td>Fresh noodles (incl. boiled noodles), boxed lunches (bento), prepared bread, prepared dishes, fresh confections</td>
</tr>
<tr>
<td></td>
<td>Fresh fish and shellfish for raw consumption</td>
</tr>
<tr>
<td></td>
<td>Boiled crabs</td>
</tr>
<tr>
<td></td>
<td>Boiled octopus</td>
</tr>
<tr>
<td></td>
<td>(2) Other processed foods</td>
</tr>
<tr>
<td></td>
<td>(3) Citrus fruits, bananas</td>
</tr>
<tr>
<td>12</td>
<td>Genetically modified products and processed foods containing genetically modified ingredients</td>
</tr>
<tr>
<td>13</td>
<td>Foods with health claims</td>
</tr>
<tr>
<td>14</td>
<td>Food additives</td>
</tr>
</tbody>
</table>
2) Law Concerning Standardization and Proper Labeling of Agricultural and Forestry Products (JAS Law) – Quality Labeling Standards

Under the JAS Law, manufacturers and retailers of final foods and beverages sold in Japan are required to affix labels to their products in compliance with the quality labeling standards of the law, to help general consumers in their selection of products. (The following foods and beverages are not subject to the JAS Law: alcoholic beverages, which are subject to the Liquor Tax Law, and drugs and quasi-drugs, which are subject to the Pharmaceutical Affairs Law.)

In recent years, there have been a number of incidents where products failing to meet the Quality Labeling Standards have circulated in the market, due to improprieties by suppliers of processed food ingredients. In the wake of these incidents, the Japanese government expanded the scope of application of the Quality Labeling Standards on April 1, 2008, to include transactions among suppliers of raw materials and other business operators. (Note: Food items packed in containers/packages and traded among business operators have conventionally been subject to labeling requirements under the Food Sanitation Law.)

Therefore, in the case of imported goods, importers must affix labels providing the necessary information, in Japanese, if they wish to sell the goods to other business operators in Japan, and exporters must provide importers with the necessary information.

Quality Labeling Standards are roughly divided into standards for fresh foods and standards for processed foods.

Labels for fresh foods must provide the name of the product and country of origin.

Labels for processed foods packed in containers/packages must provide the name of the product, names of the ingredients, weight of the content, ‘Best-before’ date, storage instructions, country of origin, and name and address of the manufacturer, in that order, in a visible location on the container/package.

In addition to generally applied rules such as the above, category-specific Quality Labeling Standards are also established in consideration of the respective characteristics of each food category. For example, fishery products must comply with requirements prescribed in the Quality Labeling Standard for Fresh Foods, as well as with requirements prescribed in the Quality Labeling Standard for Fishery Products.

[Inquiry]
Ministry of Agriculture, Forestry and Fishery, Regional Agricultural Administration Office

Headquarters of the Food and Agricultural Materials Inspection Center, Food Safety and Consumer Affairs Information Department
### Information to be provided on labels based on the Quality Labeling Standards of the JAS Law

<table>
<thead>
<tr>
<th>Product categories</th>
<th>Common items</th>
<th>Category-specific Quality Labeling Standards</th>
<th>Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agricultural products (vegetables, fruits, etc.)</td>
<td>Name</td>
<td>Quality Labeling Standard for Fishery Products</td>
<td>Labeling as “defrosted,” if defrosted</td>
</tr>
<tr>
<td>Livestock products (meat, chicken eggs, etc.)</td>
<td>Country of origin</td>
<td></td>
<td>Labeling as “cultivated,” if cultivated</td>
</tr>
<tr>
<td>Fishery products</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brown/milled rice</td>
<td></td>
<td>Quality Labeling Standard for Brown Rice and Milled Rice</td>
<td>Place of origin (country of origin, for imported products)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Variety, year of production</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Date of rice milling</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Weight of content</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Name and address of distributor</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Quality Labeling Standard for Mushrooms</td>
<td>Raw wood</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Fungus bed</td>
</tr>
<tr>
<td>Processed vegetable/fruit products</td>
<td>Name</td>
<td>Quality Labeling Standard for Frozen Vegetable Products</td>
<td>Necessity of heating/cooking</td>
</tr>
<tr>
<td>Processed grain products</td>
<td>Name of ingredients</td>
<td></td>
<td>Place of origin of ingredients</td>
</tr>
<tr>
<td>Noodles and pasta</td>
<td>Place of origin of ingredients (for designated processed foods)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meat products</td>
<td>Weight of content</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dairy products</td>
<td>Best-before date</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Processed seafood</td>
<td>Storage instruction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beverages, oil, seasonings</td>
<td>Country of origin (for imported goods)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-cooked frozen foods</td>
<td>Name and address of manufacturer</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Quality Labeling Standard for Processed Tomato Products</td>
<td>Shape (for whole tomatoes)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Usage precautions (for canned products in cans without inner coating)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(53 other items)</td>
<td></td>
</tr>
</tbody>
</table>
3) Law Concerning Liquor Business Association and Measures for Securing Revenue from Liquor Tax (Liquor Business Association Law) – Liquor Labeling

Liquor sold in Japan must be labeled in compliance with the Food Sanitation Law and the Liquor Business Association Law. To import liquor, importers must submit a “Labeling notification form” that provides information on labeling methods and a copy of a liquor sales license based on the Liquor Tax Law to the collection department in the Customs Office having jurisdiction and receive confirmation. Furthermore, the labels must be affixed in a visible location on the container/package of the product, by the time they are claimed from the bonded area.

**<Mandatory labeling items under the Liquor Business Association Law>**
- Address and name of importer (liquor sales operator), and address of the claimer of the goods
- Weight of contents
- Type of liquor (under the Liquor Tax law)
- Alcohol level
- Others

[Inquiry]
Taxation Office having jurisdiction over the relevant sales location
http://www.nta.go.jp/taxanswer/english/12003.htm

4) Law for Promotion of Effective Utilization of Resources

To promote the recycling of containers/packages, business operators are required to affix material identification symbols on containers/packages. For imported goods, the responsibility falls upon the importers/sellers of the goods.

The following five types of materials must be identified.

**Food-related identification symbols based on the Law for Promotion of Effective Utilization of Resources**

- Aluminum cans for beverages and liquor
- Steel cans for beverages and liquor
- PET bottles for foods, beverages, and liquor
- Paper containers and packages
- Plastic containers and packages

[Inquiry]
Ministry of Agriculture, Forestry and Fisheries, General Food Policy Bureau, Food Industry Policy Division, Food Industry Environment Policy Office, Containers/Packages Recycling Section
http://www.maff.go.jp/e/index.html
Part 2 Import Procedures by Food Category
1. Fresh and Frozen Vegetables

Import Procedures for Fresh and Frozen Vegetables

**Responsibilities of the exporter or importer**

**Preparations based on the Plant Protection Law**
- Check that the item to be imported is not an import-banned item.
- Receive an inspection at a governmental plant quarantine facility in the country of export and obtain a phytosanitary certificate.
- Conduct a growing-site inspection, if necessary.
- (For frozen vegetables) Prepare a document certifying that the item concerned has been frozen and preserved at temperatures below -17.8°C.

**Preparations based on the Food Sanitation Law**
- Collect the necessary information for determining whether the item concerned complies with Japan’s Food Sanitation Law.
- Conduct a self-inspection if necessary (either by the exporter or importer) and acquire a result of the inspection.
- Exporters should prepare the documents which the importer in Japan need to submit to the quarantine station along with the “Notification Form for Importation of Foods, etc.” in order to import the item concerned. Enquire with the importer or a quarantine station in Japan concerning the required documents, as they differ according to food category.

**Preparations for customs clearance in Japan**
- Exporters should prepare the relevant documents required for customs clearance in Japan.

**Import procedures based on the Plant Protection Law**
- When importing items subject to import inspection, importers must submit an import inspection application form to the Plant Protection Station, along with a phytosanitary certificate issued by a governmental agency in the country of export and other required documents.

**Import procedures based on the Food Sanitation Law**
- When importing fresh or frozen vegetables, importers must submit a “Notification Form for Importation of Foods, etc.” to the quarantine station, along with other required documents.

**Import quarantine inspection in Japan**
- Importers must submit an import declaration form to the Customs Office, along with other required documents.

**Documents to be submitted by importers**
- Import declaration form
- Invoice
- Packing list
- Bill of lading (B/L) or air waybill

**Documents to be prepared by exporters**
- Phytosanitary certificate issued by a governmental agency in the country of export.
- (For frozen vegetables) Document certifying that the item concerned has been frozen and preserved at temperatures below -17.8°C.
- Manufacturing process schedule as required.

**Documents to be prepared by exporters**
- (For frozen vegetables) List of materials.
- (For frozen vegetables) Manufacturing process schedule (Both of the above must be prepared and issued by the manufacturer, and must bear the name of the manufacturing company).
- Sanitary certificate, inspection results, etc., as required.

**Documents to be submitted by importers**
- Notification Form for Importation of Foods, etc.
- (For frozen vegetables) List of materials.
- (For frozen vegetables) Manufacturing process schedule.
- Sanitary certificate, inspection results, etc., as required.

**Documents to be submitted by importers**
- Import inspection application form.
- Phytosanitary certificate issued by a governmental agency in the country of export.
- (For frozen vegetables) Document certifying that the item concerned has been frozen and preserved at temperatures below -17.8°C.
- Manufacturing process schedule as required.
- Invoice, packing list, etc., as required.
The import of fresh and frozen vegetables is regulated by the Plant Protection Law and the Food Sanitation Law. Of primary concern is to insure that imported fresh and frozen vegetables satisfy Japanese specifications and standards related to the use of agricultural chemicals and food additives. Additionally, the Seeds and Seedlings Law prohibits the import of harvested or processed vegetables that are included in the registry of plant varieties, without the permission of plant breeders who have plant breeding rights.

[Inquiry about the Seeds and Seedlings Law]
Ministry of Agriculture, Forestry and Fisheries, Agricultural Production Bureau, Intellectual Property Division

The sections below describe import procedures and considerations under the Plant Protection Law and the Food Sanitation Law.

1) Plant Protection Law

(1) Pre-export Preparations

When importing fresh and frozen vegetables, importers must take the necessary procedures under the Plant Protection Law, to prevent the entry of foreign pests into Japan. Plant quarantine is conducted at certain seaports and airports only (specified in Article 6 of the Enforcement Regulations of the Plant Protection Law), so importers should be careful when selecting a port of entry.

Fresh and frozen vegetables are generally subject to import inspection (see p.25). Exporters need to have their goods inspected at a plant quarantine station in the country of export and obtain a phytosanitary certificate that conforms to Japan’s requirements.

Frozen vegetables require a document which certifies that (i) they have been frozen at temperatures below -17.8°C, and (ii) that the same frozen state has been maintained until import inspection in Japan. This document may be prepared either by the manufacturer or the exporter. In the case of fresh vegetables that fall under the import-banned category, items (i) and (ii) must be provided on the phytosanitary certificate.

<Import-banned items>

Some types of fresh vegetables may not be imported to Japan, depending on their country or region of export. For example, the following items may not be imported from the ASEAN countries: tomatoes, eggplants, hot peppers, kidney beans, black-eyed peas, cucumbers, melons and other fresh fruits, and the live vines, leaves, tuberous roots of sweet potatoes (see p.24) (note 1). Importers should refer to Annexed Table 2 in the Plant Protection Law Enforcement Regulations for a list of import-banned items and countries/regions from which they may not be imported.

Note that import-banned items may be allowed to be imported as an exception, in the following cases.
(i) Items approved by the Ministry of Agriculture, Forestry and Fisheries, for limited purposes such as for research and displays
(ii) Items regarding which Japan has conditionally agreed to lift the ban in a bilateral agreement with the exporting country, based on the fact that effective disinfecting technology has been established in the country of export and other such reasons

(Note 1) Even when the country of production of a food item is not among the regions from which import is banned, it may be treated as an import-banned item, if the cargo is imported to Japan via an import-banned region, unless it is proven that the container carrying the cargo has not been opened and therefore could not have been contaminated by pests in the import-banned region.
<Post-entry quarantine and growing-site inspection>

Among all items subject to import inspection, seeds and seedlings in particular are meticulously inspected for quarantine pests.

Live tuberous roots of sweet potatoes, live vines of potatoes, and live vines/leaves and underground portions of sugar canes are subject to post-entry quarantine, and are cultivated at a farm in a Plant Protection Station for a certain duration and inspected for viral diseases that cannot be detected in import inspections.

With respect to the underground portions of gingers, colocasia esculentum, and potatoes imported from Indonesia, Singapore, Thailand, the Philippines, and Malaysia, a “growing-site inspection” must be conducted in the country of export, and the passing status of the site, in the case of growing-sites that have passed the inspection, must be indicated on the phytosanitary certificate. Importers should refer to Annexed Table 1 in the Plant Protection Law Enforcement Regulations, for a list of plants and corresponding countries/regions that require a growing-site inspection.

[Information on import-banned items and growing-site inspection]

Plant Protection Station <Plant Protection Law Enforcement Regulations, Annexed Tables 1 and 2>
http://www.pps.go.jp/english/law/list1-(090911-).html (Table 1)
http://www.pps.go.jp/english/law/list2-(080911-).html (Table 2)

Plant Protection Station <Import permission for import-banned items>

[Inquiry]

Plant Protection Stations having jurisdiction over ports of entry
(2) Import Procedures

To apply for plant quarantine inspection, importers must submit a “Plant or import-banned item import inspection application form” to the Plant Protection Station having jurisdiction over the port of entry or apply online, via the PQ-NETWORK (Plant Quarantine Network) electronic processing system for imported plant inspection (note 2).

The application form must be submitted along with a phytosanitary certificate issued by a governmental agency in the country of export and other necessary documents as separately specified by the Plant Protection Station (invoice, bill of lading (B/L), packing list, certificate of frozen and preservation status, manufacturing process schedule (note 3), etc.).

The Plant Protection Station issues an inspection certificate for those items that pass the document examination and spot inspection. Items that fail to pass the inspections are ordered to be “disinfected” or “disposed of (returned to shipper).” Where disinfection is possible, an inspection certificate will be issued after disinfection, and the relevant item can then be processed through subsequent procedures based on the Food Sanitation Law.

(Note 2) Plant quarantine inspection and food sanitation inspection may be performed simultaneously, if a request for “concurrent inspection” is noted on the import inspection application form.

(Note 3) Frozen vegetables may be exempt from inspection if the manufacturing process schedule clearly indicates that the product is free of quarantine pests.

Import Inspection Procedures based on the Plant Protection Law

- **Plants and plant products**
  - **Import-banned items**
    - Plants that serve as host for pests that have not been introduced to Japan and could cause serious damage to agricultural crops if introduced, but are difficult to discover in an import inspection
      - Quarantine pests
      - Soil
    - Prohibited from being imported, in principle
  - **Application for import inspection**
    - (accompanied by a phytosanitary certificate issued in the country of export)
  - **Import inspection**
  - **Quarantine pests detected**
    - Disinfection
    - Plant Quarantine Certificate
  - **No quarantine pests detected**
    - Re-shipment, disposal
  - **Items exempt from quarantine**
    - Highly processed items
      - E.g.: processed tea, dried mango
  - **Procedures based on the Food Sanitation Law**

(3) Main Points of Examination

- Does the item comply with the provisions on “import restrictions” prescribed in Article 6 of the Plant Protection Law? (Whether a phytosanitary certificate issued by a governmental agency in the country of export is properly attached, etc.)
- Does the certificate provide all the required information?
- Does the item fall under the import-banned category?
- Have any soil and quarantine pests been detected from the item in a spot inspection?
2) Food Sanitation Law

(1) Pre-export Preparations

Both exporters and importers should sufficiently collect the necessary information for determining whether the vegetable they wish to import comply with standards prescribed in Japan’s Food Sanitation Law.

<Documents to be prepared by exporters (Japanese translations thereof, in cases where the original document is written in a language other than English)>

- List of materials (for frozen vegetables)
  Complete list specifically showing the scientific names of all materials (food ingredients) and additives used, prepared and issued by the manufacturing company and bearing the name of the company
- Manufacturing process schedule (for frozen vegetables)
  Schedule showing the complete manufacturing process from the materials to the end product, including sterilization temperatures and time, prepared and issued by and bearing the name of the manufacturing company and signed by the person in charge
- Name and address of the manufacturer and place of manufacture in the country of export, and a document showing the name of the product
- Inspection certificate (for beans containing cyanide)

<Documents to be prepared by either exporters or importers (if necessary)>

- Self-inspection results
  Importers may request a self-inspection at a laboratory registered with the Ministry of Health, Labour and Welfare or an official laboratory in the country of export and submit a copy of the results along with the inspection application form, to exempt the inspected items from inspection and expedite the import process.

[Inquiry about inspection facilities]

Ministry of Health, Labour and Welfare <List of official laboratories authorized by MHLW>

Note) In the ASEAN countries, there are official laboratories authorized by MHLW in Indonesia, Singapore, Thailand, and the Philippines. (See p.123)

[General inquiry]

MHLW quarantine stations having jurisdiction over ports of entry
http://www.mhlw.go.jp/english/topics/importedfoods/1-2.html
(2) Import Procedures

Importers who wish to import fresh or frozen vegetables for the purpose of sale or for other commercial purposes are required to submit a “Notification Form for Importation of Foods, etc.” and other required documents (list of materials, manufacturing process schedule, self-inspection results, etc.) to an MHLW quarantine station having jurisdiction over the port where the relevant goods are to be cleared through customs. After examination of the notification form and relevant documents, items that require cargo inspection are inspected in the bonded area where the cargo is being stored, and are either passed or rejected depending on the result of the inspection.

Import Procedures based on the Food Sanitation Law

(3) Main Points of Examination

- Does the item comply with manufacturing standards prescribed in the Food Sanitation Law?

  Fresh and frozen vegetables must comply with Specifications and Standards for Food, Food Additives, etc., which commonly apply to all food items (see p.19).

  Within the Specifications and Standards for Food, Food Additives, etc., the Compositional Specifications for Foods in General provide maximum residue limits (MRLs) for agricultural chemicals used in foods. In Japan, agricultural chemical residue in food is regulated according to a Positive List System. The system sets a maximum residue limit for all agricultural chemicals in principle (including uniform limits), and prohibits the import and sale of food items containing residual agricultural chemicals exceeding their limit. A uniform limit of 0.01 ppm is applied to agricultural chemicals for which maximum residue limits have not been separately established (see p.23).

- The Japan Food Chemical Research Foundation <Positive List System for agricultural chemical residues>
  http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/MRLs-p

- Association for Quality and Safety of Imported Frozen Vegetables <Guideline for requirements
Among fresh vegetables, potatoes that are irradiated to prevent germination must comply with relevant processing standards.

Beans are regulated by compositional specifications and usage standards, to ensure they are free of cyanide compounds. However, saltani, saltapia, butter, pequia, white, and lima beans are allowed to be used as the ingredients of raw bean jam, if they contain less than the maximum residue limit of agricultural chemicals (HCN 500 ppm).

Frozen vegetables are divided into two categories, according to their manufacturing methods: (i) vegetables frozen fresh, or frozen after being cut into strips, and packed in containers or packages; and (ii) vegetables frozen after being heat-processed by blanching (note 4) or frying in oil. The latter vegetables are treated as frozen foods, and are subject to compositional specifications (negative bacteria count and coliform bacteria count, etc.) and preservation standards (preserved at temperatures below -15°C, wrapped and stored in clean and sanitary synthetic resin, aluminum foil, or water-proofed paper) either as “frozen foods for consumption without heating” or “frozen foods for consumption after heating.”

(Note 4) Enzyme action causes vegetable quality to drop even after they are frozen. Therefore, enzyme action is stopped by a method of briefly heating vegetables called blanching, prior to freezing.

Food containers/packages must comply with specifications and standards for containers/packages prescribed in the Food Sanitation Law.

### Specifications and Standards for Fresh and Frozen Vegetables under the Food Sanitation Law

<table>
<thead>
<tr>
<th>Fresh vegetables</th>
<th>Frozen vegetables</th>
</tr>
</thead>
</table>
| Specifications and standards common to all food items | • Compositional Specifications for Foods in General  
• Standards for Manufacturing, Processing, and Preparation of Foods in General  
• Preservation Standards for Foods in General | • Compositional specifications and preservation standards for frozen foods [Frozen foods for consumption without heating] [Frozen foods for consumption after heating] |
| Specifications and standards that apply to individual food items | • Processing standards for potatoes  
• Compositional specifications and usage standards for beans | • Compositional specifications for potatoes  
• Compositional specifications for foods in general  
• Standards for Manufacturing, Processing, and Preparation of Foods in General  
• Preservation Standards for Foods in General |
Specifications and Standards Relating to Containers/Packages of Fresh and Frozen Vegetables

<table>
<thead>
<tr>
<th>Specifications and standards common to all containers/packages</th>
<th>Application-specific specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fresh vegetables</strong></td>
<td>None</td>
</tr>
<tr>
<td>• Specifications for General Implements, Containers, Packaging, and Component Materials</td>
<td></td>
</tr>
<tr>
<td>• Material-specific Specifications for Implements, Containers, Packaging, and Raw Materials</td>
<td></td>
</tr>
<tr>
<td>• Implement, Container, and Packaging Production Standards</td>
<td></td>
</tr>
<tr>
<td><strong>Frozen vegetables</strong></td>
<td>None</td>
</tr>
<tr>
<td>• Specifications for General Implements, Containers, Packaging, and Component Materials</td>
<td></td>
</tr>
<tr>
<td>• Material-specific Specifications for Implements, Containers, Packaging, and Raw Materials</td>
<td></td>
</tr>
<tr>
<td>• Implement, Container, and Packaging Production Standards</td>
<td></td>
</tr>
</tbody>
</table>

[Information on Specifications and Standards for Foods, Food Additives, etc.]
Japan External Trade Organization (JETRO) <Webpage on standards and regulations>
http://www.jetro.go.jp/en/reports/regulations/

Does the use of food additives comply with relevant standards?

All food additives must comply with usage standards which specify the maximum limit allowed to be used in each type of food, compositional specifications which specify purity and properties, and other relevant standards that are established for each substance, as necessary. Some food additives that are legally approved in their countries of export may not be permitted in Japan. Additionally, some additives that bear the same name may in fact be two different additives based on different compositional specifications or usage standards.

Food items that do not comply with Japanese specifications and standards for food additives may not be imported. The following are major points for confirmation regarding food additives.

- Are any undesignated food additives used in the food item, including in its materials?
  - Ministry of Health, Labour and Welfare <Food additives page – List of Designated Food Additives (Enforcement Regulations, Annexed Table 1)>

- Does the use of natural food additives conform to requirements concerning source, manufacturing method, and quality specified in the List of Existing Food Additives?
  - Ministry of Health, Labour and Welfare <Food additives page – List of Existing Food Additives>
Part 2 Import Procedures by Food Category

1. Fresh and Frozen Vegetables

- Are all food additives used properly, in amounts conforming to the standards for the use of food additives?
  - Ministry of Health, Labour and Welfare <Food additives page – List of standards for the use of food additives>

  With respect to fresh and frozen vegetables, the following uses of food additives are strictly prohibited, on the grounds that “the use of food additives in manners which may lead consumers to make an error in judgment in regard to the quality and freshness of the food item goes against the original purpose of using food additives.”

  (i) Use of phosphoric acid and their compounds as a color fixative or bleaching agent
  (ii) Use of sodium hypochlorite for the purpose of bleaching
    With the exception of its proper use as a sterilizing agent to ensure sanitation during the manufacture and preparation of foods
  (iii) Other uses of food additives (including substances other than chemically synthesized substances) as a color-fixative or bleaching agent in vegetables that are to be sold fresh

- Does the food item contain any poisonous or harmful substances?
  Food items should not contain beans that have traces of cyanide, and should be not contaminated by mycotoxins such as aflatoxin, radioactivity, chemical substances, etc.

- Does the manufacturer or place of manufacture have a history of any sanitation problems in the past?
  - Ministry of Health, Labour and Welfare <Website of the Imported Foods Inspection Services – Recent Cases of Violation of the Food Sanitation Law>
    http://www.mhlw.go.jp/english/topics/importedfoods/index.html

3) Considerations for Business Operators

(1) Compliance with the Food Sanitation Law

  The Food Safety Basic Law requires importers to take the necessary steps to ensure food safety at their own initiative. Similarly, the Food Sanitation Law encourages importers to ensure the safety of imported foods on their own responsibility, by acquiring the necessary knowledge and technologies, ensuring the safety of ingredients, and conducting self-inspections.

  Additionally, given Japanese consumers’ increasing concern and distrust of imported foods due to the recent spate of imported food poisoning incidents, importers are now more than ever expected to assure their imported goods guarantee the same level of safety as foods processed in Japan, at all stages of production in the country of export, including the selection of raw materials, production and processing, storage, and transportation.

  In regard to processed foods including frozen vegetables, the Guidelines on Hygiene Control of Import Processed Foods (http://www.mhlw.go.jp/english/topics/importedfoods/guideline/01.html) formulated by the Ministry of Health, Labour and Welfare (June 2008) outlines certain matters that importers should confirm with the manufacturer in the country of export.

  Exporters should also comply with Japan’s Food Sanitation Law and cooperate with importers, by taking careful note of matters specified in the Guidelines on Hygiene Control of Import Processed Foods, preparing the necessary information before importers request them, and striving to provide detailed
When importing/exporting the same items repeatedly, importers and exporters must check for any changes in manufacturing processes and raw materials, and conduct regular tests and inspection, to insure the items are free of harmful/ poisonous substances and pathogenic microorganisms, do not contain undesigned food additives, and comply with standards for the use of food additives as well as compositional specifications.

