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**Report Highlights:**

This report is an overview and update of Japan's food and agricultural import regulations and standards (FAIRS). For more information on Japan's certification requirements, see the FAIRS Export Certificate Report for Japan at <http://gain.fas.usda.gov/>.

**Disclaimer:**

This report was prepared by the Office of Agricultural Affairs (OAA) of the USDA/Foreign Agricultural Service in Tokyo, Japan for U.S. exporters of domestic food and agricultural products. While every possible care has been taken in preparation of this report, information provided may no longer be completely accurate either because policies have changed since its preparation or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

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## Executive Summary

There are seven major laws governing food and agricultural products in Japan. Together, these laws cover food safety and sanitation, labeling, plant health, animal health, nutrition standards, and quality assurance. The Food Sanitation Act was revised in 2018 with several changes taking effect in 2020, including the introduction of a positive list for food packaging materials. The Ministry of Health, Labour, and Welfare (MHLW) is the competent authority responsible for food safety. The Ministry of Agriculture, Forestry, and Fisheries (MAFF) is the competent authority for animal and plant health, geographical indications, and agricultural standards enforcement. The Consumer Affairs Agency (CAA) oversees labeling. Importers bear sole responsibility for compliance with Japanese labeling regulations, though some may request assistance from U.S. exporters. Commercialization of genetically-engineered (GE) food crops requires approvals from food, feed, and environmental regulators. New GE labeling requirements will come into effect in 2023. Prior to import of any food products, importers must submit the Notification Form of Importation of Foods to the MHLW quarantine stations at the port of entry. The product will be allowed entry once it is determined to be in compliance with Japanese food regulations. Quarantine officials may request additional information, such as ingredient proportions and manufacturing processes prior to granting entry. U.S. products seeking preferential tariff treatment under the U.S.-Japan Trade Agreement must meet the applicable rules of origin. The scope of this report includes all edible food products. Import regulations and standards for feed are covered in [JA2021-0091](#) and for wood products are covered in [JA2019-0214](#).

In May 2021, MAFF established green food system, "Measures for achievement of Decarbonization and Resilience with Innovation ([MeaDRI](#))". MeaDRI calls for the government and private sector importers to identify and source, changing suppliers if necessary, imports of sustainably produced ingredients ([JA2021-0078](#), [JA2021-0048](#)). To reinforcing food safety administration, all food manufacturers in Japan are required to implement Hazard Analysis Critical Control Point (HACCP) system from June 1, 2021. Also from June 1, 2021, food manufacturers, importers and distributors are required to report food recall due to non-compliance with the Food Sanitation Act to MHLW. MHLW publish food recall information to prevent potential health risks and damage.

## Section I. Food Laws

There are seven major laws in Japan governing food and agricultural products, including imports:

- 1) [Food Safety Basic Act](#): This law sets the principles for developing a food safety regime and establishes the role of the Food Safety Commission (FSC), a food-related risk assessment body.
- 2) [Food Sanitation Act](#): This law aims to protect public health by ensuring the safety and sanitation of foods and beverages. It sets specifications and standards for foods and beverages, food apparatus, food containers and packages, additives, contaminants, and agrochemical residues, and prohibits the sale and import of foods and beverages containing harmful substances. The law also sets the monitoring guidelines, plans, and inspection measures for domestic and imported foods and beverages, as well as tableware, kitchen utensils, etc. and establishes penalties for failing inspections. The law, last revised in 2018, is administered by the Ministry of Health, Labor and Welfare (MHLW), Japan's food risk management agency.
- 3) [Food Labeling Act](#): This law sets the [Food Labeling Standards](#) (e.g. Country of Origin Labeling requirements, allergen labeling, expiration date labeling, foods with functional claims, biotechnology, etc.) as well as penalties in the event of a violation. It is administered by the Consumer Affairs Agency (CAA).
- 4) [Plant Protection Act](#): This law aims to prevent plant pests and diseases from establishing or spreading in Japan. It is administered by the Ministry of Agriculture, Forestry, and Fisheries (MAFF) as Japan's national plant protection authority. Under this law, certain U.S. fresh fruits and vegetables, such as apricots, bell peppers, eggplant, pears, and sweet potatoes, are currently prohibited from import (see [full list](#)).
- 5) [Domestic Animal Infectious Diseases Control Act](#): This law aims to prevent infectious animal diseases from establishing or spreading in Japan. It is administered by MAFF as Japan's national animal health authority.
- 6) [Health Promotion Act](#) (Japanese only): This law aims to improve public health by setting guidelines and measures including those for nutrition management. It establishes a labeling system for "Food for Special Dietary Uses" for certain groups including infants, children, pregnant women, and sick people. It is administered by MHLW.
- 7) [Japanese Agricultural Standards \(JAS\) Act](#): This law establishes a voluntary quality assurance system for foods, non-alcoholic beverages and forestry products. A voluntary labeling system for food and forest products allows sellers to identify certain product specifications which meet quality standard expectations for Japanese consumers. Labels are permitted for production, handling, and testing methods. Private interests may propose new JAS standards. The law is administered by MAFF. Additional information can be found in [JA2019-0195](#) and on [MAFF's website](#).

