

Live Seafood Export Guide to Japan

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Live Seafood Export Guide to Japan

December, 2021

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Introduction to this Guide

- **The purpose of this Guide is to provide a representative example of regulatory procedures facing US products entering the Japanese market. This is the updated 2021 version of this Guide. This is not intended to be a do-it-yourself manual, but to inform you in your discussions with potential Japanese importers.**
- Please note that these requirements may change without warning. If you have any questions, please feel free to contact the Agricultural Trade Office.
- The series covers a total of 24 products listed below.
- This report is **#6 Live seafood (e.g. shellfish, lobster, etc.)** .
- **This report does not cover ornamental fish, live fish for feed or juvenile fish for further aquaculture in Japan.**

24 products covered in this series:

- | | |
|---|---|
| #1 Fresh fruits | #13 Fruit/vegetable juice |
| #2 Frozen fruits/vegetables | #14 Sugar/flavor added water |
| #3 Processed fruit puree | #15 Mineral water |
| #4 Condiments & sauces | #16 Ice Cream |
| #5 Cookies & chips | #17 Wine |
| #6 Live seafood (e.g. shellfish, lobster, etc.) | #18 Distilled spirits |
| #7 Soups | #19 Cheese |
| #8 Health bars | #20 Dough Mixes |
| #9 Chocolates | #21 Dried fruits |
| #10 Breakfast Cereals | #22 Herbal teas |
| #11 Pet Food | #23 Non-alcoholic beverage bases and syrups |
| #12 Frozen breads | #24 Frozen prepared foods |

Disclaimer

- This Guide is for general information purposes only.
- While every effort has been taken to ensure accurate information at the time of publication, neither USDA nor Meros can accept liability for any content or information contained in any other website to which this guide refers.
- Any and all information is subject to change without notice.
- Legal or other professional advice should be sought for any specific matters of concern.
- All information must be re-confirmed with importers and competent authorities.

Step-by-step Checklist



A. Pre-Embarkation

- 1. Confirm legal compliance with food standards and other regulations
- 2. Check the sanitary requirements that apply to your product
- 3. Check the import quota, tariff classification and customs duty
- 4. Create a product label
- 5. Register trademarks and other intellectual property rights

B. Embarkation

- 6. Obtain an Export Health Certificate
- 7. Clear export customs

C. Import Clearance

- 8. Clear sanitary inspection
- 9. Clear food safety quarantine procedure
- 10. Clear import customs

*After Import Clearance

Food safety issues faced after import clearance




A.

Pre-Embarkation

These steps will help confirm product eligibility for import into Japan and provide guidelines for preparing required documentation.



A. Pre-Embarkation Checklist

- 
- 1. Confirm **legal compliance with food standards** and other regulations
 - 2. Check the **sanitary requirements** that apply to your product
 - 3. Check the **import quota, tariff classification** and customs duty
 - 4. Create a **product label**
 - 5. Register **trademarks** and other intellectual property rights

1 Confirm Legal Compliance with Food Standards and Other Regulations

Japan's Food Sanitation Act (FSA) establishes the sanitary standards for food products.

Compliance with food standards will be discussed in Step 9, Food Safety Inspection at the Quarantine Station under MHLW.

Steps to take:

- ❑ 1-1 For oysters for raw consumption, confirm legal compliance regarding **product-specific standards**
- ❑ 1-2 Confirm legal compliance and risk regarding **contamination by harmful substances**
- ❑ 1-3 Have your importer confirm legal compliance through Prior Consultation at the Quarantine Station that oversees the expected port of entry of your product.

Whose responsibility is this?

The importer is responsible, but the manufacturer/exporter should be familiar with these issues.

Responsible government agency:

- [Quarantine Stations, Ministry of Health, Labour and Welfare \(MHLW\)](#)
- [Ministry of Economy, Trade and Industry \(METI\)](#)

Relevant laws/regulations:

- [The Food Sanitation Act \(FSA\)](#)
- [Specifications and Standards for Foods, Food Additives, etc. Under the FSA](#)

Best Practices

- Assess your product's compliance with food standards before moving forward.
- Since the number of English-language documents are limited and the regulations can change, collaborate closely with an importer or a trusted advisor to ensure your product meets all standards.

Key Contacts

- **ATO Tokyo**
E-mail: atotokyo@usda.gov
- [11 Quarantine Stations under MHLW](#) offer Prior Consultation for importers (Japanese only). See Step 2-4
- [MIPRO](#) also provides free phone consultation.

Confirm Legal Compliance regarding Oysters for Raw Consumption Regulations and Standards

If you export oysters for raw consumption, you must follow specific regulations and standards.

Regulation on sea areas

Japan only allows raw oysters from WA, OR, NY and CT as of Oct 2021. Raw oysters shall be from certain states/harvest areas which are approved by the Food and Drug Administration (FDA). The states must be participants in the National Shellfish Sanitation Program (NSSP) and Interstate Shellfish Sanitation Conference (ISSC). The exporter or packer of the oysters must also be included on the Interstate Certified Shellfish Shippers List (ICSSL).

In order to export raw oysters to Japan, the exporter needs to obtain an export health certificate issued by the National Oceanic and Atmospheric Administration (NOAA) (for oysters from Washington State, a certificate issued by the Washington State government is also acceptable).

Product-specific food safety standard

Oysters to be eaten raw shall meet product-specific standards under the FSA. Some of the specifics which would be important for US suppliers include:

- Bacterial count – max. 50,000 per gram
- E. coli count – max 230 per 100g
- Vibrio parahaemolyticus – max 100 per 1g
- Must be stored at below 10 degrees Celsius
- Do not use chemically synthesized additives, except chlorite water, hypochlorite water, sodium hypochlorite or hydrochloric acid and carbon dioxide which are used as hydrogen ion concentration regulators.

Note that these product-specific standards (such as the regulations regarding bacteria count) are always subject to inspection at quarantine stations.

Steps to Take:

- ❑ 1-1-1 If you export oysters for raw consumption, confirm that your product meets the regulation on harvest waters and the product-specific food safety standards
- ❑ 1-1-2 Talk with your importer about hygienic control planning and contamination risk planning.

