

General Food Export Guide to Japan

December, 2021

Agricultural Trade Office (ATO), Tokyo
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Mon-Fri 8:30 AM -5:30 PM in Japan Standard Time



General Food Export Guide to Japan

December, 2021

Prepared for the Agricultural Trade Office
U.S. Embassy, Tokyo, Japan

Prepared by



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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 **#0 General Guide**.

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. Prepare an Ingredient List and a Manufacturing Process Flowchart
- ❑ 2. Check the sanitary/phytosanitary requirements that apply to your product
- ❑ 3. Confirm legal compliance with food standards and other regulations
- ❑ 4. Check the tariff classification and customs duty
- ❑ 5. Create a product label
- ❑ 6. Register trademarks and other intellectual property rights

B. Embarkation

- ❑ 7. Obtain a Sanitary/Phytosanitary Certificate and a Certificate of Analysis
- ❑ 8. Clear export customs

C. Import Clearance

- ❑ 9. Clear sanitary/phytosanitary inspection
- ❑ 10. Clear food safety quarantine procedure
- ❑ 11. 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. Prepare an **Ingredient List** and a **Manufacturing Process Flowchart**
- 2. Check the **sanitary/phytosanitary requirements** that apply to your product
- 3. Confirm **legal compliance with food standards** and other regulations
- 4. Check the **tariff classification** and customs duty
- 5. Create a **product label**
- 6. 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 4).

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
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 3).
- [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 14):
 - **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 Marie Biscuits 180 g

Manufacturer: XYZ Foods Ltd.

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

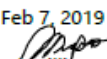
Factory: XYZ Foods Park Avenue Factory

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

INGREDIENTS:	Share
Wheat flour	54.6%
Vanilla flavored cream (sugar, vegetable oil (palm), whole milk powder, whey powder, emulsifier (sunflower lecithin), flavoring (Vanillin: 4-Hydroxy-3-Methoxybenzaldehyde, meets FSA standards.)	20.0%
Vegetable oil (palm)	8.2%
Sugar	6.3%
Glucose-fructose syrup	3.5%
Raising agent (sodium carbonate, ammonium carbonate)	2.2%
Whey powder	1.8%
Salt	1.6%
Emulsifier (sunflower lecithin)	1.1%
Flavoring (Vanillin: 4-Hydroxy-3-Methoxybenzaldehyde, meets FSA standards.)	0.698%
Antioxidant (sodium metabisulfite: less than 0.02g/kg)	0.002%

Allergen:
Contains gluten, milk and sulfites. May contain traces of soya 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.** Share by weight 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 4). 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 except for preventing potato germination.*



- 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 Check the Sanitary Requirements that Apply to Your Product

Meat and organs, bone, fat, egg, milk and dairy products, as well as some live seafood are all subject to animal health quarantine. Some processed products whose ingredients include the aforementioned products could also be subject to animal health quarantine, depending on the degree of processing and packaging.

Certain meats and/or products containing those meats are currently prohibited or have special requirements (i.e., on-site audits, restriction on antimicrobial agents, etc.) The sanitary requirements on meat products can be found here:

<https://www.fsis.usda.gov/inspection/import-export/import-export-library/japan>

<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/iregs-for-animal-product-exports/sa-international-regulations/sa-by-country/sa-jct-product-japan>

If meat or dairy products are eligible for exportation to Japan, a USDA Sanitary Certificate must accompany the shipment. (See Step 7)

Compliance with sanitary requirements will be examined in the Sanitary Inspection at the Animal Quarantine Service under MAFF (See Step 9) as well as in the food safety inspection at the Quarantine Station under MHLW (See Step 10).

Steps to Take:

- 2-1 Confirm that your product is eligible for export to Japan under sanitary regulations.
- 2-2 Confirm sanitary requirements that apply to your products.
- 2-3 Have your importer confirm those requirements through Prior Consultation at the Animal Quarantine Service office under MAFF and the Quarantine Station under MHLW that oversee the port of entry planned for your product.

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:

- [Animal Quarantine Service, Ministry of Agriculture, Forestry and Fisheries \(MAFF\)](#)
- [Quarantine Stations, Ministry of Health, Labour, and Welfare \(MHLW\)](#)

Relevant laws and regulations:

- [Act on Domestic Animal Infectious Diseases Control \(Japanese\)](#)
- [The Food Sanitation Act \(FSA\)](#)

Best Practices

- Some US products cannot be exported to Japan due to sanitary regulations. Therefore, it is best to investigate this area early in your export planning.
- USDA APHIS and FSIS maintain a registry of exporter requirements but work closely with your importer to check the sanitary requirements in detail.
- Be aware that cheese and other dairy products were recently added to the list of livestock products that must receive sanitary authorization.

Key Contacts

- **ATO Tokyo**
E-mail: atotokyo@usda.gov
- **USDA contact points** for exporters are:
 - Your local Service Centers, Veterinary Services, Animal and Plant Health Inspection Service (APHIS), USDA
https://www.aphis.usda.gov/animal_health/contact/field-operations-export-trade.pdf
 - Export Program Staff, Food Safety Inspection Service (FSIS), USDA
Tel: (202) 720-0082 or (855) 444-9904
https://www.aphis.usda.gov/animal_health/contact/field-operations-export-trade.pdf

Contact Information for Prior Consultation

- [29 Animal Quarantine Service offices under MAFF](#) and [11 Quarantine Stations under MHLW](#) offer Prior Consultation for importers (Japanese only).