## Section II. Labeling Requirements

Japanese importers bear sole responsibility for the development of labels compliant with Japanese food labeling regulations. There is no legal obligation for U.S. exporters to affix Japanese labels to their products prior to export, however they may be asked to do so by their Japanese customers. The [Food Labeling Standards](#) (Japanese only) of the Food Labeling Act set Japan's food labeling requirements. Please see the [CAA's website](#) for detailed information.

### Fresh Food Labeling

Fresh food is defined as food which has not been processed. Labels on fresh food products must contain the general name of the product and country of origin. Additional labeling requirements (see [Appendix Table 24](#) of Food Labeling Standard in Japanese only) exist for the following items:

- Rice
- Shiitake mushrooms
- Citrus, stone fruit, kiwi, banana, apple, pear, etc.
- Meat
- Milk
- Eggs with shell
- Beans containing cyanide
- Farmed seafood
- Frozen seafood
- Chilled seafood (excluding oysters and pufferfish)
  - Fresh oysters and pufferfish have separate labeling requirements

### Processed Food Labeling

Japan's Food Labeling Act (see [JA7078](#)) requires that the label on retail packages for imported processed food products include the following information in Japanese:

- General name of the product
- Country of origin of the finished product
- Name and address of the importer
- Ingredients, other than additives, in descending order of weight percentage
- Food additives in descending order of weight on a separate line from other ingredients
- Net weight in metric units only. A system of average net weight tolerances of packages or certain commodities is set by the Measuring Law.
- Best-before date
- Storage instructions
- Labeling of certain genetically engineered (GE) ingredients as "GE" or "GE non-segregated." Further details in sections below.
- Allergen labeling: Foods containing shrimp, crab, wheat, buckwheat, egg, dairy products, and peanuts, which are known to cause significant allergic reactions, are required to be labeled. Voluntary labeling is recommended for 21 additional allergens: almond, abalone, squid, salmon roe, orange, cashew nut, kiwi fruit, beef, walnut, sesame, salmon, mackerel, soybean, chicken, banana, pork, matsutake mushroom, peach, mountain yam, apple, and gelatin.
- Nutritional Labeling: Nutritional labeling is mandatory for 1) calories (kilocalories); 2) protein (grams); 3) fat (grams); 4) carbohydrate (grams); and 5) sodium (salt equivalent grams). CAA

recommends voluntary labeling of the amount of saturated fat and dietary fiber. Labeling of other nutritional components, such as fatty acids, cholesterol, sugars, minerals, and vitamins is also voluntary. However, if a certain nutritional component is advertised on the package of a product, the nutritional component must be included on the label. The U.S. nutritional fact panel is not acceptable and manufacturers/importers must convert nutritional values into the Japanese format based on Japanese Food Labeling Standards.

### **Food Additives Labeling**

The labeling of food additives, including post-harvest fungicides (PHFs), is mandatory in Japan and overseen by the CAA. CAA requires additives to be labeled by substance names (e.g., DL-Alanine), by the combination of substance names and their functions (e.g., preservative (sorbic acid)), by commonly known names (e.g., “Vitamin C” instead of “Sodium L-ascorbate”), or by collective names<sup>1</sup> (e.g., flavoring agents, acidifiers, etc.). Details on Japan’s specific labeling requirements can be found on page 21 of the [JETRO guide](#).

On July 16, 2020, the CAA revised the food additive labeling requirements, which went into effect immediately with a two-year transition period. The new rule bans language such as “artificial” and “synthetic” that may mislead consumers (see [JA2020-0084](#)).

On March 4, 2021, the CAA established a committee to develop guidelines for “food additive not used” labeling in response to consumers’ misunderstanding and/or misinterpretation- of “food additive not used” labels on food packages.

### [https://www.caa.go.jp/policies/policy/food\\_labeling/meeting\\_materials/review\\_meeting\\_006/](https://www.caa.go.jp/policies/policy/food_labeling/meeting_materials/review_meeting_006/)**Country of Origin Labeling for Certain Ingredients**

CAA requires country of origin labeling (COOL) for 22 food groups and five food items listed in Appendix Table 15 of the [Food Labeling Standards](#) (Japanese only), when used as ingredients in foods manufactured in Japan. Imported processed foods are exempt from this requirement, however CAA requires the label to contain the country of origin of the finished product.

Starting on April 1, 2022, CAA will require Japanese food manufacturers to identify the country or countries where the main ingredient, by weight, was manufactured on the label of all domestically manufactured processed products. Imported processed foods are exempt, however CAA will continue to require the country of origin of the finished product. For additional details on the revisions to Japan’s COOL labeling requirement, please see [CAA’s website](#) and [JA7132](#).

