Soups Export Guide to Japan

December, 2021

Agricultural Trade Office (ATO), Tokyo

E-mail: atotokyo@usda.gov Tel: (011-81-3) 3224-5115 Mon-Fri 8:30 AM -5:30 PM Japan Standard Time



Soups Export Guide to Japan

December, 2021

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

Prepared by



Ono Building 2FI, 1-19-3, Kanda Awajicho, Chiyoda-ku, Tokyo 101-0063 JAPAN (011-81-3) 3526-2075

www.merosconsulting.com

Authors: Lucia Vancura, Chisa Ogura, Hiroki Seki and Ayako Kuroki

For further information, please contact: Lucia Vancura, lvancura@merosconsulting.com

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 **#7 Soups.**

24 products covered in this series:

#1 I	Fresh fruits
#2 I	Frozen fruits/vegetables
#3 I	Processed fruit puree
#4 (Condiments & sauces
#5 (Cookies & chips
#6 I	Live seafood (e.g. shellfish, lobster, etc.)
#7 9	Soups
#8 I	Health bars
#9 (Chocolates
#10	Breakfast Cereals
#11	Pet Food
#12	Frozen breads

#13 Fruit/vegetable juice
#14 Sugar/flavor added water
#15 Mineral water
#16 Ice Cream
#17 Wine
#18 Distilled spirits
#19 Cheese
#20 Dough Mixes
#21 Dried fruits
#22 Herbal teas
#23 Non-alcoholic beverage bases and syrups
#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 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 Certificate and a Certificate of Analysis
- 8. Clear export customs

C. Import Clearance

- **9**. Clear sanitary inspection
- **1**0. Clear food safety quarantine procedure
- **1**1. 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 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

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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

2

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.

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 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 <u>Agricultural Trade Office (ATO), Tokyo</u> E-mail: atotokyo@usda.gov Tel: (011-81-3) 3224-5115 Mon-Fri 8:30 AM -5:30 PM in Japan time
- <u>11 Quarantine Stations under MHLW</u> located at major ports/airports offer Prior Consultation for importers (See Step 3).
- <u>The Manufactured Imports and Investment</u> <u>Promotion Organization - MIPRO</u> 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

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B. Embarkation

FOODS

C. Import Clearance

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Sample of an Ingredient List

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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: XYZ е,

- 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 13):
 - _ 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
- If an **extract** is used: extraction method, including whether organic solvent is used

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

4

INGREDIENT LIST

Product:	XYZ Brand Condensed Soup, 300 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
Sweet corn	35.0%
Wheat powder	22.0%
Sugar	12.0%
Salt	6.4%
Cream (dairy products)	5.0%
Vegetable oil	4.5%
Whey powder (dairy products)	4.0%
Dried onion	3.0%
Butter	2.0%
Thickener (modified starch)	1.5%
Seasoning (nucleic acid)	1.0%
Sodium casein (from cow milk)	0.8%
Flavoring (Vanillin: 4-Hydroxy-3-Methoxybenzaldehyde, meets FSA standards.)	0.5%
Carotene color	0.3%

Contains gluten and milk. May contain traces of soy and nuts.

Feb 7, 2019

Michael Williams Director, Manufacturing XYZ Foods Ltd.

- Product name
- Manufacturer and facility name (official name, no abbreviations) and address (physical address, not P.O. box)

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- 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

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B. Embarkation

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Sample of a Manufacturing Process Flowchart

FOODS

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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.

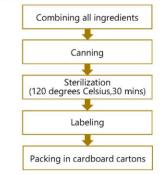
123 Woodland Avenue, City, State, ZIP, United States

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MANUFACTURING PROCESS FLOWCHART

Product:XYZ Brand Condensed Soup, 300 gManufacturer:XYZ Foods Ltd.Address:123 Woodland Avenue, City, State, ZIP, United StatesFactory:XYZ Foods Park Avenue FactoryAddress:111 Park Avenue, City, State, ZIP, United States

Manufacturing Process:



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)

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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

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2 Check the Sanitary Requirements that Apply to Your Product

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If your product contains any meat or meat extracts, consult with your importer about any sanitary requirements imposed on your product. Some processed products whose ingredients include meat products could be subject to animal health quarantine, depending on the degree of processing and packaging.