Product-specific Food Safety Standards:

- Product Specific Standards under the FSA are summarized here (English): https://www.jetro.go.jp/ext_images/en/reports/regulations/pdf/foodext2010e.pdf
- More detailed information is found here (Japanese only): https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/shokuhin/jigyousya/shokuhin_kika/ku/index.html

National Shellfish Sanitation Program

- Website of National Shellfish Sanitation Program (NSSP) <https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp>

1-2

Confirm Legal Compliance and Risk regarding Contamination by Harmful Substances

Contamination by **naturally harmful substances** (shellfish toxins, toxic fish etc.), and **pathogens** can prevent the importation of US food products.

Article 6 of the FSA states that foods involving risk to human health cannot be sold; however, each controlled substance and its standards are regulated by different ministerial notifications. There is no publicly available list of all these substances, so it is recommended that importers consult with Quarantine Stations in advance if there is any question of a harmful substance being detected in a food product.

In particular, be aware of the substances which are targets of MHLW's Imported Foods Annual Monitoring Plan (See Step 9), although other substances could be an issue as well. The right-hand column lists substances specifically mentioned in past MHLW Monitoring Plans, as well as others that Quarantine Stations have warned about.

Pathogenic microorganisms or decomposition/deterioration can develop during shipping.

Live lobsters

Japan has a standard for PSP in the hepatopancreas of lobsters of 4 MU/g. Although the risk of contamination is not high because the Japanese standard is equivalent to the US standard (80 µg saxitoxin equivalent per 100g), NOAA particularly recommends having a proper paralytic shellfish poisoning (PSP) control plan for the exporter of lobsters to Japan. For further information, refer to: <https://www.fisheries.noaa.gov/export-requirements-country-and-jurisdiction-g-m-2#japan>

Steps to Take:

- 1-2-1 Talk with your importer about contamination risk planning if your product could contain any of these harmful substances

Harmful substances by category:

1) Naturally harmful products

- Food containing toxic substances shall NOT be sold in Japan.
 - shellfish toxins (like, paralytic shellfish poisoning)
 - toxic fish, etc.

2) Pathogenic microorganisms

- Food containing pathogenic microorganisms shall NOT be sold in Japan.
 - E. coli O26, O103, O111, O157
 - Norovirus
 - Hepatitis A virus
 - Salmonella
 - Vibrio cholerae
 - Shigella, etc.

3) Other harmful products

- Food containing the following substances shall NOT be sold in Japan.
 - Mercury
 - Can not exceed these standards: total mercury 0.4ppm; methyl mercury 0.3ppm
 - PCB
 - Can not exceed these standards: Deep-sea seafood:0.5ppm, Other seafood:3 ppm

4) Decomposed or deteriorated foods/ingredients

Obtain Prior Consultation at Quarantine Stations

The importer should consult with the Quarantine Station that oversees the expected port of entry to confirm compliance with Japanese food safety regulations, as well as to obtain information related to inspections procedures for import clearance. **This step is optional, but highly recommended.**

Prior Consultation is offered only to importers. The inquiry can be made in English, but the Quarantine Station answers only in Japanese.

Steps to take:

- 1-4 -1 Confirm that your importer has undertaken Prior Consultation at the Quarantine Station for the expected port of entry for your product.

Who initiates?

Importer. The importer may engage a customs broker for this process.

What information must be submitted?

- Inquiry form by FAX, including
 - Product name, manufacturer's product code number
 - Information on the manufacturer and the factory
 - Description of the packaging
 - Ingredient List, including detailed list of food additives (chemical names, share in weight or content in ppm, etc.)
 - Manufacturing Process Flowchart

Timeframe / Cost

- The Quarantine Station will normally reply within one week of submission of the inquiry.
- No charge.

Contact Information for Prior Consultation

- The key contact point is the Quarantine Station that has jurisdiction over the port/airport through which the importer is planning to import the product.
- Contacts for the consultation service division of **13 Quarantine Stations** located at major ports/airports under MHLW :
<https://www.mhlw.go.jp/topics/yunyu/soudan/> (Japanese)
- The list of all 111 offices of Quarantine Stations under MHLW:
https://www.mhlw.go.jp/english/policy/health-medical/health/dl/contact_list_jqs.pdf (English)
- The Tokyo Quarantine Station has instructions on its Prior Consultation process:
https://www.forth.go.jp/keneki/tokyo/kanshi_hp/a013.html (Japanese)

2 Check the Sanitary Requirements that Apply to Your Product

Live aquatic animals for human consumption which will be kept in facilities which use public water sources or drain into public water sources are subject to animal health quarantine. **This is not applicable for most live seafood exports from US to Japan since most live imports are stored in fish tanks.** Confirm with your importer about this point.

The explanation of aquatic animal quarantine can be found here:

http://www.maff.go.jp/aqs/english/animal/im_aquatic_animal.html

If your products are subject to animal health quarantine, prior consultation with the Fishery and Fishery Products Safety Office of MAFF is required. A NOAA (or FDA) Export Health Certificate must accompany the shipment. (See Step 6)

Compliance with sanitary requirements will be examined during the Sanitary Inspection at the Animal Quarantine Service under MAFF (See 8) as well as in the food safety inspection at the Quarantine Station under MHLW (See Step 9).

Steps to Take:

- 2-1 Confirm sanitary requirements that apply to your products.

Whose responsibility is this?

The importer is responsible, but the manufacturer/exporter should be familiar with this process.

Timeframe / Cost:

No fees required at Prior Consultation.

Responsible government agencies:

- Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries (MAFF)
- Animal Quarantine Service, MAFF

Relevant laws and regulations:

- Act on the Protection of Fishery Resources

Best Practices

- NOAA maintains a registry of exporter requirements, but it is recommended to work closely with your importer to confirm the sanitary requirements in detail.

Key Contacts

- **ATO Tokyo**
E-mail: atotokyo@usda.gov
- **NOAA National Marine Fisheries Service (NMFS)**
NOAA Enforcement Field Offices
The contacts are here:
<https://www.fisheries.noaa.gov/contact-directory/noaa-enforcement-field-offices>

Contact Information for Prior Consultation

- Fish and Fishery Products Safety Office, Animal Products Safety Division, Food Safety and Consumer Affairs Bureau, MAFF
http://www.maff.go.jp/j/syouan/suisan/suisan_yo/index.html (Japanese only)
Tel:03-6744-2105

3 Check the Import Quota, Tariff Classification and Customs Duty

Import Quota

Scallops and several other products are subject to Import Quota of fishery products. The details are shown in the next page.