### **Organic Food Labeling**

The organic section of the [JAS Act](#), enforced by MAFF, establishes Japan’s requirements for food and feed (for import requirements for organic feed, see [JA2021-0091](#)) to carry organic labeling. Based on the [U.S.-Japan organic equivalency arrangement](#), all USDA/Agricultural Marketing Service (AMS)/National Organics Program (NOP) certified plant and livestock products within the scope of the arrangement are permitted to be labeled as organic if products are imported by JAS-certified importer(s) and imports are accompanied by a TM-11 export certificate completed by a USDA-accredited certifying agent. Alcoholic beverages are not included in the scope of the organic equivalency arrangement but

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<sup>1</sup> Collective name labeling is not presently permitted for PHFs.



may be imported and labeled as such since Japan does not currently enforce organic regulations for alcoholic beverages.

### **Genetically Engineered (GE) Product Labeling**

The [Food Labeling Standards](#) (Japanese only) (see [JA7078](#) and [JA9055](#)) requires GE labeling for eight crops (soybean, corn, potato, canola, cottonseed, alfalfa, sugar beet and papaya) and 33 processed food items that contain those crops as ingredients. The Standards exempt most highly refined products that have no remaining foreign DNA, such as cooking oil and sugar from the labeling requirement. However, CAA requires products such as high-oleic soybean oil, whose nutritional values are significantly modified by inserted foreign DNA, be labelled as GE even if no foreign DNA remains in the product ([JA2020-0173](#)).

CAA allows three types of GE related claims on food labels in Japan: GE, non-segregated, and non-GE. CAA requires products to have either GE or non-segregated labels. If a product is identity-preserved as GE, it must be labeled as GE and cannot be labeled as non-segregated. If a non-identity preserved product for which approved GE varieties exist, it must be labeled as non-segregated. Separate guidance applies to potatoes and papayas. Non-GE labels are voluntary. For additional details on current labeling requirements see [JA2020-0208](#).

The Food Labeling Act was revised in April 2019 to change the threshold of unintentional contamination of GE products from five percent to non-detectable. The revisions will become effective April 1, 2023. For more information on these upcoming changes see [JA9055](#) and the [CAA website](#) (Japanese only).

### **Genome Edited Product Labeling**

Genome edited foods without foreign DNA will not be subject to the Food Labeling Act and therefore do not require mandatory labeling. However, CAA recommends labeling for genome edited products that developers have notified to MHLW. For more information, see [JA2019-0174](#).

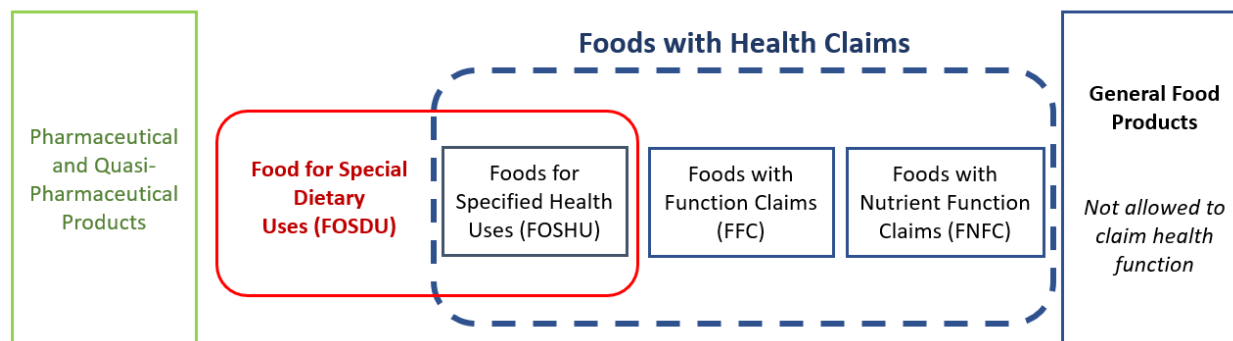
### **Alcoholic Beverage Labeling**

Japan's Liquor Tax Act, under the jurisdiction of the National Tax Agency (NTA), defines alcoholic beverages as beverages with an alcohol content of one percent or higher (those that contain less than one percent are handled as soft drinks). The labeling of alcoholic beverages is governed by the [Food Labeling Act](#), and more specific administrative instructions for alcohol labeling are stipulated under [the Act on Securing of Liquor Tax and on Liquor Business Associations](#) (Japanese only). Labeling requirements vary depending on the category to which the exported alcoholic products are classified. For a summary of alcohol beverage labeling requirements, please refer to section II of the [JETRO guide](#). Certain terms, such as "Japan Wine" are restricted to domestically produced wine (see [JA8092](#)). More information about alcoholic beverage labeling can be found on the [NTA's website](#) (Japanese only).

### **Nutritional Claims, Foods with Health Claims, and for Special Uses**

Manufactures and importers may emphasize nutritional claims, such as "rich in", "containing" or "enhanced", however, they must meet minimum content level standards required by Appendix Table 12 of [Food Labeling Standards](#) (Japanese only). Claims that include the terms "no", "less", or "reduced" with regard to calories, fat, saturated fatty acid, cholesterol, sugar or sodium, must also meet maximum content standards required by Appendix Table 13 of [Food Labeling Standards](#) (Japanese only). For

additional details, see the Japan strictly regulates health claims on food labels. There are three categories of foods which are permitted to include varying degrees of health claims: Foods with Nutrient Function Claims (FNFC), Foods with Function Claims (FFC), and Foods for Specified Health Uses (FOSHU). FNFC is the simplest of the three, followed by FFC, and FOSHU, which is the most difficult. Products outside of these three categories may not include health claims on the label.