If your product is subject to sanitary quarantine, a USDA Sanitary Certificate must accompany the shipment. (See Step 7)

Compliance with sanitary requirements will be examined during 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 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)
- <u>The Food Sanitation Act (FSA)</u>

Best Practices

 USDA APHIS and FSIS maintain a registry of exporter requirements but work closely with your importer to check the sanitary requirements in detail.

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Key Contacts

- ATO Tokyo E-mail: atotokyo@usda.gov
- USDA contact points for exporters are:
 - Export Program Staff, Food Safety Inspection Service (FSIS), USDA Tel: (202) 720-0082 or (855) 444-9904 <u>https://www.aphis.usda.gov/animal_health/contacts/field-operations-export-trade.pdf</u>

Contact Information for Prior Consultation

 <u>29 Animal Quarantine Service offices under</u> <u>MAFE and <u>11 Quarantine Stations under MHLW</u> offer Prior Consultation for importers (Japanese only).
</u>

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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, Food Safety Inspection at the Quarantine Station under MHLW .

Steps to take:

3-1 Confirm legal compliance regarding **product-specific standards**

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- **3**-2 Confirm legal compliance regarding **food additives**
- **3**-3 Confirm legal compliance regarding **other ingredient issues**
- **3**-4 Confirm legal compliance regarding **manufacturing process and packaging**
- 3-5 Have your importer confirm legal compliance through Prior Consultation at the Quarantine Station that oversees the expected port of entry of your product.

Whose responsibility is this?

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

Responsible government agency:

- Quarantine Stations, Ministry of Health, Labour, and Welfare (MHLW)
- Ministry of Economy, Trade and Industry (METI)
- Ministry of Agriculture, Forestry and Fisheries (MAFF)

Relevant laws/regulations:

- <u>The Food Sanitation Act (FSA)</u>
- Specifications and Standards for Foods, Food Additives, etc. Under the FSA

Best Practices

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

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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.
- 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
- <u>11 Quarantine Stations under MHLW</u> offer Prior Consultation for importers (Japanese only). See Step 3-5
- <u>MIPRO</u> also provides free phone consultation.

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³⁻¹ Confirm Legal Compliance regarding Product-specific Standards

Food packed in containers and sterilized by pressurization and heating

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If you export packed and sterilized soup, check the standards outlined under The Food Sanitation Act (FSA). Some specific examples of FSA's standards which would be important for US suppliers include:

- Viable bacterial cells: must test negative
- The sterilizing method must be effective in destroying any viable microorganisms.

Frozen food standards

If you export frozen soup, follow the specific standards for frozen foods which are outlined under The Food Sanitation Act (FSA). Some specific examples of FSA frozen food standards which would be important for US suppliers include:

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

Milk and dairy standards

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

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

Steps to Take:

- □ 3-1-1 If you export packed and sterilized soup, confirm that your product meets FSA's standards
- 3-1-2 If your product contains milk, confirm that dairy ingredients meet MHLW specific standards for milk and dairy products
- 3-1-3 Talk with your importer about hygiene control planning and contamination risk planning

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

- Exceeding the allowable standard for bacteria count
- Not meeting the standards for the sterilization method

List of Product-specific Standards:

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

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

2) Milk and dairy products

 Ministerial Ordinance on Ingredient Specifications for Milk and Dairy Products is found here (Japanese only): <u>https://elaws.e-</u> gov.go.jp/search/elawsSearch/elaws_search/lsg05

00/detail?lawId=326M50000100052

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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).

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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.

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

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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: <u>http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/page</u> <u>s/list-desin.add-x</u>

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: <u>http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/page</u> *s/list-general.provd.add*

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Confirm Legal Compliance regarding Agricultural Biotechnology

Foods and Food Additives Derived from Agricultural Biotechnology

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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: <u>https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/idenshi/index_00002.html</u>

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.

