

# Frozen Breads Export Guide to Japan

December, 2021

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# Frozen Breads

# Export Guide to Japan

December, 2021

Prepared for the Agricultural Trade Office

U.S. Embassy, Tokyo, Japan

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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 **#12 Frozen Breads**

## 24 products covered in this series:

- |   |   |
|---|---|
| #1 Fresh fruit                                  | #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. Prepare an Ingredient List and a Manufacturing Process Flowchart
- ❑ 2. Confirm legal compliance with food standards and other regulations
- ❑ 3. Check the tariff classification and customs duty
- ❑ 4. Create a product label
- ❑ 5. Register trademarks and other intellectual property rights

## B. Embarkation

- ❑ 6. Obtain a Certificate of Analysis
- ❑ 7. Clear export customs

## C. Import Clearance

- ❑ 8. Clear food safety quarantine procedure
- ❑ 9. 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

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- 1. Prepare an **Ingredient List** and a **Manufacturing Process Flowchart**
  - 2. Confirm **legal compliance with food standards** and other regulations
  - 3. Check the **tariff classification** and customs duty
  - 4. Create a **product label**
  - 5. Register **trademarks** and other intellectual property rights

# 1 Prepare an Ingredient List and a Manufacturing Process Flowchart

Exporters will be required to provide a list of all ingredients, as well as a manufacturing process flowchart. Generally, potential importers will request this information early in the process of vetting new products for purchase in order to confirm whether the product can be imported as food.

This information will later be submitted to the quarantine station as a **mandatory** step in the import clearance process. Importers will often provide these documents to a Quarantine Station in advance in a process known as Prior Consultation (Refer to Step 2); as well as to a Customs office to get an Advance Ruling (Refer to Step 3).

## Steps to take:

- 1-1 Prepare an **Ingredient List**
  - All ingredients
  - Food additives, colors and flavors in detail
- 1-2 Prepare a **Manufacturing Process Flowchart**
  - Manufacturing process in order
  - Details on heating and other sterilization methods

Sample documents are found on the next two pages.

## Whose responsibility is this?

**The manufacturer or exporter** is responsible for creating these documents for the importer, who will submit them to a Quarantine Station.

## Timeframe / Cost:

No fees required at submission or for Prior Consultation.

## Responsible government agency:

- [Ministry of Health, Labour and Welfare \(MHLW\)](#)

## Relevant laws/regulations:

- [The Food Sanitation Act / Ordinance for Enforcement of The Food Sanitation Act](#)

## Best Practices

- It is best to prepare these documents even before talking with importers.
- A non-disclosure agreement (NDA) can be signed by your importer or local partners before sharing these documents.

## Common Concerns

- Many manufacturers are protective of their proprietary recipes and processes. However, inadequate information can result in rejection or significant delays at import clearance. Contact the ATO Tokyo if you have doubts about how to prepare these documents.

## Key Contacts

- For further information, contact [Agricultural Trade Office \(ATO\), Tokyo](#)  
E-mail: [atotokyo@usda.gov](mailto:atotokyo@usda.gov)  
Tel: (011-81-3) 3224-5115  
Mon-Fri 8:30 AM -5:30 PM in Japan time
- [11 Quarantine Stations under MHLW](#) located at major ports/airports offer Prior Consultation for importers (See Step 2).
- [The Manufactured Imports and Investment Promotion Organization - MIPRO](#) provides free phone consultation for both exporters and importers.  
Tel (English and Japanese): (011-81-3) 3989-5151  
Mon-Fri 10:30 AM - 4:30 PM in Japan time

1-1

# Sample of an Ingredient List

The document can be prepared in English or Japanese on the Manufacturer's or Importer's letterhead. There is no required format, but should include the following:

- **All ingredients**, in descending order, by weight.
- If a processed product is used as an ingredient, a list of the ingredients in that processed product is also necessary.
- Include information on the following items, all of which are considered **food additives** in Japan (Refer to page 11):
  - **Synthetic additives, artificial colors, artificial flavors** – chemical names, international index number (for colors), CAS number (for flavors), chemical formulas (for others), the reason for use, share in weight or content in ppm (amount). Also confirm and note that it meets Japanese FSA standards;
  - **Natural food additives** – names, the reason for use, amount
  - **Natural colors and flavors** – name, description
  - **Post-harvest agrochemicals** – chemical names
- If an **extract** is used: extraction method, including whether organic solvent is used

XYZ FOODS	
123 Woodland Avenue, City, State, ZIP, United States (103) 222 2222 / (103) 222 2223	
INGREDIENT LIST	
Products:	XYZ Brand Frozen Plain Bagel, 6 pcs (510g)
Manufacturer:	XYZ Foods Ltd.
Address:	123 Woodland Avenue, City, State, ZIP, United States
Factory:	XYZ Foods Park Avenue Factory
Address:	111 Park Avenue, City, State, ZIP, United States
INGREDIENTS:	
	Share
Wheat flour	70.9 %
Sugar	12.0 %
Cornmeal	10.0 %
Salt	3.0 %
Yeast	1.5 %
Gluten	1.0 %
Vinegar	0.8 %
Thickener (Guar gum)	0.5 %
Emulsifier (Glycerol fatty acid ester)	0.3 %
Allergens: Contains gluten. May contain traces of soy and nuts.	
Feb 7, 2019  Michael Williams Director, Manufacturing XYZ Foods Ltd.	