In relation to fresh and frozen vegetables, Japan experienced a series of incidents in 2002, in which frozen spinach imported from China contained a pesticide substance called chlorpyrifos in levels exceeding the allowed limit. This became a social issue in Japan, which put Japanese consumers on alert against agricultural chemical residues in foods. To comply with the Positive List System, importers should actively collect information on agricultural chemicals at the production stage of vegetables (information on proper usage and management of agricultural chemicals, types and usage methods of agricultural chemicals that may be used, cases of violation against residue standards, etc.), and assess residue status, as necessary.

Agricultural chemicals that are approved for use within the ASEAN countries and in certain destination countries may not necessarily be approved in the Japan. Therefore, importers should take measures to thoroughly disseminate Japan’s specifications and standards in exporting countries, and to prevent such agricultural chemicals used in items destined for countries other than Japan from contaminating items intended for export to Japan.

(2) Confirmation with quarantine stations in Japan regarding information on sanitation

- What basic guidance do quarantine stations offer importers?
    http://www.mhlw.go.jp/english/topics/importedfoods/08/08-01.html

- Is the food item to be imported subject to monitoring inspection?
  - At the beginning of each fiscal year, the Ministry of Health, Labour and Welfare announces an annual schedule for the number of inspections to be conducted per food category, determined in consideration of the rate of past violations, number and weight of imported cargos, and seriousness of violations.
    http://www.mhlw.go.jp/english/topics/importedfoods/08/08-03.html

- Is the food item to be imported subject to an ordered inspection?
  - At the beginning of each fiscal year, the Ministry of Health, Labour and Welfare announces a list (target products and inspection items) of foods that are deemed to have high probability of violating the Food Sanitation Law, judging from situations in exporting countries, food properties, and cases of noncompliance by similar foods. Additional inspection orders may also be issued later, depending on the subsequent status of violations. When the Minister of Health, Labour and Welfare issues an ordered inspection, the relevant cargo is stored in a bonded area until the importer applies for an inspection at a registered laboratory (fee required) and obtains an inspection result.
    http://www.mhlw.go.jp/english/topics/importedfoods/08/08-02.html
What are the most common types of violations against the Food Sanitation Law?

A record of past violations against the Food Sanitation Law shows frequent violations in relation to agricultural chemical residue levels in fresh and frozen vegetables imported from the ASEAN countries.

Ministry of Health, Labour and Welfare <Website of the Imported Foods Inspection Services – Recent Cases of Violation of the Food Sanitation Law>
http://www.mhlw.go.jp/english/topics/importedfoods/index.html

The following is a list of precautions concerning the import of fresh and frozen vegetables.

- Many items are subject to an ordered inspection, and should be frequently confirmed.
- Beware of violations against specifications concerning microorganisms in frozen vegetables (viable bacteria count, coliform bacteria, E. coli).
- Beware of contamination by harmful or poisonous substances such as aflatoxin and cyanide.
- Note that imported foods often contain large traces of agricultural chemical residues, such as chlorpyrifos, parathion methyl, and cypermethrin.
- Beware of undesignated uses of food additives in fresh vegetables.
- The use of sodium chlorite as a bleaching agent for vegetables and butterbur intended for raw consumption is regulated by standards for the use of food additives. It must decompose or be removed by completion of the final product.
- Irradiation of vegetables is not allowed in Japan, except for the purpose of preventing germination in potatoes.

**Fresh and Frozen Vegetables – Excerpt from “Recent Cases of Violation of the Food Sanitation Law”** (January – August 2008; violations of exports from ASEAN countries)

<table>
<thead>
<tr>
<th>Item</th>
<th>Article</th>
<th>Country of export</th>
<th>Description of violation</th>
<th>Measure taken</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frozen food for consumption after heating (heated immediately before freezing): Frozen boiled cassava</td>
<td>6 Indonesia</td>
<td>14 mg/kg cyanide compound detected</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Ordered inspection</td>
<td></td>
</tr>
<tr>
<td>Frozen food for consumption after heating (heated immediately before freezing): Cassava</td>
<td>6 Thailand</td>
<td>12 mg/kg cyanide compound detected</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Ordered inspection</td>
<td></td>
</tr>
<tr>
<td>Fresh green asparagus</td>
<td>11 Thailand</td>
<td>Residue exceeding the limit stipulated in Article 11 Paragraph 3 as the amount unlikely to cause harm to human health (0.02 ppm EPN detected)</td>
<td>Entire cargo already sold Monitoring inspection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frozen food for consumption without heating: Okra (frozen okra)</td>
<td>11 Thailand</td>
<td>Residue exceeding the limit stipulated in Article 11 Paragraph 3 as the amount unlikely to cause harm to human health (0.02 ppm EPN detected)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Ordered inspection</td>
<td></td>
</tr>
<tr>
<td>Frozen red hot peppers</td>
<td>11 Thailand</td>
<td>Compositional noncompliance (0.17 ppm triazophos detected)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Self-inspection</td>
<td></td>
</tr>
<tr>
<td>Fresh okra</td>
<td>11 Philippines</td>
<td>Residue exceeding the limit stipulated in Article 11 Paragraph 3 as the amount unlikely to cause harm to human health (0.02 ppm tebuconazole detected)</td>
<td>Instructions for disposal or re-shipment Monitoring inspection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fresh okra</td>
<td>11 Philippines</td>
<td>Residue exceeding the limit stipulated in Article 11 Paragraph 3 as the amount unlikely to cause harm to human health (0.02 ppm tebuconazole detected)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Ordered inspection</td>
<td></td>
</tr>
<tr>
<td>Fresh okra</td>
<td>11 Philippines</td>
<td>Residue exceeding the limit stipulated in Article 11 Paragraph 3 as the amount unlikely to cause harm to human health (0.04 ppm difenoconazole detected)</td>
<td>Instructions for disposal or re-shipment Monitoring inspection</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
1. Fresh and Frozen Vegetables

<table>
<thead>
<tr>
<th>Item</th>
<th>Article</th>
<th>Country of export</th>
<th>Description of violation</th>
<th>Limit</th>
<th>Remarks</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fresh okra</td>
<td>11</td>
<td>Philippines</td>
<td>Residue exceeding the limit stipulated in Article 11 Paragraph 3 as the amount unlikely to cause harm to human health (0.03 ppm fluazifop detected)</td>
<td>Instructions for disposal or re-shipment</td>
<td>Monitoring inspection</td>
<td></td>
</tr>
<tr>
<td>Fresh okra</td>
<td>11</td>
<td>Philippines</td>
<td>Noncompliance with compositional specifications (0.06 ppm fluazifop detected)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Ordered inspection</td>
<td></td>
</tr>
<tr>
<td>Fresh okra</td>
<td>11</td>
<td>Philippines</td>
<td>Noncompliance with compositional specifications (0.06 ppm fluazifop detected)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Self-inspection</td>
<td></td>
</tr>
<tr>
<td>Fresh okra</td>
<td>11</td>
<td>Philippines</td>
<td>Noncompliance with compositional specifications (0.7 ppm methamidophos detected)</td>
<td>Instructions for disposal or re-shipment</td>
<td>Monitoring inspection</td>
<td></td>
</tr>
<tr>
<td>Frozen food for consumption without heating: Okra (frozen okra (slice cut))</td>
<td>11</td>
<td>Philippines</td>
<td>Noncompliance with compositional specifications (0.06 ppm fluazifop detected)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Self-inspection</td>
<td></td>
</tr>
<tr>
<td>Frozen food for consumption after heating (unheated prior to freezing): Spinach</td>
<td>11</td>
<td>Vietnam</td>
<td>Noncompliance with compositional specifications (E. coli positive)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Monitoring inspection</td>
<td></td>
</tr>
<tr>
<td>Frozen food for consumption without heating: Okra (frozen okra whole)</td>
<td>11</td>
<td>Vietnam</td>
<td>Noncompliance with compositional specifications (coliform bacteria positive)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Monitoring inspection</td>
<td></td>
</tr>
<tr>
<td>Fresh kale</td>
<td>11</td>
<td>Laos</td>
<td>Noncompliance with compositional specifications (0.011 ppm fibronil detected)</td>
<td>Instructions for disposal or re-shipment</td>
<td>Monitoring inspection</td>
<td></td>
</tr>
</tbody>
</table>

(Note) “Self-inspection” refers to the guidance provided by the quarantine station to importers regarding the implementation of a self-inspection on items that are required on the first import occasion and on regular occasions, from the standpoint of assisting importers to fulfill their food sanitation and security obligations.

(Source) Ministry of Health, Labour and Welfare <Website of the Imported Foods Inspection Services – Recent Cases of Violation of the Food Sanitation Law>
http://www.mhlw.go.jp/english/topics/importedfoods/index.html

Fresh and Frozen Vegetables – Excerpt from “Typical Cases of Violation of the Food Sanitation Law” (violations of exports from ASEAN countries)

Typical cases judged to be in violation of the Food Sanitation Law that were found in the past on the occasion of import notification, compiled by the Ministry of Health, Labour and Welfare

<table>
<thead>
<tr>
<th>Item</th>
<th>Country of export</th>
<th>Description of violation</th>
<th>Limit</th>
<th>Remarks</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fresh feverweed</td>
<td>Thailand</td>
<td>Noncompliance with compositional standard (chlorpyrifos)</td>
<td>0.01 ppm</td>
<td>Chlorpyrifos: Residual agricultural chemical</td>
<td></td>
</tr>
<tr>
<td>Fresh tulsi</td>
<td>Thailand</td>
<td>Noncompliance with compositional standard (methyl parathion)</td>
<td>1.0 ppm</td>
<td>Methyl parathion: Residual agricultural chemical</td>
<td></td>
</tr>
<tr>
<td>Fresh watercress</td>
<td>Thailand</td>
<td>Noncompliance with compositional standard (cypermethrin)</td>
<td>5.0 ppm</td>
<td>Cypermethrin: Residual agricultural chemical</td>
<td></td>
</tr>
<tr>
<td>Fresh coriander</td>
<td>Thailand</td>
<td>Noncompliance with compositional standard (chlorpyrifos)</td>
<td>0.01 ppm</td>
<td>Chlorpyrifos: Residual agricultural chemical</td>
<td></td>
</tr>
<tr>
<td>Fresh coriander</td>
<td>Thailand</td>
<td>Noncompliance with compositional standard (chlorpyrifos)</td>
<td>0.01 ppm</td>
<td>Chlorpyrifos: Residual agricultural chemical</td>
<td></td>
</tr>
<tr>
<td>Fresh rice paddy herb</td>
<td>Thailand</td>
<td>Noncompliance with compositional standard (methyl parathion)</td>
<td>1.0 ppm</td>
<td>Methyl parathion: Residual agricultural chemical</td>
<td></td>
</tr>
<tr>
<td>Fresh gotu kala</td>
<td>Thailand</td>
<td>Noncompliance with compositional standard (methyl parathion)</td>
<td>1.0 ppm</td>
<td>Methyl parathion: Residual agricultural chemical</td>
<td></td>
</tr>
<tr>
<td>Fresh dill</td>
<td>Thailand</td>
<td>Noncompliance with compositional standard (chlorpyrifos)</td>
<td>0.01 ppm</td>
<td>Chlorpyrifos: Residual agricultural chemical</td>
<td></td>
</tr>
</tbody>
</table>
Part 2 Import Procedures by Food Category

1. Fresh and Frozen Vegetables

<table>
<thead>
<tr>
<th>Item</th>
<th>Country of export</th>
<th>Description of violation</th>
<th>Limit</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fresh peppermint</td>
<td>Thailand</td>
<td>Noncompliance with compositional standard (methyl parathion)</td>
<td>1.0 ppm</td>
<td>Methyl parathion: Residual agricultural chemical</td>
</tr>
<tr>
<td>Fresh basil</td>
<td>Thailand</td>
<td>Noncompliance with compositional standard (methyl parathion)</td>
<td>1.0 ppm</td>
<td>Methyl parathion: Residual agricultural chemical</td>
</tr>
<tr>
<td>Fresh basil</td>
<td>Thailand</td>
<td>Noncompliance with compositional standard (fenobucarb)</td>
<td>0.3 ppm</td>
<td>Fenobucarb: Residual agricultural chemical</td>
</tr>
<tr>
<td>Fresh beefsteak plant leaf</td>
<td>Thailand</td>
<td>Noncompliance with compositional standard (chlorpyrifos)</td>
<td>0.01 ppm</td>
<td>Chlorpyrifos: Residual agricultural chemical</td>
</tr>
<tr>
<td>Fresh beefsteak plant leaf</td>
<td>Thailand</td>
<td>Noncompliance with compositional standard (fenitrothion)</td>
<td>0.2 ppm</td>
<td>Fenitrothion: Residual agricultural chemical</td>
</tr>
<tr>
<td>Frozen fried shallot</td>
<td>Vietnam</td>
<td>Antioxidant: T.B.H.Q. included</td>
<td>Undesignated additive</td>
<td>Frozen food for consumption without heating</td>
</tr>
</tbody>
</table>


Other considerations regarding the import of fresh and frozen vegetables

- Thoroughly control temperatures and humidity during transport and storage, to prevent rotting, degeneration, and the occurrence of molds.
- Thoroughly clean containers that are used for transport.
- Note that container/package sizes and sanitary wrapping are important aspects in Japanese business customs.
- Note that some herbs are subject to the Pharmaceutical Affairs Law, because of their pharmaceutical ingredients.
2. Fresh Fruits

Import Procedures for Fresh Fruits

Responsibilities of the exporter or importer

[Preparations based on the Plant Protection Law]
- Check that the item to be imported is not an import-banned item.
- Receive an inspection at a governmental plant quarantine facility in the country of export and obtain a phytosanitary certificate.

[Preparations based on the Food Sanitation Law]
- Collect the necessary information for determining whether the item concerned complies with Japan's Food Sanitation Law.
- Conduct a self-inspection if necessary (either by the exporter or importer) and acquire a result of the inspection.
- Exporters should prepare the documents which the importer in Japan need to submit to the quarantine station along with the "Notification Form for Importation of Foods, etc." in order to import the item concerned. Enquire with the importer or a quarantine station in Japan concerning the required documents, as they differ according to food category.

[Preparations for customs clearance in Japan]
- Exporters should prepare the relevant documents required for customs clearance in Japan.

Required documents

[Documents to be prepared by exporters]
- Phytosanitary certificate issued by a governmental agency in the country of export
- Sanitary certificate, inspection results, etc., as required

[Documents to be submitted by importers]
- Import inspection application form
- Phytosanitary certificate issued by a governmental agency in the country of export
- Invoice, packing list, etc., as required

[Documents to be submitted by importers]
- Notification Form for Importation of Foods, etc.
- Sanitary certificate, inspection results, etc., as required

- Importers must submit an import declaration form to the Customs Office, along with other required documents.
The import of fresh fruits is regulated by the Plant Protection Law and the Food Sanitation Law. Of primary concern is to insure that imported fresh fruits satisfy Japanese specifications and standards related to the use of agricultural chemicals and food additives. Additionally, the Seeds and Seedlings Law prohibits the import of harvested or processed fruits that are included in the registry of plant varieties, without the permission of plant breeders who have plant breeding rights.

[Inquiry about the Seeds and Seedlings Law]
Ministry of Agriculture, Forestry and Fisheries, Agricultural Production Bureau, Intellectual Property Division

The sections below describe procedures and considerations for the import of fresh fruits under the Plant Protection Law and the Food Sanitation Law.

1) Plant Protection Law

(1) Pre-export Preparations

When importing fresh fruits, importers must take the necessary procedures under the Plant Protection Law, to prevent the entry of foreign pests into Japan. Plant quarantine is conducted at certain seaports and airports only (specified in Article 6 of the Enforcement Regulations of the Plant Protection Law), so importers should be careful when selecting a port of entry.

Fresh fruits are generally subject to import inspection (see p.25). Exporters need to have the items to be inspected at a plant quarantine station in the country of export and obtain a phytosanitary certificate. Information provided on the certificate must satisfy Japan’s requirements.

<Import-banned items>

Some types of fresh fruits may not be imported to Japan, depending on their country or region of export. For example, the following items may not be imported from the ASEAN countries: tropical fruits (papaya, mango, mangosteen, langsat, carambola, santol, wax apple, guava, rambutan, lychee, longan, etc.); citrus fruits; fresh fruits such as apples, pears, grapes, peaches; fresh fruits such as ripe bananas (see p.24) (note1).

Importers should refer to Annexed Table 2 in the Plant Protection Law Enforcement Regulations for a list of import-banned items and countries/regions from which they may not be imported.

Note that import-banned items may be allowed to be imported as an exception, in the following cases.
(i) Items approved by the Ministry of Agriculture, Forestry and Fisheries, for limited purposes such as for research and displays
(ii) Items regarding which Japan have conditionally agreed to lift the ban in a bilateral agreement with the exporting country, based on the fact that effective disinfecting technology has been established in the country of export and other such reasons
Items that apply under case (ii) above (as of Sept. 2008)

<table>
<thead>
<tr>
<th>Country of export</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Philippines</td>
<td>Solo type of papayas</td>
</tr>
<tr>
<td>Philippines</td>
<td>Manila Super variety of mangos</td>
</tr>
<tr>
<td>Thailand</td>
<td>Nan Klarngwun variety, Nam Dorkmai variety, Pimsen Daeng variety, Mahachanok variety and Rad variety of mangos</td>
</tr>
<tr>
<td>Thailand</td>
<td>Mangosteen</td>
</tr>
<tr>
<td>Malaysia</td>
<td>Harumanis variety of mango</td>
</tr>
</tbody>
</table>

* Provided that the above items are imported directly from their countries of export and meet the standards established by the Minister of Agriculture, Forestry and Fisheries

(Note1) Even when the country of production of a food item is not among the regions from which import is banned, it may be treated as an import-banned item, if the cargo is imported to Japan via an import-banned region, unless it is proven that the container carrying the cargo has not been opened and therefore could not have been contaminated by pests in the import-banned region.

[Information on import-banned items and the field inspection]
Plant Protection Station <Plant Protection Law Enforcement Regulations, Annexed Table 2>
http://www.pps.go.jp/english/law/list2-(080911-).html
Plant Protection Station <Import permission for import-banned items>

[Inquiry]
Plant Protection Stations having jurisdiction over ports of entry

(2) Import Procedures

To apply for plant quarantine inspection, importers must submit a “Plant or import-banned item import inspection application form” to the Plant Protection Station having jurisdiction over the port of entry or apply online, via the PQ-NETWORK (Plant Quarantine Network) electronic processing system for imported plant inspection (note2).

The application form must be submitted along with a phytosanitary certificate issued by a governmental agency in the country of export and other necessary documents as separately specified by the Plant Protection Station (invoice, bill of lading (B/L), packing list, etc.).

The Plant Protection Station issues an inspection certificate for those items that pass the document examination and spot inspection. Items that fail to pass the inspections are ordered to be “disinfected” or “disposed of (returned to shipper).” Where disinfection is possible, an inspection certificate will be issued after disinfection, and the relevant item can then be processed through subsequent procedures based on the Food Sanitation Law.

(Note2) Plant quarantine inspection and food sanitation inspection may be performed simultaneously, if a request for “concurrent inspection” is noted on the import inspection application form.
(3) Main Points of Examination
- Does the item comply with the provisions on “import restrictions” prescribed in Article 6 of the Plant Protection Law? (Whether a phytosanitary certificate issued by a governmental agency in the country of export is properly attached, etc.)
- Does the certificate provide all the required information?
- Does the item fall under the import-banned category?
- Have any soil and quarantine pests been detected from the item in a spot inspection?

2) Food Sanitation Law

(1) Pre-export Preparations
Both exporters and importers should sufficiently collect the necessary information for confirming whether the fruit they wish to import comply with standards prescribed in Japan’s Food Sanitation Law.

<Documents to be prepared by exporters (a Japanese translation thereof, in cases where the original document is written in a language other than English)>
- Name and address of the manufacturer and place of manufacture in the country of export, and a document showing the name of the product

<Documents to be prepared by either exporters or importers (if necessary)>
- Self-inspection results
Importers may request a self-inspection at a laboratory registered with the Ministry of Health, Labour and Welfare or an official laboratory in the country of export and submit a copy of the results along with the inspection application form, to exempt the inspected items from inspection and expedite the import
(2) Import Procedures

Importers who wish to import fresh fruits for the purpose of sale or for other commercial purposes are required to submit a “Notification Form for Importation of Foods, etc.” and other required documents (self-inspection results, etc.) to an MHLW quarantine station having jurisdiction over the area in which the relevant goods are to be cleared through customs. After examination of the notification form and relevant documents, items that require cargo inspection are inspected in the bonded area where the cargo is being stored, and are either passed or rejected depending on the result of the inspection.

**Import Procedures based on the Food Sanitation Law**

![Import Procedures Diagram]

(3) Main Points of Examination

- Does the item comply with manufacturing standards prescribed in the Food Sanitation Law?
  
  Fresh fruits must comply with Specifications and Standards for Food, Food Additives, etc., which commonly apply to all food items (see p.19).
  
  Within the Specifications and Standards for Food, Food Additives, etc., the Compositional Specifications for Foods in General provide maximum residue limits (MRLs) for agricultural chemicals in foods. In Japan,
residues of agricultural chemicals in food are regulated according to a Positive List System. The system sets a maximum residue limit for all agricultural chemicals in principle (including uniform limits), and prohibits the import and sale of food items containing residual agricultural chemicals exceeding their limit. A uniform limit of 0.01 ppm is applied to agricultural chemicals for which maximum residue limits have not been separately established (see p.23).

- The Japan Food Chemical Research Foundation <Positive List System for agricultural chemical residues>
  http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/MRLs-p

### Specification and Standards for Fresh Fruits under the Food Sanitation Law

<table>
<thead>
<tr>
<th>Fresh fruits</th>
<th>Specifications and standards common to all food items</th>
<th>Specifications and standards that apply to individual food items</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Compositional Specifications for Foods in General</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>• Standards for Manufacturing, Processing, and Preparation of Foods in General</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Preservation Standards for Foods in General</td>
<td></td>
</tr>
</tbody>
</table>

[Information on Specifications and Standards for Foods, Food Additives, etc.]
Japan External Trade Organization (JETRO) <Webpage on standards and regulations>
http://www.jetro.go.jp/en/reports/regulations/

- Does the use of food additives comply with relevant standards?

  All food additives must comply with usage standards which specify the maximum limit allowed to be used in each type of food, compositional specifications which specify purity and properties, and other relevant standards that are established for each substance, as necessary. Some food additives that are legally approved in their countries of export may not be permitted in Japan. Additionally, some additives that bear the same name may in fact be two different additives based on different compositional specifications or usage standards.

  Food items that do not comply with Japanese specifications and standards for food additives may not be imported. The following are major points for confirmation regarding food additives.

- Are any undesignated food additives used in the food item, including in its materials?

  - Ministry of Health, Labour and Welfare <Food additives page – List of Designated Food Additives (Enforcement Regulations, Annexed Table 1)>

- Does the use of natural food additives conform to requirements concerning source, manufacturing method, and quality specified in the List of Existing Food Additives?

  - Ministry of Health, Labour and Welfare <Food additives page – List of Existing Food Additives>
2. Fresh Fruits

- Are all food additives used properly, in amounts conforming to the standards for the use of food additives?
  - Ministry of Health, Labour and Welfare <Food additives page – List of standards for the use of food additives>

Harvested fruits may rot, produce molds, or otherwise degenerate in quality during transport and storage. Japan prohibits the post-harvest use of agricultural chemicals, but some chemical agents that are used after harvesting to prevent rotting and enhance keeping qualities are regarded as food additives and allowed to be used as fungicides. They include diphenyls, ortho-phenylphenol and its compounds, thiabendazole, and imazalil, and are regulated in terms of the fruits to which they may be applied (banana, citrus fruits) and maximum residue limits. There are also standards for the use of film-forming agents and preservatives on fruit skins, as well as bans on the use of additives for the purposes of color-fixing and bleaching.

- Does the food item contain any poisonous or harmful substances?
  Food items should not be contaminated by mycotoxins such as aflatoxin and patulin, radioactivity, chemical substances, etc.

- Does the manufacturer or place of manufacture have a history of any sanitation problems in the past?
  - Ministry of Health, Labour and Welfare <Website of the Imported Foods Inspection Services – Recent Cases of Violation of the Food Sanitation Law>
    http://www.mhlw.go.jp/english/topics/importedfoods/index.html

3) Considerations for Business Operators

(1) Compliance with the Food Sanitation Law

The Food Safety Basic Law requires importers to take the necessary steps to ensure food safety at their own initiative. Similarly, the Food Sanitation Law encourages importers to ensure the safety of imported foods on their own responsibility, by acquiring the necessary knowledge and technologies, ensuring the safety of ingredients, and conducting self-inspections.

Additionally, given Japanese consumers’ increasing concern and distrust of imported foods due to the recent spate of imported food poisoning incidents, importers are now more than ever expected to assure their imported goods guarantee the same level of safety as foods processed in Japan, at all stages of production in the country of export, including the selection of raw materials, production and processing, storage, and transportation.

When importing/exporting the same items repeatedly, importers and exporters must check for any changes in manufacturing processes and raw materials, and conduct regular tests and inspection, to insure the items are free of harmful/poisonous substances, do not contain undesignated food additives, and comply with standards for the use of food additives as well as compositional specifications.

When handling fresh fruits, it is especially important to pay careful attention to standards concerning residual agricultural chemicals and standards for the use of fungicides on bananas and citrus fruits. To comply with the Positive List System, importers should make actively collect information on agricultural chemicals at the production stage of fruits (information on proper usage and management of agricultural chemicals, types and usage methods of agricultural chemicals that may be used, cases of violation against
Part 2 Import Procedures by Food Category

2. Fresh Fruits

residue standards, etc.), and assess residue status, as necessary.