Steps to Take:

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

MHLW's list of authorized GM products:

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

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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: <u>https://www.mhlw.go.jp/content/000550824.pdf</u>
- FAS Attaché reports related to this topic are found here:
 - <u>https://www.fas.usda.gov/data/japan-mhlw-updates-genome-editing-handling-procedures-crossbred-progeny</u>
 - <u>https://www.fas.usda.gov/data/japan-policies-and-procedures-genome-edited-food-and-agricultural-products</u>

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Confirm Legal Compliance regarding Other Ingredient Issues

Contamination of Harmful Substances

Contamination by **naturally harmful substances** and **pathogens** can also prevent the importation of US food products.

Article 6 of the FSA states that foods involving risk to human health cannot be sold; however, each controlled substance and its standards are regulated by different ministerial notifications. So, it is recommended that manufacturers consult with Quarantine Stations in advance if there is any question of a harmful substance being detected in a food product.

Steps to Take:

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

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

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

Steps to Take:

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

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

Examples of harmful substances by category:

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1) Naturally harmful products

 Food containing toxic substances (such as mycotoxins, cyanide, mushroom toxins, Lupine beans, etc.) shall NOT be sold in Japan.

2) Pathogenic microorganisms

 Food containing pathogenic microorganisms (such as E. coli, Listeria, Salmonella, etc.) shall NOT be sold in Japan:

3) Other harmful products

 Food containing substances such as mercury or PCB shall NOT be sold in Japan.

4) Decomposed or deteriorated foods/ingredients

CITES list:

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

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Confirm Legal Compliance regarding Manufacturing Process and Packaging

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Irradiation

3-4

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:

3-4-1 Confirm that your manufacturing process does not use irradiation.

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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:

3-4-2 Confirm that your packaging material is included in the approved list and meets the packaging standards.

Wood pallets

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

Steps to Take:

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

The positive list of packaging materials:

 The positive list including English names and CAS registry numbers is available here. (The original "Appended Table 1" in Japanese was split into two tables.)

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- <u>https://www.mhlw.go.jp/content/000638979.xlsm</u>
- https://www.mhlw.go.jp/content/000635348.xlsx
- For further instructions, refer to: https://www.mhlw.go.jp/stf/seisakunitsuite/bunya /kenkou_iryou/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: <u>http://www.maff.go.jp/pps/j/konpozai/faq_eng_20</u> 09_12.html
- For more details, refer to the instruction at National Wooden Pallet & Container Association <u>https://www.palletcentral.com/page/ISPM_15</u>

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3-5 Obtain Prior Consultation at Quarantine Stations

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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:

3-5 Confirm that your importer has undertaken Prior Consultation at the Quarantine Station for the expected port of entry for your product.

Who initiates?

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

What information must be submitted?

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

Timeframe / Cost

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

Contact Information for Prior Consultation

 The key contact point is the Quarantine Station that has jurisdiction over the port/airport through which the importer is planning to import the product.

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- Contacts for the consultation service division of 13 Quarantine Stations located at major ports/airports under MHLW : <u>https://www.mhlw.go.jp/topics/yunyu/soudan/</u> (Japanese)
- The list of all 111 offices of Quarantine Stations under MHLW: <u>https://www.mhlw.go.jp/english/policy/health-medical/health/dl/contact_list_jqs.pdf</u> (English)
- The Tokyo Quarantine Station has instructions on its Prior Consultation process: <u>https://www.forth.go.jp/keneki/tokyo/kanshi_hp/a</u> 013.html (Japanese)

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

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

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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 the 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 the USJTA.

Whose responsibility is this?

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

Responsible government agency

Japan Customs

Related laws/regulations

- <u>Customs Act</u> (Japanese only)
- Liquor Tax Act (Japanese only)
- Trade Agreement between Japan and the United States of America (English)

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Confirm Tariff Classification and Customs Duty under the USJTA

Check your product's tariff classification in the most recent Japanese Tariff Schedule and confirm the tariff rate applied on your products. The most recent Tariff Schedule is here: http://www.customs.go.ip/english/tariff/index.htm

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

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 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.

2

• The response from customs is valid for three years from the date of issuance.