2 Check the Phytosanitary Requirements that Apply to Your Product

Plant-based products are subject to phytosanitary quarantine inspection, except for certain exempted products including some dried fruits and pickled plants.

Certain fresh fruit and vegetables are currently prohibited or have special requirements (i.e. fumigation, restrictions on production area, field inspection requirements). Phytosanitary regulations by plant and country of origin can be found in this searchable MAFF database:
<http://www.pps.go.jp/eximlist/Pages/exp/conditionE.xhtml>

A USDA Phytosanitary Certificate must accompany shipments of fresh produce, but a Certificate is not required for most dried or frozen products.

Compliance with phytosanitary requirements will be discussed in Step 9, Phytosanitary Inspection at the Plant Protection Station under MAFF

Steps to Take:

- 2-1 Confirm that your product is eligible for export to Japan under phytosanitary regulations.
- 2-2 Check the phytosanitary requirements that apply to your products.
- 2-3 Have your importer confirm these requirements through Prior Consultation at the Plant Protection Station that oversees the planned port of entry of your product.

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:

- [Plant Protection Stations](#) (Japanese), [Ministry of Agriculture, Forestry and Fisheries \(MAFF\)](#)

Relevant laws and regulations:

- [Plant Protection Act \(Japanese\)](#)

Best Practices

- Some US products cannot be exported to Japan due to phytosanitary regulations. Therefore it is best to investigate this area early in your export planning.
- USDA APHIS maintain a registry of exporter requirements, but work closely with your importer to check the phytosanitary requirements in detail.

Key Contacts

- [ATO Tokyo](#)
E-mail: atotokyo@usda.gov
- **USDA contact points** for exporters are:
 - Your local Export Certification Specialists, Animal and Plant Health Inspection Service (APHIS), USDA
https://www.aphis.usda.gov/aphis/ourfocus/planthealth/SA_Export/SA_ECS
 - Trade Directors, Phytosanitary Management, APHIS, USDA
Contacts are here:
https://www.aphis.usda.gov/import_export/plants/plant_exports/downloads/trade_directors_areacoverage.pdf

Contact Information for Prior Consultation

- [5 main offices of Plant Protection Stations under MAFF](#) offer Prior Consultation for importers. (Japanese only)

3 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 10, in Food Safety Inspection at the Quarantine Station under MHLW.

Steps to take:

- ❑ 3-1 (For eligible products) Confirm legal compliance regarding **product-specific standards**
- ❑ 3-2 Confirm legal compliance regarding **food additives**
- ❑ 3-3 Confirm legal compliance regarding **agrochemical residues**
- ❑ 3-4 Confirm legal compliance and risk regarding **contamination by harmful substances**
- ❑ 3-5 Confirm legal compliance regarding **other ingredient issues** (agricultural biotechnology, medicinal ingredients, and CITES), as applicable.
- ❑ 3-6 Confirm legal compliance regarding **manufacturing process and packaging**
- ❑ 3-7 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.
- For fresh/frozen/dried fruit & vegetables, **agrochemical residues** can be a problematic issue, due to the differences in the level of tolerance between the US and Japan. A single violation can lead to 'enhanced monitoring' at quarantine stations, that can affect ALL imports of the same product from the US.
- **Harmful substances (e.g., Mycotoxins)** or **irradiation process** can also lead to US foods being ineligible for importation to Japan.

Key Contacts

- **ATO Tokyo**
E-mail: atotokyo@usda.gov
- **11 Quarantine Stations under MHLW** offer Prior Consultation for importers (Japanese only). See Step 3-7
- **MIPRO** also provides free phone consultation.

3-1

Confirm Legal Compliance regarding Product-specific Standards

Twenty-three products currently have product-specific standards, as outlined in the Product Specific Standards under The Food Sanitation Act. Those with specific standards include, among others:

- **Soft drinks** (Fruit/vegetable juice, Sugar/flavor added water, Mineral water, and Non-alcoholic beverage bases and syrups)
- **Frozen foods** (Frozen fruit/vegetable, Frozen bread, and Frozen prepared food)
- **Fresh fish and shellfish to be eaten raw** (Live seafood)
- **Oysters to be eaten raw** (Live seafood)
- **Food packed in containers and sterilized by pressurization and heating** (Soups, Sauce and Condiments - depending on packaging)

In addition, MHLW defines specific standards for **dairy products**, such as milk solids content, tolerance limits for bacteria count and sanitization methods. If you export dairy products (including Cheese and Ice cream) or products containing dairy products, check the dairy standards in MHLW's Ministerial Ordinance on Ingredient Specifications for Milk and Dairy Products.

The details of these product specific standards are discussed in each product report.

Note that these product-specific standards (including the regulations regarding bacteria count, ingredients, and the sterilization process) are always subject to inspection at quarantine stations.

Steps to Take:

- **3-1** If your product is a subject to product-specific standards, confirm that your product meets these product specific standards.