In some cases, agricultural chemicals that are allowed to be used in the ASEAN countries and other importing countries may be prohibited from use in Japan. Importers should therefore gain a thorough understanding of relevant standards in Japan, and take precautions to avoid contamination of their goods along with other export items to which such agricultural chemicals may be applied.

(2) Confirmation with quarantine stations in Japan regarding information on sanitation

- What basic guidance do quarantine stations offer importers?
    http://www.mhlw.go.jp/english/topics/importedfoods/08/08-01.html

- Is the food item to be imported subject to monitoring inspection?
  At the beginning of each fiscal year, the Ministry of Health, Labour and Welfare announces an annual schedule for the number of inspections to be conducted per food category, determined in consideration of the rate of past violations, number and weight of imported cargos, and seriousness of violations.
    http://www.mhlw.go.jp/english/topics/importedfoods/08/08-03.html

- Is the food item to be imported subject to an ordered inspection?
  At the beginning of each fiscal year, the Ministry of Health, Labour and Welfare announces a list (target products and inspection items) of foods that are deemed to have high probability of violating the Food Sanitation Law, judging from situations in exporting countries, food properties, and cases of noncompliance by similar foods. Additional inspection orders may also be issued later, depending on the subsequent status of violations. When the Minister of Health, Labour and Welfare issues an ordered inspection, the relevant cargo is stored in a bonded area until the importer applies for an inspection at a registered laboratory (fee required) and obtains an inspection result.
    http://www.mhlw.go.jp/english/topics/importedfoods/08/08-02.html

- What are the most common types of violations against the Food Sanitation Law?
  A record of past violations against the Food Sanitation Law shows frequent violations in relation to agricultural chemical residues.
  - Ministry of Health, Labour and Welfare <Website of the Imported Foods Inspection Services – Recent Cases of Violation of the Food Sanitation Law>
    http://www.mhlw.go.jp/english/topics/importedfoods/index.html

Bear in mind the following matters in regard to the import of fresh fruits.

- Regularly check what items are subject to an ordered inspection.
- Imported foods often contain traces of agricultural chemical residues such as of chlorpyrifos, cypermethrin, and profenofos.
- Disseminate proper knowledge of Japanese specifications and standards regarding the use of fungicides and film-forming agents.
Fresh Fruits – Excerpt from “Recent Cases of Violation of the Food Sanitation Law”
(January – August 2008; violations of exports from ASEAN countries)

<table>
<thead>
<tr>
<th>Item</th>
<th>Article</th>
<th>Country of export</th>
<th>Description of violation</th>
<th>Measure taken</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fresh banana</td>
<td>11</td>
<td>Thailand</td>
<td>Compositional noncompliance (0.08 ppm cypermethrin)</td>
<td>Instructions for disposal or re-shipment</td>
<td>Monitoring inspection</td>
</tr>
<tr>
<td>Fresh banana</td>
<td>11</td>
<td>Thailand</td>
<td>Compositional noncompliance (0.07 ppm cypermethrin)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Ordered inspection</td>
</tr>
<tr>
<td>Fresh mango</td>
<td>11</td>
<td>Philippines</td>
<td>Compositional noncompliance (0.11 ppm profenofos)</td>
<td>Instructions for disposal or re-shipment</td>
<td>Monitoring inspection</td>
</tr>
<tr>
<td>Fresh mango</td>
<td>11</td>
<td>Philippines</td>
<td>Compositional noncompliance (0.09 ppm cypermethrin)</td>
<td>Instructions for disposal or re-shipment</td>
<td>Monitoring inspection</td>
</tr>
<tr>
<td>Fresh mango</td>
<td>11</td>
<td>Philippines</td>
<td>Compositional noncompliance (0.20 ppm chlorpyrifos)</td>
<td>Instructions for disposal or re-shipment</td>
<td>Monitoring inspection</td>
</tr>
</tbody>
</table>

(Source) Ministry of Health, Labour and Welfare <Website of the Imported Foods Inspection Services – Recent Cases of Violation of the Food Sanitation Law>
http://www.mhlw.go.jp/english/topics/importedfoods/index.html

Other considerations regarding the import of fresh fruits

- Thoroughly control temperatures and humidity during transport and storage, to prevent rotting, degeneration, and the occurrence of molds.
- Thoroughly clean containers that are used for transport.
- Note that container/package sizes and sanitary wrapping are important aspects in Japanese business customs.
- Citrus fruits and bananas that have been treated with fungicide must bear a label indicating fungicide use on their container or package.
3. Frozen Fish and Shellfish

Import Procedures for Frozen Fish and Shellfish

<table>
<thead>
<tr>
<th>Responsibilities of the exporter or importer</th>
<th>Required documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enquire with the agency having jurisdiction over the Law for details.</td>
<td>Enquire with the agency having jurisdiction over the Law for details.</td>
</tr>
<tr>
<td>[Preparations based on the Foreign Exchange and Foreign Trade Law -- import approval and import confirmation systems under the Cabinet Order Concerning Control of Import Trade]</td>
<td>[Documents to be prepared by exporters]</td>
</tr>
<tr>
<td>• When importing items subject to the import approval system or the import confirmation system, importers must obtain import approval or import confirmation.</td>
<td>• List of materials</td>
</tr>
<tr>
<td>[Law Concerning Special Measures to Strengthen the Conservation and Management of Tuna Resources]</td>
<td>• Manufacturing process schedule (Both of the above must be prepared and issued by the manufacturer, and must bear the name of the manufacturing company)</td>
</tr>
<tr>
<td>• When importing frozen tuna, importers must submit a report to the Fisheries Agency before and after import.</td>
<td>• Description of the product</td>
</tr>
<tr>
<td>[Preparations under the Food Sanitation Law]</td>
<td>• Sanitary certificate, inspection results, etc., as required</td>
</tr>
<tr>
<td>• Collect the necessary information for determining whether the item concerned complies with Japan’s Food Sanitation Law.</td>
<td>[Documents to be prepared by exporters]</td>
</tr>
<tr>
<td>• Conduct a self-inspection if necessary (either by the exporter or importer) and acquire a result of the inspection.</td>
<td>• Invoice</td>
</tr>
<tr>
<td>• Exporters should prepare the documents which the importer in Japan need to submit to the quarantine station along with the “Notification Form for Importation of Foods, etc.” in order to import the item concerned. Enquire with the importer or a quarantine station in Japan concerning the required documents, as they differ according to food category.</td>
<td>• Packing list</td>
</tr>
<tr>
<td>[Preparations for customs clearance in Japan]</td>
<td>• Bill of lading (B/L) or air waybill</td>
</tr>
<tr>
<td>• Exporters should prepare the relevant documents required for customs clearance in Japan.</td>
<td>[Documents to be submitted by importers]</td>
</tr>
<tr>
<td>[Import procedures based on the Food Sanitation Law]</td>
<td>• Import Notification for Importation of Foods, etc. to the quarantine station, along with other required documents.</td>
</tr>
<tr>
<td>• Importers must submit an “Import Notification for Importation of Foods, etc.” to the quarantine station, along with other required documents.</td>
<td>[Documents to be submitted by importers]</td>
</tr>
<tr>
<td>• Importers must submit an import declaration form to the Customs Office, along with other required documents.</td>
<td>• Import declaration form</td>
</tr>
<tr>
<td>[Documents to be submitted by importers]</td>
<td>• Invoice</td>
</tr>
<tr>
<td>• In the case of items subject to the Foreign Exchange and Foreign Trade Law, an import approval or import confirmation is required.</td>
<td>• Packing list</td>
</tr>
<tr>
<td>[Documents to be submitted by importers]</td>
<td>• Bill of lading (B/L) or air waybill</td>
</tr>
</tbody>
</table>
The import of frozen fish and shellfish for human consumption is regulated by the Food Sanitation Law. Some frozen fish and shellfish products also require import permission based on the Foreign Exchange and Foreign Trade Law. Importers should therefore check whether the product they wish to import is subject to this regulation, before it is exported from the country of export.

When importing frozen tuna, importers have a reporting obligation under the Law Concerning Special Measures to Strengthen the Conservation and Management of Tuna Resources.

1) Foreign Exchange and Foreign Trade Law
   (Cabinet Order Concerning Control of Import Trade)

Under the Foreign Exchange and Foreign Trade Law, the Cabinet Order Concerning Control of Import Trade stipulates specific means of import control, such as the Import Notice System import-related matters are defined and announced by the Minister of Economy, Trade and Industry) and Import Approval System (importers of specified items must obtain the approval of the Minister of Economy, Trade and Industry).

The Import Approval System consists of the (i) Import Quota System, (ii) Paragraph 2 and Paragraph 2-2 Approval System, and (iii) Confirmation System. As most foods subject to the Import Approval System are fishery products, importers should check whether the frozen fish/shellfish product they wish to import is subject to the system.

If the food to be imported is subject to the Import Approval System, importers must obtain an import license or an import confirmation according to the specified procedure.

Import Quota System

The Import Quota System sets a limit to the total weight (amount) of cargos containing specified items that may be imported within a certain duration, and allocates a quota of import quantity (amount) to importers who satisfy certain requirements.

Items subject to the Import Quota System are listed in the Import Notice, as either “non-liberalized items” or “items restricted under the Montreal Protocol.”

The following fish species are subject to the Import Quota System as “non-liberalized items.”

<Fish and shellfish subject to the import quota system> (as of Aug. 18, 2008)

Herring, Pacific Ocean hearing, cod, cod eggs, yellowtail, mackerel, sardine, horse mackerel, saury, walleye pollack, scallop, scallop eyes, squid

An “import announcement” is made once a year, per item, to provide information on application procedures for an import quota. Import quota applications are accepted after these import announcements are made.

The Import Notice and import announcement also appear in the METI public bulletin, in the “Tsusho Koho” publication issued by JETRO, and on the website of the Ministry of Economy, Trade and Industry.

To import items that are subject to the Import Quota System, importers must submit an import quota application form along with other required documents to the Agricultural and Marine Products Office in the Trade and Economic Cooperation Bureau of METI, and separately complete an import approval application form after receiving a quota allocation. After receiving back the import quota application form stamped with the seal of the Agricultural and Marine Products Office, the stamped form and the completed import approval application form should then be submitted to a Bureau of Economy, Trade and Industry or an
International Trade Office, to receive import approval.

Import Quota Application Procedure

- Submit two sets of application forms for import (quota/approval) to the section in charge in the Ministry of Economy, Trade and Industry
- Document examination
- Quota is decided based on the standard quota for each item
- The application is stamped and returned. (Import quota certificate)
- Submit the application form for import (quota/approval) together with the import quota certificate to the Ministry of Economy, Trade and Industry or International Trade Offices to obtain import approval (in the case of fishery products)
- Submit the documents to Customs when making an import declaration

[Inquiry]
Ministry of Economy, Trade and Industry, Trade and Economic Cooperation Bureau, Agricultural and Marine Products Office

Paragraph 2 and Paragraph 2-2 Approval System
To fulfill the agreements of international treaties concerning import regulations, importers of the following must receive prior import approval from METI.

- Specified items from designated places of origin or ports
  (This is called “Paragraph 2 Approval,” because the items are specified in paragraph 2 of the Import Notice.)

- Specified items from all places of origin and ports
  (This is called “Paragraph 2-2 Approval,” because the items are specified in paragraph 2-2 of the Import Notice.)

The following fish and shellfish products require Paragraph 2 Approval.
Those who wish to import items subject to an import quota must obtain import approval by submitting an import approval application form and the documents listed under import precautions, to the Ministry of Economy, Trade and Industry, Trade and Economic Cooperation Bureau, Agricultural and Marine Products Office.
<Fish and shellfish requiring Paragraph 2 Approval> (as of Aug. 18, 2008)

- Whale and whale meat products
- Fresh and chilled bluefin tuna raised from the Atlantic Ocean or the Mediterranean Sea, and originating from countries other than the Philippines
- Fresh and chilled southern bluefin tuna originating from countries other than the Philippines
- Bigeye tuna and bigeye tuna products originating from Bolivia and Georgia
- Salmon, trout, and processed foods made from them, imported from or loaded in China, North Korea, and Taiwan
- Fish, shellfish, and seaweed loaded in non-Japanese waters (such as those loaded on the waters and directly imported to Japan)

[Inquiry]
Ministry of Economy, Trade and Industry, Trade and Economic Cooperation Bureau, Agricultural and Marine Products Office

Confirmation System

The Confirmation System ensures fulfillment of international agreements on resource management and proper import control. It consists of two different types of confirmation: prior confirmation by the Minister of Economy, Trade and Industry, and confirmation by the Customs Office during customs clearance procedures.

[Prior confirmation]
To import items requiring preliminary confirmation as specified in the Import Notice, importers must submit a confirmation application form along with other required documents to the Agricultural and Marine Products Office in the Trade and Economic Cooperation Bureau of METI and obtain prior confirmation from the Minister of Economy, Trade, and Industry prior to importing the items concerned.

<Fish and shellfish requiring prior confirmation> (as of Aug. 18, 2008)

- Frozen bluefin tuna, southern bluefin tuna, bigeye tuna, broadbill swordfish
- Tuna and swordfish other than the above, imported by ship
- Patagonian toothfish
- Whale and whale meat products (excluding items requiring Paragraph 2 Approval)
3. Frozen Fish and Shellfish

**Prior Confirmation Application Procedure**

<table>
<thead>
<tr>
<th>Tuna</th>
<th>Frozen cargo</th>
<th>Fresh cargo</th>
</tr>
</thead>
</table>
| Fisheries Agency | • Apply for a Fisheries Agency confirmation certificate  
• Submit an import notification | Agricultural and Marine Products Office, METI  
• Submit the Fisheries Agency confirmation certificate  
• Apply for a METI confirmation certificate | To customs  
• Submit the METI confirmation certificate |

[Customs confirmation]

To import items requiring customs confirmation as specified in the Import Notice, importers must submit a statistics report for the item concerned to the Customs Office during customs clearance and obtain confirmation.

<Fish and shellfish requiring customs confirmation> (as of Aug. 18, 2008)

- Fresh and frozen bluefin tuna
- Fresh and frozen southern bluefin tuna
- Fresh and frozen broadbill swordfish

[Inquiry]
Ministry of Economy, Trade and Industry, Trade and Economic Cooperation Bureau, Agricultural and Marine Products Office

2) Law Concerning Special Measures to Strengthen the Conservation and Management of Tuna Resources

As a countermeasure to fishing boats that escape international controls for the conservation and management of tuna resources and engage in disorderly fishing operations, international organizations call for the provision of information on the import status of tuna in each country.

In response to this call for information, Japan requires importers of frozen tuna to submit a prescribed report to the Fisheries Agency before and after import, as of July 2007, under the Law Concerning Special Measures to Strengthen the Conservation and Management of Tuna Resources. (The pre-import report must include the ship responsible for the catch, transportation conditions, and the scheduled date of import; the post-import report must include the name of the operator to whom the goods were sold and information on the species of the imported tuna.) The report must be accompanied by copies of the certificate of nationality showing the present and previous nationality of the ship, bill of lading (B/L), invoice, and statistics report.

[Inquiry]
Fisheries Agency, Resources Management Department, Far Seas Fisheries Division, Marine Fishery Resources Management Unit
http://www.maff.go.jp/e/index.html
3) **Food Sanitation Law**

(1) **Pre-export Preparations**

Both exporters and importers should sufficiently collect the necessary information for determining whether the item they wish to import comply with standards prescribed in Japan’s Food Sanitation Law.

*<Documents to be prepared by exporters (Japanese translations thereof, where the original document is written in a language other than English)>*

- **List of materials**
  Complete list specifically showing the scientific names of all materials (food ingredients) and additives used, prepared and issued by the manufacturing company and bearing the name of the company
- **Manufacturing process schedule**
  Schedule showing the complete manufacturing process from the materials to the end product, including sterilization methods, temperatures and time, prepared and issued by and bearing the name of the manufacturing company and signed by the person in charge
- **Name and address of the manufacturer and place of manufacture in the country of export, and a document showing the name of the product**
- **Description of the product**
- In the case of blowfish, a sanitation certificate issued by a governmental agency in the country of export

*<Documents to be prepared by either exporters or importers (if necessary)>*

- **Self-inspection report**
  Importers may request a self-inspection at a laboratory registered with the Ministry of Health, Labour and Welfare or an official laboratory in the country of export and submit a copy of the results along with the inspection application form, to exempt the inspected items from inspection and expedite the import process.

**[Inquiry about quarantine stations]**

Ministry of Health, Labour and Welfare

*Note* In the ASEAN countries, there are official laboratories authorized by MHLW in Indonesia, Singapore, Thailand, and the Philippines. (See p.123)

(2) **Import Procedures**

Importers who wish to import fish and shellfish for the purpose of sale or for other commercial purposes are required to submit a “Notification Form for Importation of Foods, etc.” and other required documents (list of materials, manufacturing process schedule, self-inspection results, etc.) to a MHLW quarantine station having jurisdiction over the port where the relevant goods are to be cleared through customs. After examination of the notification form and relevant documents, items that require cargo inspection are inspected in the bonded area where the cargo is being stored, and are either passed or rejected depending on the result of the inspection.
(3) Main Points of Examination

Does the item comply with manufacturing standards prescribed in the Food Sanitation Law?

Fish and shellfish must comply with Specifications and Standards for Food, Food Additives, etc., which commonly apply to all food items (see p.19).

Within the Specifications and Standards for Food, Food Additives, etc., the Compositional Specifications for Foods in General provide maximum limits of fisheries medicine in fish and shellfish. In Japan, residues of fisheries medicine in food are regulated according to a Positive List System, as are agricultural chemicals. The system sets a maximum residue limit (MRL) for all fisheries medicine, in principle (including uniform limits), and prohibits the import and sale of food items containing residues exceeding their limits (see p.23).

Antibiotics and antimicrobial agents that are not regulated by individual standards are foremost subject to the Compositional Specifications for Foods in General, which stipulate that “foods shall not contain antibiotic substances or chemically synthesized antimicrobial substances,” unlike in the case of agricultural chemicals, in which a uniform limit (0.01 ppm) is applied.

The Japan Food Chemical Research Foundation <Positive List System for agricultural chemical residues>

http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/MRLs-p

Manufactured or processed foods and fillet or shelled fresh fish/shellfish that have been frozen and packed in containers or packages are treated as “frozen foods.” There are four types of frozen foods: those intended for consumption as they are after thawing, those intended for consumption after cooking with heat, those which were frozen after heating, and those intended for raw consumption. Different compositional specifications apply to each type of frozen food. Frozen fish and shellfish intended for raw consumption, in particular, are subject to detailed manufacturing standards. They must be fresh; the water used for
processing must be potable water, sterilized seawater, or artificial seawater made from potable water; chemically synthesized food additives (with the exception of sodium hypochlorite) must not be used; and implements used for processing must be easy to clean and sterilize, and must be cleaned and sterilized before use.

Preservation standards for frozen foods stipulate that they must be preserved at temperatures below -15°C, wrapped in clean and sanitary synthetic resin, aluminum foil, or waterproofed paper.

### Specifications and Standards for Frozen Fish and Shellfish under the Food Sanitation Law

<table>
<thead>
<tr>
<th>Specifications and standards common to all food items</th>
<th>Specifications and standards that apply to individual food items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frozen fish and shellfish</td>
<td>• Frozen foods (compositional specifications, preservation standards, processing standards)</td>
</tr>
<tr>
<td>• Compositional Specifications for Foods in General</td>
<td>• Frozen boiled crab (compositional specifications, preservation standards, processing standards)</td>
</tr>
<tr>
<td>• Standards for Manufacturing, Processing, and Preparation of Foods in General</td>
<td>• Frozen boiled octopus (compositional specifications, preservation standards, processing standards)</td>
</tr>
<tr>
<td>• Preservation Standards for Foods in General</td>
<td></td>
</tr>
</tbody>
</table>

(Note) Products made mostly of fish paste are subject to compositional specifications, manufacturing standards, and preservation standards, as “fish paste products.”

### Compositional Specifications of Microorganisms in Frozen Foods, Frozen Boiled Crab, and Frozen Boiled Octopus

<table>
<thead>
<tr>
<th>Frozen foods</th>
<th>Bacteria count</th>
<th>Coliform bacteria</th>
<th>Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frozen foods for consumption without heating</td>
<td>Less than 100,000/g</td>
<td>Negative</td>
<td>—</td>
</tr>
<tr>
<td>Frozen foods for consumption after heating</td>
<td>Heated immediately before freezing</td>
<td>Less than 100,000/g</td>
<td>Negative</td>
</tr>
<tr>
<td>All others</td>
<td>Less than 3,000,000/g</td>
<td>—</td>
<td>E.coli negative</td>
</tr>
<tr>
<td>Frozen fish and shellfish for raw consumption</td>
<td>Less than 100,000/g</td>
<td>Negative</td>
<td>Vibrio parahaemolyticus most probable number: less than 100/g</td>
</tr>
<tr>
<td>Frozen boiled crab</td>
<td>Less than 100,000/g</td>
<td>Negative</td>
<td>Vibrio parahaemolyticus negative</td>
</tr>
<tr>
<td>Frozen boiled octopus</td>
<td>Less than 100,000/g</td>
<td>Negative</td>
<td>Vibrio parahaemolyticus negative</td>
</tr>
</tbody>
</table>

### Specifications and Standards Related to Containers/Packages of Frozen Fish and Shellfish

<table>
<thead>
<tr>
<th>Specifications and standards common to all containers/packages</th>
<th>Application-specific specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frozen fish and shellfish</td>
<td>None</td>
</tr>
<tr>
<td>• Standards for General Implements, Containers, Packaging, and Component Materials</td>
<td></td>
</tr>
<tr>
<td>• Material-specific Specifications for Implements, Containers, Packaging, and Raw Materials</td>
<td></td>
</tr>
<tr>
<td>• Implement, Container, and Packaging Production Standards</td>
<td></td>
</tr>
</tbody>
</table>
[Information on Specifications and Standards for Foods, Food Additives, etc.]
Japan External Trade Organization (JETRO) <Webpage on standards and regulations>
http://www.jetro.go.jp/en/reports/regulations/

Does the use of food additives comply with relevant standards?

All food additives must comply with usage standards which specify the maximum limit allowed to be used in each type of food, compositional specifications which specify purity and properties, and other relevant standards that are established for each substance, as necessary. Some food additives that are legally approved in their countries of export may not be permitted in Japan. Additionally, some additives that bear the same name may in fact be two different additives based on different compositional specifications or usage standards.

Food items that do not comply with Japanese standards for food additives may not be imported. The following are major points for confirmation regarding food additives.

- Are any undesignated food additives used in the food item, including in its materials?
  - Ministry of Health, Labour and Welfare <Food additives page – List of Designated Food Additives (Enforcement Regulations, Annexed Table 1)>

- Does the use of natural food additives conform to requirements concerning source, manufacturing method, and quality specified in the List of Existing Food Additives?
  - Ministry of Health, Labour and Welfare <Food additives page – List of Existing Food Additives>

- Are all food additives used properly, in amounts conforming to the standards for the use of food additives?
  - Ministry of Health, Labour and Welfare <Food additives page – List of standards for the use of food additives>

Standards for the use of antioxidants (B.H.T., B.H.A.) apply to frozen fish and shellfish (with the exception of those intended for raw consumption) (less than 1 g/kg of immersion fluid).

Standards for the use of bleaching agents (sodium sulfite, potassium pyrosulfite, etc.) apply to shrimp and frozen raw crab (sulfur dioxide residue in shelled meat of less than 0.10 g/kg).

The use of coloring agents, carbon monoxide, freshness enhancers, and other food additives that may give false impression of quality and freshness is prohibited in fish and shellfish products.

- Does the food item contain any poisonous or harmful substances?
  Be sure that the fish is not ciguateric or poisonous, that shellfish are not contaminated by shellfish poison, etc.

- Does the manufacturer or place of manufacture have a history of any sanitation problems in the past?
  - Ministry of Health, Labour and Welfare <Website of the Imported Foods Inspection Services – Recent Cases of Violation of the Food Sanitation Law>
    http://www.mhlw.go.jp/english/topics/importedfoods/index.html
4) Considerations for Business Operators

(1) Compliance with the Food Sanitation Law

The Food Safety Basic Law requires importers to take the necessary steps to ensure food safety at their own initiative. Similarly, the Food Sanitation Law encourages importers to ensure the safety of imported foods on their own responsibility, by acquiring the necessary knowledge and technologies, ensuring the safety of ingredients, and conducting self-inspections.

Additionally, given Japanese consumers’ increasing concern and distrust of imported foods due to the recent spate of imported food poisoning incidents, importers are now more than ever expected to assure their imported goods guarantee the same level of safety as foods processed in Japan, at all stages of production in the country of export, including the selection of raw materials, production and processing, storage, and transportation.

The Guidelines on Hygiene Control of Import Processed Foods formulated by the Ministry of Health, Labour and Welfare (June 2008) outlines certain matters that importers should confirm with the manufacturer in the country of export (http://www.mhlw.go.jp/english/topics/importedfoods/guideline/01.html).

Exporters should also comply with Japan’s Food Sanitation Law and cooperate with importers, by taking careful note of matters specified in the Guidelines on Hygiene Control of Import Processed Foods, preparing the necessary information before importers request them, and striving to provide detailed information.

When importing/exporting the same items repeatedly, importers and exporters must check for any changes in manufacturing processes and raw materials, and conduct regular tests and inspection, to insure the items are free of harmful/poisonous substances and pathogenic microorganisms, do not contain undesignated food additives, and comply with standards for the use of food additives as well as compositional specifications.