Responsible government agency

Japan Customs

Related laws/regulations

- <u>Customs Act</u> (Japanese only)
- <u>Liquor Tax Act</u> (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.

6

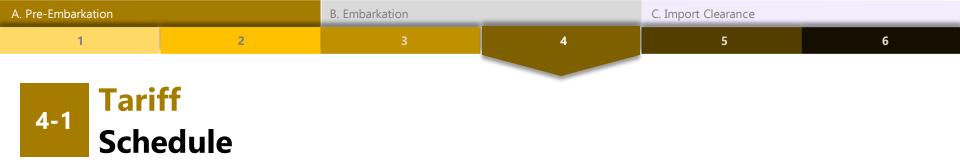
- The product classification, particularly for processed products, can differ depending on the ratio of ingredients. Getting an Advance Ruling is especially useful for processed products to avoid spending time at the port of entry trying to confirm the product category.
- Tariffs for competing suppliers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

Common Concerns

 Importers may require the ratios of ingredients in order to obtain Advance Ruling.
 For further information, contact
 <u>ATO Tokyo</u> 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 (<u>C-1000</u>, 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.)



- The tariff schedule does not have a detailed definition for each classification. Therefore, getting Advance Ruling is especially useful to avoid time being spent at the port of entry trying to confirm the product category.
- Note that the product you plan to export might be categorized into a category which is not listed here, depending on its ingredients and manufacturing method. If your product qualifies as an originating product as defined by the USJTA, please use the rate in the "USJTA" column in the table below.
- Based on the USJTA, tariffs on some products will gradually be reduced over time. New tariff reductions go into effect every year on April
 1st. Check the most recent tariff schedules <u>here</u>.

	Tariff Schedule				
		Tariff			
Import HS Code	Description	As of April 1, 2021		As of April 1, 2022	
		WTO bound rate	USJTA	USJTA	
210410010	Soups and broths and preparations therefor, of vegetable, in airtight containers	7%	0%	0%	
210410020	Soups and broths and preparations therefor, Other	8.4%	0%	0%	

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5

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)

2

- 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: <u>USJTA Rules of Origin and Origin Procedures</u>

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 the 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.

6

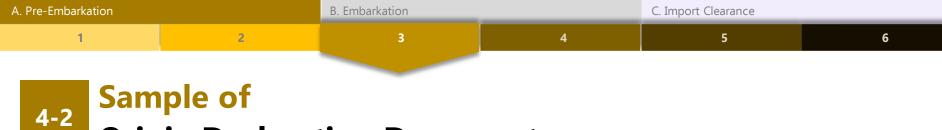
Format of the Documents

 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: <u>http://www.customs.go.jp/question2.htm#c</u>
- What information must be submitted?
 - Inquiry form (<u>C-1000-2</u>, 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.



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 XYZ Foods Ltd. 123 Woodland Avenue, City, State, ZIP, United States 2. Producer Name and Address Same as above 3. Importer Name and Address Importer's Meros Trading address must 1-19-3. Kanda Awajicho, Chiyoda-ku Tokyo, 101-0063 03-3526-3075 be in Japan 4. Products Detail (Name and Invoice #) 5. HS Code 6. Criteria No. (6 digits) List each product XYZ Brand Condensed Soup 300g; XYZ-9876543 1 2104.10 PE separately Invoice: ABC-D-1234 (2020.1.15)

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

7. Othe	r Remarks			
	e & Address ros Trading	Date		
	9-3. Kanda Awajicho, Chiyoda-ku Tokyo	2020/	/01/28	

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Sample of Detailed Origin Declaration Document