Some examples of legal non-compliance in US products regarding product-specific standards:

- Exceeding the allowable standards for bacteria count (frozen foods, frozen bread, etc.)
- Detection of coliforms (mineral water, cheese, fruit/vegetable juice, etc.)
- Unmet the standards of sterilization method (flavor added water)
- Offensive odor, foreign objects, exceeding standards for food additive residue, such as Bromic acid, Formaldehyde or Chlorine. (mineral water)

List of Product-specific Standards:

1) 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

2) Product specific standards under the FSA (23 products)

- 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_kikaku/index.html

3-2

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:

- ❑ 3-2-1 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)
- ❑ 3-2-2 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 (gummy candies)
- TBHQ (cookies, chocolate, biscuits)
- Stearoyl sodium lactate (biscuits, dough)
- Methyl parahydroxybenzoate (cookies, syrups)
- Polysorbate (snacks, chocolate, condiments)
- Sodium aluminum phosphate (dough, mixes)
- Zinc oxide (soft drinks, frozen bread), etc.

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

- Imazalil (fresh citrus)
- Tricalcium phosphate (gummy candies)
- Potassium sorbate (dried fruit, frozen bread, flavor added water, condiments, CBD elixir)
- Sulfur dioxide (flavor added water, chocolate, dried fruit, condiments)
- Ester gum (flavor added water)
- Polysorbate 20 & 80 (CBD softgel)

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>

3-3

Confirm Legal Compliance regarding Agrochemical Residue

Japan has a **Positive List System for agrochemical residue**, which means it is prohibited to distribute any foods which contain agrochemicals, unless MHLW has specifically approved their use and set a maximum residue limit (MRL).

Under the Japanese definition, agrochemicals include **pesticides, feed additives** and **veterinary drugs**.

MRLs for around 800 agrochemicals have been established by MHLW. Note that there is a zero tolerance set for antibiotics and synthetic antibacterial substances in foods. There are also another 20 agrochemicals which have zero tolerance for foods. Any other substances are subject to the default MRL of 0.01 ppm. (See column on the right.)

For processed foods, the Quarantine Station calculates MRLs based on the ratios of ingredients in the final processed product.

Agrochemical residue can be a problematic issue, due to the occasional differences in the MRLs between the US and Japan. You may want to get a Certificate of Analysis for agrochemical residue in advance to reduce the risk of detection of excessive MRLs during the food safety inspection at the port of entry. (See Step 7)

Steps to Take:

- ❑ 3-3 For fresh/frozen produce, as well as dried fruit, confirm that any agrochemical residues are within the maximum residue limits by comparing product-specific MRLs in the MHLW's lists of MRLs with the agrochemicals applied to your product (check by chemical formula or CAS number).

What if an agrochemical residue contained in your product cannot meet the standards for use?

- ❑ Consider ways to avoid using that agrochemical for exports to the Japanese market.
- ❑ Consult with ATO Tokyo.

Some recent cases involving **agrochemical residues** on US products:

- | | |
|--------------------------------|--|
| • Methamidophos (fresh celery) | • Dihydrostreptomycin and streptomycin (fresh grapefruit) |
| • Acephate (fresh celery) | • Etoxazole (fresh raspberry) |
| • Bifentrin (fresh celery) | • Methoxyfenozide (fresh raspberry) |
| • Triazophos (chili pepper) | • 2, 4-D (chocolate paste/cacao powder, US was not the country of origin of cacao) |
| • Buprofezin (fresh blueberry) | |

MHLW's lists of agrochemical MRLs by category:

1) Substances with designated MRLs

- MRLs for around 800 agrochemicals have been designated by MHLW.
- Some of them are still provisional and will be modified later. New MRLs are also designated from time to time. Thus, the list changes frequently.
- MRLs by product can be found at: <http://db.ffcr.or.jp/front/?lng=en>

2) Substances with zero tolerance

- Antibiotics and synthetic antibacterial substances have zero tolerance for foods.
- FSA also banned 20 agrochemicals for use in foods (zero tolerance). The list of 20 agrochemicals is here: <https://www.ffcr.or.jp/en/zanryu/the-japanese-positive/positive-list-system---not-detected.html>

3) Substances having no potential to cause damage to human health

- There are 74 substances specified as substances having no potential to cause damage to human health by the MHLW. These are exempted from MRLs. The list is here: <https://www.ffcr.or.jp/en/positive-list-system---exempted-substances.html>

4) Other substances

- Any other substances which are not included above three categories are subject to the uniform, default MRL of 0.01 ppm.
- Such regulation is shown here: <https://www.ffcr.or.jp/en/zanryu/the-japanese-positive/positive-list-system---uniform-limit.html>

3-4

Confirm Legal Compliance and Risk regarding Contamination by Harmful Substances

Contamination by **naturally harmful substances** (mycotoxins, cyanide, shellfish toxins, etc.), 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. 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 10), 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.

Mycotoxins, pathogenic microorganisms or decomposition/deterioration can develop during shipping.

Steps to Take:

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

Some examples of legal compliance issues for US products regarding harmful substances:

- Aflatoxin (fresh almond, dried fruit, chocolate containing nuts, etc.)
- Cyanide (chocolate granola butter, breakfast cereals)

Harmful substances by category:

1) Naturally harmful products

- Food containing toxic substances shall NOT be sold in Japan.
 - mycotoxins (aflatoxin, less than 10µg/kg (cereals, nuts, spices, etc.); patulin (apple juice) etc.)
 - toxic fish
 - shellfish toxins
 - cyanide (bean, cassava, bitter almond, etc.)
 - mushroom toxins
 - Lupine beans (processed food), etc.