Products classified as FNFC are those which include one or more of the supplemental nutritional components listed in Appendix Table 11 of the [Food Labeling Standards](#) (Japanese only). The contained nutritional component must be between the minimum and maximum value on the table. Japan does not require advance permission, but the health claim and notes on intake must identically match the language from the standards. Products classified as FFC may display a specific health benefit and an associated area of the human body. FFC products must be registered to the CAA. Products classified as FOSHU require an assessment by CAA and approval from MHLW in order to claim physiological effects on the human body. See [JA5025](#), [JA2020-0068](#) and the [CAA's website](#) (Japanese only) for more information.

### Plant-Based Meat/Dairy Alternative Labeling

Food Labeling Standards require that the label on retail processed food products include a general name of the product. The general name can be found in Appendix [Table 4](#) of the Food Labeling Standards or be coined a general name for new or unconventional products. General names cannot reference ingredients not included in the processed food products. Therefore, “alternative meat” cannot be used as a general name for plant-based processed food products. Companies often use “soy-based processed food” instead. Meeting this labeling requirement is the responsibility of Japanese importers and has no bearing on the package design or product name of imported processed food products.

### Misleading Representations

Any products sold in Japan must follow the [Act against Unjustifiable Premiums and Misleading Representations](#) (established in 1962) monitored by CAA. Misleading representations are strictly prohibited by the law.

## Section III. Packaging and Container Regulations

The Food Sanitation Act prohibits the sale, manufacture, or import of apparatuses, containers and packages containing toxic or injurious substances. It establishes specifications for synthetic resins, metal cans, and containers/packages made of glass, ceramic, enamel, or rubber. See details in [Chapter I](#)

- the [Ordinance for Enforcement of the Food Sanitation Act](#), [Chapter III of the Food Sanitation Act](#), and [Standards for Materials, Specifications for Synthetic Resins, Metal Cans and Apparatus and Containers](#).

Since June 2020, MHLW has implemented a positive list system for food packaging materials (for additional information, see [JA8045](#)) with a five-year transition period. The positive list contains synthetic resins used in the manufacture of food containers in Japan and in containers used for imported foods. Interested parties are encouraged to consult MHLW as Japan will only permit packaging materials included in the list after the end of the transition period. More details are available in [JA2020-0130](#) and [JA2020-0094](#).

## Packaging Sustainability Measures

With the aim of reducing garbage and promoting reuse of containers and packaging, the Container Packaging Recycling Law mandates businesses to recycle glass, plastic and paper containers and packaging and polyethylene terephthalate bottles, and requires food manufacturers and retailers to label the following recycling identification logos on retail food and beverages containers and packaging. Importers bear primary responsibility for labeling imported products, but U.S. manufacturers and exporters may be asked to help with the required labeling. More details are available on the [Ministry of Economy, Trade and Industry's website](#) and in [JA3022](#).



To reduce Japan's plastic consumption, from July 1, 2020, all Japanese retailers, including grocery stores and restaurants, will be required to assess a mandatory fee of at least 1 yen (approximately \$0.01) per plastic shopping bags. The mandatory plastic bag fee program is implemented in the [ministerial ordinance](#) related to the [Container Packaging Recycling Law under the jurisdiction of](#) the Ministry of Economy, Trade and Industry (METI) ([JA2020-0134](#)).

Aiming to facilitate the shift to a circular economy, the [Plastic Resource Circulation Act](#) was established in June 4, 2021 to mandate retailers and service providers to reduce single-use plastics including plastic spoons, forks, straws, knives and muddler. Mandatory fee is one of the ways businesses may choose to reduce these products if these products are currently provided free of charge. The Act will enter into force within one year after the establishment of the Act and the Ministry of Environment is aiming to implement on April 1, 2022.

## Section IV. Food Additive Regulations

The Food Sanitation Act defines food additives as (i) “substances used in or on food in the process of manufacturing food” or (ii) “substances used for the purpose of processing or preserving food.” Japan requires regulatory approval of substances to be used as food additives. The Act prohibits the sale of products containing unapproved food additives. The full list of approved additives is available on the [MHLW website](#). Compounds used as processing aids (such as infiltration-supporting agents) or

antimicrobial treatments, vitamins, minerals and amino acids, post-harvest fungicides, and flavoring agents are defined as food additives under the Food Sanitation Act.