Tariff Classification and Customs Duty

Check your product's tariff classification in the most recent Japanese Tariff Schedule and confirm the tariff rate applied on your products. The most recent Tariff Schedule is here:

<http://www.customs.go.jp/english/tariff/index.htm>

In order to expedite the customs clearance process, as well as to confirm the duties imposed on your product, your importer may get an Advance Ruling from the customs office that confirms the classification of your product.

Steps to Take:

- 3-1 Confirm with importer about Import Quota condition, if your product is applicable.
- 3-2 Check tariff classification and confirm the customs duty imposed on your products.
- 3-3 Confirm that the importer has received an Advance Ruling on the classification of your product from a Customs office in advance, especially for processed products.

Whose responsibility is this?

The **importer** is responsible, but the manufacturer/exporter should be familiar with the process.

Timeframe / Cost:

- No fees required for Advance Ruling.
- Customs will reply within 30 days of submission of the application.
- The response from customs is valid for three years from the date of issuance.

Responsible government agency

- [Japan Customs](#)
- [Ministry of Economy, Trade and Industry](#)

Related laws/regulations

- [Customs Act](#) (Japanese only)
- [Foreign Exchange and Foreign Trade Act](#)

Best Practices

- Check the tariff classification carefully because the Japanese classification can be different from the US classification.
- Tariffs for competing suppliers can also be checked.
- For further information, contact [ATO Tokyo](#)
Email: atotokyo@usda.gov

Contact Information for Advance Ruling

- Advance Ruling is available at **9 regional Customs offices**. Contacts (in Japanese): <http://www.customs.go.jp/question2.htm#b>
- **What information must be submitted?**
 - Inquiry form ([C-1000](#), Japanese), including:
 - Ingredient List with ratios indicated for each ingredient,
 - Manufacturing Process Flowchart
 - Packaging details, etc.
 - Documents to show the business relationship between the importer and the supplier (sales contract, etc.)

3-1

Confirm Legal Compliance regarding Trade control

In order to protect domestic fishery industries, as well as to avoid trade in products obtained through illegal fishing, the Ministry of Economy, Trade and Industry (METI) has placed some control measures on seafood trade. Some regulations which would be important for US suppliers include:

- **Import Quota (IQ):**
METI has introduced an IQ system for 19 seafood items, which includes scallops. Once a year, METI allots quotas to importers who have applied for the IQ and provides an import quota certificate.
- **No. 2 Approval System:**
The importer needs to obtain pre-approval from METI for marine products which are restricted from importation:
 - Bluefin tuna from specific origins
 - All marine products which are transshipped to other vessels at sea
- **Prior or Customs Clearance Confirmation System:**
For king crab and snow crab, it is required to prove that the origin is not Russia. US exporters can obtain a certificate of origin from the USDC Seafood Inspection Program under NOAA.

Steps to Take:

- 3-1-1 Confirm with your importer about the applicability of those measures to your product.

Trade control regulations policy:

METI announces an overview of trade control policy here
https://www.meti.go.jp/english/policy/external_economy/my/trade_control/index.html

- **Import Quota (IQ)** for seafoods is explained here (Japanese only)
https://www.meti.go.jp/policy/external_economy/trade_control/03_import/04_suisan/index.html
- **No. 2 Approval** is explained here (Japanese only):
https://www.meti.go.jp/policy/external_economy/trade_control/04_kamotsu/02_import/import_2go.html
- **Prior or Customs Clearance Confirmation System** for crabs is explained here (Japanese only):
https://www.meti.go.jp/policy/external_economy/trade_control/03_import/07_kani/kani.html

3-1

Tariff Schedule

- The tariff schedule does not have a detailed definition of each classification. Therefore, getting Advance Ruling is especially useful to avoid time being spent at the port of entry trying to confirm the product category.
- Note that the product you plan to export might be categorized into a category which is not listed here, depending on its ingredients and manufacturing method. Seafood is not subject to a preferential tariff under the USJTA.

Tariff Schedule (as of April 1, 2021)		
Import HS Code	Description	Tariff
030631000, 030632000	Rock lobster, lobster and other sea crawfish (live, fresh, chilled)	1%
030633	Crabs (live, fresh, chilled)	4%
030634000	Norway lobsters (live, fresh, chilled)	2%
030635	Cold-water shrimps and prawns (live, fresh, chilled)	1%
030639100	Ebi (live, fresh, chilled)	2%
030639900	Other crustaceans (live, fresh, chilled)	7%
030711000	Oysters (live, fresh, chilled)	7%
030721000	Scallops (live, fresh, chilled)	10%
030742010	Mongo ika, cuttlefish (live, fresh, chilled)	3.5%
030742090	Other cuttle fish and squid (live, fresh, chilled)	5%
030751000	Octopus (live, fresh or chilled)	7%
030771100	Adductors of shellfish (live, fresh or chilled)	10%
030771200	Hard clam (live, fresh or chilled)	3.5%
030771310, 030771320, 030771390	Akagai, baby clam and other clam (live, fresh or chilled)	7%

4 Create a Product Label

Product labels must be prepared in Japanese in accordance with Japanese regulations.

Live seafood has only general labeling obligations (name of the product and country of origin; if the seafood is farmed, indicate this on the label).

Generally, a product label is prepared by the importer with information from the exporter /manufacturer.

Product labels can be affixed to products in the US or in Japan before commercial distribution. Consult with your importer on how to handle labeling.

The new Food Labeling Act was fully implemented from April 2020 and all labelling must conform to the Act.

Steps to take

- 4-1 Provide the importer with all necessary product information and prepare the product label according to the Japanese food labeling regulations. (Details on the following page)

Whose responsibility is this?

Importer

Related law/regulation and responsible government agency

- [Food Labeling Act, Labeling Standards \(general and product-specific\)](#) (Japanese only), [Consumer Affairs Agency \(CAA\)](#)
- [recycling symbol on packaging]: [Act on Promotion of Effective Utilization of Resources, Ministry of Environment \(MOE\)](#)
- [product-specific standards]: [JAS Law, Ministry of Agriculture, Forestry and Fisheries \(MAFF\)](#)

Best Practices

- Labeling regulations are varied, are often different from US regulations and **change frequently**, so consult closely with your importer about the labeling.

Common Concerns

- Only alcoholic beverage product labels are subject to inspection at customs clearance. However, all labels are subject to the on-going in-market monitoring inspections by prefectural Health Centers. If a Health Center finds that your product label is incorrect, a product recall may be ordered.