2) Pathogenic microorganisms

- Food containing pathogenic microorganisms shall NOT be sold in Japan.
 - E. coli O26, O103, O111, O157 (meat, cheese, vegetable, fruit)
 - Listeria (meat, cheese, dairy products, frozen vegetable & fruit)
 - Norovirus (shellfish)
 - Hepatitis A virus (shellfish, fresh & frozen fruit)
 - Salmonella (meat, cheese, ice cream, fresh and frozen seafood, egg, frozen food, spice, nuts)
 - Vibrio cholerae (seafood)
 - Shigella (seafood, frozen food), etc.

3) Other harmful products

- Food containing the following substances shall NOT be sold in Japan.
 - Mercury (fish and shellfish)
Can not exceed these standards: total mercury 0.4ppm; methyl mercury 0.3ppm
 - PCB (fish, shellfish, meat, etc.)
Can not exceed these standards: Deep-sea seafood: 0.5ppm, Other seafood: 3 ppm, Dairy products: 1ppm, Meat: 0.5ppm, etc.
 - Methanol (distilled spirit, wine): 1 ppm

4) Decomposed or deteriorated foods/ingredients

3-5

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/identshi/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:

- 3-5-1 Your product should not contain any unapproved GM products or ingredients derived from unapproved GM microorganisms
- 3-5-2 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>

3-5

Confirm Legal Compliance regarding Other Ingredient Issues

Ingredients considered to be medicinal products

If your product uses specific herbs with medicinal effects, check MHLW's notice defining medicinal ingredients. If a product includes ingredients that are approved exclusively for medicinal use, the product CANNOT be sold as or in food.

Steps to Take:

- 3-5-4 Confirm that your product does not contain ingredients to be used exclusively for medicines.

MHLW's list of ingredients for medicinal use:

- The List of Ingredients (raw materials) Used Exclusively for Medicines is found here (Japanese only):
[MHLW Notice on Control of Unapproved Medicine](#)

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:

- 3-5-5 Check whether any of your product ingredients are listed in CITES.
- 3-5-6 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."

CITES list:

- METI's regulations regarding imports of goods related to CITES are found here:
http://www.meti.go.jp/english/policy/external_eco_nomy/CITES/cites_imports.html
- You can search the CITES list by scientific name here:
<https://speciesplus.net/>

3-6

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:

- 3-6-1 Confirm that your manufacturing process does not use irradiation, except to prevent potato germination.

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:

- 3-6-2 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:

- 3-6-3 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 were 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

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
- For more details, refer to the instruction at National Wooden Pallet & Container Association https://www.palletcentral.com/page/ISPM_15

3-7

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:

- 3-7 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)

A. Pre-Embarkation	B. Embarkation	C. Import Clearance
1	2	3
		4
		5
		6

4 Confirm Tariff Classification, Customs Duty and Country of Origin Regulations under USJTA

Check your product’s tariff classification in the most recent Japanese Tariff Schedule under the US Japan Trade Agreement (USJTA) (and Liquor Tax, in the case of liquor) and confirm the tariff rate (and liquor tax rate, in the case of liquor) applied to your products.

In order to receive the preferential duty rate under 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:

- ❑ 4-1 Check tariff classification and confirm the customs duty (and Liquor Tax, in the case of liquor) imposed on your products under USJTA.
- ❑ 4-2 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 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.

Responsible government agency

- [Japan Customs](#)

Related laws/regulations

- [Customs Act](#) (Japanese only)
- [Liquor Tax Act](#) (Japanese only)
- [Trade Agreement between Japan and the United States of America](#) (English)

4-1

Confirm Tariff Classification and Customs Duty under 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 USJTA, look under the column "JP-US Trade Agreement".

For alcoholic beverages, also confirm the liquor tax rate, which is defined in the Article 23 of the Liquor Tax Act. A brief summary in English of liquor tax rates is here:

http://www.customs.go.jp/english/c-answer_e/kojin/3105_e.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:

- 4-1-1 Check tariff classification and confirm the customs duty imposed on your products.
- 4-1-2 For alcoholic beverages, confirm the liquor tax which applies to your product.
- 4-1-3 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](#)

Related laws/regulations

- [Customs Act](#) (Japanese only)
- [Liquor Tax Act](#) (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

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.)

4-2 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:

- 4-2-1 Check whether your product is eligible for the preferential tariff under USJTA.
- 4-2-2 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.

4-2

Sample of Origin Declaration Document

The 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 US Fruit Company 10000 South Grand Av. Suite 100, Los Angeles, CA 90000			
2. Producer Name and Address Same as above			
3. Importer Name and Address Kudamono Company 1-1-1 Ginza, Chuo-ku, Tokyo 03-3000-1000			
No.	4. Products Detail (Name and Invoice #)	5. HS Code	6. Criteria
1	Dried Fruit (Cranberry) XYZ-987654 Invoice: DEF012345, 2020.1.15	2008.93	PE
7. Other Remarks			
8. Name & Address Kudamono Company 1-1-1 Ginza, Chuo-ku, Tokyo		Signature	

Importer's address must be in Japan

List each product separately

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

(Source) USJTA Rules of Origin and Origin Procedures

4-2

Sample of Detailed Origin Declaration Document

The document can be prepared in English. 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 DEF012345, 2020.1.15	
2. Product Number on Origin Declaration Document Same as Above	3. HS Code 2008.93
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 the above criteria [Note: This section should be written in Japanese]	
<p><Ingredients></p> <ol style="list-style-type: none"> Cranberry (HS:08) Harvested in the United States (originating product) Sugar (HS:17) Produced in the United States (originating product) Glycerin (HS:29) Made in the United States (originating product) <p><Manufacturing process></p> <p>To manufacture the product, the above ingredients are sliced, mixed, and dried at the factory in the United States.</p> <p><Criteria></p> <p>Ingredient 1 is a wholly obtained product. 2 and 3 are also originating materials under USJTA. Since the product is produced exclusively from these materials in the United States, it is a U.S. originating material under USJTA. These facts can be seen in the attached documents.</p>	
6. Other Remarks	
7. Name & Address Kudamono Company 1-1-1 Ginza, Chuo-ku,	Signature 2020/1/29

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 nor 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](#)

5 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.