- Product name
- Manufacturer and Facility name (official name, no abbreviations) and address (physical address, not P.O. Box)
- **Share by weight is optional, except for synthetic additives. It is not mandatory for quarantine clearance. However, it may be required by the importer for customs clearance and for Advance Ruling in order to determine the tariff classification (See Step 3). You may be able to provide share by weight as a range (e.g. 40-45%).**
- Information related to **allergens** (mandatory for eggs, milk, wheat, buckwheat, peanut, shrimp and crab)
- Date of document preparation, person responsible, title, company name, signature



1-2

# Sample of a Manufacturing Process Flowchart

The document can be prepared in English or Japanese. Use the Manufacturer's or Importer's letterhead. There is no required format, but should include the following:

- Description of **the entire manufacturing process** from raw materials to packaging.
- A manufacturing process description is mandatory but can be written in a way that protects proprietary information.
- **Heating/cooling and other sterilization methods**
  - **Heating process:**
    - Heating method. (e.g., hot water, boil, steam, etc.)
    - Temperature & heating time.
    - Center temperature, if the product needs to meet specific conditions.
  - **Cooling after heating:**
    - Cooling methods (e.g., running water cooling, natural cooling)
    - Temperature and time
  - **Other sterilization process:**
    - For chemical sterilization: the name and amount of the agent used.
    - *Note: Irradiation is banned.*

XYZ  
FOODS

123 Woodland Avenue,  
City, State, ZIP, United States  
(103) 222 2222 / (103) 222 2223

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MANUFACTURING PROCESS FLOWCHART

**Products:** XYZ Brand Frozen Plain Bagels, 6 pcs (510g)

**Manufacturer:** XYZ Foods Ltd.

**Address:** 123 Woodland Avenue, City, State, ZIP, United States

**Factory:** XYZ Foods Park Avenue Factory

**Address:** 111 Park Avenue, City, State, ZIP, United States

**Manufacturing Process:**

```

graph TD
    A[Combining all ingredients] --> B[Retarding  
(0 degrees Celsius, 2 hrs)]
    B --> C[Placing into molds]
    C --> D[Fermenting  
(30 degrees Celsius, 1.5 hrs)]
    D --> E[Freezing (minus 30 degrees Celsius, 1 hr)]
    E --> F[Individual packaging and labeling]
    F --> G[Visual Inspection]
    G --> H[Packing in cardboard cartons]
            
```

Feb 7, 2019

Michael Williams  
Director, Manufacturing  
XYZ Foods Ltd.

- Product name
- Manufacturer and facility name (official name, no abbreviations) and address (physical address, not P.O. box)
- *Including specific information about your quality control methods is recommended, since importers often ask exporters for additional details about this step.*
- Date of document preparation, person responsible, title of the person, company name, signature

# 2 Confirm Legal Compliance with Food Standards and Other Regulations

Japan's Food Sanitation Act (FSA) establishes the sanitary standards for food products. Depending on the product category, you may need to check compliance with other related regulations.

*Compliance with food standards will be discussed in Step 8, Food Safety Inspection at the Quarantine Station under MHLW.*

## Steps to take:

- ❑ 2-1 Confirm legal compliance regarding **food additives**
- ❑ 2-2 Confirm legal compliance regarding **specific standards for frozen foods and dairy products**
- ❑ 2-3 Confirm legal compliance regarding **other ingredient issues**
- ❑ 2-4 Confirm legal compliance regarding **manufacturing process and packaging**
- ❑ 2-5 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 \(METI\)](#)
- [Ministry of Agriculture, Forestry and Fisheries \(MAFF\)](#)

## Relevant laws/regulations:

- [The Food Sanitation Act \(FSA\)](#)
- [Specifications and Standards for Foods, Food Additives, etc. Under the FSA](#)
- [MHLW Notice on Control of Unapproved Medicine \(Japanese\)](#)

## 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.

## Common Concerns

- **Food additive** regulations are very strict. Japan has approved only about 800 additives (excluding natural flavorings), while the US FDA has approved around 1,600 additives.

## Key Contacts

- **ATO Tokyo**  
E-mail: [atotokyo@usda.gov](mailto:atotokyo@usda.gov)
- [11 Quarantine Stations under MHLW](#) offer Prior Consultation for importers (Japanese only). See Step 2-7
- [MIPRO](#) also provides free phone consultation.

# Confirm Legal Compliance regarding Food Additives

Japan has a **Positive List System for food additives**, which means a food additive is not permitted at all unless MHLW has specifically approved it.

Food additives, according to the Japanese definition, include **vitamins, minerals, amino acids, flavors, colors** and **post-harvest agrochemicals** (e.g., anti-mold agents for produce).

For some food additives, MHLW defines allowable standards, including accepted usages, target food products and tolerance levels.

The most common reasons for US processed foods to be found ineligible for import are inclusion of unapproved additives or having additives that exceed allowable standards.

## Steps to Take:

- ❑ 2-1-1 Confirm that all food additives contained in your product are listed in one of the MHLW's lists of authorized additives. (See column on the right)
- ❑ 2-1-2 Confirm that all food additives contained in your product meet allowable standards. For such ingredients, add a note in your Ingredient List explaining that this ingredient meets the FSA standards.

## What if some additives contained in your product are not listed or do not meet the standards for use?

- ❑ Consider reformulation to avoid using non-listed food additives.
- ❑ Contact the ATO Tokyo for further help if you are considering requesting Japan's approval for a new food additive.

Some recent cases involving **food additives** in US products:

### Unlisted additives

- Potassium Iodide
- TBHQ
- Stearoyl sodium lactate
- Sodium aluminum phosphate
- Zinc oxide, etc.

### Listed, but often does not meet allowable FSA standards (accepted usage, tolerance levels, etc.)

- Potassium sorbate, etc.