(2) Confirmation with quarantine stations in Japan regarding information on sanitation

- **What basic guidance do quarantine stations offer importers?**
    - http://www.mhlw.go.jp/english/topics/importedfoods/08/08-01.html

- **Is the food item to be imported subject to monitoring inspection?**
  - At the beginning of each fiscal year, the Ministry of Health, Labour and Welfare announces an annual schedule for the number of inspections to be conducted per food category, determined in consideration of the rate of past violations, number and weight of imported cargos, and seriousness of violations.
    - http://www.mhlw.go.jp/english/topics/importedfoods/08/08-03.html

- **Is the food item to be imported subject to an ordered inspection?**
  - At the beginning of each fiscal year, the Ministry of Health, Labour and Welfare announces a list (target products and inspection items) of foods that are deemed to have high probability of violating the Food Sanitation Law, judging from situations in exporting countries, food properties, and cases of noncompliance by similar foods. Additional inspection orders may also be issued later, depending on the
subsequent status of violations. When the Minister of Health, Labour and Welfare issues an ordered inspection, the relevant cargo is stored in a bonded area until the importer applies for an inspection at a registered laboratory (fee required) and obtains an inspection result.

http://www.mhlw.go.jp/english/topics/importedfoods/08/08-02.html

What are the most common types of violations against the Food Sanitation Law?

A record of past violations against the Food Sanitation Law in relation to frozen fish and shellfish from the ASEAN countries shows frequent violations in specifications of residues of fisheries medicine and microorganisms (coli form bacteria, viable bacteria count, E. coli) in “frozen foods.”

The main considerations in regard to the import of frozen fish and shellfish, by fish/shellfish species, are as follows.

<Squid and shrimp>
- Beware of residues of fisheries medicine that should not be detected from foods in Japan, such as chloramphenicol, furazolidone (AOZ), furalaltadone (AMOZ), nitrofurazone (SEM), and nitrofurantoin (AHD).

<Tuna and fresh fish in general>
- Note that the use of coloring agents, carbon monoxide, and other food additives that give a false impression of quality and freshness is prohibited.

<Shellfish>
- The toxicity of shellfish differs according to the sea area, season, and shellfish species. Therefore, shellfish toxin should be checked through surveys that prove that the shellfish was collected from sea areas where shellfish toxin is properly monitored, in addition to regular tests and inspections.

<Poisonous fish>
- Many tropical and subtropical fish are ciguateric. Therefore, it is important to confirm the species and the sea area habitat of the fish to be imported, as well as to consult with experts to confirm fish species, fish species name (scientific name), and history of consumption in the place of production. Be especially careful regarding the import of filleted and shelled fish or shellfish that are difficult to identify.

<Swellfish>
- Swellfish species (21 species) and the sea areas from where they may be imported (Sea of Japan, Bo Hai, Yellow Sea, East China Sea) are restricted. Therefore, properly identify the fish species and prevent the import of poisonous swellfish.
Frozen Fish and Shellfish – Excerpt from “Recent Cases of Violation of the Food Sanitation Law” (January – August 2008; violations of exports from ASEAN countries)

<table>
<thead>
<tr>
<th>Item</th>
<th>Article</th>
<th>Country of export</th>
<th>Description of violation</th>
<th>Measure taken</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frozen food for consumption after heating (frozen without heating): shelled shrimp</td>
<td>11</td>
<td>Indonesia</td>
<td>Compositional nonconformance (live bacteria count $4.6 \times 10^6/g$)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Monitoring inspection</td>
</tr>
<tr>
<td>Frozen seafood for raw consumption: tuna fillet (horn flesh (nakaochi))</td>
<td>11</td>
<td>Indonesia</td>
<td>Compositional nonconformance (coliorm bacteria positive)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Monitoring inspection</td>
</tr>
<tr>
<td>Frozen shellfish: cultivated shrimp</td>
<td>11</td>
<td>Indonesia</td>
<td>Compositional nonconformance (0.001 ppm furazolidone detected (as AOZ))</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Ordered inspection</td>
</tr>
<tr>
<td>Frozen cultivated shrimp (frozen shrimp)</td>
<td>11</td>
<td>Indonesia</td>
<td>Compositional nonconformance (0.003 ppm nitrofurantoin detected)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Ordered inspection</td>
</tr>
<tr>
<td>Frozen sillago fillet: frozen kisu fillet for raw consumption</td>
<td>11</td>
<td>Thailand</td>
<td>Compositional nonconformance (live bacteria count $2.0 \times 10^5/g$)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Self-inspection</td>
</tr>
<tr>
<td>Boiled octopus</td>
<td>11</td>
<td>Philippines</td>
<td>Nonconformance to usage standards (0.036 g/kg sulfur dioxide detected)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Self-inspection</td>
</tr>
<tr>
<td>Frozen seafood for raw consumption: squid (frozen giant squid tanzaku)</td>
<td>11</td>
<td>Philippines</td>
<td>Compositional nonconformance (live bacteria count $3.5 \times 10^5/g$, coliorm bacteria positive)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Self-inspection</td>
</tr>
<tr>
<td>Frozen food for consumption without heating: tuna for tuna rice roll (yellowfin tuna stick)</td>
<td>11</td>
<td>Philippines</td>
<td>Compositional nonconformance (coliorm bacteria positive)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Self-inspection</td>
</tr>
<tr>
<td>Frozen food for consumption without heating: seared smoked tuna</td>
<td>10</td>
<td>Philippines</td>
<td>Undesignated additive (770 µg/kg carbon monoxide detected)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Self-inspection</td>
</tr>
<tr>
<td>Frozen food for consumption without heating: shrimp (vannamei sushi ebi)</td>
<td>11</td>
<td>Vietnam</td>
<td>Compositional nonconformance (0.005 ppm furazolidone detected (as AOZ))</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Ordered inspection</td>
</tr>
<tr>
<td>Frozen food for consumption after heating (frozen without heating): chopped shrimp and squid</td>
<td>11</td>
<td>Vietnam</td>
<td>Compositional nonconformance (0.0014 ppm chloramphenicol detected)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Ordered inspection</td>
</tr>
<tr>
<td>Frozen food for consumption after heating: shrimp (frozen nobashi shrimp (peeled))</td>
<td>11</td>
<td>Vietnam</td>
<td>Compositional nonconformance (E. coli positive)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Self-inspection</td>
</tr>
<tr>
<td>Frozen food for consumption without heating: opened shrimp</td>
<td>11</td>
<td>Vietnam</td>
<td>Compositional nonconformance (0.017 ppm furazolidone detected (as AOZ))</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Ordered inspection</td>
</tr>
</tbody>
</table>

(Note) “Self-inspection” refers to the guidance provided by the quarantine station to importers regarding the implementation of a self-inspection on items that are required on the first import occasion and on regular occasions, from the standpoint of assisting importers to fulfill their food sanitation and security obligations.

(Source) Ministry of Health, Labour and Welfare <Website of the Imported Foods Inspection Services – Recent Cases of Violation of the Food Sanitation Law>
http://www.mhlw.go.jp/english/topics/importedfoods/index.html
**Frozen fish and Shellfish – Excerpt from “Typical Cases of Violation of the Food Sanitation Law”** (violations of exports from ASEAN countries)

Typical cases judged to be in violation of the Food Sanitation Law that were found in the past on the occasion of import notification, compiled by the Ministry of Health, Labour and Welfare

<table>
<thead>
<tr>
<th>Item</th>
<th>Country of export</th>
<th>Description of violation</th>
<th>Limit</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frozen brown-marbled grouper</td>
<td>Indonesia</td>
<td>Poisonous fish (ciguateric fish)</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Frozen trout</td>
<td>Indonesia</td>
<td>Compositional nonconformance (coliform bacteria)</td>
<td>Negative</td>
<td>Frozen seafood for raw consumption</td>
</tr>
<tr>
<td>Frozen boiled octopus</td>
<td>Indonesia</td>
<td>Compositional nonconformance (coliform bacteria)</td>
<td>Negative</td>
<td>Boiled octopus</td>
</tr>
<tr>
<td>Frozen squid fillet</td>
<td>Indonesia</td>
<td>Compositional nonconformance (live bacteria count)</td>
<td>Less than 100,000/g</td>
<td>Frozen seafood for raw consumption</td>
</tr>
<tr>
<td>Frozen tuna fillet</td>
<td>Indonesia</td>
<td>Antioxidant: use of carbon monoxide</td>
<td>Undesignated additive</td>
<td>Frozen seafood for raw consumption</td>
</tr>
<tr>
<td>Frozen cultivated shrimp</td>
<td>Indonesia</td>
<td>Compositional nonconformance (tetracycline)</td>
<td>Antibiotics, excepting those for standards have been established, may not be used</td>
<td>Tetracycline: antibiotic substance</td>
</tr>
<tr>
<td>Frozen bigfin reef squid noodle</td>
<td>Thailand</td>
<td>Compositional nonconformance (coliform bacteria)</td>
<td>Negative</td>
<td>Frozen seafood for raw consumption</td>
</tr>
<tr>
<td>Frozen deep-water shrimp</td>
<td>Thailand</td>
<td>Compositional nonconformance (coliform bacteria)</td>
<td>Negative</td>
<td>Frozen seafood for raw consumption</td>
</tr>
<tr>
<td>Frozen squid</td>
<td>Thailand</td>
<td>Compositional nonconformance (coliform bacteria)</td>
<td>Negative</td>
<td>Frozen food for consumption without heating</td>
</tr>
<tr>
<td>Frozen boiled botan shrimp</td>
<td>Thailand</td>
<td>Compositional nonconformance (live bacteria count)</td>
<td>Less than 100,000/g</td>
<td>Frozen food for consumption without heating</td>
</tr>
<tr>
<td>Frozen spear squid rings</td>
<td>Thailand</td>
<td>Compositional nonconformance (coliform bacteria)</td>
<td>Negative</td>
<td>Frozen food for consumption after heating (frozen after heating)</td>
</tr>
<tr>
<td>Frozen bigfin reef squid for sushi</td>
<td>Thailand</td>
<td>Compositional nonconformance (coliform bacteria)</td>
<td>Negative</td>
<td>Frozen food for consumption without heating</td>
</tr>
<tr>
<td>Frozen boiled bigfin reef squid for sushi</td>
<td>Thailand</td>
<td>Compositional nonconformance (coliform bacteria)</td>
<td>Negative</td>
<td>Frozen food for consumption without heating</td>
</tr>
<tr>
<td>Frozen bigfin reef squid for sushi</td>
<td>Thailand</td>
<td>Compositional nonconformance (coliform bacteria)</td>
<td>Negative</td>
<td>Frozen food for consumption without heating</td>
</tr>
<tr>
<td>Frozen slitted cuttlefish</td>
<td>Thailand</td>
<td>Compositional nonconformance (coliform bacteria)</td>
<td>Negative</td>
<td>Frozen food for consumption without heating</td>
</tr>
<tr>
<td>Frozen yellowfin tuna meat</td>
<td>Philippines</td>
<td>Compositional nonconformance (live bacteria count)</td>
<td>Less than 100,000/g</td>
<td>Frozen seafood for raw consumption</td>
</tr>
<tr>
<td>Frozen spider conch</td>
<td>Philippines</td>
<td>Compositional nonconformance (live bacteria count)</td>
<td>Less than 100,000/g</td>
<td>Frozen seafood for raw consumption</td>
</tr>
<tr>
<td>Frozen sillago fillet</td>
<td>Vietnam</td>
<td>Compositional nonconformance (live bacteria count)</td>
<td>Less than 100,000/g</td>
<td>Frozen seafood for consumption after heating (frozen after heating)</td>
</tr>
<tr>
<td>Frozen scallop eye</td>
<td>Vietnam</td>
<td>Compositional nonconformance (coliform bacteria)</td>
<td>Negative</td>
<td>Frozen seafood for raw consumption</td>
</tr>
<tr>
<td>Frozen spear squid slices</td>
<td>Vietnam</td>
<td>Compositional nonconformance (coliform bacteria)</td>
<td>Negative</td>
<td>Frozen seafood for consumption after heating (frozen after heating)</td>
</tr>
</tbody>
</table>
### Part 2 Import Procedures by Food Category

#### 3. Frozen Fish and Shellfish

<table>
<thead>
<tr>
<th>Item</th>
<th>Country of export</th>
<th>Description of violation</th>
<th>Limit</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frozen akegai clam</td>
<td>Vietnam</td>
<td>Compositional nonconformance (live bacteria count)</td>
<td>Less than 3,000,000/g</td>
<td>Frozen seafood for consumption after heating (frozen without heating)</td>
</tr>
<tr>
<td>Frozen sushi shrimp</td>
<td>Vietnam</td>
<td>Compositional nonconformance (live bacteria count)</td>
<td>Less than 100,000/g</td>
<td>Frozen food for consumption without heating</td>
</tr>
<tr>
<td>Frozen sushi shrimp</td>
<td>Vietnam</td>
<td>Compositional nonconformance (coliform bacteria)</td>
<td>Negative</td>
<td>Frozen food for consumption without heating</td>
</tr>
<tr>
<td>Frozen squid</td>
<td>Malaysia</td>
<td>Compositional nonconformance (live bacteria count)</td>
<td>Less than 100,000/g</td>
<td>Frozen food for consumption without heating</td>
</tr>
<tr>
<td>Frozen squid fillet</td>
<td>Malaysia</td>
<td>Compositional nonconformance (coliform bacteria)</td>
<td>Less than 100,000/g</td>
<td>Frozen seafood for raw consumption</td>
</tr>
<tr>
<td>Frozen squid fillet</td>
<td>Malaysia</td>
<td>Compositional nonconformance (coliform bacteria)</td>
<td>Negative</td>
<td>Frozen seafood for raw consumption</td>
</tr>
</tbody>
</table>

(Source) Ministry of Health, Labour and Welfare <Website of the Imported Foods Inspection Services – Typical Cases of Violation of the Food Sanitation Law that were Found on the Occasion of Import Notification>  

- **Other considerations regarding the import of frozen fish and shellfish**
  - Prevent the proliferation of microorganisms, by ensuring proper sanitation management and storage temperature management not only of raw ingredients, but also of processing plants and cooking implements. Note that regulations concerning Vibrio parahaemolyticus are thoroughly enforced, because the Japanese people are fond of eating fishery foods raw, and many incidents of food poisoning occur in relation to Vibrio parahaemolyticus.
  - To comply with the Positive List System for fisheries medicine, importers should actively collect information on fisheries medicine from the production stage of raw ingredients (information on proper usage and management of fisheries medicine, types and usage methods of fisheries medicine that may be used, cases of violation against residue standards, etc.), and assess residue status, as necessary.
  - Note that container/package sizes and sanitary wrapping are important aspects in Japanese business customs.
4. Teas and Coffees

Import Procedures for Teas and Coffees

### Pre-export preparations

- **Responsibilities of the exporter or importer**
  - [Preparations based on the Plant Protection Law]
    - If the item concerned is subject to import inspection, receive an inspection at a governmental plant quarantine facility in the country of export and obtain a phytosanitary certificate.
    - Check that the item to be imported is not an import-banned item.
  - [Preparations based on the Food Sanitation Law]
    - Collect the necessary information for determining whether the item to be imported complies with Japan’s Food Sanitation Law.
    - Conduct a self-inspection if necessary (either by the exporter or importer) and acquire a result of the inspection.
    - Exporters should prepare the documents which the importer in Japan need to submit to the quarantine station along with the “Notification Form for Importation of Food, etc.” in order to import the item concerned. Enquire with the importer or a quarantine station in Japan concerning the required documents, as they differ according to food category.
  - [Preparations for customs clearance in Japan]
    - Exporters should prepare the relevant documents required for customs clearance in Japan.

- **Required documents**
  - [Documents to be prepared by exporters]
    - Phytosanitary certificate issued by a governmental agency in the country of export
    - Manufacturing process schedule, as required
  - [Documents to be prepared by exporters]
    - List of materials
    - Manufacturing process schedule
    - Sanitary certificate, inspection results, etc., as required
  - [Documents to be submitted by importers]
    - Import declaration form
    - Import inspection application form
    - Phytosanitary certificate issued by a government agency in the country of export
    - Invoice, packing list, manufacturing process schedule, etc., as required

### Import quarantine inspection in Japan

- **Import procedures based on the Plant Protection Law**
  - When importing items subject to import inspection, importers must submit an import inspection application form to the Plant Protection Station, along with a phytosanitary certificate issued by a governmental agency in the country of export and other required documents.

- **Import procedures based on the Food Sanitation Law**
  - When importing tea or coffee, importers must submit a “Notification Form for Importation of Foods, etc.” to the quarantine station, along with other required documents.

- Importers must submit an import declaration form to the Customs Office, along with other required documents.

### Customs clearance in Japan

- [Documents to be submitted by importers]
  - Import declaration form
  - Invoice
  - Packing list
  - Bill of lading (B/L) or air waybill

- [Documents to be submitted by importers]
  - Import declaration form
  - Invoice
  - Packing list
  - Bill of lading (B/L) or air waybill

- **Import procedures based on the Plant Protection Law**
  - When importing items subject to import inspection, importers must submit an import inspection application form to the Plant Protection Station, along with a phytosanitary certificate issued by a governmental agency in the country of export and other required documents.

- **Import procedures based on the Food Sanitation Law**
  - When importing tea or coffee, importers must submit a “Notification Form for Importation of Foods, etc.” to the quarantine station, along with other required documents.

- Importers must submit an import declaration form to the Customs Office, along with other required documents.
The import of teas and coffees is regulated by the Food Sanitation Law. Of primary concern is to insure that they satisfy Japanese specifications and standards related to the use of agricultural chemicals and food additives.

Tea leaves that have simply been dried and raw coffee beans are also regulated by the Plant Protection Law.

The sections below describe import procedures and considerations under the Plant Protection Law and the Food Sanitation Law.

1) Plant Protection Law

(1) Pre-export Preparations

When importing tea leaves that have simply been dried (such as non heat-processed herb teas) and raw coffee beans, importers must take the necessary procedures under the Plant Protection Law, to prevent the entry of foreign pests into Japan. Plant quarantine is conducted at certain seaports and airports only (specified in Article 6 of the Enforcement Regulations of the Plant Protection Law), so importers should be careful when selecting a port of entry.

The above types of teas and raw coffee beans are subject to import inspection (see p.25). Exporters need to have their goods inspected at a plant quarantine station in the country of export and obtain a phytosanitary certificate. Information provided on the certificate must satisfy Japan’s requirements.

Manufactured tea and other such types of processed teas, roasted coffee beans, and teas and coffees packed and sealed in containers for retail sale are exempt from inspection.

[Inquiry]
Plant Protection Stations having jurisdiction over ports of entry

(2) Import Procedures

To apply for plant quarantine inspection, importers must submit a “Plant or import-banned item import inspection application form” to the Plant Protection Station having jurisdiction over the port of entry or apply online, via the PQ-NETWORK (Plant Quarantine Network) electronic processing system for imported plant inspection (note 1).

The application form must be submitted along with a phytosanitary certificate issued by a governmental agency in the country of export and other necessary documents as separately specified by the Plant Protection Station (invoice, bill of lading (B/L), packing list, manufacturing process schedule, etc.).

The Plant Protection Station issues an inspection certificate for those items that pass the document examination and spot inspections. Items that fail to pass the inspections are ordered to be “disinfected” or “disposed of (returned to shipper).” Where disinfection is possible, an inspection certificate will be issued after disinfection, and the relevant item can then be processed through subsequent procedures based on the Food Sanitation Law.

(Note 1) Plant quarantine inspection and food sanitation inspection may be performed simultaneously, if a request for “concurrent inspection” is noted on the import inspection application form.
(3) Main Points of Examination

- Does the item comply with the provisions on “import restrictions” prescribed in Article 6 of the Plant Protection Law? (Whether a phytosanitary certificate issued by a governmental agency in the country of export is properly attached, etc.)
- Does the certificate provide all the required information?
- Does the item fall under the import-banned category? (Check all plant ingredients, etc.)
- Have any soil and quarantine pests been detected from the item in a spot inspection?

2) Food Sanitation Law

(1) Pre-export Preparations

Both exporters and importers should sufficiently collect the necessary information for determining whether the tea or coffee they wish to import complies with standards prescribed in Japan’s Food Sanitation Law.

Teas made from plants other than tea plants (such as herb teas) may also be subject to the Pharmaceutical Affairs Law, if they contain raw ingredients that are only allowed to be used in medical drugs (see p.13). In this case, importers must provide the scientific name (Japanese name) of the raw ingredient and clarify the part of the plant used as an ingredient and its effect, and at the same time confirm with the pharmaceutical department in the local government whether the ingredient is subject to the Pharmaceutical Affairs Law.
<Documents to be prepared by exporters (Japanese translations thereof, in cases where the original document is written in a language other than English)>

- List of materials
  Complete list specifically showing the scientific names of all materials (food ingredients) and additives used, prepared and issued by the manufacturing company and bearing the name of the company

- Manufacturing process schedule
  Schedule showing the complete manufacturing process from the materials to the end product, including sterilization temperatures and time, prepared and issued by and bearing the name of the manufacturing company and signed by the person in charge

- Name and address of the manufacturer and place of manufacture in the country of export, and a document showing the name of the product

<Documents to be prepared by either exporters or importers (if necessary)>

- Self-inspection report
  Importers may request a self-inspection at a laboratory registered with the Ministry of Health, Labour and Welfare or an official laboratory in the country of export and submit a copy of the results along with the inspection application form, to exempt the inspected items from inspection and expedite the import process.

<Documents to be prepared by importers (if necessary)>

- Depending on the raw ingredients, a document showing the steps that have been taken to check the product against the requirements of the Pharmaceutical Affairs Law (verification date, verifying organization, identification of relevant substances and their handling, etc.)

[Inquiry about inspection facilities]
Ministry of Health, Labour and Welfare <List of official laboratories authorized by MHLW>
Note) In the ASEAN countries, there are official laboratories authorized by MHLW in Indonesia, Singapore, Thailand, and the Philippines. (See p.123 )

[General inquiry]
MHLW quarantine stations having jurisdiction over ports of entry
http://www.mhlw.go.jp/english/topics/importedfoods/1-2.html

(2) Import Procedures

Importers who wish to import teas and coffees for the purpose of sale or for other commercial purposes are required to submit a “Notification Form for Importation of Foods, etc.” and other required documents (list of materials, manufacturing process schedule, self-inspection results, etc.) to an MHLW quarantine station having jurisdiction over the port where the relevant goods are to be cleared through customs. After examination of the notification form and relevant documents, items that require cargo inspection are inspected in the bonded area where the cargo is being stored, and are either passed or rejected depending on the result of the inspection.
(3) Main Points of Examination

☐ Does the item comply with manufacturing standards prescribed in the Food Sanitation Law?

Teas and coffees must comply with Specifications and Standards for Food, Food Additives, etc., which commonly apply to all food items (see p.19).

Within the Specifications and Standards for Food, Food Additives, etc., the Compositional Specifications for Foods in General provide maximum residue limits (MRLs) of agricultural chemicals in foods. In Japan, agricultural chemical residue in food is regulated according to a Positive List System. The system sets a maximum residue limit for all agricultural chemicals in principle (including uniform limits), and prohibits the import and sale of food items containing residual agricultural chemicals exceeding their limit. A uniform limit of 0.01 ppm is applied to agricultural chemicals for which maximum residue limits have not been separately established (see p.23).

☐ The Japan Food Chemical Research Foundation <Positive List System for agricultural chemical residues>

http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/MRLs-p

Tea and coffee containers/packages must comply with the Standards for Containers/Packages prescribed in the Food Sanitation Law.
### Specifications and Standards for Teas and Coffees under the Food Sanitation Law

<table>
<thead>
<tr>
<th>Specifications and standards common to all food items</th>
<th>Specifications and standards that apply to individual food items</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teas</strong></td>
<td>None</td>
</tr>
<tr>
<td>• Compositional Specifications for Foods in General</td>
<td></td>
</tr>
<tr>
<td>• Standards for Manufacturing, Processing, and Preparation of Foods in General</td>
<td></td>
</tr>
<tr>
<td>• Preservation Standards for Foods in General</td>
<td></td>
</tr>
<tr>
<td><strong>Coffees</strong></td>
<td>None</td>
</tr>
<tr>
<td>• Compositional Specifications for Foods in General</td>
<td></td>
</tr>
<tr>
<td>• Standards for Manufacturing, Processing, and Preparation of Foods in General</td>
<td></td>
</tr>
<tr>
<td>• Preservation Standards for Foods in General</td>
<td></td>
</tr>
</tbody>
</table>

### Specifications and Standards Related to Containers/Packages of Teas and Coffees

<table>
<thead>
<tr>
<th>Specifications and standards common to all containers/packages</th>
<th>Application-specific specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teas</strong></td>
<td>None</td>
</tr>
<tr>
<td>• Standards for General Implements, Containers, Packaging, and Component Materials</td>
<td></td>
</tr>
<tr>
<td>• Material-specific Specifications for Implements, Containers, Packaging, and Raw Materials</td>
<td></td>
</tr>
<tr>
<td>• Implement, Container, and Packaging Production Standards</td>
<td></td>
</tr>
<tr>
<td><strong>Coffees</strong></td>
<td>None</td>
</tr>
<tr>
<td>• Standards for General Implements, Containers, Packaging, and Component Materials</td>
<td></td>
</tr>
<tr>
<td>• Material-specific Specifications for Implements, Containers, Packaging, and Raw Materials</td>
<td></td>
</tr>
<tr>
<td>• Implement, Container, and Packaging Production Standards</td>
<td></td>
</tr>
</tbody>
</table>

[Information on Specifications and Standards for Foods, Food Additives, etc.]
Japan External Trade Organization (JETRO) <Webpage on standards and regulations>
[http://www.jetro.go.jp/en/reports/regulations/]

Does the use of food additives comply with relevant standards?