For alcoholic beverages, the importer needs to provide the label as part of the application form for customs clearance.

Steps to take

- 5-1 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 \(MOE\)](#)
- [alcoholic beverages]: [Liquor Tax Act](#) (Japanese only), [National Tax Agency \(NTA\)](#)
- [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
- Food Labeling Division, Consumer Affairs Agency Consultation service is available (Japanese only):: https://www.caa.go.jp/policies/policy/food_labeling/information/contact/
- [For alcohol] Regional Offices of National Tax Agency Contacts are here (Japanese only) <http://www.nta.go.jp/taxes/sake/sodan/index.htm>

5-1

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**

- Fresh food products have only general labeling obligations (name of the product, country of origin), except for some specific products (e.g., postharvest anti-mold agents must be labelled for specific fruits).
- **Fair Competition Codes** were made by various industry organizations based on Japan's Act against Unjustifiable Premiums and Misleading Representations. These Codes define some product specific labeling standards for products such as chocolate, ice cream, cheese, whiskey, dressing, biscuit and fruit juice. For dairy ingredients, follow MHLW's Ministerial Ordinance on Ingredient Specifications for Milk and Dairy Products. Details are shown in each product report.

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
- 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 10 pages 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>

5-1

Sample of a Product Label

Milk Chocolate Bar

Name of the product:	Chocolate
Ingredients:	Sugar, milk, chocolate, cocoa butter, milk fat / Emulsifier (soy origin), flavor
Net weight:	73g
Best-before date:	Shown on the lower right
Storage instructions:	Avoid direct sunshine, high temperature and high humidity. Keep in a cool and dry place.
Country of origin:	United States
Importer:	Meros Trading 1-19-3, Kanda Awajicho, Chiyoda-ku, Tokyo

- Manufactured in a facility that uses peanuts.
- Consume as soon as possible after opening.
- Once chocolates have reached a high temperature and melted, the fat content may on occasion turn white after it returns to solid form. It can be eaten in this condition, but the taste and flavor could be inferior
- If there are any problems with the quality, please contact us. We will send a replacement and cover the shipping charges. Contact phone no: 03-3526-2075

Recycling symbol: *plastic*

Best-before date: *Apr 1, 2022*

Nutrition Information per 100g

Calories	259 Kcal
Proteins	1.7 g
Fat	1.1 g
Carbohydrates	60.7 g
Sodium	35.9 mg

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

ミルクチョコレートバー

名称:	チョコレート
原材料名:	砂糖、牛乳、カカオマス、ココアバター、乳脂肪/乳化剤(大豆由来)、香料
内容量:	73g
賞味期限:	この面右下に記載
保存方法:	直射日光・高温多湿を避けて涼しい乾燥したところに保存してください。
原産国名:	アメリカ
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

- ピーナッツを使用した工場で製造しています。・開封後はお早めにお召し上がりください。
- チョコレートは高温になると溶けて、脂肪分が白く固まることがあります。召し上がっても差支えありませんが、風味が劣ります。・万一製品に異常がありましたら、ご一報ください。代品と郵送料をお送りいたします。お問い合わせ先: 03-3526-2075

栄養成分(内容量100gあたり)

エネルギー	259 Kcal
たんぱく質	1.7 g
脂質	1.1 g
炭水化物	60.7 g
ナトリウム	35.9 mg

- The order should be Year.Month.Date.
- Some other variations allowed include: "2022.4.1.", "20220401", "2022年4月1日".
- For most processed food products, 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



賞味期限
2022.04.01

*Expiration dates are not legally required for some processed products including frozen fruit, alcoholic beverages, ice cream and some soft drinks and water. Nevertheless, importers may expect expiration dates.

6 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

- 6-1 Confirm that the name you want to trademark is not already registered in Japan.
- 6-2 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



7. Obtain a Sanitary/Phytosanitary Certificate and a Certificate of Analysis

8. Clear export customs

7 Obtain a Sanitary/Health Certificate

If your product is subject to Sanitary Inspection, a USDA Sanitary/Health Certificate **must** accompany the shipment.

Steps to take

- 7-1 Obtain a **USDA Sanitary/Health Certificate** (See below.)

Whose responsibility is this?

Manufacturer / exporter

Timeframe / Cost

- Varies by Product

Further instructions by product:

Prepared foods containing meats

Prepared foods containing meats and poultry for export to Japan must meet attestations of Meat and Poultry Export Certificate of Wholesomeness (FSIS Form 9060-5) and of regulatory compliance and regulatory equivalence (FSIS Form 9290-1). In addition, some meat products and prepared foods containing meats are required to submit specific additional documentation. For more details, see [FSIS Export Library for Japan](#) and [USDA APHIS | Japan iRegs](#)

Egg products

FSIS Form 9060-5EP is required. Due to contagious diseases such as avian influenza, some poultry products may not permit to be exported to Japan depending on slaughtered place and date. Please confirm the eligibility with FSIS and APHIS.