Key Contacts

- [ATO Tokyo](#)
E-mail: atotokyo@fas.usda.gov
- Food Labeling Division, Consumer Affairs Agency Consultation service is available (Japanese only):: https://www.caa.go.jp/policies/policy/food_labeling/information/contact/

4-1

Sample of a Product Label

US Washington Oyster

Name of product:	Raw oyster
Use application:	Should not be consumed raw.
Storage instruction:	Store below 10 degrees C.
Country of origin:	United States
Importer:	Meros Supermarket 1-19-3, Kanda Awajicho, Chiyoda-ku, Tokyo

- Contact phone no: 03-3526-2075

Recycling symbol: plastic

Best-before date: Apr 1, 2022

アメリカ産 生かき

名称:	生かき
用途:	加熱調理用
保存方法:	10°C以下
原産国名:	アメリカ
加工者:	東京都千代田区神田淡路町1-19-3 株式会社メロススーパー

- お問い合わせ先：03-3526-2075



賞味期限： 2022.04.01

- The order is Year.Month.Date.
- Some other variations allowed include: "2022.4.1.", "20220401", "2022年4月1日".

5 Register Trademarks and other Intellectual Property Rights

To protect your trademarks in the Japanese market, you or your importer may want to register your trademarks. You may also consider using the Madrid System to register a trademark internationally.

Manufacturers may want to design logos, brand names or distinctive packaging specifically for the Japanese market and therefore the trademarks that you register for the Japanese market may differ from the trademarks you have registered for the products sold in US.

Existing trademark registrations in Japan can be looked up here.

<https://www.j-platpat.inpit.go.jp/t0100>

Steps to take

- 5-1 Confirm that the name you want to trademark is not already registered in Japan.
- 5-2 Apply for trademarks and other intellectual property rights in Japan with the Japan Patent Office (JPO).

Whose responsibility is this?

Manufacturer / Exporter / Importer, depending on the situation

Application Information

- Refer to the Japan Patent Office (JPO)'s 'How to apply?'
<https://www.jpo.go.jp/e/faq/yokuaru/apply.html>

Sample form is available here. <https://www.jpo.go.jp/e/faq/yokuaru/forms.html>

Timeframe / Cost

- It normally takes around 9 months for trademark registration.
(For fast track, less than 3 months, if certain conditions are met.)
- For a trademark, JPO's application charge is JPY 3,400 + JPY 8,600/per classification.
It may be necessary to consider additional patent attorney fees as well.

Government agency & law

- [Japan Patent Office \(JPO\)](#)
- [Trademark Act](#)

Best Practices

- Since trademark registration takes time, starting the process as early as possible is recommended.
- Consult with your importer. Your importer may be willing to help register the trademarks of your product/brand, for example, if they have exclusive import rights to the product.
- If your company does not have a representative office in Japan, you will need to appoint a Patent Administrator located in Japan.
- Be sure to check the name you want to trademark both in English and in Japanese (*katakana*). There are cases of US companies finding that there is already an existing trademark on the name they want to register.

Key Contacts

- International Affairs Division,
General Affairs Department
Japan Patent Office
Address: 3-4-3 Kasumigaseki, Chiyoda-ku Tokyo
100-8915, Japan
Tel: (011-81-3) 3581-1101
Email: PA0842@jpo.go.jp
Website: : <https://www.jpo.go.jp/e/index.html>
- Japan Patent Attorney Association
Tel: (011-81-3) 3581-1211
E-mail: master@jpaa.or.jp
Website: <https://www.jpaa.or.jp/en/>
The JPAA can be helpful in finding a representative for you in Japan.

B.

Embarkation

The following are steps to be taken upon embarkation.



B. Embarkation Checklist



6. Obtain an Export Health Certificate

7. Clear export customs

6 Obtain an Export Health Certificate

NOAA Export Health Certificate for Fresh Oysters

To export oysters for raw consumption to Japan, state governments need to individually request permission from MHLW. Japan currently allows oyster imports from Connecticut, New York, Oregon and Washington states.

To export oysters for raw consumption, the manufacturer/exporter must obtain an export health certificate issued by NOAA (for oysters from Washington, a certificate issued by the Washington State government is also acceptable).

For more information, see [Japan Accepts NOAA Sanitary Certificate for US Fresh](#)

NOAA Export Health Certificate for Product subject to Sanitary Inspection

If your product is subject to Sanitary Inspection, a NOAA Export Health Certificate **must** accompany the shipment. A certificate will be issued upon request by the Japanese authorities.

Steps to take:

- ☐ 6-1 If your product is fresh oyster or subject to Sanitary Inspection, obtain a **NOAA Export Health Certificate** (or a Washington State Certificate, if applicable)

Whose responsibility is this?

Manufacturer / exporter

Timeframe / Cost

- Varies by Product
- Check with the laboratory you have chosen

Key Contacts

- **ATO Tokyo**
E-mail: atotokyo@usda.gov

Where to obtain a Health Certificate?

- **NOAA Fisheries Seafood Inspection Program**
<https://www.fisheries.noaa.gov/contact-directory/contact-your-local-seafood-inspection-office>
- **Washington State Department of Health, Export Certificates**
<https://www.doh.wa.gov/CommunityandEnvironment/Shellfish/CommercialShellfish/Export>

7 Clear Export Customs

Electronic Export Information (EEI) filing is a common practice for export control documents. It is required for shipments above US\$2,500 in value and for shipments of products which require an export license. It should be filed electronically through the Automated Export System (AES).

After embarkation, send the documents required for Japanese import clearance: Commercial Invoice, Packing List, Bill of Lading (B/L) or Airway Bill, as well as any sanitary certificates required. You may need to confirm with the importer (and with the customs broker) about the format and content of those documents in advance.

Steps to take

- 7-1 Prepare the following documents:
 - Commercial Invoice
 - Packing List
 - Shipping Instructions (These are instructions for shipping prepared by the exporter and provided to the shipping company.)
- 7-2 Declare export through EEI filing with the above documents, proceed through export customs clearance, and receive a B/L after loading.
- 7-3 Send the documents for import clearance to the importer.
 - Commercial Invoice
 - Packing List
 - B/L or Airway Bill
 - Sanitary Certificates, as needed

Whose responsibility is this?