## MHLW's lists of authorized additives by category, but not limited to:

### 1) Designated additives (post 1995)

- Designated by MHLW based on Article 10 of FSA.
- The list (472 in total as of Jan 15, 2021) is here: <http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/page/s/list-desin.add-x>  
Standards for use are here: <http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/page/s/stanrd.use>

### 2) Existing food additives

- Additives that had already had a long history of use for human consumption in Japan at the time of the FSA revision in 1995.
- The list (365 in total) is here: <http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/page/s/list-exst.add>  
Standards for use are here: <http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/page/s/stanrd.use>

### 3) Natural flavoring agents

- Natural agents derived from animals/plants and used as flavoring. No designated standards for use, if used as flavoring.
- The list (612 in total) is here: <http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/page/s/list-nat.flavors>

### 4) Ordinary foods used as food additives

- The list of foods (e.g., strawberry juice, agar) which can be used as additives. No designated standards for use
- The list (abt. 100 in total) is here: <http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/page/s/list-general.provd.add>

# Confirm Legal Compliance regarding Product-specific Standards

## Frozen food standards

Specific standards for frozen foods are outlined under The Food Sanitation Act (FSA). Some specific examples of FSA frozen food standards which would be important for US suppliers include:

- Frozen food to be consumed without heating, and frozen food to be consumed after heating:  
Bacterial count – max. 100,000 per gram; E. coli – no detection; must be stored at below -15°C
- Frozen food other than above:  
Bacterial count – max. 3,000,000 per gram; E. coli – no detection; must be stored at below -15°C

## Milk and dairy standards

If your product contains milk, check the dairy standards in MHLW's Ministerial Ordinance on Ingredient Specifications for Milk and Dairy Products.

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

## Steps to Take:

- 2-2-1 Confirm that your product meets the FSA's frozen foods standards
- 2-2-2 Confirm that dairy ingredients meet MHLW specific standards for milk and dairy products
- 2-2-3 Talk with your importer about hygienic control planning and contamination risk planning

## List of Product-specific Standards:

### 1) Product specific standards under the FSA (23 products, including frozen foods)

- Product Specific Standards under the FSA are summarized here (English):  
[https://www.jetro.go.jp/ext\\_images/en/reports/regulations/pdf/foodext2010e.pdf](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](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/shokuhin/jigyousya/shokuhin_kika_ku/index.html)

### 2) Milk and dairy products

- Ministerial Ordinance on Ingredient Specifications for Milk and Dairy Products is found here (Japanese only):  
[https://elaws.e-gov.go.jp/search/elawsSearch/elaws\\_search/lsg0500/detail?lawId=326M50000100052](https://elaws.e-gov.go.jp/search/elawsSearch/elaws_search/lsg0500/detail?lawId=326M50000100052)

## Some examples of legal non-compliance in US frozen breads regarding product-specific standards:

- Exceeding the allowable standards for bacteria count

## Confirm Legal Compliance regarding Agricultural Biotechnology

### Foods and Food Additives Derived from Agricultural Biotechnology

MHLW regulates food products derived from agricultural biotechnology in two ways: genetically modified (GM) products and genome edited products. For MHLW's definitions of these technologies, refer to the following links.

- Genetically modified:  
[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou\\_iryou/shokuhin/idenshi/index\\_00002.html](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/idenshi/index_00002.html)
- Genome edited  
<https://www.mhlw.go.jp/content/000550824.pdf>

Food which is genetically modified (GM) or food products that include GM ingredients or products derived from GM microorganisms, must be approved by MHLW. Currently, the major GM crops commercially grown in the US have already been approved by MHLW but be aware of potential risks related to the speed of future approvals.

Food which is genome edited or food products that include genome edited ingredients or products derived from genome edited microorganisms require the importer to conduct prior consultation with MHLW. MHLW may require notification, depending on their judgement about the product. Foods manufactured and processed using previously notified foods derived from genome editing technology do not require notification.

For further information, contact the ATO Tokyo.

#### Steps to Take:

- 2-3-1 Your product should not contain any unapproved GM products or ingredients derived from unapproved GM microorganisms
- 2-3-2 Tell your importer if your product contains food or food additives produced by genome editing technology. MHLW may ask that additional information be submitted by the importer.

#### MHLW's list of authorized GM products:

- The list of GM products that have undergone MHLW's safety assessment is found here:  
<https://www.mhlw.go.jp/english/topics/food/index.html> (Refer to 'Section 2. List of the Products')

#### MHLW's instructions related to food products derived from genome editing technology:

- Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing, Dec 2020 Technology (English) is found here:  
<https://www.mhlw.go.jp/content/000550824.pdf>
- FAS Attaché reports related to this topic are found here:
  - <https://www.fas.usda.gov/data/japan-mhlw-updates-genome-editing-handling-procedures-crossbred-progeny>
  - <https://www.fas.usda.gov/data/japan-policies-and-procedures-genome-edited-food-and-agricultural-products>

# Confirm Legal Compliance regarding Other Ingredient Issues

## Contamination of Harmful Substances

Contamination by **naturally harmful substances** and **pathogens** can also 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. So, it is recommended that manufacturers consult with Quarantine Stations in advance if there is any question of a harmful substance being detected in a food product.

### Steps to Take:

- 2-3-4 Talk with your importer about contamination risk planning if your product could contain any of these harmful substances

## CITES (Convention on International Trade in Endangered Species of Wild Fauna and Flora) list

CITES is an international treaty that regulates the world's wildlife trade. If your product includes CITES-listed ingredients, it is necessary to declare non-violation of the treaty.