MHLW classifies food additives into four categories: (i) designated additives, (ii) [existing food additives](#), (iii) [natural flavoring agents](#), and (iv) ordinary foods used as food additives <https://www.ffcr.or.jp/en/tenka/list-of-plant/list-of-plant-or-animal-sources-of-natural-flavorings.html>. MHLW mandates that the use of designated additives is limited to a specific product at a set tolerance level and for a specific purpose only. The list of approved uses and tolerances for these additives is available on the [MHLW Food Additives page](#) and the [Japan Food Chemical Foundation website](#). . Unapproved or excessive use of additives is a common cause of regulatory non-compliance for U.S. products exported to Japan, particularly in cases where Japanese standards of use are stricter than those of the United States. Unapproved or excessive use of additives is a common cause of regulatory non-compliance for U.S. products exported to Japan, particularly in cases where Japanese standards of use are stricter than those of the United States. For more details of food additive categories, please consult [MHLW's description of food additives](#).

To facilitate MHLW's import inspections, importers must have the following information readily available to port inspectors at the time of import:

1. The chemical names and content in parts per million (ppm) of all designated additives, along with Japan's maximum tolerance levels set for the chemical;
2. Names of all food additives in three additional categories described above;
3. Artificial colors identified by their chemical name and international color index number. Natural color descriptions must also be provided to determine acceptability for the specific product imported
4. Artificial flavors identified by their chemical name as they appear on the Japanese approved additive list for the specific product imported.

### **Food Additive Approval Process**

MHLW accepts applications for the approval of new food additives and new uses (e.g., use of approved additives for new target foods) as well as revisions of the tolerances for existing additives. After a preliminary review, MHLW will transfer the dossier to the FSC for a safety review. After the FSC completes a risk assessment, MHLW sets the specific use limit on a food additive for each food based on the acceptable daily intake. The application procedure for approval of new food additives or new uses of approved additives is described in MHLW's [Guidelines for Designation of Food Additives and for Revision of Standards for Use of Food Additives](#).

The [Food Additive Designation Consultation Center](#) (FADCC) in Japan's National Institute of Health Science is available to assist companies with applications for food additive use in Japan, thereby reducing the time needed to obtain regulatory approval. The FADCC provides consultations free of charge. FADCC can be reached via email. All in-person interactions must be in Japanese. Accordingly, the FADCC requests that non-Japanese applicants be accompanied by an interpreter, as necessary.

### **Additives in Alcohol**

Additives used in alcoholic beverages require additional approval by the NTA under the [Liquor Tax Act Enforcement Regulation](#) (Japanese only). MHLW approval is required before an application can be submitted to the NTA. The [NTA's requirements](#) (Japanese only) for application are as follows:

1. Name of the substance to be registered

2. Alcoholic beverage that the additive will be blended with
3. Purpose of use
4. Usage guidelines
5. Efficacy and component analyses
6. Production method
7. Name of the commercial product for which the material specified will be used, names of all the constitutive materials, and their respective weights
8. Manufacturer's name and address

## Section V. Pesticides and Other Contaminants

Japan uses a positive list system for residues of agricultural chemicals (i.e., pesticides, feed additives, and veterinary drugs) in food. This system establishes maximum residue limits (MRLs) for a pairing of an agricultural chemical and a commodity. The complete list of MRLs for agricultural chemicals in foods can be found at <http://db.ffcr.or.jp/front/>. There are [74 exempted substances](#) that have been determined to pose no adverse health risks and therefore do not have MRLs. There are [20 agrochemicals and other chemical substances](#) which are banned from use (i.e. zero tolerance).

For compound-commodity combinations with no official or provisional MRLs, MHLW applies a uniform standard of 0.01 parts per million (ppm) as the maximum allowable limit, with the exception of antibiotics. For antibiotics without established or provisional MRLs, MHLW applies zero tolerance policy. MHLW maintains a crop categorization for the designation of MRLs which may differ from U.S. crop categorizations (see [MHLW Food Classifications](#)). The [Global MRL Database™](#) allows for a comparison of U.S., Japanese and Codex MRLs.

MHLW also tests agricultural chemical residues in the processed food and determines compliance with Japanese regulations based on a calculation of the relative proportion of ingredients in the final product. Therefore, U.S. exporters may be asked to provide recipes or the proportional content of the ingredients in question. Additional information about Japan's positive list system can be found on the [MHLW's Positive List System webpage](#). Japan's current MRLs can be found at the Japan Food [Chemical Research Foundation website](#). MHLW's monitoring plan for imported foods (e.g. [Japanese Fiscal Year 2021 monitoring plan](#)), which MHLW updates annually, details commodities and compound types that are subject to import inspections.