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

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

2

 Invoice Number and Date ABC-D-1234 (2020.1.15) Product Number on Origin Declaration Document Same as above Criteria 	3. HS Code 2104.10	Check one of the three criteria: WO, PE or PSR. If y check PSR and DMI is applicable, check DMI as we
 □ WO ⊠PE □ PSR □ DMI 5 Explanations why the product satisfies above criteri <ingredients> 1. Sweet corn: Harvested in the US 2. Wheat flower: Produced in the US 3. Sugar: Produced in the US 4. Salt: Produced in the US 5. Vegetable oil: Produced in the US 6. Whey powder: Produced in the US 8. Butter: Produced in the US To manufacture the product, the above ingredients are the factory in the United States. </ingredients> <	re mixed and canned with sterilization at o originating materials under USJTA. Since ials in the United States, it is a U.S.	 Explain how the product fulfills the criteria: WO: Facts confirming that the food was wholl obtained in the US PE: Facts confirming that the food product wa produced in the US using only US and/or Japa ingredients PSR: Facts confirming that the food product w produced in the US using non-US or non-Japa ingredients, providing the final product results the necessary HS code transformation DMI: Facts confirming that the value of the necessary the value of the product

5

4

5 Create a Product Label

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

2

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

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

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

Steps to take

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

- <u>Food Labeling Act</u>, <u>Labeling Standards (general and product-specific)</u> (Japanese only), <u>Consumer Affairs Agency (CAA)</u>
- [recycling symbol on packaging]: <u>Act on Promotion of Effective Utilization of Resources</u>, <u>Ministry of Environment (MOE)</u>
- [organic claims]: <u>JAS Law</u>, <u>Ministry of Agriculture</u>, <u>Forestry and Fisheries (MAFF</u>).

Best Practices

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

6

Common Concerns

 Only alcoholic beverage product labels are subject to inspection at customs clearance. However, all labels are subject to the on-going inmarket 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):: <u>https://www.caa.go.jp/policies/policy/food_labelin</u> g/information/contact/

1

C. Import Clearance

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6

Product Label Contents and Key Issues

2

A food product label should include:

a. Name of the product

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

Key Issues to be considered:

e. Shelf life:

The shelf life should be shown in one of the following two ways: best-before date or use-by date. The explanation is found here:

https://www.caa.go.jp/en/policy/food_labeling/assets/food_labeling_210511_0001.pdf

4

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 <u>USDA FAS Report</u>) 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 <u>here</u>. Contact ATO Tokyo for further information.

Nutritional and health claims:

 Japan has strict rules on functional and nutritional claims on food labeling. Refer to page 10 of <u>USDA FAIRS</u> 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

1 2 3 4 5 6 Sample of product Label Image: Interpret to the second sec	A. Pre-Embarkation		B. Embarkation		C.	. Import Clearance		
Corn Soup You can also list them on one line. Use a backslash "/" between the ingredients and additives, as above "/" between the ingredients and additives, as above powder (dairy product), dried onion, butter, soy protein/Thickener (modified starch), seasoning (nucleic acid), sodium casein (milk origin), flavoring, carotene color Nutrition Information per 100g Net weight: 305g Best-before date: Shown on the lower right Storage instruction: Avoid direct sunshine, store at room temperature. Country of origin: United States Importer: Meros Trading 1-19-3, Kanda Awajicho, Chiyoda-ku, Tokyo • Preparation Method (3 servings): Combine one can of soup and one can of milk (about 300ml) in a pot. Simmer over medium heat and stir slowly. When heated, mix well with a whisk or eggbeater to ensure	1	2	3	4		5	6	
no preservatives have been used. Caution: Metal edges of the can are sharp. - Product Inquiries: 03-3526-2075	Name of product: Ingredients: Net weight: Best-before date: Storage instruction Country of origin: Importer: - Preparation Me Simmer over m optimal flavor. no preservative	Condensed Soup Sweet corn, wheat powder (dairy pro- starch), seasoning color 305g Shown on the low at Avoid direct sunsh United States Meros Trading 1- ethod (3 servings): Combine of edium heat and stir slowly. V Manufactured in a facility the s have been used. Caution: N	Corn Soup powder, sugar, salt, cream (da duct), dried onion, butter, soy p (nucleic acid), sodium casein (er right ine, store at room temperature 19-3, Kanda Awajicho, Chiyoda one can of soup and one can o Vhen heated, mix well with a w at uses peanuts. Consume as	protein/Thickener (modifi milk origin), flavoring, car a-ku, Tokyo f milk (about 300ml) in a hisk or eggbeater to ensu soon as possible after op	I, whey ed otene	ngredients and additives They can be written on two Ingredients: Sweet corn Food additives: Thicken You can also list them or /" between the ingredie Nutrition Informati Calories Proteins Fat Carbohydrates Salt equivalent Recycling symbol: Steal can	s to be listed separately. wo separate lines: a, wheat powder, er, n one line. Use a backsla nts and additives, as abo on per 100g 81 Kcal 1.7 g 2.2 g 13.5 g 1.6 g Best before date:	
コーンスープ 名称: スイートコーン,小麦粉,砂糖,食塩,クリーム(乳製品),植物油,ホエイパウダー 栄養成分(内容量100gあたり)	名称:					栄養成分(内容量10	00gあたり)	