### Steps to Take:

- 2-3-5 Check whether any of your product ingredients are listed in CITES.
- 2-3-6 If your product uses CITES-listed products, declare that it does not violate the treaty in your Ingredient List prepared in Step 1, such as "The vanilla in this product is from cultivated plants."

### Examples of harmful substances by category:

#### 1) Naturally harmful products

- Food containing toxic substances (such as mycotoxins, cyanide, etc.) shall NOT be sold in Japan.

#### 2) Pathogenic microorganisms

- Food containing pathogenic microorganisms shall NOT be sold in Japan:
  - Salmonella (meat, cheese, ice cream, fresh and frozen seafood, egg, frozen food, spice, nuts)
  - Shigella (seafood, frozen food), etc.

#### 3) Other harmful products

- Food containing the substances (such as mercury, PCB, etc.) shall NOT be sold in Japan.

#### 4) Decomposed or deteriorated foods/ingredients

### CITES list:

- METI's regulations regarding imports of goods related to CITES are found here: [http://www.meti.go.jp/english/policy/external\\_economy/CITES/cites\\_imports.html](http://www.meti.go.jp/english/policy/external_economy/CITES/cites_imports.html)
- You can search the CITES list by scientific name here: <https://speciesplus.net/>

2-4

# Confirm Legal Compliance regarding Manufacturing Process and Packaging

## Irradiation

Irradiation is generally prohibited for foods sold in Japan. In some cases, products that meet US standards for irradiation have been rejected in Japan.

### Steps to Take:

- 2-4-1 Confirm that your manufacturing process does not use irradiation.

## Food packaging

The Food Sanitation Act introduced a positive list system for materials allowed for food packaging. This means only packaging materials whose safety has been assessed by MHLW, and which MHLW has designated for use, are permitted in the Japanese market. Synthetic resins, metal cans, rubber glass, ceramic and enamel must meet certain specifications (Refer to the box on the right).

### Steps to Take:

- 2-4-2 Confirm that your packaging material is included in the approved list and meets the packaging standards.

## Wood pallets

Note that wood pallets must be fumigated and be certified by the American Lumber Standard Committee (ALSC) and the National Wooden Pallet and Container Association (NWPCA). The International Plant Protection Convention (IPPC)'s International Standards for Phytosanitary Measures Guidelines for Regulating Wood Packaging Material in International Trade (ISPM 15) regulates this protocol.

### Steps to Take:

- 2-4-3 If you use wood pallets, confirm that the wood pallets are all fumigated and have an ISPM 15 treatment certification stamp.

### The positive list of packaging materials:

- The positive list including English names and CAS registry numbers is available here. (The original "Appended Table 1" in Japanese was split into two tables.)
  - <https://www.mhlw.go.jp/content/000638979.xlsm>
  - <https://www.mhlw.go.jp/content/000635348.xlsx>
- For further instructions, refer to:
  - [https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou\\_iryuu/shokuhin/kigu/index\\_00003.html](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/shokuhin/kigu/index_00003.html)

### Standards of packaging materials:

- The packaging standards for synthetic resins, metal cans, rubber, glass, ceramic and enamel are found here:
  - <https://www.ffcr.or.jp/en/kigu/index.html>

### IPPC standard:

- ISPM 15 and applicable Japanese regulations are explained here:
  - [http://www.maff.go.jp/pps/j/konpozai/faq\\_eng\\_2009\\_12.html](http://www.maff.go.jp/pps/j/konpozai/faq_eng_2009_12.html)
- For more details, refer to the instruction at National Wooden Pallet & Container Association
  - [https://www.palletcentral.com/page/ISPM\\_15](https://www.palletcentral.com/page/ISPM_15)

2-5

## 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.

### Step to take:

- 2-5 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](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](https://www.forth.go.jp/keneki/tokyo/kanshi_hp/a013.html) (Japanese)



# 3 Confirm Tariff Classification, Customs Duty, Levy and Country of Origin Regulations under the USJTA

Check your product's tariff classification in the most recent Japanese Tariff Schedule under the US Japan Trade Agreement (USJTA) 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 receive the preferential duty rate under the USJTA, check the regulations related to Country of Origin and help your importer prepare the document required to confirm that your products meet the country of origin criteria.

## Steps to Take:

- 3-1 Check tariff classification and confirm the customs duty and levy imposed on your products under the USJTA.
- 3-2 Check Country of Origin Regulations and help your importer to prepare the Origin Declaration Document and other supplementary documents to receive benefits from the preferential duty under the USJTA.

## Whose responsibility is this?

The **importer** is responsible, but the manufacturer/exporter should be familiar with the process, and should provide the importer with the necessary data for the documents to confirm Country of Origin

## 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 Agriculture, Forestry and Fisheries \(MAFF\)](#)

## Related laws/regulations

- [Customs Act](#) (Japanese only)
- [Act on Stabilization of Supply, Demand and Prices for Staple Food](#) (Japanese only)
- [Trade Agreement between Japan and the United States of America](#) (English)

## 3-1

# Confirm Tariff Classification, Customs Duty, Levy under the USJTA

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>

For the preferential duty rate under the USJTA, look under the column "JP-US Trade Agreement".

If the share of wheat, rice flour and/or starch accounts for 85% or more of the total weight of your product, the importer may need to pay a **levy** to the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) based on the Act on Stabilization of Supply, Demand and Prices for Staple Food. If your product is subject to a levy, the importer is required to send an application to MAFF and proceed payment of the levy prior to import clearance.