Manufacturer / exporter. The export clearance procedures often are consigned to a customs broker.

US export customs clearance instructions:

Further instructions can be found in:

- Export Education, The International Trade Administration, U.S. Department of Commerce
<https://www.export.gov/export-education>
- Basic Importing and Exporting, U.S. Customs and Border Protection
<https://www.cbp.gov/trade/basic-import-export>

List of documents to be sent to the importer

- **Commercial Invoice:**
This is an invoice for the goods from the manufacturer/exporter to the importer. The invoice will be used by both US and Japan customs to determine the value of goods. It should include:
 - Information about the exporter (seller) and the importer (buyer)
 - descriptions of goods
 - quantity and unit price
 - payment information
 - mode of transport and its details
 - country of origin
- **Packing List:**
This gives detailed information about the shipment, including:
 - information about the exporters and importers
 - invoice number
 - date of shipment
 - mode of transport and its details
 - the type of packaging
 - the quantity of packages
 - total net and gross weight (in kilograms)
 - total dimensions, etc.
- **Bill of Lading (B/L) or Airway Bill:**
This is a contract between the exporter (owner of the goods) and the shipping company (carrier), which will be prepared based on the Shipping Instructions, and will be issued by the shipping company after loading. B/L is for sea freight and Airway Bill is for air cargo. The importer usually needs the original document as proof of ownership of the goods.

C.

Import Clearance

The following steps must be completed before entering Japan

C. Import Clearance Checklist

- ❑ 8. Clear sanitary inspection
- ❑ 9. Clear food safety quarantine procedures
- ❑ 10. Clear import customs

After Import Clearance

Food safety issues faced after Import Clearance

8 Clear Sanitary Inspection

Import clearance starts from Sanitary Inspection at the **Animal Quarantine Service**, if the product is subject to such inspection (See Step 2). **(This is not applicable to most live seafood exports from US to Japan since most live seafood exports are stored in fish tanks)**

Steps to take:

- ❑ 8-1 Submit an application for Sanitary Inspection to the Animal Quarantine Service with the **NOAA Export Health Certification** obtained in Step 6.
 - The Animal Quarantine Service may require other documents, such as the Commercial Invoice, Packing List, B/L and Manufacturing Process Flowchart.
 - The application can be submitted electronically through the Nippon Automated Cargo and Port Consolidated System (NACCS) or by paper copy.
 - Applications are accepted from as early as three days prior to the scheduled arrival of the cargo, and no later than one day prior to scheduled arrival.
- ❑ 8-2 Undergo document examination and on-site **Sanitary Inspection**.
- ❑ 8-3 If disease is detected, the Animal Quarantine Service will order either disposal or return of the shipment.
- ❑ 8-4 Once the shipment passes inspection, receive the **Inspection Certificate**.

Whose responsibility is this?

Importer. The entire import clearance process is often consigned to a customs broker.

Timeframe / Cost

- The Sanitary Inspection is free of charge. However, the importer needs to cover the cost of disposal or shipment return if ordered.
- The customs broker will usually charge 2000-5000 JPY for submitting the application, and they will add expenses for disposal or return if ordered.
- Timeframe for sanitary inspection varies from 10 mins to half a day.

Responsible government agency and relevant law/regulation

- [Animal Quarantine Service](#), Ministry of Agriculture, Forestry and Fisheries (MAFF)
- [Act on Domestic Animal Infectious Diseases Control](#)

Key Contacts

- **ATO Tokyo**
E-mail: atotokyo@usda.gov
- Fish and Fishery Products Safety Office,
Animal Products Safety Division,
Food Safety and Consumer Affairs Bureau,
MAFF
http://www.maff.go.jp/j/syouan/suisan/suisan_yo/bo/index.html (Japanese only)
Tel:03-6744-2105

9 Clear Food Safety Quarantine Procedures

The next step will be clearing food safety inspections at the **Quarantine Station**. This step checks legal compliance with food standards (See Step 1).

Steps to take:

- 9-1 Submit **Notification for Importation of Foods** to the Quarantine Station with:
 - Ingredient List and Manufacturing Process Flowchart
 - Any other required documents by Quarantine Station
 The application can be submitted electronically through Nippon Automated Cargo and Port Consolidated System (NACCS) or by paper copy. Applications can be submitted as early as 7 days prior to the scheduled arrival date.
- 9-2 Undergo document examination and on-the-spot examination by the quarantine officials.
- 9-3 Undergo **Food Safety Inspection**, if required.

There are three possible types of inspection: **(A) Self-inspection**, **(B) Ordered inspection**, and **(C) Monitoring inspection**. These three inspections are discussed in the next slides. *Most first-time imports require (A) Self-inspection.*
- 9-4 Upon passing all food safety inspections, receive a **Certificate of Notification for Importation of Foods**.

Whose responsibility is this?

Importer. The entire import clearance process is often consigned to a customs broker.

Timeframe / Cost

- The import notification itself is free of charge. The customs broker will usually charge 2000-5000 JPY for submitting the notification.
- If the product is subjected to (A) Self-inspection or (B) Ordered inspection, the inspection costs must be covered by the importer. The inspection costs for (C) Monitoring Inspections are covered by the Quarantine Station.
- Document examination normally takes a few hours. If inspection is required, it normally takes **up to a week**.

Responsible government agency and relevant law/regulation

- Quarantine Stations, [Ministry of Health, Labour and Welfare \(MHLW\)](#)
- [The Food Sanitation Act \(FSA\)](#), [Specifications and Standards for Foods, Food Additives, etc.](#)

Best Practices

- Exporters often start with a **small test shipment** in order to clear the food safety inspections required for first-time exports. In general, these test results will be valid for one year.
- A single food safety violation can impact other shipments of the same product from other US exporters. Therefore, careful preparation for food safety inspections is critical.

Common Concerns

- **Insufficient information or documentation can cause significant delays at the Quarantine Station.** If your food safety clearance process takes more than one week, contact ATO Tokyo for consultation.

Rejection Rates at Sanitary Inspection

- The rate of US food imports subjected to one of the three food safety inspection types was 7.9% in 2019 and 7.6% in 2020.
- The rate of rejected cases among inspected products was 0.8% in 2019 and 0.7% in 2020.