(Export Requirements for Japan) <https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/requirements-for-processed-egg-products/japan-processed-egg-products>)

Key Contacts

- [ATO Tokyo](#)
E-mail: atotokyo@usda.gov

Where to obtain a Sanitary/Health Certificate?

- Dairy products: **Veterinary Service Center (SC)**, Animal and Plant Health Inspection Service (APHIS), USDA
https://www.aphis.usda.gov/animal_health/downloads/nies_contacts/sc.pdf
- Meat products: **Food Safety and Inspection Service (FSIS)**, USDA (Meat products)
<https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/export-library-requirements-by-country/Japan>

7 Obtain a Sanitary/Health Certificate

Further instructions by product:

Dairy products and prepared foods containing dairy products

Japan requires a veterinary certificate issued by APHIS for dairy products imported from the United States. From March 1, 2020, APHIS started to endorse a new version of the veterinary certificate for dairy products exported to Japan. The certificate has been updated to satisfy a new requirement under Japan's Food Sanitation Law which entered into force on June 1, 2020. The specific certificate requirement differs according to whether the product is for human or animal consumption, as well as other factors such as whether or not the product contains other animal origin ingredients. For a full list of the required certificates, please consult:

[USDA APHIS | Japan iRegs.](#)

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 import oysters for raw consumption, importers must submit a sanitary certificate issued by the competent state authorities detailing the following eight items:

1. Name of the imported food product (e.g., live oysters)
2. Weight AND quantity of imported oysters (e.g., 120 pieces at 12 kilogram)
3. Water area where the oysters were caught (e.g., Penn Cove, Hood Canal)
4. Catch date
5. The name and address of the facility that handled/processed the oysters
6. Shipper's name and address
7. Importer's name and address
8. Statement confirming the equivalency of production and handling standards for oysters between the exporting country and Japan.

For more information, see [Japan Revises Sanitary Certificate Requirements for Fresh Oyster Imports](#)

Key Contacts

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

Where to obtain a Sanitary/Health Certificate?

- Dairy products: **Veterinary Service Center (SC)**, Animal and Plant Health Inspection Service (APHIS), USDA
https://www.aphis.usda.gov/animal_health/downloads/nies_contacts/sc.pdf
- Meat products: **Food Safety and Inspection Service (FSIS)**, USDA (Meat products)
<https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/export-library-requirements-by-country/Japan>
- Oysters: Oyster exporters can request a sanitary certificate either from **NOAA** or, if appropriate, Washington State Department of Health.
<https://www.fisheries.noaa.gov/content/export-certification>

7 Obtain a Phytosanitary Certificate

If your product is subject to Phytosanitary Inspection, a USDA Phytosanitary Certificate **must** accompany the shipment.

Steps to take

- 7-1 Obtain a **USDA Phytosanitary Certificate** ([PPQ Form577](https://www.aphis.usda.gov/aphis/ourfocus/planthealth/sa_export/ct_export_certification_specialists)) from your local APHIS authorized certification official. You can search for them at:
https://www.aphis.usda.gov/aphis/ourfocus/planthealth/sa_export/ct_export_certification_specialists

For additional information, please visit APHIS's Plant Health Export Information portal:
https://www.aphis.usda.gov/aphis/ourfocus/planthealth/SA_Export

Whose responsibility is this?

Manufacturer / exporter

Timeframe / Cost

- Timeframe: Check with your local officials
- Fees are found here:
https://www.aphis.usda.gov/aphis/ourfocus/planthealth/sa_export/sa_userfees/ct_userfees_export_certificate

Key Contacts

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

Where to obtain a Phytosanitary Certificate?

- **Authorized certification agencies** (Export Certification Specialists) of the Animal and Plant Health Inspection Service (APHIS), USDA, in your State or the State of export
- Contacts are here:
https://www.aphis.usda.gov/aphis/ourfocus/planthealth/SA_Export/SA_ECS

7 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:

- 7-1 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>

8 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

- ❑ 8-1 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.)
- ❑ 8-2 Declare export through EEI filing with the above documents, proceed through export customs clearance, and receive a B/L after loading.
- ❑ 8-3 Send the documents for import clearance to the importer.
 - Commercial Invoice
 - Packing List
 - B/L or Airway Bill
 - Sanitary and Phytosanitary 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

- ❑ 9. Clear sanitary/phytosanitary inspection
- ❑ 10. Clear food safety quarantine procedures
- ❑ 11. Clear import customs

After Import Clearance

Food safety issues faced after Import Clearance



9 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 inspection aims to prevent the spread of animal diseases.

Steps to take:

- ❑ 9-1 Submit an application for Sanitary Inspection to the Animal Quarantine Service with the **USDA Sanitary Certification** obtained in Step 7.
 - 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.
- ❑ 9-2 Undergo document examination and on-the-site **Sanitary Inspection**.
- ❑ 9-3 If disease is detected, the Animal Quarantine Service will order either disposal or return of the shipment.
- ❑ 9-4 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](#)

Sanitary inspection/sterilization method

Inspection method

The inspection method is described here (Japanese only):
[Import Inspection Procedure of Livestock Products](http://www.maff.go.jp/aqs/hou/attach/pdf/96-22.pdf)
<http://www.maff.go.jp/aqs/hou/attach/pdf/96-22.pdf>

Sampling size

The inspection method indicates the sampling size. For example, dairy products will require 3 samples regardless of the size of the shipment.