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:

- 3-1-1 Check tariff classification and confirm the customs duty and levy imposed on your products.
- 3-1-2 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 Agriculture, Forestry and Fisheries \(MAFF\)](#)

## Related laws/regulations

- [Customs Act](#) (Japanese only)
- [Act on Stabilization of Supply, Demand and Prices for Staple Food](#) (Japanese only)
- [Trade Agreement between Japan and the United States of America](#) (English)

## Best Practices

- Check the tariff classification carefully because the Japanese classification can be different from the US classification.
- The product classification, particularly for processed products, can differ depending on the ratio of ingredients. Getting an Advance Ruling is especially useful for processed products to avoid spending time at the port of entry trying to confirm the product category.
- Tariffs for competing suppliers can also be checked.

## Common Concerns

- Importers may require the ratios of ingredients in order to obtain Advance Ruling. For further information, contact [ATO Tokyo](#) Email: [atotokyo@usda.gov](mailto:atotokyo@usda.gov)

## Contact Information for Advance Ruling

- Advance Ruling is available at **9 regional Customs offices**. Contacts (in Japanese) for Customs Duty Advance Ruling: <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

# 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. If your product qualifies as an originating product as defined by the USJTA, please use the rate in the "USJTA" column in the table below.
- Based on the USJTA, tariffs on some products will gradually be reduced over time. New tariff reductions go into effect every year on April 1<sup>st</sup>. Check the most recent tariff schedules [here](#).

Tariff Schedule				
Import HS Code	Description	Tariff		
		As of April 1, 2021		As of April 1, 2022
		WTO bound rate	USJTA	USJTA
190590100	Bread, ship's biscuits and other ordinary bakers' wares, not containing added sugar, honey, eggs, fats, cheese or fruit	9%	4.5%	3.3%
190590319	Other, containing added sugar	25.5%	8.5%	4.2%
190590329	Other, other	21.3%	7.1%	3.5%

## 3-2 Confirm Country of Origin Regulations and Prepare Origin Declaration Document

In order to receive preferential tariff treatment under the US-Japan Trade Agreement, food products must meet one of the following criteria;

- Foods that are wholly obtained or produced in the US (**WO**)
- Food products produced exclusively in the US using US and/or Japanese ingredients (**PE**)
- Food products produced in the US using non-US or Japanese ingredients, providing the final product results in the necessary HS code transformation (**PSR**).

Even if a product contains materials of non-US or non-Japanese origin and does not fulfill the HS Code transformation to qualify as **PSR**, the product may still receive preferential tariff treatment under the de minimus criteria (**DMI**) if the value of the non-US or non-Japanese materials does not exceed ten percent of the value of the final product. More details can be found here: [USJTA Rules of Origin and Origin Procedures](#)

To receive preferential treatment, importer needs to submit an Origin Declaration Document and a Detailed Origin Declaration Document. In addition, supplementary documents such as invoices of all ingredients and a manufacturing flow chart may also be requested. In order to expedite the origin declaration process, as well as to confirm whether your product is eligible for the preferential treatment, your importer may get an Advance Ruling from the Customs office.

### Steps to Take:

- 3-2-1 Check whether your product is eligible for the preferential tariff under the USJTA.
- 3-2-2 Provide your importer with information for making the Origin Declaration Document, Detailed Origin Declaration Document and other supplementary documents.

### Whose responsibility is this?

The **importer** is responsible. However, if Customs requests supplemental material from the importer, these supplementary documents can be provided to Customs directly from the exporter or producer.

### Responsible government agency

- [Japan Customs](#)

### Related laws/regulations

- [Trade Agreement between Japan and the United States of America \(English\)](#)

### Best Practices

- By using the Advance Ruling system, it is possible to know in advance whether or not preferential tariffs will be applied. This helps manufacturers and exporters in planning their costs and developing their sales strategies. In addition, Advance Ruling may allow for smoother customs clearance.

### Format of the Documents

- The format for the Origin Declaration Document and Detailed Origin Declaration Document are available here: <https://www.customs.go.jp/roo/procedure/index.htm> (Japanese)

### Contact Information for Advance Ruling about Country of Origin

- Advance Ruling is available at **9 regional Customs offices**. Contacts (in Japanese) for Country of Origin Advance Ruling: <http://www.customs.go.jp/question2.htm#c>
- **What information must be submitted?**
  - Inquiry form (C-1000-2, Japanese)
  - This may include reference materials such as detailed ingredient list, manufacturing process chart, price lists samples, photographs, drawings as requested by Customs or recommended by your importer.

3-2

## Sample of Origin Declaration Document

This document can be prepared in English or Japanese. There is no required format but should include the information below.

### Origin Declaration Document (USJTA)

1. Exporter Name and Address XYZ Foods Ltd. 123 Woodland Avenue, City, State, ZIP, United States			
2. Producer Name and Address Same as above			
3. Importer Name and Address Meros Trading 1-19-3. Kanda Awajicho, Chiyoda-ku Tokyo, 101-0063 03-3526-3075			
No.	4. Products Detail (Name and Invoice #)	5. HS Code (6 digits)	6. Criteria
1	XYZ Brand Frozen Plain Bagel, 6 pcs (510g); XYZ-9876543 Invoice: ABC-D-1234 (2020.1.15)	1905.90	PE
7. Other Remarks			
8. Name & Address Meros Trading 1-19-3. Kanda Awajicho, Chiyoda-ku Tokyo		Date 2020/01/28	

Importer's  
address must  
be in Japan

List each product  
separately

Choose the applicable  
criteria (WO, PE, PSR) and  
if needed also note DMI

3-2

## Sample of Detailed Origin Declaration Document

This document must be prepared in Japanese. There is no required format but should include the information below.