るか・	_{涙釉スーフ} スイートコーン, 小麦粉, 砂糖, 食塩, クリーム(乳製品), 植物油, ホエイパウダー	栄養成分(内容量	100gあたり)
原材料名:	(乳製品),乾燥玉ねぎ,バター,大豆たんぱく/増粘剤(加工でんぷん),調味料(核酸), カゼインNa(乳由来),香料、カロチン色素	エネルギー たんぱく質	81 Kcal 1.7 g
内容量:	305g	脂質	2.2 g
賞味期限:	本欄面右下に記載	炭水化物	13.5 g
保存方法:	直射日光を避けて常温で保存してください。	食塩相当量	1.6 g
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	\frown	
	スプーン等で中身を鍋にあけ、空き缶一杯分(約300ml、お好みで調節)の牛乳を	T 7 T _	賞味期限
徐々に加えながら中火でゆっ	くりかき混ぜ温めます。最後に泡だて器でよく混ぜることが美味しさの秘訣です。		2022.04.01
・ピーナッツを使用した工場	。で製造しています。・保存料は一切使用しておりませんので、開缶後はお早めに		
お使いください。・缶の切り	口で手を切らないよう、ご注意ください。・製品のお問合せ先:03-3526-2075	 The order is Yea 	r.Month.Date.

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

5

Register Trademarks and other Intellectual Property Rights

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

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

Existing trademark registrations in Japan can be looked up here. <u>https://www.j-platpat.inpit.go.jp/t0100</u>

2

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

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.

6

- 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: <u>PA0842@jpo.go.jp</u> Website: <u>https://www.jpo.go.jp/e/index.html</u>
- 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

D7. Obtain a Sanitary Certificate and a Certificate of Analysis

■8. Clear export customs

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.

Key Contacts

 <u>ATO Tokyo</u> E-mail: atotokyo@usda.gov

Where to obtain a Sanitary/Health Certificate?

 Meat products: Food Safety and Inspection Service (FSIS), USDA (Meat products) <u>https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/export-library-requirements-by-country/Japan</u>

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.

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:

7-2 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: <u>https://www.mhlw.go.jp/topics/yunyu/5/dl/a3.pdf</u>

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 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.
- **D** 8-3 Send the documents for import clearance to the importer.
 - Commercial Invoice
 - Packing List
 - B/L or Airway Bill
 - Sanitary Certificates, as needed

Whose responsibility is this?

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

US export customs clearance instructions:

Further instructions can be found in:

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

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 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.
- **D** 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

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: <u>https://www.maff.go.jp/aqs/english/attach/pdf/contactus-18.pdf</u> (Japanese only)

10

11

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:

- **D** 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.

- **1** 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, <u>Ministry of Health, Labour, and Welfare (MHLW)</u>

The Food Sanitation Act (FSA), Specifications and Standards for Foods, Food Additives, etc.

Best Practices

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

Common Concerns

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

Rejection Rates at Sanitary Inspection

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

Key Contacts

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

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10-3 Explanation of Food Safety Inspection Types(A) Self Inspection

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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
- · Agrochemical residue (mainly for products which have had issues in the past)

Sampling size

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

Timeframe / Cost

The importer should cover the cost for Self Inspection. (Refer to fees on the right.) Normally, the registered laboratory visits the warehouse for sampling and sends the Certificate of Analysis within **a week or less** after getting the samples.