Key Contacts

- **ATO Tokyo**
E-mail: atotokyo@usda.gov
- Contacts for the 111 **Quarantine Station** offices
https://www.mhlw.go.jp/english/policy/health-medical/health/dl/contact_list_jqs.pdf

9-3 Explanation of Food Safety Inspection Types

(A) Self Inspection

Self Inspection refers to food safety testing arranged by the Importer with a MHLW-registered inspection laboratory.

Legally, Self Inspection is a 'voluntary action' by the importer. It is based on Article 3 of the Food Sanitation Act (FSA) which states that the food business operator, including importer, shall take responsibility to ensure food safety, and for that purpose, shall conduct voluntary inspections of food for sale.

Although technically voluntary, in practice, Self Inspection is mandatory once it is requested by the Quarantine Station. If the importer does not follow the Quarantine Station's guidance on testing targets and methods at this stage, the Quarantine Station can – and likely will – reject the shipment.

After testing, the Importer obtains a **Certificate of Analysis** (a report of the test results) from the laboratory and provides this to the Quarantine Station.

Self inspection is **usually required when a product is imported to Japan for the first time.**

In order to minimize the risk of rejection at the port of entry and to shorten the time for import clearance, it is possible to get a Certificate of Analysis from a MHLW-certified laboratory in the US (e.g., agrochemical residue test for fresh produce and food additive test for wine). (See Step 6) Contact ATO Tokyo for further information.

Who initiates?

The **importer** should consign the inspection to a **MHLW-registered inspection laboratory.**

Target items to be inspected

The Quarantine Station specifies the items to be tested after the document examination and conducts an on-the-spot examination. In general, the items to be tested include:

- **Harmful products**, like toxic mold, pathogenic bacteria, methanol
- **Product specifics**, like bacteria count, for food categories which have product-specific standards such as soft drinks and frozen food
- **Food additives**: artificial coloring, preservatives, additives which have maximum tolerance levels, and additives which have had issues in the past;
- **Agrochemical residue** (mainly for products which have had issues in the past)

Sampling size

Around 300-1,000 grams; the laboratory will specify the exact amount depending on the product.

Timeframe / Cost

The importer should cover the cost for Self Inspection. (Refer to fees on the right.)

Normally, the registered laboratory visits the warehouse for sampling and sends the Certificate of Analysis within **a week or less** after getting the samples.

Term of validity of the Certificate of Analysis

- The Certificate of Analysis is **normally valid for one year**. Once the Certificate of Analysis expires, Self Inspection must be conducted again and a new Certificate of Analysis will be required. If trouble has occurred with previous shipments, the Quarantine Station may ask the importer to conduct Self Inspection again, even if the importer has a valid Certificate.

Some exceptions to the Certificate of Analysis term of validity:

- There are some test items which are examined every time, like bacteria count, toxic mold, etc.
- In some cases, Certificate of Analysis test results regarding additives will be accepted for more than a year, if the importer submits documents to the Quarantine Station which indicate that the food product is manufactured with the same ingredients, the same manufacturing process, and at the same factory as the product whose additives were previously tested.

Contacts of MHLW-registered laboratories

A list of the registered laboratories is here (Japanese):

https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/ke nkou_iryuu/shokuhin/jigyousya/kikan/index.html

Approximate Inspection Fees

- Food additives: 6,000-20,000 JPY per target item
- Bacteria: 3,500-25,000 JPY per target bacteria
- Agrochemical residue: 10,000-30,000 JPY per target chemical

9-3 Explanation of Food Safety Inspection Types (B) Ordered Inspection

For some products from specific exporters/countries which have had issues in the past, the Quarantine Station will order the importer to conduct inspection on **all shipments**. This is called **Ordered Inspection**.

The target products/exporters/countries are shown in the annual Ordered Inspection plan, which is explained briefly in [MHLW's Imported Foods Annual Monitoring Plan \(English\)](#) and in more detail in the **Notice of the Implementation of Ordered Inspection** (Japanese only):
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/shokuhin/yunyu_kanshi/kanshi/index.html

MHLW may add more target products or countries if/when any serious issues are detected from more than one supplier from a particular country.

Once the product is targeted for Ordered Inspection, it will require 2 years of non-detection (or 1 year and at least 300 inspections without detection) to be exempted from further Ordered Inspection.

Who is responsible?

The **importer** should consign the inspection to a **MHLW-registered inspection laboratory**.

Target items to be inspected and testing/sampling method

The Quarantine Station specifies the items to be inspected, as well as the testing and sampling method.

Timeframe / Cost

The importer should cover the cost for ordered inspection. (For the cost of inspection, refer to the previous page.)

Normally, the registered laboratory visits the warehouse for sampling and sends the Certificate of Analysis within **a week or less** after receiving the sample.

9-3

Explanation of Food Safety Inspection Types

(C) Monitoring Inspection

Monitoring Inspection occurs when the Quarantine Station randomly selects shipments and conducts their own testing for the purpose of overall monitoring of the food safety of imported products.

The target products/countries are shown in the annual ordered inspection plan, which is explained briefly in [MHLW's Imported Foods Annual Monitoring Plan \(English\)](#), and in more detail in the **Monitoring Plan for Imported Foods and Other Related Products** (Japanese only) which can be found here: https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/shokuhin/yunyu_kanshi/kanshi/index.html

MHLW may increase the frequency of monitoring, as well as add more targeted test items, products or countries if/when any serious issues are detected.

Who is responsible?

The Quarantine Station conducts the inspection.

Target items to be inspected and testing/sampling method

The target items for inspection and the testing/sampling method are specified in the Monitoring Plan.

Timeframe / Cost

The Quarantine Station will cover the inspection cost.

Normally, it will take a week or less to get the results of the monitoring inspection.

You can clear customs and distribute the products to the market even before getting the results of the Monitoring Inspection. However, it is recommended that the importer hold the products in a bonded area until the results are received, in case some issue is detected. If an issue is detected, the Quarantine Station will order a recall. The importer normally is expected to cover the cost of storage during the inspection.

The Target Items for Monitoring Inspection in 2021, based on the Monitoring Plan for Imported Foods and Other Related Products of FY2021, are shown here.

<https://www.mhlw.go.jp/content/000759467.pdf>

General targets:

- Harmful and toxic substances
- Decayed and foreign objects
- Pathogenic microorganisms
- Food additives
- Irradiation
- Unapproved genetically modified food

Specific targets:

- Seafood
 - *Vibrio parahaemolyticus* (Seafood for raw consumption)
 - Diarrhetic/Paralytic shellfish poisons (shellfish)
 - Residual veterinary drugs
 - Residual feed additives
 - Histamine

10 Clear Import Customs

Finally, clear import customs and pay applicable import taxes (See Step 3) at the **Customs office**.