### Example of Detailed Specification Declaration of Origin (USJTA) (Write in Japanese Only)

1. Invoice Number and Date ABC-D-1234 (2020.1.15)	
2. Product Number on Origin Declaration Document Same as above	3. HS Code 1905.90
4. Criteria <input type="checkbox"/> WO <input checked="" type="checkbox"/> PE <input type="checkbox"/> PSR <input type="checkbox"/> DMI	
5. Explanations why the product satisfies above criteria <Ingredients> 1. Wheat flour: Produced in the US 2. Sugar: Produced in the US 3. Cornmeal: Produced in the US 4. Salt: Produced in the US 5. Yeast: Made in the US 6. Gluten: Made in the US 7. Vinegar: Produced in the US 8. Thickener (Guar gum): Made in the US <Manufacturing process> To manufacture the product, the above ingredients are mixed, retarded and fermented after being placed into molds at the factory in the United States. After being frozen, the product is packaged. <Criteria> Ingredients 1-8 are all originating materials under USJTA. Since the product is produced exclusively from these materials in the United States, it is a US originating material under USJTA. These facts can be seen in the attached documents.	
6. Other Remarks	
7. Name & Address Meros Trading 1-19-3. Kanda Awajicho, Chiyoda-ku Tokyo	Date 2020/01/28

Check one of the three criteria: WO, PE or PSR. If you check PSR and DMI is applicable, check DMI as well.

Explain how the product fulfills the criteria:

- **WO:** Facts confirming that the food was wholly obtained in the US
- **PE:** Facts confirming that the food product was produced in the US using only US and/or Japanese ingredients
- **PSR:** Facts confirming that the food product was produced in the US using non-US or non-Japanese ingredients, providing the final product results in the necessary HS code transformation
- **DMI:** Facts confirming that the value of the non-US or non-Japanese materials does not exceed ten percent of the value of the product

More samples of Detailed Origin Declaration Documents can be found here, [USJTA Rules of Origin and Origin Procedures](#)

# 4 Create a Product Label

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

Generally, a product label is prepared by the importer with information from the exporter /manufacturer. However, the manufacturer will, at times, create the design if they want to print directly on the original packaging.

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 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 \(MOE\)](#)
- [some product-specific labeling standards, like chocolate, ice cream, cheese, whiskey, dressing, biscuit and fruit juice]: [Fair Competition Code](#) (Japanese only), Federation of Fair Trade Conferences / [Ministry of Economy, Trade and Industry \(METI\)](#)
- [organic claims]: [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@usda.gov](mailto:atotokyo@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/](https://www.caa.go.jp/policies/policy/food_labeling/information/contact/)

# Product Label

## Contents and Key Issues

### A food product label should include:

- a. **Name of the product**
- b. **Ingredients**, other than additives, in descending order in weight.
- c. **Food additives**, in descending order of weight, and on a separate line from other ingredients
- d. **Net weight**, in metric units only
- e. **Shelf life** (Best-before date or use-by date)
- f. **Storage instructions**
- g. **Country of origin**, of the finished product
- h. **Info. of the importer**, name and address
- i. **Allergen information**
- j. **Nutrition contents**
- k. **Recycling symbol**

### Key Issues to be considered:

#### e. Shelf life:

- The shelf life should be shown in one of the following two ways: **best-before date** or **use-by date**. The explanation is found here: [https://www.caa.go.jp/en/policy/food\\_labeling/assets/food\\_labeling\\_210511\\_0001.pdf](https://www.caa.go.jp/en/policy/food_labeling/assets/food_labeling_210511_0001.pdf)
- Most wholesalers/retailers require that at least half the shelf-life indicated on the label remains when they receive an imported product. Furthermore, most will not accept products whose expiration date is earlier than the expiration date of the shipment they previously received.

#### i Allergen information

- Notify the importer about the possibility of contamination by any of the seven allergens whose labeling is mandatory: shrimp, crab, wheat, buckwheat, egg, dairy products, and peanut.

#### j. Nutrition contents:

- Notify the importer about 1) calories (kilocalories); 2) protein (grams); 3) fat (grams); 4) carbohydrate (grams); and 5) sodium (salt equivalent grams). The size of one unit of food can be decided by the labeler, but must be specified (e.g., 100 g, 100 ml.). From 2020, nutritional labeling will be mandatory for these 5 elements.
- The US nutritional fact panel is not acceptable, and labels must use the Japanese format.

#### k. Recycling symbol:

- Notify the importer about the packaging materials used. The importer is required to cover all costs associated with recycling of the packaging.
- The recycling symbol (aluminum, steel, paper, plastic and PET) must be printed on the packaging.

### Other Areas You May Need to be Familiar with:

#### GM labeling:

- GM labeling is required for certain products which use soybean, corn, potato, alfalfa, sugar beet and papaya (See Table 4 of [USDA FAS Report](#)) if the GM ingredient is within the top three ingredients by volume and more than five percent of total weight. Changes to GM labeling requirements will go into effect in April 2023. More information on these upcoming changes can be found [here](#). Contact ATO Tokyo for further information.

#### Nutritional and health claims:

- Japan has strict rules on functional and nutritional claims on food labeling. Refer to page 10 of [USDA FAIRS report](#).