All food additives must comply with usage standards which specify the maximum limit allowed to be used in each type of food, compositional specifications which specify purity and properties, and other relevant standards that are established for each substance, as necessary. Some food additives that are legally approved in their countries of export may not be permitted in Japan. Additionally, some additives that bear the same name may in fact be two different additives based on different compositional specifications or usage standards.

Food items that do not comply with Japanese standards for food additives may not be imported. The
following are major points for confirmation regarding food additives.

- Are any undesignated food additives used in the food item, including in its materials?
  - Ministry of Health, Labour and Welfare <Food additives page – List of Designated Food Additives (Enforcement Regulations, Annexed Table 1)>

- Does the use of natural food additives conform to requirements concerning source, manufacturing method, and quality specified in the List of Existing Food Additives?
  - Ministry of Health, Labour and Welfare <Food additives page – List of Existing Food Additives>

- Are all food additives used properly, in amounts conforming to the standards for the use of food additives?
  - Ministry of Health, Labour and Welfare <Food additives page – List of standards for the use of food additives>

  The use of certain coloring agents in tea is restricted, and the use of other food additives for the purpose of color-fixing or bleaching is prohibited.

- Does the food item contain any poisonous or harmful substances?
  - Food items should not be contaminated by mycotoxins such as aflatoxin, radioactivity, chemical substances, etc.

- Does the manufacturer or place of manufacture have a history of any sanitation problems in the past?
  - Ministry of Health, Labour and Welfare <Website of the Imported Foods Inspection Services – Recent Cases of Violation of the Food Sanitation Law>
    http://www.mhlw.go.jp/english/topics/importedfoods/index.html

3) Considerations for Business Operators

(1) Compliance with the Food Sanitation Law

The Food Safety Basic Law requires importers to take the necessary steps to ensure food safety at their own initiative. Similarly, the Food Sanitation Law encourages importers to ensure the safety of imported foods on their own responsibility, by acquiring the necessary knowledge and technologies, ensuring the safety of ingredients, and conducting self-inspections.

Additionally, given Japanese consumers’ increasing concern and distrust of imported foods due to the recent spate of imported food poisoning incidents, importers are now more than ever expected to assure their imported goods guarantee the same level of safety as foods processed in Japan, at all stages of production in the country of export, including the selection of raw materials, production and processing, storage, and transportation.

The Guidelines on Hygiene Control of Import Processed Foods formulated by the Ministry of Health, Labour and Welfare (June 2008) gives matters that importers should confirm with the manufacturer in the country of export (http://www.mhlw.go.jp/english/topics/importedfoods/guideline/01.html).
Exporters should also comply with Japan’s Food Sanitation Law and cooperate with importers, by taking careful note of matters specified in the Guidelines on Hygiene Control of Import Processed Foods, preparing the necessary information before importers request them, and striving to provide detailed information.

When importing/exporting the same items repeatedly, importers and exporters must check for any changes in manufacturing processes and raw materials, and conduct regular tests and inspection, to insure the items are free of harmful/poisonous substances and pathogenic microorganisms, do not contain undesignated food additives, and comply with standards for the use of food additives as well as compositional specifications.

Between April and July 2008, raw coffee beans imported from Ethiopia were found to be in violation of the standard limits of agricultural chemical residues (γ-BHC, chlordane, heptachlor, DDT), on a number of occasions. These incidents prompted a reinforcement of inspections against Ethiopian coffee beans. To comply with the Positive List System, importers should actively collect information on agricultural chemicals from the production stage of teas and coffees (information on proper usage and management of agricultural chemicals, types and usage methods of agricultural chemicals that may be used, cases of violation against residue standards, etc.), and assess residue status, as necessary.

(2) Confirmation with quarantine stations in Japan regarding information on sanitation

- What basic guidance do quarantine stations offer importers?
  http://www.mhlw.go.jp/english/topics/importedfoods/08/08-01.html

- Is the food item to be imported subject to monitoring inspection?
  At the beginning of each fiscal year, the Ministry of Health, Labour and Welfare announces an annual schedule for the number of inspections to be conducted per food category, determined in consideration of the rate of past violations, number and weight of imported cargos, and seriousness of violations.
  http://www.mhlw.go.jp/english/topics/importedfoods/08/08-03.html

- Is the food item to be imported subject to an ordered inspection?
  At the beginning of each fiscal year, the Ministry of Health, Labour and Welfare announces a list (target products and inspection items) of foods that are deemed to have high probability of violating the Food Sanitation Law, judging from situations in exporting countries, food properties, and cases of noncompliance by similar foods. Additional inspection orders may also be issued later, depending on the subsequent status of violations. When the Minister of Health, Labour and Welfare issues an ordered inspection, the relevant cargo is stored in a bonded area until the importer applies for an inspection at a registered laboratory (fee required) and obtains an inspection result.
  http://www.mhlw.go.jp/english/topics/importedfoods/08/08-02.html

- What are the most common types of violations against the Food Sanitation Law?
  A record of past violations against the Food Sanitation Law in relation to teas and coffees shows frequent
violations in relation to the use of food additives. Since January 2008, however, no violations of the Food Sanitation Law have been found among tea and coffee imports from the ASEAN countries.

Ministry of Health, Labour and Welfare <Website of the Imported Foods Inspection Services – Recent Cases of Violation of the Food Sanitation Law>
http://www.mhlw.go.jp/english/topics/importedfoods/index.html

The following is a list of precautions concerning the import of teas and coffees.

- Frequently check what items are subject to an ordered inspection.
- In regard to harmful and poisonous substances, beware of contamination by aflatoxin.
- Beware of the use of coloring agents that should not be used in tea.
- Beware of residues of sulfur dioxide used as a bleaching agent or antioxidant.
- Disseminate Japanese standards for agricultural chemical residues.

**Teas and Coffees – Excerpt from “Typical Cases of Violation of the Food Sanitation Law”**

Typical cases judged to be in violation of the Food Sanitation Law that were found in the past on the occasion of import notification, compiled by the Ministry of Health, Labour and Welfare

<table>
<thead>
<tr>
<th>Item</th>
<th>Country of export</th>
<th>Description of violation</th>
<th>Limit</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instant tea</td>
<td>USA</td>
<td>Manufacturing agent: Sodium aluminum silicate included</td>
<td>Undesignated additive</td>
<td></td>
</tr>
<tr>
<td>Coffee beans (decaffeinated)</td>
<td>USA</td>
<td>Manufacturing agent: methylene chloride included</td>
<td>Undesignated additive</td>
<td></td>
</tr>
<tr>
<td>Tea alternative (marigold)</td>
<td>Italy</td>
<td>Antioxidant: excessive residue of sulfur dioxide</td>
<td>Other foods: less than 0.030 g/kg</td>
<td></td>
</tr>
<tr>
<td>Tea alternative (dried karela)</td>
<td>Vietnam</td>
<td>Bleaching agent: excessive residue of sulfur dioxide</td>
<td>Other foods: less than 0.030 g/kg</td>
<td></td>
</tr>
<tr>
<td>Concentrated coffee extract</td>
<td>USA</td>
<td>Preservative: undesigned use of potassium sorbate</td>
<td>—</td>
<td></td>
</tr>
</tbody>
</table>

(Source) Ministry of Health, Labour and Welfare <Website of the Imported Foods Inspection Services – Typical Cases of Violation of the Food Sanitation Law that were Found on the Occasion of Import Notification>

Other considerations regarding the import of teas and coffees

- When importing teas and coffees in bulks, dried tea leaves may be contaminated by mite and other foreign animal matter. Check the processing method and preservation and transportation conditions in the country of origin.
- Teas made of plants other than tea plants but referred to as “tea” nevertheless, may contain raw ingredient plants that are not considered edible in Japan. It is necessary to check the dietary situation and any other issues related to food sanitation in the country of export.
- Note that some herbs are subject to the Pharmaceutical Affairs Law, because of their pharmaceutical ingredients, and may not be imported and sold as food. Also be aware that herbs that claim medical effects/efficacy and dosage regimen may be in violation of the Pharmaceutical Affairs Law (see p.32).
## 5. Prepared Foods (Canned, Bottled, Retort Foods)

### Import Procedures for Prepared Foods

#### Responsibilities of the exporter or importer

- **[Preparations based on the Domestic Animal Infectious Diseases Control Law]**
  - In the case of prepared foods containing meat and other items designated by the above law, collect the necessary information on whether they are acceptable in Japan and, if so, the requirements for their acceptance.
  - Exporters should prepare documents by which a decision can be made concerning whether the product concerned is subject to inspection.
  - If subject to inspection, obtain a health certificate issued by a governmental agency in the country of export.

- **[Preparations based on the Food Sanitation Law]**
  - Collect information for determining whether the product complies with Japan’s Food Sanitation Law.
  - Conduct a self-inspection if necessary (either by the exporter or importer) and acquire a result of the inspection.
  - Exporters should prepare the documents which the importer in Japan need to submit to the quarantine station along with the "Notification Form for Importation of Foods, etc." in order to import the item concerned. Enquire with the importer or a quarantine station in Japan concerning the required documents, as they differ according to food category.

- **[Preparations for customs clearance in Japan]**
  - Exporters should prepare the relevant documents required for customs clearance in Japan.

- **[Import procedures based on the Domestic Animal Infectious Diseases Control Law]**
  - When importing items subject to animal quarantine inspection, importers must submit an import inspection application form to the Animal Quarantine Service, along with a health certificate issued by a governmental agency in the country of export and other required documents.

- **[Import procedures based on the Food Sanitation Law]**
  - When importing prepared foods, importers must submit an "Import Notification for Importation of Foods, etc." to the quarantine station, along with other required documents.

- Importers must submit an import declaration form to the Customs Office, along with other required documents.

#### Required documents

- **[Documents to be prepared by exporters]**
  - List of materials
  - Manufacturing process schedule
  - Health certificate issued by a governmental organization in the country of export

- **[Documents to be prepared by exporters]**
  - List of materials
  - Manufacturing process schedule
  - Health certificate issued by a governmental organization in the country of export

- **[Documents to be prepared by exporters]**
  - Description of the product
  - Sanitary certificate, inspection results, etc. as required

- **[Documents to be prepared by exporters]**
  - Invoice
  - Packing list
  - Bill of lading (B/L) or air waybill

- **[Documents to be submitted by importers]**
  - Import inspection application form
  - Health certificate issued by a governmental agency in the country of export
  - List of materials, manufacturing process schedule, invoice, packing list, etc. as required

- **[Documents to be submitted by importers]**
  - Import Notification for Importation of Food, etc.
  - List of materials
  - Manufacturing process schedule
  - Description of the product
  - Sanitary certificate, inspection results, etc. as required

- **[Documents to be prepared by importers]**
  - Import declaration form
  - Invoice
  - Packing list
  - Bill of lading (B/L) or air waybill

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84
The import of prepared foods (canned, bottled, retort) is regulated by the Food Sanitation Law. Additionally, the Domestic Animal Infectious Diseases Control Law apply to prepared foods containing beef, pork, or chicken meat, and the Foreign Exchange and Foreign Trade Law, to prepared foods that include items that are regulated by the Washington Convention, such as sea turtles, in their raw ingredients. Importers should therefore check whether the item they wish to import is subject to those laws, before the item is exported from the country of export.

[Inquiry about the Foreign Exchange and Foreign Trade Law]
Ministry of Economy, Trade and Industry, Trade and Economic Cooperation Bureau, Trade Licensing Division

The sections below describe import procedures and considerations under the Domestic Animal Infectious Diseases Control Law and the Food Sanitation Law.

1) Domestic Animal Infectious Diseases Control Law

(1) Pre-export Preparations

When importing prepared foods containing meat (beef, pork, chicken, etc.) or other items designated by the Domestic Animal Infectious Diseases Control Law, importers need to observe animal quarantine procedures, to prevent the entry of foreign pathogenic microorganisms that could cause infectious diseases among domestic animals in Japan. Depending on processing methods, some canned and retort foods may be exempt from animal quarantine inspection. The major grounds for determining whether an item is subject to inspection is based on whether it has been thoroughly sterilized by heating for long shelf-life, determined by its ingredients, processing method, and condition of its container.

However, the decision to exempt a product from animal quarantine inspection is made on a case-by-case basis for each product, so importers should prepare a list of materials and manufacturing process schedule for the product concerned and enquire with the Animal Quarantine Service prior to exportation.

Products from countries that have no agreement with Japan regarding “domestic animal sanitation requirements” may not be imported. Additionally, meat and livestock products for import into Japan may only be handled by facilities authorized by Japan or the country of export. Those handled by undesignated facilities may not be imported. Note also that the export and import of livestock products may be temporarily suspended in the event of an outbreak of infectious diseases among livestock, such as bird flu.

Importers who wish to import livestock products should therefore enquire with the Animal Quarantine Service regarding the status of their acceptance in Japan, import conditions, and other such matters.

[Inquiry]
Animal Quarantine Services having jurisdiction over ports of entry

(2) Import Procedures

To import products subject to animal quarantine inspection, importers must submit an application for import inspection to the Animal Quarantine Service having jurisdiction over the port of entry (in principle, by the day prior to the desired day of inspection) or apply online, via the ANIPAS (Animal Inspection Procedure Automated System) electronic processing system for animal quarantine inspection (note).

The application form must be submitted along with a health (veterinary) certificate issued by a governmental agency in the country of export and other necessary documents as separately specified by the
Animal Quarantine Service (invoice, bill of lading (B/L), packing list, list of materials, manufacturing process schedule, etc.).

Products that pass the document examination and spot inspection are issued an import quarantine certificate from the Animal Quarantine Service, and may then be processed through subsequent procedures based on the Food Sanitation Law. Products that fail to pass the inspection are ordered to be incinerated or returned to the shipper.

(Note) Animal quarantine inspection and food sanitation inspection may be performed simultaneously, if a request for “concurrent inspection” is noted on the import inspection application form.

Import Inspection Procedures for Livestock Products based on the Domestic Animal Infectious Diseases Control Law

(3) Main Points of Examination
- Has the inspection application form been properly filled out, and are the required documents attached, including a health (veterinary) certificate issued by a governmental agency in the country of export?
- Does the product fall under the import-banned category?
- Has the content of the application form been found to be consistent with the content of the cargo, through a spot inspection?
- Has the product been confirmed to be safe from infectious diseases?

2) Food Sanitation Law

(1) Pre-export Preparations

Both exporters and importers should sufficiently collect the necessary information for determining whether the product they wish to import comply with standards prescribed in Japan’s Food Sanitation Law.

<Documents to be prepared by exporters (Japanese translations thereof, in cases where the
Part 2 Import Procedures by Food Category

5. Prepared Foods (Canned, Bottled, Retort Foods)

- List of materials
  Complete list specifically showing the scientific names of all materials (food ingredients) and additives used, prepared and issued by the manufacturing company and bearing the name of the company

- Manufacturing process schedule
  Schedule showing the complete manufacturing process from the materials to the end product, including sterilization temperatures and time, prepared and issued by and bearing the name of the manufacturing company and signed by the person in charge

- Name and address of the manufacturer and place of manufacture in the country of export, and a document showing the name of the product

- Description of the product

- A health (veterinary) certificate issued by a governmental agency in the country of export, in the case of products that fall under the “meat products” category under the Food Sanitation Law

- If the food item contains beef or beef-derived substances among the materials, a written document showing the country in which the cattle were nurtured, slaughtered and processed, and the parts of the cattle used as raw ingredients

<Documents to be prepared by importers (if necessary)>

- Depending on the materials, a document showing the steps that have been taken to check the product against the requirements of the Pharmaceutical Affairs Law (verification date, verifying organization, identification of relevant substances and their handling, etc.)
  * For health foods and food items containing Japanese or Chinese herbal medicine, importers should provide the scientific name (Japanese name) of the material and clarify the part of the plant that is used as an ingredient and its effect, and at the same time confirm with the pharmaceutical department in the local government whether the ingredient is subject to the Pharmaceutical Affairs Law.

<Documents to be prepared by either exporters or importers (if necessary)>

- Self-inspection results
  Importers may request a self-inspection at a laboratory registered with the Ministry of Health, Labour and Welfare or an official laboratory in the country of export and submit a copy of the report along with the inspection application form, to exempt the inspected items from inspection and expedite the import process.

[Inquiry about inspection facilities]
Ministry of Health, Labour and Welfare <List of official laboratories authorized by MHLW>

Note) In the ASEAN countries, there are official laboratories authorized by MHLW in Indonesia, Singapore, Thailand, and the Philippines. (See p.123)

[Inquiry]
MHLW quarantine stations having jurisdiction over ports of entry
http://www.mhlw.go.jp/english/topics/importedfoods/1-2.html

(2) Import Procedures

Importers of prepared foods for the purpose of sale or for other commercial purposes are required to submit a “Notification Form for Importation of Foods, etc.” and other required documents (list of materials, manufacturing process schedule, self-inspection results, etc.) to an MHLW quarantine station having jurisdiction over the port of entry where the relevant goods are to be cleared through customs. After
examination of the notification form and relevant documents, items that require cargo inspection are inspected in the bonded area where the cargo is being stored, and are either passed or rejected depending on the result of the inspection.

**Import Procedures based on the Food Sanitation Law**

![Flowchart](attachment:flowchart.png)

(3) Main Points of Examination

- Does the product comply with manufacturing standards prescribed in the Food Sanitation Law?

Prepared foods must comply with Specifications and Standards for Food, Food Additives, etc., which commonly apply to all food items (see p.19).

Retort foods are classified as “pressure and heat-sterilized foods in containers/packages,” and must comply with relevant manufacturing standards and compositional specifications.

Canned or bottled foods are not regulated by any specific manufacturing standards, but the Ministry of Health, Labour and Welfare defines “canned and bottled foods” as follows, based on the Food Sanitation Law:

“‘Canned foods’ or ‘bottled foods’ refer to those foods which have been canned or bottled after implementing measures for preventing rotting from contamination by bacteria or preventing oxidation by sealing from air, with the intention of preserving them for a relatively long period of time. They must be hermetically capped or sealed in a manner that prevents the contents from being able to be re-packed once the airtightness of the can or bottle is compromised.” (cited from the Food Sanitation Law, response to an inquiry)

According to the above definition, foods packed and sealed simply for convenience sake in selling, carrying and transporting, cannot be referred to as “canned or bottled foods,” even if they are packed and sealed in a can or bottle.

Food containers/packages must comply with specifications and standards for containers/packages
prescribed in the Food Sanitation Law. Particular care must be given to retort foods, as they are also regulated by application-specific standards.

[Information on Specifications and Standards for Foods, Food Additives, etc.]
Japan External Trade Organization (JETRO) <Webpage on standards and regulations>
http://www.jetro.go.jp/en/reports/regulations/

### Specifications and Standards for Prepared Foods under the Food Sanitation Law

<table>
<thead>
<tr>
<th>Specifications and standards common to all food items</th>
<th>Specifications and standards that apply to individual food items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retort foods</td>
<td>Pressure and heat-sterilized foods in containers/packages (manufacturing standards, compositional specifications)</td>
</tr>
<tr>
<td>• Compositional Specifications for Foods in General</td>
<td></td>
</tr>
<tr>
<td>• Standards for Manufacturing, Processing, and Preparation of Foods in General</td>
<td></td>
</tr>
<tr>
<td>• Preservation Standards for Foods in General</td>
<td></td>
</tr>
<tr>
<td>Canned or bottled foods</td>
<td>None</td>
</tr>
<tr>
<td>• Compositional Specifications for Foods in General</td>
<td></td>
</tr>
<tr>
<td>• Standards for Manufacturing, Processing, and Preparation of Foods in General</td>
<td></td>
</tr>
<tr>
<td>• Preservation Standards for Foods in General</td>
<td></td>
</tr>
</tbody>
</table>

### Specifications and Standards Relating to Containers/Packages of Prepared Foods

<table>
<thead>
<tr>
<th>Specifications and standards common to all containers/packages</th>
<th>Application-specific specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retort foods</td>
<td>Application-specific standards for containers/packages – Pressure and heat-sterilized foods in containers/packages</td>
</tr>
<tr>
<td>• Standards for General Implements, Containers, Packaging, and Component Materials</td>
<td></td>
</tr>
<tr>
<td>• Material-specific Specifications for Implements, Containers, Packaging, and Raw Materials</td>
<td></td>
</tr>
<tr>
<td>• Implement, Container, and Packaging Production Standards</td>
<td></td>
</tr>
<tr>
<td>Canned or bottled foods</td>
<td>None</td>
</tr>
<tr>
<td>• Standards for General Implements, Containers, Packaging, and Component Materials</td>
<td></td>
</tr>
<tr>
<td>• Material-specific Specifications for Implements, Containers, Packaging, and Raw Materials</td>
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<tr>
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All food additives must comply with usage standards which specify the maximum limit allowed to be used in each type of food, compositional specifications which specify purity and properties, and other relevant standards that are established for each substance, as necessary. Some food additives that are legally approved in their countries of export may not be permitted in Japan. Additionally, some additives that bear the same name may in fact be two different additives based on different compositional specifications or usage standards.
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  - Ministry of Health, Labour and Welfare <Food additives page – List of Designated Food Additives (Enforcement Regulations, Annexed Table 1)>

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  - Ministry of Health, Labour and Welfare <Food additives page – List of Existing Food Additives>

- Are all food additives used properly, in amounts conforming to the standards for the use of food additives?
  - Ministry of Health, Labour and Welfare <Food additives page – List of standards for the use of food additives>

- Does the food item contain any poisonous or harmful substances?
  Food items should not include beans that have traces of cyanide, should not include poisonous fish containing ciguatera toxins, should not be contaminated by mycotoxins such as aflatoxin, nor by radioactivity or chemical substances, etc.

- Does the manufacturer or place of manufacture have a history of any sanitation problems in the past?
  - Ministry of Health, Labour and Welfare <Website of the Imported Foods Inspection Services – Recent Cases of Violation of the Food Sanitation Law>
    http://www.mhlw.go.jp/english/topics/importedfoods/index.html

3) Considerations for Business Operators

(1) Compliance with the Food Sanitation Law

The Food Safety Basic Law requires importers to take the necessary steps to ensure food safety at their own initiative. Similarly, the Food Sanitation Law encourages importers to ensure the safety of imported foods on their own responsibility, by acquiring the necessary knowledge and technologies, ensuring the safety of ingredients, and conducting self-inspections.

Additionally, given Japanese consumers’ increasing concern and distrust of imported foods due to the recent spate of imported food poisoning incidents, importers are now more than ever expected to assure their imported goods guarantee the same level of safety as foods processed in Japan, at all stages of production in the country of export, including the selection of raw materials, production and processing, storage, and transportation.

The Guidelines on Hygiene Control of Import Processed Foods formulated by the Ministry of Health, Labour and Welfare (June 2008) outlines certain matters that importers should confirm with the manufacturer in the country of export (http://www.mhlw.go.jp/english/topics/importedfoods/guideline/01.html).
Exporters should also comply with Japan’s Food Sanitation Law and cooperate with importers, by taking careful note of matters specified in the Guidelines on Hygiene Control of Import Processed Foods, preparing the necessary information before importers request them, and striving to provide detailed information.

When importing/exporting the same items repeatedly, importers and exporters must check for any changes in manufacturing processes and raw materials, and conduct regular tests and inspection, to insure the items are free of harmful/poisonous substances and pathogenic microorganisms, do not contain undesignated food additives, and comply with standards for the use of food additives as well as compositional specifications.

(2) Confirmation with quarantine stations in Japan regarding information on sanitation

- What basic guidance do quarantine stations offer importers?

- Is the food item to be imported subject to monitoring inspection?
  - At the beginning of each fiscal year, the Ministry of Health, Labour and Welfare announces an annual schedule for the number of inspections to be conducted per food category, determined in consideration of the rate of past violations, number and weight of imported cargos, and seriousness of violations.
    - http://www.mhlw.go.jp/english/topics/importedfoods/08/08-03.html

- Is the food item to be imported subject to an ordered inspection?
  - At the beginning of each fiscal year, the Ministry of Health, Labour and Welfare announces a list (target products and inspection items) of foods that are deemed to have high probability of violating the Food Sanitation Law, judging from situations in exporting countries, food properties, and cases of noncompliance by similar foods. Additional inspection orders may also be issued later, depending on the subsequent status of violations. When the Minister of Health, Labour and Welfare issues an ordered inspection, the relevant cargo is stored in a bonded area until the importer applies for an inspection at a registered laboratory (fee required) and obtains an inspection result.
    - http://www.mhlw.go.jp/english/topics/importedfoods/08/08-02.html

- What are the most common types of violations against the Food Sanitation Law?
  - A record of past violations against the Food Sanitation Law shows frequent violations in relation to the use of food additives in prepared foods imported from the ASEAN countries.
The following is a list of precautions concerning canned foods, by type.

**<Canned/bottled fruits and vegetables>**
- Beware of excessive residues of sulfur dioxide used as a bleaching agent.
- Cyclamic acid, which is commonly used as a sweetener, is not approved for use in Japan.
- Beware of the use of sorbic acid (preservative) for purposes other than its intended uses.
- Be sure that jams and marmalades do not contain azorubine (coloring), benzoic acid (preservative), or cyclamic acid (sweetener), as they are food additives not approved for use in Japan. Also beware of excessive residues of glutinous starch syrup, gelatin, and dried fruit-derived sulfur dioxide in raw ingredients. The use of acid tar dye and other synthetic dyes in marmalade is not allowed in Japan.