Foods found to contain residues that exceed established MRLs are considered to be in violation of the Food Sanitation Act and are barred from entry to Japan. A single violation can lead to "enhanced monitoring" (increasing inspection rate to 30 percent) for all imports of the same product from that exporting country. Under the enhanced monitoring regime, consignments can clear customs without waiting for inspection results. MHLW will lift the enhanced monitoring regime after 60 compliant test results (across the entire industry, excluding the violator) or no further violations for a year following the initial violation. For imports from the violating exporter, MHLW initiates a 100 percent test and hold during which each shipment of the same commodity is tested prior to entry. MHLW will lift the 100 percent test and hold requirement after 60 compliant tests from the violating exporter or one year from the date of the initial violation if 60 tests have not been conducted. MHLW publishes the list of violations with commodity, company and country names, and the list of imports subject to enhanced

monitoring (see Schedules 2 and 3 of the “Monitoring Plan”) and inspection orders on its [website](#). For additional information, please consult “(2) Imported Foods Monitoring and Guidance Plan” found at [MHLW’s “Imported Foods Inspection Services Home Page.”](#)

After two violations of a specific MRL by two different exporters from the same country, all imports of the affected commodity from that country will be subject to a 100 percent hold and test, called “inspection order”. In this case, MHLW requires 300 compliant tests of the product from the country within one year before lifting the order. Alternatively, if no further violations are reported for the specific commodity-compound combination from that exporting country for two years, MHLW may lift the inspection order.

### **Establishment/Amendment of MRLs for Agricultural Chemicals**

To establish a new MRL or to change an existing MRL, interested parties must submit an application to MHLW for an extensive review process, including a risk assessment by the FSC. The documentation required for evaluation usually includes data on acute toxicity, sub-acute toxicity, chronic toxicity, carcinogenicity, reproductive toxicity, teratogenicity, mutagenicity, pharmacokinetic and general pharmacological parameters, animal metabolism, and plant metabolism, as well as residue data (for commodities treated with the pesticide in question). MHLW provides [guidelines](#) and [expected processing time](#) for applications. The executive summary of the application should be in Japanese, but other accompanying documents, such as study reports, may be written in English. MHLW does not require translation of the original reference articles. MHLW will also accept applications for import tolerances even if the MRL for the agricultural chemical has not been finalized in the exporting country.

When MHLW revises existing and provisional MRLs, MHLW notifies proposed MRLs to trading partners via the Food Safety Group (FSG) and World Trade Organization (WTO) notifications. FAS/Japan informs U.S. stakeholders about FSG’s MRL proposals and comment deadlines via [GAIN reports](#).

### **Other Contaminants and Potential Factors Leading to a Violation**

National and local Japanese health officials look for the following items in foods susceptible to (i) naturally occurring harmful substances, (ii) contamination with other harmful substances, or (iii) germs during the manufacturing process. Unlike with agricultural chemical residues, a single violation involving these contaminants results in an immediate inspection order for all imports of that commodity from the exporting country.

1. Aflatoxin in tree nuts and peanuts, as well as processed products containing tree nuts or peanuts (at a rate higher than 30 percent), spices, and some grain products such as corn
2. Enterohemorrhagic *E. coli* O26, O103, O111 and O157 in beef, horse meat, and unheated livestock products to be consumed without further cooking, such as natural cheese
3. Norovirus in bivalves and other shellfish for raw consumption
4. Hepatitis A virus in bivalves and other shellfish for raw consumption
5. Mercury in fish and shellfish
6. Polychlorinated Biphenyls (PCB) in beef, pork, fish and shellfish
7. Poisonous fish (e.g., *Sphyraena barracuda*)
8. Shellfish poisons (e.g., diarrhetic shellfish poison and paralytic poison of bivalves)
9. Cyanogen in butter beans, white beans, saltani beans, etc.
10. Methanol in distilled spirits and wines



11. Gossypol in cottonseeds other than for oil extraction
12. Salmonella in meat for raw consumption
13. *Listeria* in unheated meat products to be consumed without further cooking and natural cheese
14. Trichina in game birds, etc.
15. Radioactive substances
16. Decomposed or deteriorated (i.e., spoiled) foods of all kinds

### **Irradiation**

Irradiation of food is not permitted in Japan, with the exception of potatoes, which may be irradiated for the purpose of suppressing germination only and must be labeled accordingly. Irradiation inspection is conducted on a wide range of foods including (but not limited to): livestock products (e.g., meats and dairy), seafood (e.g., fish and shellfish), plant foods (e.g., vegetables, fruits, nuts, grains, and spices) and processed foods containing livestock, seafood and plant products. For further details, please refer to [Section IV-vii of the Implementation of Imported Foods Monitoring Plan for FY 2021](#). [Schedule 1](#) lists items subject to irradiation inspections, as well as annual monitoring frequencies.

## **Section VI: Other Requirements, Regulations, and Registration Measures**

### **Facility Registration**

U.S. establishments exporting beef, sheep (lamb), and goat meat and meat products must be approved specifically for export to Japan. Beef establishments must be listed on the [AMS Official Listing of Approved Suppliers for the USDA QSA Program](#) for Japan under the QAD 1030J program. Warehouses exporting beef to Japan must be listed as [Cold Storage Facilities Eligible to Export Beef to Japan](#). Sheep and goat meat establishments must be listed on the [AMS Official Listing for Ovine and Caprine Export Verification Programs](#) for Japan. Establishments using alternate certification for heat-treated liquid egg product exports must be listed on the [FSIS Export Requirements for Japan \(Egg Products\)](#). Processing facilities for fresh oysters must be listed on the [Interstate Certified Shellfish Shippers List \(ICSSL\)](#).