#### Organic claims:

- Japan's organic food standards were established in the Japan Agricultural Standards (JAS). The US and Japan have an equivalency arrangement for organic plant products. The further details of the equivalency arrangement can be found here:

USDA AMS, Organic Certification, International Trade Policies: Japan  
<https://www.ams.usda.gov/services/organic-certification/international-trade/Japan>



## 4-1

# Sample of a Product Label

## Frozen Plain Bagel

Name of product:	Frozen bagel
Ingredients:	Flour, sugar, cornmeal, salt, yeast, gluten, brewed vinegar/Thickener (guar gum), emulsifier
Net weight:	6 pcs (510g)
Best-before date:	Shown on the lower right
Storage instruction:	Store at below -18 degrees C.
Heat treatment	Heat treated before freezing process
Necessity of heat cooking	Heat before consuming
Country of origin:	United States
Importer:	Meros Trading 1-19-3, Kanda Awajicho, Chiyoda-ku, Tokyo

- How to prepare: Place the frozen bagel in a preheated toaster oven (1300W), toast for about 2.5 minutes until it becomes light brown. Turn off the oven and keep the bagel in the warm oven for about 4 more minutes.
- Manufactured in a facility that uses peanuts.
- Best-before date indicates the period for which quality will be maintained when stored in an unopened state.
- Refreezing after thawing will result in inferior quality.
- Contact Tel. 03-3526-2075

- The Food Labeling Law (April 2020) requires ingredients and additives to be listed separately.
- They can be written on two separate lines:  
Ingredients: Flour, sugar, ...  
Food additives: Thickener, ...
- You can also list them on one line. Use a backslash "/" between the ingredients and additives, as shown here.

### Nutrition Information per 100g

Calories	250	Kcal
Proteins	10	g
Fat	1.5	g
Carbohydrates	49	g
Salt Equivalent	1.1	g

Recycling symbol:  
plastic

Best before date:  
Apr 1, 2022

- The order is Year.Month.Date.
- Other variations allowed include: "2022.4.1.", "20220401", "2022年4月1日".
- If the expiration period is longer than three months, the date can be written as Year and Month only: 2022.4, 22.4 or 2204.

## プレーンベーグル(要冷凍)

名称:	冷凍パン
原材料名:	小麦粉, 砂糖, コーンミール, 食塩, イースト, グルテン, 醸造酢/増粘剤(グァーガム), 乳化剤
内容量:	6個(510g)
賞味期限:	この面右下に記載
保存方法:	-18°C以下で保存してください。
原産国名:	アメリカ
凍結前加熱の有無:	加熱してあります。
加熱調理の必要性:	加熱してお召し上がりください。
輸入者:	東京都千代田区神田淡路町1-19-3 株式会社メロス貿易

- お召し上がり方: ①予熱したオーブントースター(1300W)で、凍ったままの本品を薄いきつね色になるまで約2分半焼きます。②そのまま庫内に置き、予熱で約4分温めると出来上がりです。
- ピーナッツを使用した工場で製造しています。・賞味期限は、未開封の状態での保存された場合に品質が保たれる期限です。・一度解けた本品を再び凍らせると、品質が変わり風味が落ちることがありますのでご注意ください。・お問合せ先: 03-3526-2075

### 栄養成分(内容量100gあたり)

エネルギー	250	Kcal
たんぱく質	10	g
脂質	1.5	g
炭水化物	49	g
食塩相当量	1.1	g



賞味期限  
2022.04.01

# 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 the 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 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](mailto: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](mailto: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 a Certificate of Analysis

7. Clear export customs

# 6 Obtain a Certificate of Analysis

A Certificate of Analysis is a document that certifies the results of the required laboratory testing.

In order to be exempted from food safety inspections by the Quarantine Station upon arrival and to shorten the time required for import clearance, it is possible to get a Certificate of Analysis from a MHLW-certified laboratory in the US.

However, this is not a common practice, except for agrochemical residue testing for fresh produce and food additive testing for wine.

For fresh produce, it is a common practice to obtain a Certificate of Analysis which includes results of agrochemical residue testing.

For wine, it is a common practice to obtain a Certificate of Analysis (Analysis Report) which includes the results of food additive testing, especially for sulfur dioxide and sorbic acid.

If you do wish to obtain a Certificate of Analysis in advance, it is necessary to confirm what laboratory tests will be required with the Quarantine Station. Advance laboratory testing could target:

- Artificial coloring
- Artificial preservatives
- Additives which have maximum usage limits
- Agrochemical residues, etc.

## Step to take:

- 6-1 If the importer requests it, obtain a Certificate of Analysis from a MHLW-registered lab in the US. **This process is optional.**

## Whose responsibility is this?

**Manufacturer / exporter**, upon request from the importer

## Timeframe / Cost

- Check with the laboratory you have chosen

## Key Contacts

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

## Where to obtain a Certificate of Analysis?

- **US laboratories registered with MHLW.**
- The list is found here:  
<https://www.mhlw.go.jp/topics/yunyu/5/dl/a3.pdf>

# 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/phytosanitary 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

## 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 food safety quarantine procedures
- ❑ 9. Clear import customs

### After Import Clearance

Food safety issues faced after Import Clearance





# 8 Clear Food Safety Quarantine Procedures

Import clearance starts with clearing food safety inspections at the **Quarantine Station**. This step checks legal compliance with food standards (See Step 2).