Steps to take:

- ❑ 10-1 Submit Import Declaration to Customs:
The application can be submitted electronically through Nippon Automated Cargo and Port Consolidated System (NACCS) or by paper copy.
The application can be submitted after disembarkation or up to 2 weeks prior to scheduled arrival of cargo.
- ❑ 10-2 Clear document examination
- ❑ 10-3 Clear on-the-spot **Customs Inspections** (See the right column), if required
- ❑ 10-4 Pay the import tax and consumption tax
- ❑ 10-5 Receive an **Import Permit**

Whose responsibility is this?

Importer. The entire import clearance process is often consigned to a customs broker.

Timeframe / Cost

If the product is not subject to inspection, customs clearance only takes a couple hours.

Product inspection can take up to half a day.

Customs will not charge for customs clearance procedures.

The customs broker will charge from about JPY 3000 to 10,000 for customs clearance procedures and will add other extra costs if the product becomes subject to inspection.

Responsible government agency and relevant law/regulation

- [Japan Customs](#)
- [Customs Act](#) (Japanese only)

Customs Inspection

- **What will be inspected?**
 - Prohibited items such as drugs, guns, counterfeits
 - The Inspection Certificate and the Certificate of Import Notification of Foods in order (if they are required)
 - Indications of misrepresentation or misleading in regards to the place of origin
 - Whether or not a proper tax filing has been submitted
- **Inspection method**
Major inspection methods include:
 - [For drugs, guns, etc.] X-ray inspection
 - [For counterfeits] Visual confirmation
- **Cost**
Inspection is free of charge, but the importer needs to cover transportation costs to the inspection site.

Key Contacts

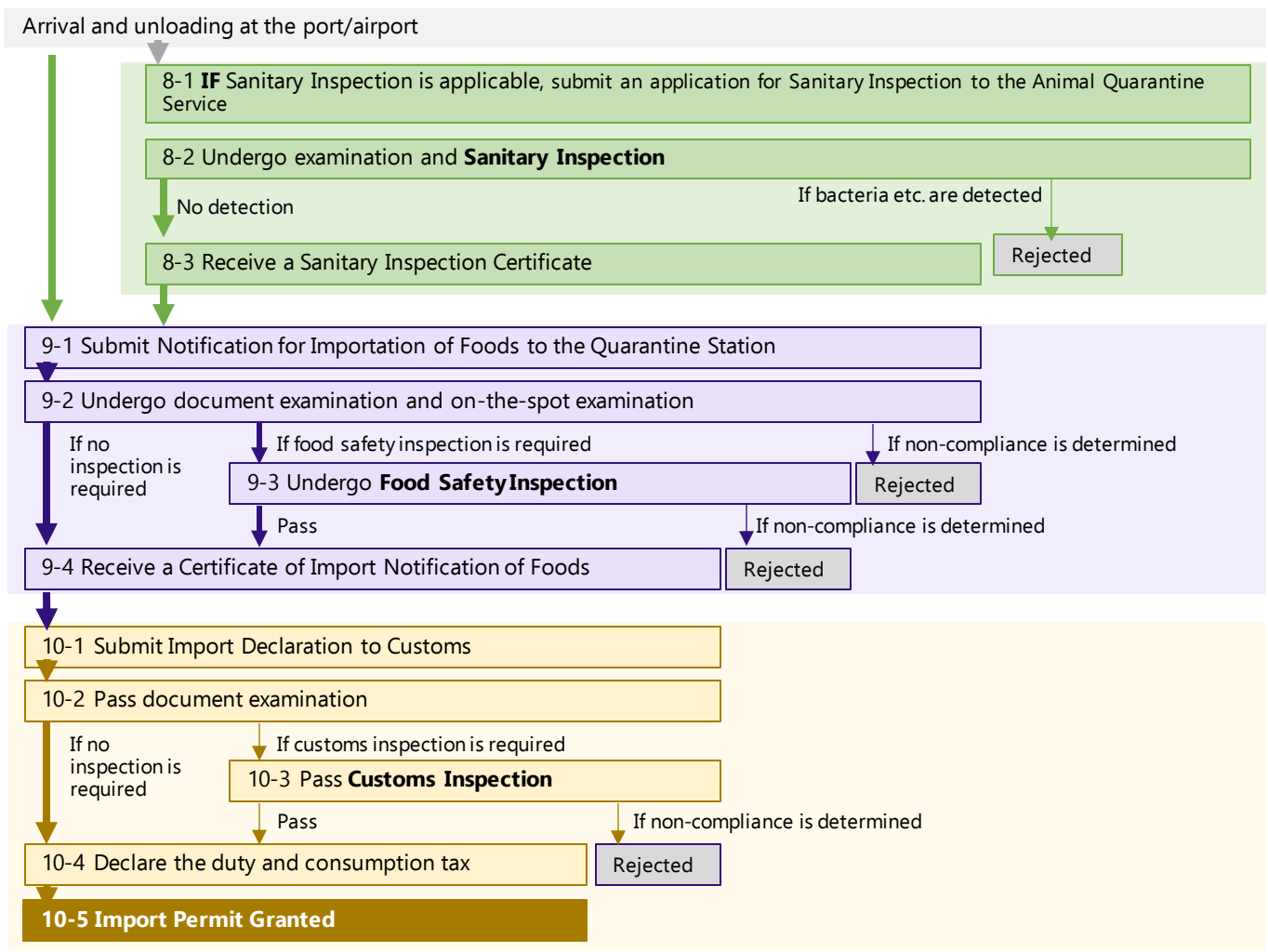
- Contact points of the 9 regional Customs offices (English):
http://www.customs.go.jp/question_e.htm

Summary Import Clearance Flow

Animal Quarantine Service

Quarantine Station

Customs



Average duration

From arrival to unloading into bonded storage:
40 hrs. (port)
3.5hrs. (airport)

From bonded storage to import declaration:
44 hrs. (port)
43 hrs. (airport)

- Sanitary Inspection at Animal Quarantine Service takes from 10 mins to half a day.