### **Product Registration**

Product registration is not mandatory. However, MHLW administers voluntary product registration processes that serve to expedite the import quarantine process. When imported foods are confirmed to be compliance with the Food Sanitation act, MHLW will register the product and the manufacturer and waive some import inspections. Product registration is valid for three years. Foreign food manufacturers request product registration with MHLW through respective foreign governments.

## **Section VII. Other Specific Standards**

### **Foods from Genetic Engineering (GE) Technology**

In most cases, the commercialization of GE food crops in Japan requires approvals from food, feed, and environmental regulators. Varieties of GE food plants that regulators have approved include soybeans, canola, corn, potatoes, sugar beets, cotton, alfalfa, and papaya. MHLW monitors imports for unapproved varieties of biotechnology. MHLW will deny entry of any shipment found to contain an

unapproved GE variety. As of August 13, 2021, Japan has approved 326 GE events for food use, please see [MHLW's website](#) for a complete list. Additional information can be found at [JA2020-0208https://www.usdajapan.org/market-research/reports/policy\\_reports/6149/](#).

### **Foods from Genome Editing Technology**

Developers of products derived from genome editing should notify the relevant regulatory authority prior to commercialization in Japan. MHLW is the regulatory authority for food safety ([JA9096](#) and [JA2019-0011](#)). MAFF is the regulatory authority for environmental safety ([JA2019-0196](#)) as well as feed safety ([JA2020-0034](#)). Japan's regulatory policies for foods from genome editing technology are summarized in [JA2021-0106](#).

### **Feed, Feed Ingredients and Feed Additives**

Please see [JA2021-0091](#).

### **Wood Products and Biofuels**

Please see [JA2019-0214](#).

## **Section VIII. Trademarks, Brand Names and Intellectual Property Rights**

International registration of trademarks under the Madrid Protocol is permitted in Japan. For more information on Japan's trademark registration system, please refer to the [Japan Patent Office website](#).

### **Protected Geographical Indications**

The "Act on Protection of the Names of Specific Agricultural, Forestry and Fishery Products and Foodstuffs" ([Geographical Indication \(GI\) Act](#)) protects the names of certain agricultural, forestry, and fishery products as intellectual property and allows for the registration of foreign products for protection in Japan. The National Tax Agency (NTA) establishes [guidelines](#) for the GI system for alcoholic beverages. A list of approved food, agricultural, forestry, and fishery product GIs is available on MAFF's website ([registered GIs](#) and [designated GIs](#)). A list of approved GIs for alcoholic beverages is available on the NTA website. For more information see [JA8065](#) and [JA5008](#).

### **Regional Collective Trademarks**

Since 2006, members of certain associations can own Regional Collective Trademarks, which consist of "the name of the region" and "the common name of goods or services." As of August 2021, there were 441 registered regional collective trademarks of agriculture, forestry and fisheries products (including three foreign products). Regional Collective Trademarks differ from GIs in that they have specific owners while GI products become common assets of a region. For additional information, see the [Japan Patent Office website](#).

## **Section IX. Import Procedures**

MHLW is the lead agency ensuring that imported foods comply with the Food Sanitation Act (a [flowchart](#) outlining the import procedures). Firms seeking to import food, food additives, containers/packages, or any other food-related apparatus into Japan must submit a [Notification Form of](#)



[Importation of Foods, etc.](#) to the Food Sanitation Inspection Section of the MHLW quarantine stations. Products selected for examination will be inspected on the spot at a designated bonded warehouse. Port officials will collect samples for laboratory analysis from a subset of the shipment. If the imported product is under an inspection order, it will be allowed entry into Japan once it is examined and found to be in compliance with Japanese food regulations. Imported products not on an inspection order will usually be permitted to clear customs while the laboratory testing is ongoing. The Notification Form will receive a stamp of approval prior to entry.

### **Required Importation Documents**

Import documents required for entry into Japan are as follows:

1. Import notification - two copies of the [Notification Form of Importation of Foods, etc.](#)
2. Export certificate, if required (see FAIRS Export Certificate Report at <https://gain.fas.usda.gov/> for additional information)
3. Documents showing ingredients, additives and the manufacturing process (e.g. manufacturer's certification), if required
4. Test results to verify compliance with the [Specifications and Standards for Food and Food Additives, etc.](#) (if necessary)

Importing companies should be able to guide exporters through the required steps and the appropriate level of detail needed for these documents. Cargo found in violation of the Food Sanitation Act must be re-exported, destroyed, diverted to non-food use (if applicable), or otherwise discarded.

In addition to the MHLW inspections, imports of plants and plant products and animal products are subject to biosecurity inspections. Japan does not have import permit systems, but requires imports to satisfy phytosanitary and animal health requirements. Importers are required to submit import notices and relevant export certificates (see FAIRS Export Certificate Report at <https://gain.fas.usda.gov/> for additional information) to MAFF Plant Protection Stations and MAFF Animal Quarantine Service prior to biosecurity inspections.