## Steps to take:

- 8-1 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.
- 8-2 Undergo document examination and on-the-spot examination by the quarantine officials.
- 8-3 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.*
- 8-4 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](mailto: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](https://www.mhlw.go.jp/english/policy/health-medical/health/dl/contact_list_jqs.pdf)

# 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:

- **Food additives:** artificial coloring, preservatives, additives which have maximum tolerance levels, and additives which have had issues in the past;
- **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
- **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/kenkou\\_iryuu/shokuhin/jigyousya/kikan/index.html](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_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

# 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](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.

### Contacts of MHLW-registered laboratories

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

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou\\_iryuu/shokuhin/jigyousya/kan/index.html](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/shokuhin/jigyousya/kan/index.html)

# 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](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

# 9 Clear Import Customs

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

## Steps to take:

- ❑ 9-1 Submit Import Declaration (and Origin Declaration Document, if applicable) 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.
- ❑ 9-2 Clear document examination
- ❑ 9-3 Clear on-the-spot **Customs Inspections** (See the right column), if required
- ❑ 9-4 Pay the import tax and consumption tax
- ❑ 9-5 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

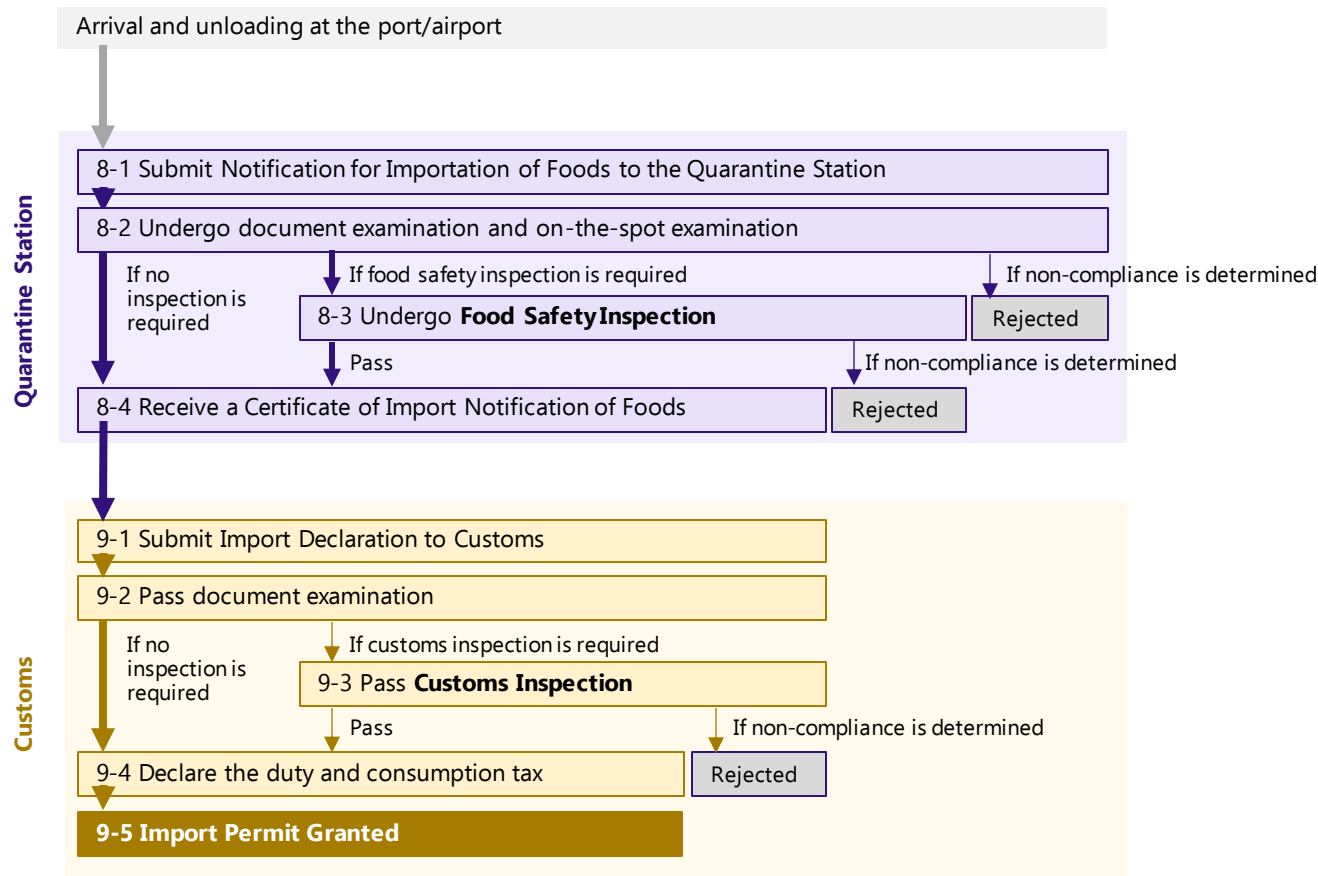
- **What will be inspected?**
  - Prohibited items such as drugs, guns, counterfeits
  - The Inspection Certificate and the Certificate of Import Notification of Foods in order (if they are required)
  - Indications of misrepresentation or misleading in regards to the place of origin
  - Whether or not 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](http://www.customs.go.jp/question_e.htm)

# Summary

## Import Clearance Flow



### 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)

- *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](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](mailto:atotokyo@usda.gov)

#### **Agricultural Trade Office (ATO), Tokyo**

Embassy of the United States of America, Tokyo, Japan

E-mail: [atotokyo@usda.gov](mailto: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](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](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](mailto: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](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>

### Levy

Grain Trade and Operation Division,  
Crop Production Bureau  
Tel: (011-81-3) 6744-1257  
[http://www.maff.go.jp/j/seisaku\\_tokatu/boeki/kome\\_yunyu.html](http://www.maff.go.jp/j/seisaku_tokatu/boeki/kome_yunyu.html)

### Organic JAS Standard

Standards and Conformity Assessment Policy Office,  
Food Manufacture Affairs Division, Food Industry Affairs Bureau  
Tel: (011-81-3) 6744-7180  
[https://www.maff.go.jp/j/jas/jas\\_kikaku/yuuki.html](https://www.maff.go.jp/j/jas/jas_kikaku/yuuki.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/](https://www.caa.go.jp/en/policy/food_labeling/)