**<Canned/bottled seasoning>**
- Note that benzoic acid may be used in soy sauce, but not in fish sauce.
- Beware of the use of sorbic acid (preservative) for purposes other than its intended uses (they may not be used in sauces, mayonnaise, and dressings).
- The use of antioxidant T.B.H.Q. and emulsion stabilizer polysorbate is not allowed.

**<Canned/bottled fishery products>**
- Beware of excessive residues of antioxidants (calcium disodium ethylenediaminetetraacetate, disodium ethylenediaminetetraacetate) and bleaching agents (sulfur dioxide, sodium sulfite).

**<Canned/bottled livestock products>**
- Food additives that are only allowed for use in meat products (sodium sulfite, potassium nitrate, sorbic acid, etc.) are not allowed for other products.

### Prepared Foods – Excerpt from “Recent Cases of Violation of the Food Sanitation Law”
(January – August 2008; violations of exports from ASEAN countries)

<table>
<thead>
<tr>
<th>Item</th>
<th>Article</th>
<th>Country of export</th>
<th>Description of violation</th>
<th>Measure taken</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chili sauce</td>
<td>10</td>
<td>Thailand</td>
<td>Undesignated food additive (polysorbate detected)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Self-inspection (Polysorbate was designated as a food additive in the revised standards (April 30, 2008))</td>
</tr>
<tr>
<td>Mango puree</td>
<td>11</td>
<td>Philippines</td>
<td>Compositional noncompliance (0.757 g/kg sulfur dioxide detected)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Self-inspection</td>
</tr>
</tbody>
</table>

(Note) “Self-inspection” refers to the guidance provided by the quarantine station to importers regarding the implementation of self-inspection on items that are required on the first import occasion and on regular occasions, from the standpoint of assisting importers to fulfill their food sanitation and security obligations.

(Source) Ministry of Health, Labour and Welfare <Website of the Imported Foods Inspection Services – Recent Cases of Violation of the Food Sanitation Law>
http://www.mhlw.go.jp/english/topics/importedfoods/index.html
### Part 2 Import Procedures by Food Category

5. Prepared Foods (Canned, Bottled, Retort Foods)

#### Prepared Foods – Excerpt from “Typical Cases of Violation of the Food Sanitation Law”

(violations of exports from ASEAN countries)

Typical cases judged to be in violation of the Food Sanitation Law that were found in the past on the occasion of import notification, compiled by the Ministry of Health, Labour and Welfare

<table>
<thead>
<tr>
<th>Item</th>
<th>Country of export</th>
<th>Description of violation</th>
<th>Limit</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuna flake</td>
<td>Thailand</td>
<td>Antioxidant: T.B.H.Q. included</td>
<td>Undesignated additive</td>
<td>Pressure and heat-sterilized food in container/package</td>
</tr>
<tr>
<td>Canned nata de coco</td>
<td>Indonesia</td>
<td>Preservative: undesignated use of potassium sorbate</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Oilled tuna</td>
<td>Thailand</td>
<td>Antioxidant: T.B.H.Q. included</td>
<td>Undesignated additive</td>
<td>Pressure and heat-sterilized food in container/package</td>
</tr>
<tr>
<td>Mixed pickles</td>
<td>Indonesia</td>
<td>Preservative: undesignated use of benzoic acid</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Dried mango (in syrup)</td>
<td>Philippines</td>
<td>Antioxidant: excessive residue of sulfur dioxide</td>
<td>Other foods: less than 0.030 g/kg</td>
<td>—</td>
</tr>
<tr>
<td>Soup stock cube</td>
<td>Vietnam</td>
<td>Preservative: undesignated use of sorbic acid</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Seasoning (chili sauce)</td>
<td>Indonesia</td>
<td>Preservative: undesignated use of benzoic acid</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Seasoning (chili sauce)</td>
<td>Singapore</td>
<td>Preservative: undesignated use of sorbic acid</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Seasoning (mango vinegar)</td>
<td>Philippines</td>
<td>Antioxidant: excessive residue of sulfur dioxide</td>
<td>Other foods: less than 0.030 g/kg</td>
<td>Fruit juice used as ingredient</td>
</tr>
<tr>
<td>Seasoning (fish sauce)</td>
<td>Philippines</td>
<td>Reinforcing agent: sodium iodide included</td>
<td>Undesignated additive</td>
<td>—</td>
</tr>
<tr>
<td>Seasoning (for fried rice)</td>
<td>Indonesia</td>
<td>Antioxidant: T.B.H.Q. included</td>
<td>Undesignated additive</td>
<td>—</td>
</tr>
<tr>
<td>Seasoning (soy sauce)</td>
<td>Philippines</td>
<td>Preservative: undesignated use of sorbic acid</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Seasoning (vinegar)</td>
<td>Philippines</td>
<td>Preservative: brominated oil included</td>
<td>Undesignated additive</td>
<td>—</td>
</tr>
<tr>
<td>Seasoning (for stir-fried vegetables)</td>
<td>Singapore</td>
<td>Preservative: undesignated use of sorbic acid</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Seasoning (for stir-fried vegetables)</td>
<td>Singapore</td>
<td>Preservative: undesignated use of benzoic acid</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Prepared beans</td>
<td>Philippines</td>
<td>Preservative: undesignated use of benzoic acid</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Oil (candlenut oil)</td>
<td>Indonesia</td>
<td>Excessive use of BHT</td>
<td>Oil: 0.20 g/kg (total amount when used with BHA)</td>
<td>Oil</td>
</tr>
</tbody>
</table>

(Source) Ministry of Health, Labour and Welfare <Website of the Imported Foods Inspection Services – Typical Cases of Violation of the Food Sanitation Law that were Found on the Occasion of Import Notification>  
Other considerations regarding the import of prepared foods

- Note that *clostridium botulinum* may be detected from bottled foods that are not heated at high temperatures for a long time.
- Prepared foods are subject to the Positive List System for residual agricultural chemicals under the Food Sanitation Law, but the system does not oblige business operators to conduct an analysis of agricultural chemical residues in foods. To comply with the system, importers should actively collect information on agricultural chemicals at the production stage of raw ingredients (information on proper usage and management of agricultural chemicals, types and usage methods of agricultural chemicals that may be used, cases of violation against residue standards, etc.), and assess residue status, as necessary.
- Note that container/package sizes and sanitary wrapping are important aspects in Japanese business customs.
- Products with high oil content should be transported and stored without exposing them to high temperatures and direct sunlight. They should also be prepared in small lots for imports, to prevent oil oxidation.
### Import Procedures for Confectionery and Snack Foods

#### Responsibilities of the exporter or importer

**Pre-export preparations**
- [Preparations based on the Food Sanitation Law]
  - Collect information for determining whether the product concerned complies with Japan’s Food Sanitation Law.
  - Conduct a self-inspection if necessary (either by the exporter or importer) and acquire a result of the inspection.
  - Exporters should prepare the documents which the importer in Japan need to submit to the quarantine station along with the "Notification Form for Importation of Foods, etc." in order to import the item concerned. Enquire with the importer or a quarantine station in Japan concerning the required documents, as they differ according to food category.

**Preparations for customs clearance in Japan**
- Exporters should prepare the relevant documents required for customs clearance in Japan.

**Import quarantine inspection in Japan**
- [Import procedures based on the Food Sanitation Law]
  - When importing confectionery or snack foods, importers must submit an "Import Notification for Importation of Foods, etc." to the quarantine station, along with other required documents.
  - Importers must submit an import declaration form to the Customs Office, along with other required documents.

#### Required documents

**Documents to be prepared by exporters**
- List of materials
- Manufacturing process schedule (Both of the above must be prepared and issued by the manufacturer, and must bear the name of the manufacturing company)
- Description of the product
- Sanitary certificate, inspection results, etc., as required

**Documents to be submitted by importers**
- Import declaration form
- Invoice
- Packing list
- Bill of lading (B/L) or air waybill

**Documents to be prepared by exporters**
- Invoice
- Packing list
- Bill of lading (B/L) or air waybill
The import of confectionery and snack foods is regulated by the Food Sanitation Law.

The sections below describe procedures and considerations for the import of confectionery and snack foods under the Food Sanitation Law.

1) Food Sanitation Law

(1) Pre-export Preparations

Exporters and importers should sufficiently collect the necessary information for confirming whether the item they wish to import complies with standards prescribed in Japan’s Food Sanitation Law.

<Documents to be prepared by exporters (Japanese translations thereof, in cases where the original document is written in a language other than English)>

- List of materials
  Complete list specifically showing the scientific names of all materials (food ingredients) and additives used, prepared and issued by the manufacturing company and bearing the name of the company

- Manufacturing process schedule
  Schedule showing the complete manufacturing process from the materials to the end product, including sterilization temperatures and time, prepared and issued by and bearing the name of the manufacturing company and signed by the person in charge

- Name and address of the manufacturer and place of manufacture in the country of export, and a document showing the name of the product

- Description of the product

- If the food item contains beef or beef-derived substances such as beef extracts or gelatin among the materials, a written document showing the country in which the cattle were nurtured, slaughtered and processed, and the parts of the cattle used as materials

<Documents to be prepared by importers (if necessary)>

- Depending on the materials, a document showing the steps that have been taken to check the product against the requirements of the Pharmaceutical Affairs Law (verification date, verifying organization, identification of relevant substances and their handling, etc.)
  * For health foods and food items containing Japanese or Chinese herbal medicine, importers should provide the scientific name (Japanese name) of the material and clarify the part of the plant that is used as an ingredient and its effect, and at the same time confirm with the pharmaceutical department in the local government whether the ingredient is subject to the Pharmaceutical Affairs Law.

<Documents to be prepared by either exporters or importers (if necessary)>

- Self-inspection results
  Importers may request a self-inspection at a laboratory registered with the Ministry of Health, Labour and Welfare or an official laboratory in the country of export and submit a copy of the results along with the inspection application form, to exempt the inspected items from inspection and expedite the import process.

[Inquiry about inspection facilities]
Ministry of Health, Labour and Welfare <List of official laboratories authorized by MHLW>

Note) In the ASEAN countries, there are official laboratories authorized by MHLW in Indonesia, Singapore, Thailand, and the Philippines. (See p.123)
[Inquiry]
MHLW quarantine stations having jurisdiction over ports of entry
http://www.mhlw.go.jp/english/topics/importedfoods/1-2.html

(2) Import Procedures

Importers who wish to import confectionery and snack foods for the purpose of sale or for other commercial purposes are required to submit a “Notification Form for Importation of Foods, etc.” and other required documents (list of materials, manufacturing process schedule, self-inspection results, etc.) to an MHLW quarantine station having jurisdiction over the port of entry where the relevant goods are to be cleared through customs. After examination of the notification form and relevant documents, items that require cargo inspection are inspected in the bonded area where the cargo is being stored, and are either passed or rejected depending on the result of the inspection.

**Import Procedures based on the Food Sanitation Law**

![Flowchart]

(3) Main Points of Examination

- Does the product comply with manufacturing standards prescribed in the Food Sanitation Law?

Confectionery and snack foods are not regulated by any specific production standards, but must comply with Specifications and Standards for Food, Food Additives, etc., which commonly apply to all food items (see p.19).

Food containers/packages must comply with specifications and standards for containers/packages prescribed in the Food Sanitation Law.
### Specifications and Standards for Confectionery and Snack Foods under the Food Sanitation Law

<table>
<thead>
<tr>
<th>Confectionery and snack foods</th>
<th>Specifications and standards common to all food items</th>
<th>Specifications and standards that apply to individual food items</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Compositional Specifications for Foods in General</td>
<td>None (note)</td>
</tr>
<tr>
<td></td>
<td>• Standards for Manufacturing, Processing, and Preparation of Foods in General</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Preservation Standards for Foods in General</td>
<td></td>
</tr>
</tbody>
</table>

Note: Though not a specification or standard, “confectionery processed using oil (confectionery containing more than 10% (weight %) of oil as crude fat)” should comply with the “Confectionery Guidelines.”

### Specifications and Standards Relating to Containers/Packages of Confectionery and Snack Foods

<table>
<thead>
<tr>
<th>Confectionery and snack foods</th>
<th>Specifications and standards common to all containers/packages</th>
<th>Application-specific specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Standards for General Implements, Containers, Packaging, and Component Materials</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>• Material-specific Specifications for Implements, Containers, Packaging, and Raw Materials</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Implement, Container, and Packaging Production Standards</td>
<td></td>
</tr>
</tbody>
</table>

[Information on Specifications and Standards for Foods, Food Additives, etc.]
Japan External Trade Organization (JETRO) <Webpage on standards and regulations>
http://www.jetro.go.jp/en/reports/regulations/

Does the use of food additives comply with relevant standards?

All food additives must comply with usage standards which specify the maximum limit allowed to be used in each type of food, compositional specifications which specify purity and properties, and other relevant standards that are established for each substance, as necessary. Some food additives that are legally approved in their countries of export may not be permitted in Japan. Additionally, some additives that bear the same name may in fact be two different additives based on different compositional specifications or usage standards.

Food items that do not comply with Japanese standards for food additives may not be imported. The following are major points for confirmation regarding food additives.

- Are any undesignated food additives used in the food item, including in its materials?

Ministry of Health, Labour and Welfare <Food additives page – List of Designated Food Additives (Enforcement Regulations, Annexed Table 1)>
Part 2 Import Procedures by Food Category

6. Confectionery and Snack Foods

- Does the use of natural food additives conform to requirements concerning source, manufacturing method, and quality specified in the List of Existing Food Additives?
  - Ministry of Health, Labour and Welfare <Food additives page – List of Existing Food Additives>
    [http://www.mhlw.go.jp/english/topics/foodsafety/foodadditives/index.html]

- Are all food additives used properly, in amounts conforming to the standards for the use of food additives?
  - Ministry of Health, Labour and Welfare <Food additives page – List of standards for the use of food additives>
    [http://www.mhlw.go.jp/english/topics/foodsafety/foodadditives/index.html]

- Does the food item contain any poisonous or harmful substances?
  Food items should not be contaminated by mycotoxins such as aflatoxin, radioactivity, chemical substances, etc.

- Does the manufacturer or place of manufacture have a history of any sanitation problems in the past?
  - Ministry of Health, Labour and Welfare <Website of the Imported Foods Inspection Services – Recent Cases of Violation of the Food Sanitation Law>
    [http://www.mhlw.go.jp/english/topics/importedfoods/index.html]

2) Considerations for Business Operators

(1) Compliance with the Food Sanitation Law

The Food Safety Basic Law requires importers to take the necessary steps to ensure food safety at their own initiative. Similarly, the Food Sanitation Law encourages importers to ensure the safety of imported foods on their own responsibility, by acquiring the necessary knowledge and technologies, ensuring the safety of ingredients, and conducting self-inspections.

Additionally, given Japanese consumers’ increasing concern and distrust of imported foods due to the recent spate of imported food poisoning incidents, importers are now more than ever expected to assure their imported goods guarantee the same level of safety as foods processed in Japan, at all stages of production in the country of export, including the selection of raw materials, production and processing, storage, and transportation.

The Guidelines on Hygiene Control of Import Processed Foods formulated by the Ministry of Health, Labour and Welfare (June 2008) outlines certain matters that importers should confirm with the manufacturer in the country of export ([http://www.mhlw.go.jp/english/topics/importedfoods/guideline/01.html](http://www.mhlw.go.jp/english/topics/importedfoods/guideline/01.html)).

Exporters should also comply with Japan’s Food Sanitation Law and cooperate with importers, by taking careful note of matters specified in the Guidelines on Hygiene Control of Import Processed Foods, preparing the necessary information before importers request them, and striving to provide detailed information.

When importing/exporting the same items repeatedly, importers and exporters must check for any changes in manufacturing processes and raw materials, and conduct regular tests and inspection, to insure the items are free of harmful/poisonous substances, do not contain undesignated food additives, and comply with standards for the use of food additives as well as compositional specifications.
(2) Confirmation with quarantine stations in Japan regarding information on sanitation

- What basic guidance do quarantine stations offer importers?
  http://www.mhlw.go.jp/english/topics/importedfoods/08/08-01.html

- Is the food item to be imported subject to monitoring inspection?
  At the beginning of each fiscal year, the Ministry of Health, Labour and Welfare announces an annual schedule for the number of inspections to be conducted per food category, determined in consideration of the rate of past violations, number and weight of imported cargos, and seriousness of violations.
  http://www.mhlw.go.jp/english/topics/importedfoods/08/08-03.html

- Is the food item to be imported subject to an ordered inspection?
  At the beginning of each fiscal year, the Ministry of Health, Labour and Welfare announces a list (target products and inspection items) of foods that are deemed to have high probability of violating the Food Sanitation Law, judging from situations in exporting countries, food properties, and cases of noncompliance by similar foods. Additional inspection orders may also be issued later, depending on the subsequent status of violations. When the Minister of Health, Labour and Welfare issues an ordered inspection, the relevant cargo is stored in a bonded area until the importer applies for an inspection at a registered laboratory (fee required) and obtains an inspection result.
  http://www.mhlw.go.jp/english/topics/importedfoods/08/08-02.html

- What are the most common types of violations against the Food Sanitation Law?
  Most confectionery and snack foods are made using food additives. Therefore, a past record of typical violations of the Food Sanitation Law shows many violations in relation to the use of food additives. Since January 2008, however, no violations of the Food Sanitation Law have been found among imports of confectionery and snack foods from the ASEAN countries.

  The following is a list of precautions concerning the import of confectionery and snack foods.

  <Confectionery and snack foods in general>
  - Beware of undesignated uses of food additives that are not allowed in Japan.
    E.g.: The use of quinoline yellow, azorubine, patent blue V (coloring agents), T.B.H.Q. (antioxidant), polysorbate (emulsifying agent), and iodinated salt (reinforcing agent) are not allowed. The undesignated use of sorbic acid (preservative). Excessive residue of sulfur dioxide used as a bleaching agent or antioxidant.

  <Candies>
  - Note that sulfur dioxide may be detected from candies, if it is used as a bleaching agent in the production of glutinous starch syrup, which is the main ingredient of candies.
  - Note that magnesium stearate (food processing agent) may not be used in foods other than foods with health claims in capsules and tablets.
Part 2 Import Procedures by Food Category

6. Confectionery and Snack Foods

- Beware of the use of cyclamic acid (sweetener).

**<Chewing gum>**

- The only designated food additives allowed to be used as chewing gum base are ester gum, polybutene, polyisobutylene, and polyvinyl acetate resin. Make sure existing food additives used (chicle, gutta hang kang, gutta percha, jelutong, etc.) are included in the list of existing food additives.
- Beware of excessive residues of saccharin (sweetener).

**<Chocolate>**

- Frequent violations are made in regard to the use of undesignated additives as coloring agents. However, in addition to coloring agents, also beware of the use of polysorbate (emulsifying agent) and the undesignated use of sorbic acid (preservative).

**<Biscuits>**

- Note that cookies made using large amounts of oil should not contain T.B.H.Q.
- Beware of biscuits with jam that may contain sorbic acid used as a preservative (undesignated use in biscuits).

**<Snack foods made from rice>**

- Note that fried rice crackers and other rice snacks made using oil should not contain antioxidants and emulsifying agents such as T.B.H.Q. as a food additive in the oil used.
- In addition to oil, beware of food additives derived from auxiliary raw materials (shrimp, sesame seeds, soy sauce, spices, etc.).

**<Snack foods>**

- Note that potato chips and other such snack foods made using oil should not contain antioxidants such as T.B.H.Q. as a food additive in the oil used.

**<Peanuts and other nuts>**

- Processed peanut products (limited to those made principally of peanuts) are subject to an ordered inspection in regard to the mycotoxin aflatoxin B1. Processed nut products are not subject to an ordered inspection, but frequently contain greater levels of aflatoxin B1 than the provisional limit. In either case, make sure peanut and other nut products are properly preserved and managed before export and during transport.
- Beware of the use of cyclamic acid (sweetener) in flavored products.
Confectionery and Snack Foods — Excerpt from “Typical Cases of Violation of the Food Sanitation Law” (violations of exports from ASEAN countries)

Typical cases judged to be in violation of the Food Sanitation Law that were found in the past on the occasion of import notification, compiled by the Ministry of Health, Labour and Welfare

<table>
<thead>
<tr>
<th>Item</th>
<th>Country of export</th>
<th>Description of violation</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cookies (cashew nuts)</td>
<td>Malaysia</td>
<td>Preservative: undesignated use of benzoic acid</td>
<td>—</td>
</tr>
<tr>
<td>Snack food</td>
<td>Thailand</td>
<td>Reinforcing agent: sodium iodide included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Snack food</td>
<td>Philippines</td>
<td>Antioxidant: T.B.H.Q. included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Biscuit</td>
<td>Indonesia</td>
<td>Antioxidant: T.B.H.Q. included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Baked foods</td>
<td>Philippines</td>
<td>Antioxidant: T.B.H.Q. included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Snack food (shrimp cracker)</td>
<td>Singapore</td>
<td>Antioxidant: excessive residue of sulfur dioxide</td>
<td>Other foods: less than 0.030 g/kg</td>
</tr>
<tr>
<td>Fried bean snack</td>
<td>Thailand</td>
<td>Antioxidant: T.B.H.Q included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Western-style snack food (egg pie)</td>
<td>Philippines</td>
<td>Preservative: undesignated use of sorbic acid</td>
<td>—</td>
</tr>
<tr>
<td>Western-style snack food (egg pie)</td>
<td>Philippines</td>
<td>Preservative: undesignated use of benzoic acid</td>
<td>—</td>
</tr>
<tr>
<td>Peanut (small size)</td>
<td>Indonesia</td>
<td>Detection of aflatoxin (mycotoxin)</td>
<td>—</td>
</tr>
<tr>
<td>Peanut (small size)</td>
<td>Vietnam</td>
<td>Detection of aflatoxin (mycotoxin)</td>
<td>—</td>
</tr>
</tbody>
</table>

(Source) Ministry of Health, Labour and Welfare <Website of the Imported Foods Inspection Services – Typical Cases of Violation of the Food Sanitation Law that were Found on the Occasion of Import Notification>


Other considerations regarding the import of confectionery and snack foods

- Confectionery and snack foods are subject to the Positive List System for residual agricultural chemicals under the Food Sanitation Law, but the system does not oblige business operators to conduct an analysis of agricultural chemical residues in foods. To comply with the system, importers should actively collect information on agricultural chemicals at the production stage of raw ingredients (information on proper usage and management of agricultural chemicals, types and usage methods of agricultural chemicals that may be used, cases of violation against residue standards, etc.), and assess residue status, as necessary.
- Note that container/package sizes and sanitary wrapping are important aspects in Japanese business customs.
- Products with high oil content should be transported and stored without exposing them to high temperatures and direct sunlight, and should be prepared in small lots for imports, to prevent oil oxidation.
- Confectionery and snack foods made of cereals are particularly susceptible to insect damage. As biscuits and other products that degrade with humidity also fall under this category, take proper care regarding the airtightness and materials of their containers/packages, and make sure they are properly preserved and managed before export and during transport.
- In regard to chocolates, biscuits, and chewing gum, also take note of the definitions and classifications provided in the Fair Competition Code (see p.30).
## 7. Soft Drinks

### Import Procedures for Soft Drinks

#### Responsibilities of the exporter or importer

**[Preparations based on the Food Sanitation Law]**
- Collect information for determining whether the product concerned complies with Japan's Food Sanitation Law.
- Conduct a self-inspection if necessary (either by the exporter or importer) and acquire a result of the inspection.
- Exporters should prepare the documents which the importer in Japan need to submit to the quarantine station along with the “Notification Form for Importation of Foods, etc.” in order to import the item concerned. Enquire with the importer or a quarantine station in Japan concerning the required documents, as they differ according to food category.

**[Preparations for customs clearance in Japan]**
- Exporters should prepare the relevant documents required for customs clearance in Japan.

#### Required documents

**[Documents to be prepared by exporters]**
- List of materials
- Manufacturing process schedule*
- Description of the product
- Sanitary certificate, inspection results, etc., as required
*To import mineral water, a document on manufacturing standards is also required (based on the quarantine station notification)

**[Documents to be submitted by importers]**
- Import Notification for Importation of Food, etc.
- List of materials
- Manufacturing process schedule
- Description of the product
- Sanitary certificate, inspection results, etc., as required
- Document showing that the product has been checked against the requirements of the Pharmaceutical Affairs Law, as required

**[Documents to be prepared by importers]**
- Import declaration form
- Invoice
- Packing list
- Bill of lading (B/L) or air waybill

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**Import procedures based on the Food Sanitation Law**
- When importing soft drinks, importers must submit an “Import Notification for Importation of Foods, etc.” to the quarantine station, along with other required documents.

**Import quarantine inspection in Japan**
- Importers must submit an import declaration form to the Customs Office, along with other required documents.
The import of soft drinks is regulated by the Food Sanitation Law.

The sections below describe import procedures and considerations under the Food Sanitation Law.

1) Food Sanitation Law

(1) Pre-export Preparations

Both exporters and importers should sufficiently collect the necessary information for determining whether the item they wish to import complies with standards prescribed in Japan’s Food Sanitation Law.

<Documents to be prepared by exporters (Japanese translations thereof, in cases where the original document is written in a language other than English)>

- List of materials
  Complete list specifically showing the scientific names of all materials (food ingredients) and additives used, prepared and issued by the manufacturing company and bearing the name of the company
- Manufacturing process schedule
  Schedule showing the complete manufacturing process from the materials to the end product, including sterilization temperatures and time, prepared and issued by and bearing the name of the manufacturing company and signed by the person in charge
- Name and address of the manufacturer and place of manufacture in the country of export, and a document showing the name of the product
- Description of the product
- If the food item contains beef or beef-derived substances among the materials, a written document showing the country in which the cattle were nurtured, slaughtered and processed, and the parts of the cattle used as materials

* Notes on importing mineral water

To import mineral water, the Notice of the quarantine station (Sanitation Inspection No. 152, “Handling Mineral Water”) requires manufacturers to prepare the following documents that provide information on manufacturing standards.