Designated sterilization method

Sterilization is mainly for bones, skins, etc., and not for meat and dairy products.

Rejection Rates at Sanitary Inspection

- The rejection rate at Sanitary Inspection for US dairy products was 0.3% in 2019 and 0.2% in 2020.
- The overall rejection rate for US meat products was 0.9% in 2019 and 0.8% in 2020, but for air cargo it was 9.2% in 2019 and 7.5% in 2020.

Key Contacts

- **ATO Tokyo**
E-mail: atotokyo@usda.gov
- The 28 **Animal Quarantine Service** contact points:
<https://www.maff.go.jp/aqs/english/attach/pdf/contactus-18.pdf>

9 Clear Phytosanitary Inspection

Import clearance starts with Phytosanitary Inspection at a **Plant Protection Station**, if the product is subject to such inspection (See Step 2). This inspection **Station** aims to prevent the spread of plant diseases and pests.

Steps to take:

- ❑ 9-1 Submit an application for Phytosanitary Inspection to the Plant Protection Station with the **USDA Phytosanitary Certification** obtained in Step 7.
 - The Plant Protection Station may require other documents, such as the Commercial Invoice, Packing List, and B/L.
 - 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 7 days prior to the scheduled arrival. At the latest, applications can be submitted immediately after arrival at the port of entry.
- ❑ 9-2 Undergo document examination and on-site **Phytosanitary Inspection**.
- ❑ 9-3 If pests/diseases are detected, the Plant Protection Station will order either sterilization, disposal or return of the shipment.
- ❑ 9-4 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 Phytosanitary Inspection is free of charge. However, the importer needs to cover the cost of sterilization, disposal or shipment return if it is ordered.
- The customs broker will usually charge 2000-5000 JPY for submitting the application, and they will add expenses for sterilization, disposal or return if ordered.
- Timeframe for Phytosanitary Inspection varies from 10 mins to half a day.

Responsible government agency and relevant law/regulation

- [Plant Protection Stations](#), Ministry of Agriculture, Forestry and Fisheries (MAFF)
- [Plant Protection Act](#)

Phytosanitary inspection/sterilization method

- **Inspection method** is shown here:
Import Plant Phytosanitary Inspection Regulations
https://www.maff.go.jp/pps/j/law/houki/kokuji/kokuji_9.html (Japanese only)
- **Sampling size** is shown in Table 1 of the above regulations indicates sampling size.
E.g., 1,000-2,000 kg of fresh oranges – more than 60 kg for sampling; 50-2,000 kg of fresh blueberries – more than 10 kg, etc.
- **Designated sterilization methods** are specified in Table 1 of the following document:
Import Fruits and Vegetables Quarantine Manual
https://www.maff.go.jp/pps/j/law/houki/yoko/yoko_52.html (Japanese)
E.g., produce with thrips, whitefly or scale insects detected on the surface requires hydrocyanic acid gasification for 30 mins; produce with other pests requires methyl bromide sterilization for 2-4 hours.

Rejection Rates at Phytosanitary Inspection

- The rejection rate for US fresh fruits was 0.8% in 2019 and 1.4% in 2020. The percentage requiring sterilization was 4.3% in 2019 and 5.5% in 2020. The disposal rates were higher for cherries and nectarines, and sterilization was higher for raspberries, grapefruit, pomegranates, and blackberries.
- There was no rejection of frozen vegetables in 2019 and in 2020. There was one rejection of frozen fruit in 2019.

Key Contacts

- **ATO Tokyo**
E-mail: atotokyo@usda.gov
- The 5 **Plant Protection Stations** contact points are:
<http://www.maff.go.jp/pps/j/guidance/outline/contact.html> (Japanese only)

10 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 3).

Steps to take:

- ❑ 10-1 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.
- ❑ 10-2 Undergo document examination and on-the-spot examination by the quarantine officials.
- ❑ 10-3 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.
- ❑ 10-4 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.
- Aflatoxin detection in dried fruit, nuts and nut products accounted for 36.0% in 2019 and 45.2% in 2020 of the rejected cases.

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

10-3

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 7) 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

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

10-3

Explanation of Food Safety Inspection Types

(B) Ordered Inspection

For some products from certain 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.

Examples of the target products for Ordered Inspection in 2021, from the 24 products covered in this series of guides, based on Notice of the Implementation of Ordered Inspection of FY2021, are shown here:

https://www.mhlw.go.jp/stf/newpage_17621.html

- Dried figs (all countries) – Total aflatoxins (not exceeding 10µg/kg)
- Dried dates (US) – Total aflatoxins (not exceeding 10µg/kg)
- Mixed spice (all countries) – Total aflatoxins (not exceeding 10µg/kg)
- Soft and semi-hard natural cheese (US, manufactured by certain manufacturers) - Listeria monocytogenes
- Processed food products (US, manufactured by a specific manufacturer) – Irradiation

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

10-3

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:

- Cheese/Ice Cream
 - E. Coli (Natural cheese)
 - Listeria (Natural cheese)
 - Residual pesticides
 - Residual veterinary drugs
 - Residual feed additives
- Seafood
 - Vibrio parahaemolyticus (Seafood for raw consumption)
 - Diarrhetic/Paralytic shellfish poisons (shellfish)
 - Residual veterinary drugs
 - Residual feed additives
 - Histamine
- Vegetable and Fruit
 - Aflatoxin and patulin (Cereals, legumes, spices, apple juice, etc.)
 - Nitril glycoside
 - E. Coli (Vegetables for raw consumption)
 - Residual pesticides

11 Clear Import Customs

Finally, clear import customs and pay applicable import taxes (See Step 4) at the **Customs office**.