- Document examination at Quarantine Station takes few hours. If food safety inspection is required, it could take up to one week

For customs clearance:
3 hrs. (port)
0.5 hrs. (airport)

Food Safety

Issues Faced After Import Clearance

Even after imported food products pass customs and enter the Japan market, there is on-going food safety monitoring of imported food products. Importers remain responsible for the food safety of imported products as long as the products are circulating. This includes any costs or damages related to product recalls or consumer health complaints.

▪ Voluntary Recall

The importer might recall a product voluntarily, if they themselves foresee any compliance issues.

In Tokyo, voluntary recalls must be reported to the local government. Applicable cases can be found here (Japanese only): <http://www.fukushiho-ken.metro.tokyo.jp/shokuhin/jisyukaisyuu/jyohou.html> One example is a recall of chocolate bars with a milk contamination risk that was not mentioned on the label.

▪ Food Safety Inspection by Prefectural Health Centers

The Food Sanitation Act requires each prefecture to have a plan for monitoring food safety in accordance with national guidelines. Thus, each prefecture monitors the safety of food products in the market and provides guidance to importers, wholesalers, and retailers. Prefectural Health Centers are in charge of this monitoring.

The monitoring includes imported food product sampling (which may include checking for the existence of unapproved genetically modified ingredients, agrochemical residue, irradiation), on-site inspection of importers' food safety assurance systems and monitoring of food labeling.

If a violation is detected, prefectures may order a recall.

For example, the Tokyo government reports the results of its inspections and violations here: http://www.fukushihoken.metro.tokyo.jp/shokuhin/ihan/nendo_index.html

▪ Financial Liability for Recalls and Food Safety Risk

Importers usually purchase various forms of insurance to reduce the financial risk from recalls and consumer complaints related to imported food products. This includes product liability insurance (to cover the risk of illness or accidents incurred by end users) and recall insurance.

Financial liability for recalls or other damages have been issues of dispute between Japanese importers and US exporters/manufacturers.

Best Practices:

- It is best to discuss in-market food safety risk planning with importers in advance and confirm that your importer is aware of all insurance needed.

Contacts

General Help Desks

Need help? Contact ATO Tokyo

 atotokyo@usda.gov

Agricultural Trade Office (ATO), Tokyo

Embassy of the United States of America, Tokyo, Japan

E-mail: atotokyo@usda.gov

Tel: (011-81-3) 3224-5115
(Mon-Fri 8:30 AM – 5:30 PM Japan Standard Time)

Fax: (011-81-3) 3582-6429

Address: Unit 9800, Box 591, DPO AP 96303-0591

Further contact information available at:

https://apps.fas.usda.gov/overseas_post_directory/ovs_directory_result.asp?posts=580

Website: <http://www.usdajapan.org/>

Twitter: @USDAJapan

Free consultation service is also available at:

Japan External Trade Organization

Trade & Investment Consulting

Tel (English and Japanese): (011-81-3) 3582-5651
(Mon-Fri 9:00 AM-12:00 PM and 1:00 PM- 5:00 PM in Japan time)

Online Inquiry Form (English):

<https://www.jetro.go.jp/form5/pub/csa/contact-en>

Address: Ark Mori Building, 6F, 1-12-32, Akasaka,
Minato-ku, Tokyo

The Manufactured Imports and Investment Promotion Organization (MIPRO)

Tel (English and Japanese): (011-81-3) 3989-5151
(Mon-Fri 10:30 AM-4:30 PM in Japan time)

Online Inquiry Form (Japanese only):

https://krs.bz/mipro/m/advisement_form_web

Address: World Import Mart Building, 6F, 3-1-3,
Higashi Ikebukuro, Toshima-ku, Tokyo

Contacts of Competent Authorities in Japan

Ministry of Health, Labour, and Welfare (MHLW)

Address: 1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-8916, Japan
Website: <https://www.mhlw.go.jp/english/>
Email: www-admin@mhlw.go.jp

Food safety standards:

Standards and Evaluation Division
Policy Planning Division for Environmental Health and Food Safety,
Pharmaceutical Safety and Environmental Health Bureau
Tel: (011-81-3) 3595-2341

Imported food safety monitoring:

Office of Quarantine Station Administration,
Policy Planning Division for Environmental Health and Food Safety,
Pharmaceutical Safety and Environmental Health Bureau
Web:
<https://www.mhlw.go.jp/english/topics/importedfoods/index.html>
Tel: (011-81-3) 3595-2333 Fax: (011-81-3) 3591-8029

Quarantine Stations:

Contacts of 11 Quarantine Stations under MHLW at ports/airports:
<https://www.mhlw.go.jp/general/sosiki/sisetu/ken-eki.html>

Ministry of Finance (MOF)

Address: 3-1-1 Kasumigaseki, Chiyoda-ku, Tokyo
Website: <https://www.mof.go.jp/english/index.htm>

Customs

Japan Customs
Website: <http://www.customs.go.jp/english/index.htm>
Contacts for inquiries: http://www.customs.go.jp/question_e.htm

Ministry of Agriculture, Forestry and Fisheries (MAFF)

Address: 1-2-1, Kasumigaseki, Chiyoda-ku, Tokyo
Website: <http://www.maff.go.jp/e/>
Online inquiry form:
<https://www.contactus.maff.go.jp/j/form/kanbo/koho/160807.html>

Fish and Fishery Products Safety Office

Animal Products Safety Division, Food Safety and Consumer Affairs
Bureau
Tel: (011-81-3) 6744-2105
http://www.maff.go.jp/j/syouan/suisan/suisan_yobo/index.html
(Japanese)

Animal Quarantine Service

Animal Health Division, Food Safety and Consumer Affairs Bureau
Tel: (011-81-3) 3502-5994
Website: <http://www.maff.go.jp/aqs/languages/info.html>
Inquiries can be sent to Animal Quarantine Stations listed at:
<http://www.maff.go.jp/aqs/sosiki/attach/pdf/address-6.pdf>
(Japanese)

Fisheries Agency

Tel: (011-81-3) 3502-8111
<https://www.jfa.maff.go.jp/e/index.html>

Consumer Affairs Agency (CAA)

Address: Central Common Government Offices No.4, 3-1-1
Kasumigaseki, Chiyoda-ku, Tokyo
Website: <https://www.caa.go.jp/en/>

Food Labeling

Food Labelling Division
Tel: (011-81-3) 3507-8800
Website: https://www.caa.go.jp/en/policy/food_labeling/