<table>
<thead>
<tr>
<th>Manufacturing standards</th>
<th>Products that have been sterilized/disinfected</th>
<th>Products that have not been sterilized/disinfected</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Analysis results showing that the raw water used complies with criteria for raw water (18 items) stipulated by mineral water manufacturing standards</td>
<td>Required (on first import occasion)</td>
<td>Required (on first import occasion)</td>
</tr>
<tr>
<td>2) Detailed diagram of the manufacturing process *3</td>
<td>Required *4 (on first import occasion)</td>
<td>Required (on first import occasion)</td>
</tr>
<tr>
<td>3a- Sterilization/sanitation method</td>
<td>Required (on first import occasion)</td>
<td>-</td>
</tr>
<tr>
<td>3b- In cases where the product has not been sterilized/disinfected Document showing that the product complies with regulations for sanitation management (a – g) under manufacturing standards</td>
<td>-</td>
<td>Required *1 (on first import occasion)</td>
</tr>
</tbody>
</table>
### 7. Soft Drinks

<table>
<thead>
<tr>
<th>Compositional specifications</th>
<th>Products that have been sterilized/disinfected</th>
<th>Products that have not been sterilized/disinfected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Required *2 (each import occasion)</td>
<td>Required *2 (each import occasion)</td>
<td></td>
</tr>
</tbody>
</table>

*1 Mineral water products from the EU that have not been sterilized/disinfected are regarded as complying with sanitation management regulations (a – g) under mineral water manufacturing standards, if a manufacturing certificate (agreement with EU) issued by the country of export can be presented, and the fact that they are included in the EU list can be confirmed in official gazettes.

*2 All items included in the compositional specifications must be inspected on the first import occasion.

*3 A document showing the manufacturing process, from the collection of water from the spring, to bottling, needs to be checked. Information on the sterilization of bottles may also be required (in cases where bottles are recycled, etc.).

*4 Provide the following if sterilization methods other than heat-sterilization are used:
- UV sterilization: UV irradiance (µW/see/cm²), permeability (%)
- Ozone sterilization: Dissolved ozone (mg/L), treatment time (min)
  For products that are sanitized, indicate the mesh size of the filter used.

#### <Documents to be prepared by importers (if necessary)>
- Depending on the materials, a document showing the steps that have been taken to check the product against the requirements of the Pharmaceutical Affairs Law (verification date, verifying organization, identification of relevant substances and their handling, etc.)
  * For health foods and food items containing Japanese or Chinese herbal medicine, importers should provide the scientific name (Japanese name) of the material and clarify the part of the plant that is used as an ingredient and its effect, and at the same time confirm with the pharmaceutical department in the local government whether the ingredient is subject to the Pharmaceutical Affairs Law.

#### <Documents to be prepared by either exporters or importers (if necessary)>
- Self-inspection results
  Importers may request a self-inspection at a laboratory registered with the Ministry of Health, Labour and Welfare or an official laboratory in the country of export and submit a copy of the report along with the inspection application form, to exempt the inspected items from inspection and expedite the import process.

#### [Inquiry about inspection facilities]
- Ministry of Health, Labour and Welfare [List of official laboratories authorized by MHLW]
  Note) In the ASEAN countries, there are official laboratories authorized by MHLW in Indonesia, Singapore, Thailand, and the Philippines. (See p.123)

#### [General inquiry]
- MHLW quarantine stations having jurisdiction over ports of entry
  [http://www.mhlw.go.jp/english/topics/importedfoods/1-2.html](http://www.mhlw.go.jp/english/topics/importedfoods/1-2.html)

#### (2) Import Procedures
- Importers who wish to import soft drinks for the purpose of sale or for other commercial purposes are required to submit a “Notification Form for Importation of Foods, etc.” and other required documents (list of materials, manufacturing process schedule, self-inspection results, etc.) to an MHLW quarantine station having jurisdiction over the port where the relevant goods are to be cleared through customs. After examination of the notification form and relevant documents, items that require cargo inspection are inspected in the bonded area where the cargo is being stored, and are either passed or rejected depending on the result of the inspection.
Import Procedures based on the Food Sanitation Law

(3) Main Points of Examination

Does the item comply with manufacturing standards prescribed in the Food Sanitation Law?
Soft drinks must comply with Specifications and Standards for Food, Food Additives, etc., which commonly apply to all food items (see p.19), in addition to compositional specifications, manufacturing standards, and preservation standards that are specifically prescribed for soft drinks. (Under the Food Sanitation Law, soft drinks refer to beverages other than lactic acid beverages, milk and dairy products, and alcoholic beverages (with an alcohol level of 1% or higher).)

Food containers/packages must comply with specifications and standards for containers/packages prescribed in the Food Sanitation Law, in addition to application-specific specifications for soft drinks.

The Compositional Specifications for Foods in General prescribe individual standards of residual agricultural chemicals in tomato, orange, citrus fruit, apple, and grape juices, and mineral water. Under these standards, a survey on the use of agricultural chemicals must be conducted in the growing-site and guidance on drug holidays must be provided, in the case of juices. In the case of mineral water, a survey on the use of seasonal drugs in the water collection area and its surroundings must be conducted, in addition to an inspection of water sources.
**Specifications and Standards for Soft Drinks under the Food Sanitation Law**

<table>
<thead>
<tr>
<th>Specifications and standards common to all food items</th>
<th>Specifications and standards that apply to individual food items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soft drinks</td>
<td>Soft drinks (compositional specifications, manufacturing standards, preservation standards) (note)</td>
</tr>
<tr>
<td>• Compositional Specifications for Foods in General</td>
<td></td>
</tr>
<tr>
<td>• Standards for Manufacturing, Processing, and Preparation of Foods in General</td>
<td></td>
</tr>
<tr>
<td>• Preservation Standards for Foods in General</td>
<td></td>
</tr>
</tbody>
</table>

(Note) Compositional specifications: Note that there are additional standards for mineral water (products with a carbon dioxide pressure inside their containers of less than 98 kPa at 20°C, and that are not sterilized or sanitized), squeezed apple juice, and products made solely of squeezed apple.

Manufacturing standards: There are individual standards for mineral water, frozen fruit drinks, and fruit juices that are intended for use as raw ingredients.

Preservation standards: There are individual standards for beverages bottled in glass bottles sealed with a paper cap, and for frozen fruit drinks.

**Specifications and Standards Relating to Soft Drink Containers/Packages**

<table>
<thead>
<tr>
<th>Specifications and standards common to all containers/packages</th>
<th>Application-specific specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soft drinks</td>
<td>Application-specific standards for containers/packages – Soft drinks</td>
</tr>
<tr>
<td>• Specifications for General Implements, Containers, Packaging, and Component Materials</td>
<td></td>
</tr>
<tr>
<td>• Material-specific Specifications for Implements, Containers, Packaging, and Raw Materials</td>
<td></td>
</tr>
<tr>
<td>• Implement, Container, and Packaging Production Standards</td>
<td></td>
</tr>
</tbody>
</table>

[Information on Specifications and Standards for Foods, Food Additives, etc.]
Japan External Trade Organization (JETRO) <Webpage on standards and regulations>
http://www.jetro.go.jp/en/reports/regulations/

Does the use of food additives comply with relevant standards?
All food additives must comply with usage standards which specify the maximum limit allowed to be used in each type of food, compositional specifications which specify purity and properties, and other relevant standards that are established for each substance, as necessary. Some food additives that are legally approved in their countries of export may not be permitted in Japan. Additionally, some additives that bear the same name may in fact be two different additives based on different compositional specifications or usage standards.

Food items that do not comply with Japanese standards for food additives may not be imported. The following are major points for confirmation regarding food additives.

- Are any undesignated food additives used in the food item, including in its materials?

Ministry of Health, Labour and Welfare <Food additives page – List of Designated Food Additives (Enforcement Regulations, Annexed Table 1)>
7. Soft Drinks

- Does the use of natural food additives conform to requirements concerning source, manufacturing method, and quality specified in the List of Existing Food Additives?
  - Ministry of Health, Labour and Welfare <Food additives page – List of Existing Food Additives>

- Are all food additives used properly, in amounts conforming to the standards for the use of food additives?
  - Ministry of Health, Labour and Welfare <Food additives page – List of standards for the use of food additives>

- Does the food item contain any poisonous or harmful substances?
  Soft drink items should not be contaminated by mycotoxins such as patulin, radioactivity, chemical substances, etc.

- Does the manufacturer or place of manufacture have a history of any sanitation problems in the past?
  - Ministry of Health, Labour and Welfare <Website of the Imported Foods Inspection Services – Recent Cases of Violation of the Food Sanitation Law>
    http://www.mhlw.go.jp/english/topics/importedfoods/index.html

2) Considerations for Business Operators

1) Compliance with the Food Sanitation Law

   The Food Safety Basic Law requires importers to take the necessary steps to ensure food safety at their own initiative. Similarly, the Food Sanitation Law encourages importers to ensure the safety of imported foods on their own responsibility, by acquiring the necessary knowledge and technologies, ensuring the safety of ingredients, and conducting self-inspections.

   Additionally, given Japanese consumers’ increasing concern and distrust of imported foods due to the recent spate of imported food poisoning incidents, importers are now more than ever expected to assure their imported goods guarantee the same level of safety as foods processed in Japan, at all stages of production in the country of export, including the selection of raw materials, production and processing, storage, and transportation.

   The Guidelines on Hygiene Control of Import Processed Foods formulated by the Ministry of Health, Labour and Welfare (June 2008) outlines certain matters that importers should confirm with the manufacturer in the country of export (http://www.mhlw.go.jp/english/topics/importedfoods/guideline/01.html).

   Exporters should also comply with Japan’s Food Sanitation Law and cooperate with importers, by taking careful note of matters specified in the Guidelines on Hygiene Control of Import Processed Foods, preparing the necessary information before importers request them, and striving to provide detailed information.

   When importing/exporting the same items repeatedly, importers and exporters must check for any changes in manufacturing processes and raw materials, and conduct regular tests and inspection, to insure the items are free of harmful/poisonous substances and pathogenic microorganisms, do not contain undesignated food additives, and comply with standards for the use of food additives as well as compositional specifications.
(2) Confirmation with quarantine stations in Japan regarding information on sanitation

- What basic guidance do quarantine stations offer importers?
    http://www.mhlw.go.jp/english/topics/importedfoods/08/08-01.html

- Is the food item to be imported subject to monitoring inspection?
  - At the beginning of each fiscal year, the Ministry of Health, Labour and Welfare announces an annual schedule for the number of inspections to be conducted per food category, determined in consideration of the rate of past violations, number and weight of imported cargos, and seriousness of violations.
      http://www.mhlw.go.jp/english/topics/importedfoods/08/08-03.html

- Is the food item to be imported subject to an ordered inspection?
  - At the beginning of each fiscal year, the Ministry of Health, Labour and Welfare announces a list (target products and inspection items) of foods that are deemed to have high probability of violating the Food Sanitation Law, judging from situations in exporting countries, food properties, and cases of noncompliance by similar foods. Additional inspection orders may also be issued later, depending on the subsequent status of violations. When the Minister of Health, Labour and Welfare issues an ordered inspection, the relevant cargo is stored in a bonded area until the importer applies for an inspection at a registered laboratory (fee required) and obtains an inspection result.
      http://www.mhlw.go.jp/english/topics/importedfoods/08/08-02.html

- What are the most common types of violations against the Food Sanitation Law?
  - A record of recent violations against the Food Sanitation Law (January – August 2008) shows no violations in relation to soft drinks neither from the ASEAN countries nor non-ASEAN countries. However, products are frequently found to be noncompliant with the Food Sanitation Law in prior consultations at quarantine stations. They include uses of food additives that are not allowed in Japan, undesignated uses of food additives, and noncompliance with production standards (standards for seals/stoppers and sterilization/disinfection methods, raw water specifications, etc.).
    - Typical violations of compositional specifications include the detection of stannum at levels over the 150 ppm limit, coliform bacteria positive, and undesignated uses of food additives (sorbic acid).

The following is a list of precautions concerning soft drinks, by type.

<Soft drinks in general>

- As soft drinks are subject to compositional specifications, manufacturing standards, and preservation standards under the Food Sanitation Law, make sure the product to be imported conform to these specifications and standards. Importers are recommended to obtain documents showing manufacturing methods from manufacturers in the country of export and receive prior consultation at a quarantine station in Japan.
Note that sterilization/disinfection requirements and heat-sterilization conditions differ according to the carbon dioxide pressure, pH, and water activity of the product. Records of sterilization temperature and time must be kept for 6 months.

* Is carbon dioxide pressure inside the container greater than 98 kPa (at 20°C)? Does it contain plant or animal tissue components?
* Is pH greater or less than 4.0?
* Does pH and water activity exceed 4.6 and 0.94, respectively?

- Confirm in advance that the raw water conforms to relevant specifications and standards.
- Beware of uses of food additives that are not allowed in Japan and violations of usage standards.
  - E.g.: The use of reinforcing agents such as potassium iodide and manganese gluconate, manufacturing agents such as potassium sulfate, potassium benzoate (preservative), and cyclamic acid (sweetener); undesignated use of sorbic acid and potassium sorbate (preservative); excessive residue of benzoic acid (preservative) and sulfur dioxide (bleaching agent)

- Given the understanding that benzoic acid (preservative) and ascorbic acid may react under certain conditions and produce benzene, products containing more than 10 ppb of those substances are requested to be recalled voluntarily. A preliminary survey must be conducted of products that use the two substances together.

**<Mineral water>**

- Make sure in advance that the raw water conforms to specifications and standards. Besides the 18 criteria for raw water, products that are not sterilized/disinfected and have a carbon dioxide pressure of less than 98 kPa (at 20°C) must also satisfy additional requirements.
- Products that have a pH of more than 4.6, a water activity level exceeding 0.94, and that are not sterilized according to methods for sufficiently killing microorganisms present in the raw ingredients must be preserved at temperatures below 10°C. Ensure proper storage conditions during transport and temperature management.
- Mineral water is specifically subject to detailed specifications and standards under the Food Sanitation Law, which may be difficult to judge by importers. Therefore, be sure to consult with the quarantine station in advance.

**<Fruit beverages>**

- Beware of nonconformance to compositional specifications, such as contamination by precipitation, foreign matter, and coliform bacteria, and noncompliance with manufacturing standards, such as failure to comply with sterilization/disinfection standards. Also check sanitation management status after sterilization.
- Note that apple juice (squeezed apple juice and products made solely of squeezed apple) is subject to an additional compositional specification concerning levels of the mycotoxin patulin (less than 0.050 ppm).
- Frozen fruit drinks must be stored at temperatures below -15°C. Ensure proper storage conditions during transport and temperature management.
**Soft Drinks – Excerpt from “Typical Cases of Violation of the Food Sanitation Law”**

(violations of exports from ASEAN countries)

Typical cases judged to be in violation of the Food Sanitation Law that were found in the past on the occasion of import notification, compiled by the Ministry of Health, Labour and Welfare

<table>
<thead>
<tr>
<th>Item</th>
<th>Country of export</th>
<th>Description of violation</th>
<th>Limit</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soft drink</td>
<td>Philippines</td>
<td>Compositional nonconformance (stannum)</td>
<td>150 ppm or less</td>
<td></td>
</tr>
<tr>
<td>Soft drink</td>
<td>Thailand</td>
<td>Compositional nonconformance (coliform bacteria)</td>
<td>Negative</td>
<td>Frozen coconut juice</td>
</tr>
<tr>
<td>Soft drink</td>
<td>Philippines</td>
<td>Preservative: undesignated use of sorbic acid</td>
<td>-</td>
<td>Mango nectar</td>
</tr>
</tbody>
</table>


**Soft Drinks – Violations of the Food Sanitation Law found on the occasion of prior import consultation**

<table>
<thead>
<tr>
<th>Item</th>
<th>Country of export</th>
<th>Description of violation</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral water</td>
<td>Canada</td>
<td>Violation of manufacturing standards (hermetic cap/seal)</td>
<td>*2</td>
</tr>
<tr>
<td>Mineral water</td>
<td>Norway</td>
<td>Violation of raw water specifications and standards (arsenic)</td>
<td>Less than 0.05 mg/L</td>
</tr>
<tr>
<td>Mineral water</td>
<td>Finland</td>
<td>Violation of raw water specifications and standards (live bacteria count)</td>
<td>Number of colonies: 100/ml or less</td>
</tr>
<tr>
<td>Mineral water</td>
<td>France</td>
<td>Violation of raw water specifications and standards (barium)</td>
<td>Less than 1 mg/L</td>
</tr>
<tr>
<td>Mineral water</td>
<td>Taiwan</td>
<td>Violation of raw water specifications and standards (sulfide)</td>
<td>Less than 0.05 mg/L (as hydrogen sulfide)</td>
</tr>
<tr>
<td>Mineral water</td>
<td>Canada</td>
<td>Violation of raw water specifications and standards (fluoride)</td>
<td>Less than 2 mg/L</td>
</tr>
<tr>
<td>Soft drink</td>
<td>UK, Italy, China, Singapore, USA</td>
<td>Violation of manufacturing standards (sterilization/disinfection)</td>
<td>*1</td>
</tr>
<tr>
<td>Soft drink (aloe vera juice, etc.)</td>
<td>South Korea, China</td>
<td>Violation of manufacturing standards (sterilization condition)</td>
<td>*1</td>
</tr>
<tr>
<td>Soft drink</td>
<td>USA</td>
<td>Chewing gum base: undesignated use of ester gum</td>
<td>—</td>
</tr>
<tr>
<td>Soft drink</td>
<td>USA</td>
<td>Reinforcing agent: manganese citrate included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Soft drink</td>
<td>USA, Spain</td>
<td>Reinforcing agent: copper gluconate included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Soft drink</td>
<td>USA</td>
<td>Reinforcing agent: selenomethionine included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Soft drink</td>
<td>USA</td>
<td>Reinforcing agent: biotin included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Soft drink</td>
<td>USA</td>
<td>Reinforcing agent: ferrous fumarate included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Soft drink</td>
<td>USA</td>
<td>Reinforcing agent: potassium iodide included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Soft drink</td>
<td>USA</td>
<td>Reinforcing agent: chromium chloride included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Soft drink</td>
<td>USA</td>
<td>Reinforcing agent: magnesium oxide included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Soft drink</td>
<td>USA</td>
<td>Reinforcing agent: zinc oxide included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Soft drink</td>
<td>USA</td>
<td>Reinforcing agent: tocopherol acetate included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Soft drink (herbal syrup drink)</td>
<td>Spain</td>
<td>Reinforcing agent: magnesium gluconate included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Soft drink (herbal syrup drink)</td>
<td>Spain</td>
<td>Reinforcing agent: magnesium gluconate included</td>
<td>Undesignated additive</td>
</tr>
</tbody>
</table>
### 7. Soft Drinks

<table>
<thead>
<tr>
<th>Item</th>
<th>Country of export</th>
<th>Description of violation</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soft drink (herbal syrup drink)</td>
<td>Spain</td>
<td>Reinforcing agent: lithium gluconate included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Soft drink (herbal syrup drink)</td>
<td>Spain</td>
<td>Reinforcing agent: copper gluconate included</td>
<td>—</td>
</tr>
<tr>
<td>Soft drink</td>
<td>Germany</td>
<td>Reinforcing agent: biotin included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Soft drink</td>
<td>USA</td>
<td>Manufacturing agent: undesignated use of L-cystein hydrochloride</td>
<td>—</td>
</tr>
<tr>
<td>Soft drink</td>
<td>France</td>
<td>Manufacturing agent: dimethyl pyrocarbonate included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Soft drink</td>
<td>Pakistan, Brazil</td>
<td>Preservative: undesignated use of sorbic acid</td>
<td>—</td>
</tr>
<tr>
<td>Soft drink</td>
<td>USA, China</td>
<td>Preservative: undesignated use of potassium sorbate</td>
<td>—</td>
</tr>
<tr>
<td>Soft drink (aloe vera juice)</td>
<td>South Korea</td>
<td>Excessive use of benzoic acid</td>
<td>Soft drinks: 0.60 g/kg</td>
</tr>
<tr>
<td>Soft drink</td>
<td>USA</td>
<td>Preservative: potassium benzoate included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Soft drink</td>
<td>USA</td>
<td>Preservative: brominated oil included</td>
<td>Undesignated additive</td>
</tr>
<tr>
<td>Soft drink</td>
<td>Thailand, Philippines, Sri Lanka, USA</td>
<td>Antioxidant: excessive residue of sulfur dioxide</td>
<td>Other foods: less than 0.030 g/kg</td>
</tr>
<tr>
<td>Soft drink</td>
<td>South Africa</td>
<td>Sweetener: potassium acesulfame included</td>
<td>Undesignated additive</td>
</tr>
</tbody>
</table>

*1: Beverages must be sterilized after being filled into a container and capped or sealed hermetically; or must be capped or sealed hermetically after being sterilized in a sterilizer or other equipment with an automatic thermometer or after being disinfected by a filter or other equipment and automatically filled into a container. In these cases, sterilization or disinfection must be conducted following the instructions below (refer to Notification No. 370 of the Ministry of Health and Welfare). Neither sterilization nor disinfection is necessary for beverages that have a carbon dioxide pressure of 98 kPa or higher at 20°C inside the container and does not contain any plant or animal tissue components.

*2: Mineral water must be sterilized after being filled into a container and capped or sealed hermetically; or must be capped or sealed hermetically after being sterilized in a sterilizer or other equipment with an automatic thermometer or after being disinfected by a filter or other equipment and automatically filled into a container.

(Source) Material from the Ministry of Health, Labour and Welfare, Pharmaceutical and Food Safety Bureau, Dept. of Food Safety, Inspection and Safety Division, Safety for Imported Food Section

### Other considerations regarding the import of soft drinks

- Soft drinks are subject to the Positive List System for residual agricultural chemicals under the Food Sanitation Law, but the system does not oblige business operators to conduct an analysis of agricultural chemical residues in foods. To comply with the system, importers should actively collect information on agricultural chemicals at the production stage of raw ingredients (information on proper usage and management of agricultural chemicals, types and usage methods of agricultural chemicals that may be used, cases of violation against residue standards, etc.), and assess residue status, as necessary.

- For customs purposes, soft drinks, excluding mineral water, are classified into different categories depending on whether or not they contain sugar, and are subject to different duty rates. Fruit beverages are classified into even smaller categories. The duty rates of beverages that contain sugar may differ depending on whether the sugar content is less than or more than 10% the entire weight of the product, and the duty rates of orange juice may differ depending on their brix value (note). Therefore, it is important to check the ingredients of soft drinks in advance, against a raw ingredient chart.

(Note) A Brix value is the value indicated on a brix hydrometer or refractometer at a temperature of 20°C.

- The Enforcement Regulations of the Food Sanitation Law mandate labeling standards for soft drinks (see p.34). Fruit beverages, carbonated beverages, carrot juice, and mixed carrot juice are also subject to
individual quality labeling standards under the JAS Law, and require prior confirmation. For example, in order to label a fruit beverage as some type of “juice,” it must contain 100% fruit or vegetable juice or reduced juice. Also take note of the Fair Competition Code for fruit beverages and coffee beverages.
8. Alcoholic Beverages

Import Procedures for Alcoholic Beverages

**Responsibilities of the exporter or importer**

- **Preparations based on the Food Sanitation Law**
  - Collect information for determining whether the product concerned complies with Japan’s Food Sanitation Law.
  - Conduct a self-inspection if necessary (either by the exporter or importer) and acquire a result of the inspection.
  - Exporters should prepare the documents which the importer in Japan need to submit to the quarantine station along with the “Notification Form for Importation of Foods, etc.” in order to import the item concerned. Enquire with the importer or a quarantine station in Japan concerning the required documents, as they differ according to food category.

- **Preparations for customs clearance in Japan**
  - Exporters should prepare the relevant documents required for customs clearance in Japan.

**Required documents**

- **Documents to be prepared by exporters**
  - List of materials
  - Manufacturing process schedule
  - Both of the above must be prepared and issued by the manufacturer, and must bear the name of the manufacturing company
  - Description of the product
  - Sanitary certificate, inspection results, etc., as required

- **Documents to be submitted by importers**
  - Import Notification for Importation of Foods, etc.
  - List of materials
  - Manufacturing process schedule
  - Description of the product
  - Sanitary certificate, inspection results, etc. as required

- **Import procedures based on the Food Sanitation Law**
  - When importing soft drinks, importers must submit an “Import Notification for Importation of Foods, etc.” to the quarantine station, along with other required documents.

- **Documents to be submitted by importers**
  - Import declaration form
  - Invoice
  - Packing list
  - Bill of lading (B/L) or air waybill

*Prior to import declaration, importers must submit 2 copies of the notification form for labeling methods prescribed by the Liquor Business Association Law (note) and a copy of a liquor sales license prescribed by the Liquor Tax Law, to the authorization officer in the collection section of the taxation office having jurisdiction over the relevant sales area.

Note) Law Concerning Liquor Business Association and Measures for Securing Revenue from Liquor Tax
8. Alcoholic Beverages

The import of alcoholic beverages is regulated by the Food Sanitation Law, which defines “alcoholic beverages” as beverages with an alcoholic content of 1% or more. Under the Law Concerning Liquor Business Association and Measures for Securing Revenue from Liquor Tax, importers of alcoholic beverages must submit a notification that provides information on labeling methods prior to making an import declaration (see p.37). Furthermore, the goods must have a label affixed in a visible location on the container or package by the time they are claimed from the bonded area. Also note that a liquor sales license prescribed in the Liquor Tax Law is needed to sell liquor, and a copy of the license must be submitted along with the import notification.