Steps to take:

- ❑ 11-1 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.
- ❑ 11-2 Clear document examination
- ❑ 11-3 Clear on-the-spot **Customs Inspections** (See the right column), if required
- ❑ 11-4 Pay the import tax, consumption tax, and liquor tax for alcoholic beverages.
- ❑ 11-5 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

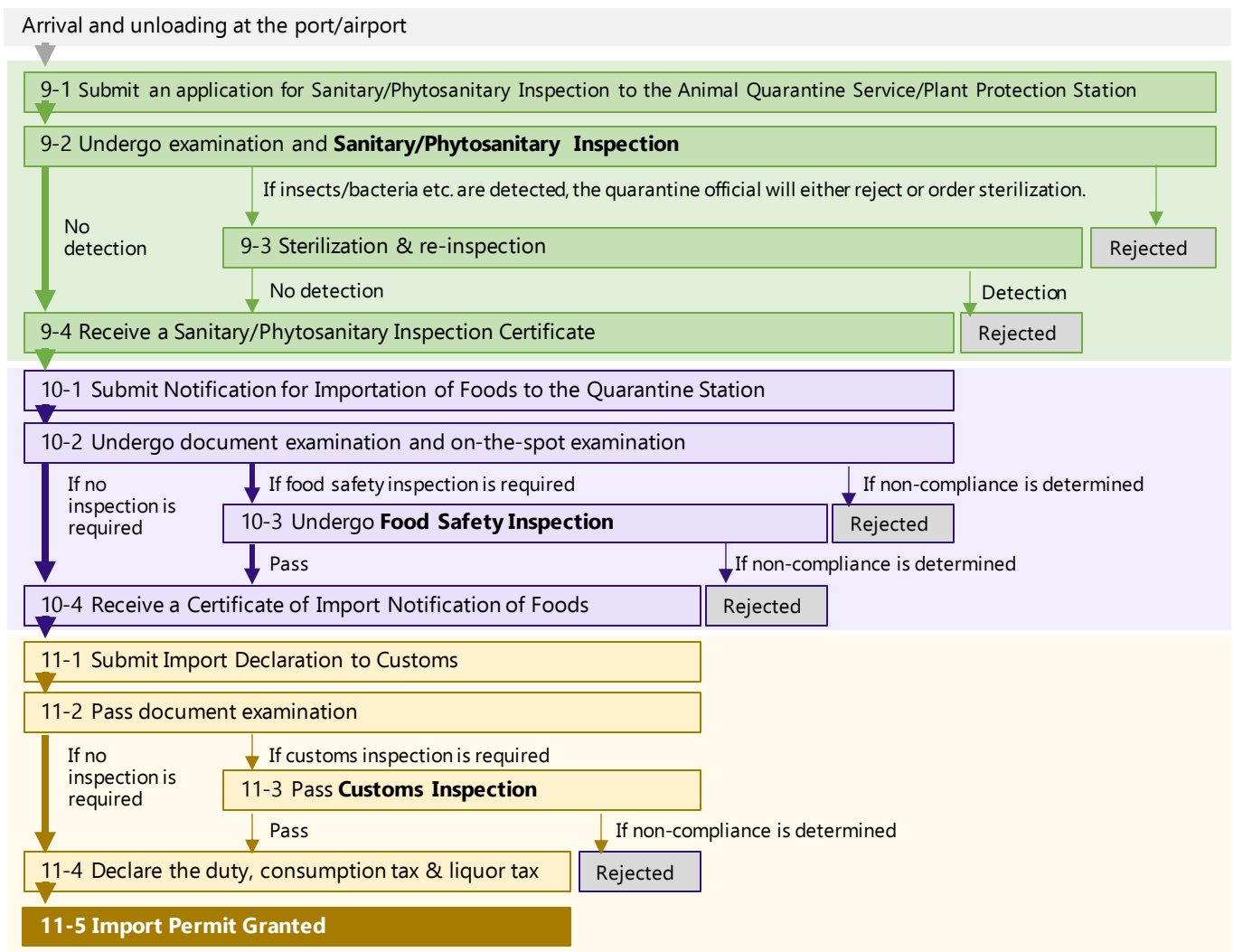
- Contact points of the 9 regional Customs offices (English):
http://www.customs.go.jp/question_e.htm

Summary Import Clearance Flow

Animal Quarantine Service/ Plant Protection Station

Quarantine Station

Customs



Average duration

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

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

• *Sanitary/Phytosanitary Inspection at Animal Quarantine Service / Plant Protection Station 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 in 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

Liquor Tax

National Tax Agency
https://www.nta.go.jp/english/taxes/liquor_administration/index.htm
Contacts for inquiries are shown here (Japanese):
<https://www.nta.go.jp/taxes/sake/sodan/index.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>

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)

Plant Protection Stations

Plant Protection Division, Food Safety and Consumer Affairs Bureau
Tel: (011-81-3) 3502-5976
Website: <http://www.pps.go.jp/english/index.html>
Inquiries can be made through the website at:
http://www.maff.go.jp/pps/j/introduction/english_exp.html#faq

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

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/