Term of validity of the Certificate of Analysis

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

Some exceptions to the Certificate of Analysis term of validity:

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

Contacts of MHLW-registered laboratories

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

https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/ke nkou_iryou/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

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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 <u>MHLW's Imported Foods Annual Monitoring Plan (English)</u> and in more detail in the **Notice of the Implementation of Ordered Inspection** (Japanese only): <u>https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/yunyu_kanshi/kanshi/index.html</u>

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

- Mixed spice (all countries) Total aflatoxins (not exceeding10µg/kg)
- 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/ke nkou_iryou/shokuhin/jigyousya/kikan/index.html

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10-3 Explanation of Food Safety Inspection Types(C) Monitoring Inspection

10

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 <u>MHLW's Imported Foods Annual Monitoring Plan (English)</u> 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_iryou/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

B. Embarkation

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 and consumption tax
- **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
- <u>Customs Act</u> (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:

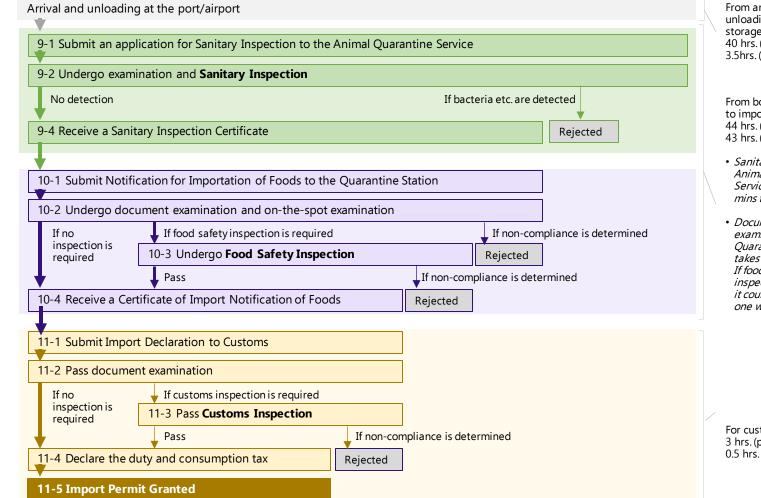
- [For drugs, guns, etc.] X-ray inspection
- [For counterfeits] Visual confirmation
- Cost

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): <u>http://www.customs.go.jp/question_e.htm</u>

Summary Import Clearance Flow



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

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

- Sanitary Inspection at Animal Quarantine Service takes from 10 mins to half a day.
- Document examination at Quarantine Station takes few hours. If food safety inspection is required, it could take up to one week

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

Food Safety Issues Faced After Import Clearance

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

Voluntary Recall

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

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

Food Safety Inspection by Prefectural Health Centers

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

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

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

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

Financial Liability for Recalls and Food Safety Risk

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

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

Best Practices:

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

Contacts General Help Desks

Need help? Contact ATO Tokyo

< atotokyo@usda.gov

Agricultural Trade Office (ATO), Tokyo

Embassy of the United States of America, Tokyo, Japan E-mail: atotokyo@usda.gov Tel: (011-81-3) 3224-5115 (Mon-Fri 8:30 AM – 5:30 PM Japan Standard Time) Fax: (011-81-3) 3582-6429 Address: Unit 9800, Box 591, DPO AP 96303-0591 Further contact information available at: https://apps.fas.usda.gov/overseas_post_directory/ovs_ directory_result.asp?posts=580 Website: http://www.usdajapan.org/ Twitter: @USDAJapan Free consultation service is also available at:

Japan External Trade Organization

Trade & Investment Consulting

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

Online Inquiry Form (English): https://www.jetro.go.jp/form5/pub/csa/contact-en

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

The Manufactured Imports and Investment Promotion Organization (MIPRO)

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

Online Inquiry Form (Japanese only): https://krs.bz/mipro/m/advisement_form_web

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

Contacts of Competent Authorities in Japan

Ministry of Health, Labour, and Welfare (MHLW)

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

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

Ministry of Agriculture, Forestry and Fisheries (MAFF)

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

Animal Quarantine Service

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

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: <u>https://www.caa.go.jp/en/</u>

Food Labeling

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