[Inquiry about the Liquor Tax Law and the Law Concerning Liquor Business Association and Measures for Securing Revenue from Liquor Tax]
Regional Taxation Bureaus
http://www.nta.go.jp/taxanswer/english/12003.htm

The sections below describe import procedures and considerations under the Food Sanitation Law.

1) Food Sanitation Law

(1) Pre-export Preparations

Both exporters and importers should sufficiently collect the necessary information for determining whether the item they wish to import complies with standards prescribed in Japan’s Food Sanitation Law.

<Documents to be prepared by exporters (Japanese translations thereof, in cases where the original document is written in a language other than English)>

- List of materials
  Complete list specifically showing the scientific names of all materials (food ingredients) and additives used, prepared and issued by the manufacturing company and bearing the name of the company
- Manufacturing process schedule
  Schedule showing the complete manufacturing process from the materials to the end product, including sterilization temperatures and time, prepared and issued by and bearing the name of the manufacturing company and signed by the person in charge
- Name and address of the manufacturer and place of manufacture in the country of export, and a document showing the name of the product
- Description of the product

<Documents to be prepared by importers (if necessary)>

- Depending on the materials, a document showing the steps that have been taken to check the product against the requirements of the Pharmaceutical Affairs Law (verification date, verifying organization, identification of relevant substances and their handling, etc.)
  * For health foods and food items containing Japanese or Chinese herbal medicine, importers should provide the scientific name (Japanese name) of the material and clarify the part of the plant that is used as an ingredient and its effect, and at the same time confirm with the pharmaceutical department in the local government whether the ingredient is subject to the Pharmaceutical Affairs Law.
8. Alcoholic Beverages

<Documents to be prepared by either exporters or importers (if necessary)>

- Self-inspection results
  Importers may request a self-inspection at a laboratory registered with the Ministry of Health, Labour and Welfare or an official laboratory in the country of export and submit a copy of the result along with the inspection application form, to exempt the inspected items from inspection and expedite the import process.

[Inquiry about inspection facilities]
Ministry of Health, Labour and Welfare <List of official laboratories authorized by MHLW>
Note) In the ASEAN countries, there are official laboratories authorized by MHLW in Indonesia, Singapore, Thailand, and the Philippines. (See p.123)

[General inquiry]
MHLW quarantine stations having jurisdiction over ports of entry
http://www.mhlw.go.jp/english/topics/importedfoods/1-2.html

(2) Import Procedures
Importers who wish to import alcoholic beverages for the purpose of sale or for other commercial purposes are required to submit a “Notification Form for Importation of Foods, etc.” and other required documents (list of materials, manufacturing process schedule, self-inspection results, etc.) to an MHLW quarantine station having jurisdiction over the port where the relevant goods are to be cleared through customs. After examination of the notification form and relevant documents, items that require cargo inspection are inspected in the bonded area where the cargo is being stored, and are either passed or rejected depending on the result of the inspection.

Import Procedures based on the Food Sanitation Law

- Prior consultation
- Prior collection of information (manufacturing method, use of additives, etc.)
- Self-inspection (official laboratory in the country of export or laboratories registered with the Ministry of Health, Labour and Welfare)
- Submission of a notification to the quarantine station (Notification Form for Importation of Foods, etc.)
- Examination
  - Goods requiring inspection
    - Rejected
    - Passed
      - Re-ship, disposal, or use for purposes other than as food
      - Issuance of a Certificate of Notification or a certificate of approval
  - Goods not requiring inspection
    - Issuance of a Certificate of Notification or a certificate of approval
    - Customs declaration
(3) Main Points of Examination

Does the item comply with manufacturing standards prescribed in the Food Sanitation Law?

Alcoholic beverages are not regulated by any specific specification or standard, but must comply with Specifications and Standards for Food, Food Additives, etc., which commonly apply to all food items (see p.19). Also, an official notice prescribes a criterion of less than 1 mg/cm³ for methanol content.

Food containers/packages must comply with specifications and standards for containers/packages prescribed in the Food Sanitation Law.

**Specifications and Standards for Alcoholic Beverages under the Food Sanitation Law**

<table>
<thead>
<tr>
<th>Specifications and standards common to all food items</th>
<th>Specifications and standards that apply to individual food items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compositional Specifications for Foods in General</td>
<td>None</td>
</tr>
<tr>
<td>Standards for Manufacturing, Processing, and Preparation of Foods in General</td>
<td></td>
</tr>
<tr>
<td>Preservation Standards for Foods in General</td>
<td></td>
</tr>
</tbody>
</table>

**Specifications and Standards Relating to Containers/Packages for Alcoholic Beverages**

<table>
<thead>
<tr>
<th>Specifications and standards common to all containers/packages</th>
<th>Application-specific specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specifications for General Implements, Containers, Packaging, and Component Materials</td>
<td>None</td>
</tr>
<tr>
<td>Material-specific Specifications for Implements, Containers, Packaging, and Raw Materials</td>
<td></td>
</tr>
<tr>
<td>Implement, Container, and Packaging Production Standards</td>
<td></td>
</tr>
</tbody>
</table>

[Information on Specifications and Standards for Foods, Food Additives, etc.]
Japan External Trade Organization (JETRO) <Webpage on standards and regulations>
http://www.jetro.go.jp/en/reports/regulations/

Does the use of food additives comply with relevant standards?

All food additives must comply with usage standards which specify the maximum limit allowed to be used in each type of food, compositional specifications which specify purity and properties, and other relevant standards that are established for each substance, as necessary. Some food additives that are legally approved in their countries of export may not be permitted in Japan. Additionally, some additives that bear the same name may in fact be two different additives based on different compositional specifications or usage standards.

Food items that do not comply with Japanese standards for food additives may not be imported. The following are major points for confirmation regarding food additives.

- Are any undesignated food additives used in the food item, including in its materials?
  - Ministry of Health, Labour and Welfare <Food additives page – List of Designated Food Additives (Enforcement Regulations, Annexed Table 1)>
8. Alcoholic Beverages

- Does the use of natural food additives conform to requirements concerning source, manufacturing method, and quality specified in the List of Existing Food Additives?
  - Ministry of Health, Labour and Welfare <Food additives page – List of Existing Food Additives>
  

- Are all food additives used properly, in amounts conforming to the standards for the use of food additives?
  - Ministry of Health, Labour and Welfare <Food additives page – List of standards for the use of food additives>
  

- Does the food item contain any poisonous or harmful substances?
  - Ministry of Health, Labour and Welfare <Website of the Imported Foods Inspection Services – Recent Cases of Violation of the Food Sanitation Law>
  
  http://www.mhlw.go.jp/english/topics/importedfoods/index.html

2) Considerations for Business Operators

(1) Compliance with the Food Sanitation Law

The Food Safety Basic Law requires importers to take the necessary steps as appropriate to ensure food safety at their own initiative. Similarly, the Food Sanitation Law encourages importers to ensure the safety of imported foods on their own responsibility, by acquiring the necessary knowledge and technologies, ensuring the safety of ingredients, and conducting self-inspections.

Additionally, given Japanese consumers’ increasing concern and distrust of imported foods due to the recent spate of imported food poisoning incidents, importers are now more than ever expected to assure their imported goods guarantee the same level of safety as foods processed in Japan, at all stages of production in the country of export, including the selection of raw materials, production and processing, storage, and transportation.

The Guidelines on Hygiene Control of Import Processed Foods formulated by the Ministry of Health, Labour and Welfare (June 2008) outlines certain matters that importers should confirm with the manufacturer in the country of export (http://www.mhlw.go.jp/english/topics/importedfoods/guideline/01.html).

Exporters should also comply with Japan’s Food Sanitation Law and cooperate with importers, by taking careful note of matters specified in the Guidelines on Hygiene Control of Import Processed Foods, preparing the necessary information before importers request them, and striving to provide detailed information.

When importing/exporting the same items repeatedly, importers and exporters must check for any changes in manufacturing processes and raw materials, and conduct regular tests and inspection, to insure the items are free of harmful/poisonous substances and pathogenic microorganisms, do not contain undesignated food additives, and comply with standards for the use of food additives as well as compositional specifications.
(2) Confirmation with quarantine stations in Japan regarding information on sanitation

- What basic guidance do quarantine stations offer importers?
  
    
  http://www.mhlw.go.jp/topics/yunyu/dl/08kanshi_en.pdf

- Is the food item to be imported subject to monitoring inspection?
  
  At the beginning of each fiscal year, the Ministry of Health, Labour and Welfare announces an annual schedule for the number of inspections to be conducted per food category, determined in consideration of the rate of past violations, number and weight of imported cargos, and seriousness of violations.
  
    
  http://www.mhlw.go.jp/english/topics/importedfoods/08/08-03.html

- Is the food item to be imported subject to an ordered inspection?
  
  At the beginning of each fiscal year, the Ministry of Health, Labour and Welfare announces a list (target products and inspection items) of foods that are deemed to have high probability of violating the Food Sanitation Law, judging from situations in exporting countries, food properties, and cases of noncompliance by similar foods. Additional inspection orders may also be issued later, depending on the subsequent status of violations. When the Minister of Health, Labour and Welfare issues an ordered inspection, the relevant cargo is stored in a bonded area until the importer applies for an inspection at a registered laboratory (fee required) and obtains an inspection result.
  
    
  http://www.mhlw.go.jp/english/topics/importedfoods/08/08-02.html

- What are the most common types of violations against the Food Sanitation Law?
  
  Between January and August 2008, the only violation of the Food Sanitation Law in relation to alcoholic beverages from the ASEAN countries was by an import of beer from Vietnam (excessive residue of sulfur dioxide).
  
  Though not from the ASEAN countries, some typical violations of alcoholic beverages include the detection of methanol in excess amounts and the use of undesignated food additives.

The following is a list of precautions concerning alcoholic beverages, by type.

- **<Fruit wine>**
  
  - Fruit wine is frequently found to be in violation of the Food Sanitation Law, in relation to the use of preservatives, coloring agents, and sweeteners. Beware of the use of undesignated additives such as sodium cyclamate (sweetener), the undesignated use of saccharin sodium (sweetener), and the excessive uses of sorbic acid, potassium sorbate (preservatives), and sulfur dioxide (bleaching agent).

- **<Liqueur>**
  
  - Liqueur products are frequently found to be in violation of the Food Sanitation Law in relation to the use of coloring agents. Beware of the uses of azorubine, quinoline yellow, patent blue, and L-malic acid...
8. Alcoholic Beverages

- Also beware of the undesignated use of sorbic acid, the excessive use of potassium sorbate, and the use of other preservatives.

- Liqueur products that include medicinal herbs in their raw ingredients or claim medicinal effects may be subject to the Pharmaceutical Affairs Law as medicinal goods. Therefore, check with the pharmaceutical department in the local government, in advance.

**<Brandy and whisky>**

- Beware of excessive residues of methanol. As methanol is produced as a resolvent in the evaporation process, it is important to ensure proper manufacturing processes in the manufacturing country.

- Where crystal bottles are used, check that they conform to the specifications for zinc content, determined through elution tests based on material-specific standards for containers and packaging.

**<Beer>**

- Beware of violations in relation to the excessive use of sulfur dioxide (bleaching agent) and the use of food additives.

Alcoholic Beverages – Excerpt from “Recent Cases of Violation of the Food Sanitation Law” (January – August 2008; violations of exports from ASEAN countries)

<table>
<thead>
<tr>
<th>Item</th>
<th>Article</th>
<th>Country of export</th>
<th>Description of violation</th>
<th>Measure taken</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beer</td>
<td>11</td>
<td>Vietnam</td>
<td>Violation of usage standards (0.032 g/kg sulfur dioxide detected)</td>
<td>Instructions for disposal or re-shipment (impoundment of entire cargo)</td>
<td>Self-inspection</td>
</tr>
</tbody>
</table>

(Note) “Self-inspection” refers to the guidance provided by the quarantine station to importers regarding the implementation of a self-inspection on items that are required on the first import occasion and on regular occasions, from the standpoint of assisting importers to fulfill their food sanitation and security obligations.

(Source) Ministry of Health, Labour and Welfare <Website of the Imported Foods Inspection Services – Recent Cases of Violation of the Food Sanitation Law>
http://www.mhlw.go.jp/english/topics/importedfoods/index.html

Alcoholic Beverages – Excerpt from “Typical Cases of Violation of the Food Sanitation Law”

Typical cases judged to be in violation of the Food Sanitation Law that were found in the past on the occasion of import notification, compiled by the Ministry of Health, Labour and Welfare

<table>
<thead>
<tr>
<th>Item</th>
<th>Country of export</th>
<th>Description of violation</th>
<th>Limit</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brandy</td>
<td>France</td>
<td>Excess amount of methyl alcohol</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Brandy (grappa)</td>
<td>Italy</td>
<td>Excess amount of methyl alcohol</td>
<td>—</td>
<td>Distilled liquor made by re-fermenting the residue of grapes from wine brewing</td>
</tr>
<tr>
<td>Liqueur</td>
<td>USA</td>
<td>Preservative: undesignated use of sorbic acid</td>
<td>Miscellaneous liquor: 0.20 g/kg</td>
<td>Miscellaneous liquor</td>
</tr>
<tr>
<td>Liqueur</td>
<td>France</td>
<td>Excess amount of methyl alcohol</td>
<td>—</td>
<td></td>
</tr>
</tbody>
</table>
### Part 2 Import Procedures by Food Category

#### 8. Alcoholic Beverages

<table>
<thead>
<tr>
<th>Item</th>
<th>Country of export</th>
<th>Description of violation</th>
<th>Limit</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liqueur</td>
<td>Italy, France, Austria, the Netherlands, Spain, Germany</td>
<td>Coloring agent: azorubine included</td>
<td>Undesignated coloring agent</td>
<td></td>
</tr>
<tr>
<td>Liqueur</td>
<td>France, South Africa</td>
<td>Coloring agent: quinoline yellow included</td>
<td>Undesignated coloring agent</td>
<td></td>
</tr>
<tr>
<td>Liqueur</td>
<td>France</td>
<td>Coloring agent: patent blue V included</td>
<td>Undesignated coloring agent</td>
<td></td>
</tr>
<tr>
<td>Liqueur</td>
<td>France</td>
<td>Acidulant: L-malic acid included</td>
<td>Undesignated additive</td>
<td></td>
</tr>
<tr>
<td>Fruit wine (sangria)</td>
<td>Spain</td>
<td>Sweetener: sodium cyclamate included</td>
<td>Undesignated additive</td>
<td></td>
</tr>
<tr>
<td>Fruit wine (sangria)</td>
<td>Spain</td>
<td>Sweetener: undesignated use of saccharin sodium</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Fruit wine (wine)</td>
<td>Austria, Germany</td>
<td>Antioxidant: excessive residue of sulfur dioxide</td>
<td>Fruit wine: 0.35 g/kg</td>
<td></td>
</tr>
<tr>
<td>Fruit wine (wine)</td>
<td>France, Spain, Slovenia, USA, Australia</td>
<td>Preservative: Excessive use of sorbic acid</td>
<td>Fruit wine: 0.20 g/kg</td>
<td></td>
</tr>
<tr>
<td>Fruit wine (kiwi fruit wine)</td>
<td>China</td>
<td>Preservative: Excessive use of sorbic acid</td>
<td>Fruit wine: 0.20 g/kg</td>
<td></td>
</tr>
<tr>
<td>Fruit wine (wine cooler)</td>
<td>Mexico</td>
<td>Preservative: undesignated use of benzoic acid</td>
<td>—</td>
<td></td>
</tr>
</tbody>
</table>


### Other considerations regarding the import of alcoholic beverages

- Alcoholic beverages are subject to the Positive List System for residual agricultural chemicals under the Food Sanitation Law, but the system does not oblige business operators to conduct an analysis of agricultural chemical residues in foods. To comply with the system, importers should actively collect information on agricultural chemicals at the production stage of raw ingredients (information on proper usage and management of agricultural chemicals, types and usage methods of agricultural chemicals that may be used, cases of violation against residue standards, etc.), and assess residue status, as necessary.
- Also pay particular attention to the agricultural chemical residues in fruits and other raw ingredients of alcoholic beverages.
- The Liquor Tax also defines beverages with an alcoholic content of 1% or more as liquor, and classifies alcoholic beverages according to type and category, as shown below. As manufacturing methods, tax rates, and label items vary for each, be sure to check under which classification the product to be imported falls.
Liquor Categories and Items based on the Liquor Tax Law

<table>
<thead>
<tr>
<th>Type of liquor (classification)</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sparkling liquor</td>
<td>Beer, low-malt beer, and other sparkling alcoholic beverages (alcoholic beverages other than beer and low-malt beer that have an alcoholic content of less than 10% and effervescent properties)</td>
</tr>
<tr>
<td>Fermented liquor</td>
<td>Sake, fruit wine, and other fermented alcoholic beverages</td>
</tr>
<tr>
<td>Distilled liquor</td>
<td>Continuously distilled shochu, batch distilled shochu, whisky, brandy, raw material alcohol, spirits</td>
</tr>
<tr>
<td>Mixed liquor</td>
<td>Sake compounds, mirin (sweet rice wine for cooking), sweet fruit wine, liqueur, powder liquor, miscellaneous liquor</td>
</tr>
</tbody>
</table>

- The Enforcement Regulations of the Food Sanitation Law prescribe labeling standards for alcoholic beverages (see p.33). Additionally the Law Concerning Liquor Business Association and Measures for Securing Revenue from Liquor Tax (see p.37) specify mandatory label items, and labeling standards to prevent alcoholic consumption by minors require alcoholic beverages to display labels that clearly state that “consumption of liquors by minors is prohibited by law.” Label items differ according to category, so it is important to check in advance.

Also take note of the Fair Competition Code for imported whisky and beer, as it regulates misleading representations and prescribes labeling standards for designated label items.

(3) Acquisition of Liquor Sales License based on the Liquor Tax Law

Under the Liquor Tax Law, persons who wish to sell imported liquor in Japan must obtain a specified liquor sales license according to their type of sale.

<table>
<thead>
<tr>
<th>License Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imported liquor wholesale license</td>
<td>For sale of imported liquor to liquor retail outlets. Sale of domestic liquor is not allowed.</td>
</tr>
<tr>
<td>General liquor retail license</td>
<td>For sale of liquor to general consumers, eating and drinking establishments, and manufacturers of confections. Wholesale is not allowed.</td>
</tr>
<tr>
<td>Mail-order liquor retail license</td>
<td>For retail sale through mail order. No restrictions on import/domestic classification and sales volume.</td>
</tr>
</tbody>
</table>

For details on requirements for obtaining a license, enquire with a local taxation office (liquor guidance officer).

[Inquiry]
Regional Taxation Bureaus
http://www.nta.go.jp/taxanswer/english/12003.htm
<table>
<thead>
<tr>
<th>検査機関名 (Name)</th>
<th>検査機関住所 (Address)</th>
<th>コード</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A 公的検査機関 (Official laboratories)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Ministry of Health and Welfare Refik Saydam Public Health Center Directorate</td>
<td>SSYB: Refik Saydam Hifzisihha, Merkez Baskanligi, Sihhiye, Ankara, Turkey</td>
<td>TR10001</td>
</tr>
<tr>
<td>2 T.C.SAĞLIK BAKANLIĞI İZMIR BÖLGE HIFZISSIHHHA ENSTITÜSÜ MÜDÜRLÜĞÜ</td>
<td>52/18 Sokak No:4 35350-Hatay-IZMIR</td>
<td>TR10002</td>
</tr>
<tr>
<td>3 T.C. SAGLIK BAKANLIĞI İSTANBUL BÖLGE HIFZISSIHHHA ENSTITÜSÜ MÜDÜRLÜĞÜ</td>
<td>10 VIL CADDESİ ÇINOGLU CIKMIZI NO.10 İCKULE ZEV TinBURNU İSTANBUL</td>
<td>TR10003</td>
</tr>
<tr>
<td>4 Cekmece Nuclear Research and Training Center</td>
<td>Kucuk Cekmece, Iatanbul, Turkey</td>
<td>TR10004</td>
</tr>
<tr>
<td>5 T.C. AFYONKARAHİSAR VALİLİĞİ İİ Kontrol Laboratuvar Müdürlüğü</td>
<td>Yükari Pazar Cd. No: 1 AFYONKARAHİSAR</td>
<td>TR10005</td>
</tr>
<tr>
<td>6 T.C. AMASYA VALİLİĞİ İİ Kontrol Laboratuvar Müdürlüğü</td>
<td>Savadiye Mah. Mirhamza Sok. No:3 AMASYA</td>
<td>TR10006</td>
</tr>
<tr>
<td>7 T.C. ÇORUM VALİLİĞİ İİ Kontrol Laboratuvar Müdürlüğü</td>
<td>ÇORUM</td>
<td>TR10007</td>
</tr>
<tr>
<td>8 T.C. GAZIANTEP TİCARET BORSASI ÖZEL GIDA KONTROL LABORATUVARI</td>
<td>Gatem Bölgesi Borsa Sarayı 27170 P.K.142 GAZIANTEP</td>
<td>TR10008</td>
</tr>
<tr>
<td>9 T.C. İSTANBUL BÜYÜKȘEHİR BELEDİYE BAŞKANLIĞI Sağlık ve Sosyal Hizmetler Daire Başkanlığı Sağlık ve Hifzissiha Müdürlüğü</td>
<td>Atatürk Bulvarı No: 16 Vefa Eminönü / İSTANBUL</td>
<td>TR10009</td>
</tr>
<tr>
<td>10 T.C. TARIM VE KÖYİŞLERİ BAKANLIĞI A.K.U. Veteriner Fakültesi Özel Gida Kontrol Laboratuvari</td>
<td>Afyon Kocatepe Üniversitesi Veteriner Fakültesi Gazlıgıl Yolu / Afyonkarahisar</td>
<td>TR10010</td>
</tr>
<tr>
<td>11 TC. TARIM VE KÖYİŞLERİ BAKANLIĞI Adana İİ Kontrol Laboratuvar Müdürlüğü</td>
<td>Köprüli Mahallesi Mithat Öszan Bulvarı 01230 Yüreğir ADANA TÜRKİYE</td>
<td>TR10011</td>
</tr>
<tr>
<td>12 TC. TARIM VE KÖYİŞLERİ BAKANLIĞI AIR ALAŞEHİR ANALYTİK ÖZEL GIDA KONTROL LABORATUVARI</td>
<td>Kurtuluş mah. Baklaci yolu 41 sokak No: 34/1 Alasehir/MANISA</td>
<td>TR10012</td>
</tr>
<tr>
<td>13 T.C. TARIM VE KÖYİŞLERİ BAKANLIĞI Ankara İİ Kontrol Laboratuvari Müdürlüğü</td>
<td>Gayret Mah.Şehit Cem Ersever Cad. No: 12 Yenimahalle · ANKARA</td>
<td>TR10013</td>
</tr>
<tr>
<td>14 T.C. TARIM VE KÖYİŞLERİ BAKANLIĞI Antalya İİ Kontrol Laboratuvar Müdürlüğü</td>
<td>Antalya Toptancı Hal İçi · ANTALYA</td>
<td>TR10014</td>
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<tr>
<td>15 T.C. TARIM VE KÖYİŞLERİ BAKANLIĞI Balikesir İİ Kontrol Laboratuvar Müdürlüğü</td>
<td>Akınçlar Mahallesi Gazi Bulvarı No: 1 10100 BALIKESİR</td>
<td>TR10015</td>
</tr>
<tr>
<td>検査機関名 (Name)</td>
<td>検査機関住所 (Address)</td>
<td>コード</td>
</tr>
<tr>
<td>------------------</td>
<td>----------------------</td>
<td>-------</td>
</tr>
<tr>
<td>16 T.C. TARIM VE KÖYİSLERİ BAKANLIĞI</td>
<td>Hürriyet Cad. No 126 PK.3</td>
<td>TR10016</td>
</tr>
<tr>
<td>BURSA GIDA KONTROL VE MERKEZ</td>
<td>HÜRRIYET/BURSA</td>
<td></td>
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<tr>
<td>ARAŞTIRMA ENSTITUSÜ MÜDÜRLÜĞÜ</td>
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<td></td>
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<tr>
<td>17 T.C. TARIM VE KÖYİSLERİ BAKANLIĞI</td>
<td>ATATÜRK CAD.NO: 33 17100</td>
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</tr>
<tr>
<td>ÇANAKKALE İL KONTROL LABORATUVAR</td>
<td>ÇANAKKALE</td>
<td></td>
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<tr>
<td>MÜDÜRLÜĞÜ</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18 T.C. TARIM VE KÖYİSLERİ BAKANLIĞI</td>
<td>Sirakapılar Mah. 1523. Sok. No: 1 20010</td>
<td>TR10018</td>
</tr>
<tr>
<td>Denizli İl Kontrol Laboratuvar Müdürüluğu</td>
<td>DENIZLİ</td>
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<td>19 T.C. TARIM VE KÖYİSLERİ BAKANLIĞI</td>
<td>P.K.91 Edirne</td>
<td>TR10020</td>
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<tr>
<td>Diyarbakır İl Kontrol Laboratuvar Müdürlüğü</td>
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<td></td>
</tr>
<tr>
<td>Edirne İl Kontrol Laboratuvar Müdürlüğü</td>
<td></td>
<td></td>
</tr>
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<td>Şenol Sokak No: 3 Feride İş Merkezi D:3-4 34394 Gayrettepe-Şişli  ·  İSTANBUL</td>
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<td>56 BAGEM FOOD CONTROL LABORATORY</td>
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<td>Büyükkesıt mh. Kaptanpaşa Sk. No: 2 / 1·2 06700 G.O.P.  ·  ANKARA</td>
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