### **Sample Products**

The Notification Form is not required for products imported as commercial samples. However, depending on the product and/or the quarantine station, officials may require a document attesting that the product is a sample only and will be used for "internal company consideration." There is no restriction on the volume of products permitted for entry as commercial samples, however the volume should not exceed a reasonable or justifiable amount.

Sample products for exhibition at a trade fair also do not require submission of the Notification Form. However, if the product will be distributed to the general public, even free of charge, then all standard import procedures must be followed, including import notification. As with commercial samples, depending on the product and/or the quarantine station, officials may require a document attesting that the product is to be used only "for exhibition at a trade fair."

Products requiring certification with animal or plant health attestations will not be permitted without that certification, even if imported for sample purposes. U.S. exporters are advised to consult with importers and MHLW quarantine stations in advance to minimize potential delays and disruptions at the border.

## **Import Duties**

Import duties can be found at [Japan's Tariff Schedule](#). Inquiries may be made to the [Customs Counselor Offices](#) via email. The email addresses of regional Customs Counselor Offices can be found at [http://www.customs.go.jp/question\\_e.htm](http://www.customs.go.jp/question_e.htm).

## **Preferential Duties and Rules of Origin**

To receive preferential treatment under the U.S.-Japan Trade Agreement (USJTA), a good must be an originating good and meet the preferential rules of origin of USJTA. Section C of Annex I of the Agreement identifies the rules of origin used to determine if a good is eligible for preferential tariffs. Japan Customs applies the rules of origin described in USJTA as well as Japanese laws, regulations, or procedures that govern additional information required to verify product origin. Generally, U.S. goods are considered originating if they are wholly obtained or produced; produced entirely exclusively from originating materials; or the final product results in the necessary harmonized system code transformation. Additionally, there is a de minimis exception for non-originating materials that do not exceed 10 percent of the total value of a good even if they do not meet the rules of origin criteria.

To receive preferential treatment, Japan Customs may require an importer to submit an origin declaration document, a detailed origin declaration document, and supplementary documentation affirming product origin at the time of import. U.S. exporters are not permitted to initiate the submission of any documents to Japan Customs, however, exporters may submit supplementary documents directly to Japan Customs in coordination with the importer. Additional information on preferential rules of origin is available on the Japan Customs [website](#) and [JA2020-0049](#). Additional information on USJTA is available at <http://www.usdajapan.org/usjta>.

## **Section X: Trade Facilitation**

### **Advance Ruling**

Japan provides an Advance Classification Ruling System where importers and other related parties can inquire about the tariff classification and duty rate of the goods prior to importation and receive a response from customs. Inquiries are, in principle, to be made in writing using the inquiry form ([C-1000](#), in Japanese) including, but not limited to, the following: ingredient list with ratios indicated for each ingredient, manufacturing process flowchart, and packaging details, together with documents showing the business relationship between the importer and supplier. Upon submission, customs will reply within 30 days. No fees are required for the advance ruling. The response from customs is valid for three years from the date of issuance. Generally, importers rather than exporters apply for these advance rulings.

MHLW administers several voluntary product registration processes that serve to expedite the import quarantine process. These programs are listed on [MHLW's website](#). Please note that these processes are customarily initiated by Japanese importers rather than U.S. exporters.

### **Acceptance of Test Results**

For all imported foods, MHLW accepts test results except for bacteria, mycotoxins and other that may change during transportation issued by registered foreign official laboratories, and waives some import

inspections. The list of the registered foreign official laboratories is found [here](#). To be added to the list of MHLW-registered Foreign Official Laboratories, the laboratories must be either state or federal government-affiliated laboratories or laboratories approved or designated by a state or federal government. Laboratories also must carry out inspection by internationally recognized methods (such as the AOAC method). For details, please visit MHLW's site for [Foreign Official Laboratories](#) or see this [MHLW's document on foreign official laboratories](#).

### **E-certificates**

Japan operates an e-Cert system that can electronically receive overseas-issued export inspection certificates for animal quarantine inspections. As of September 30, 2021, only one country (Australia) is currently eligible to use this system. There is no e-certificate system in place for plant quarantine inspections.

During the COVID-19 pandemic, Japan has temporarily accepted electronic copies of sanitary and phytosanitary certificates to clear import quarantine requirements. Details for animal products are available in [JA2020-0089](#) and for select horticultural products in [JA2020-0111](#). Japan does not use the IPPC Global e-phyto hub.

### **Fees**

Applicable fees during import include the import duty, consumption tax, and liquor tax for alcoholic beverages. If subject to customs inspection, the importer will need to pay transportation costs to the inspection site. Additional customs fees can be found on the [Japan Customs website](#).

### **Release Times**

The average release time for general cargo (from the arrival of goods to the issuance of an import permit) is 0.5 days for air freight and 2.6 days for ocean freight (source: [Ministry of Finance Customs Survey 2018](#)). For agriculture and food products, the most common reason for delay is incomplete documentation or discrepancies within the required paperwork. This is particularly true for animal product imports which often require numerous export certificates issued by the competent authority of the exporting country. U.S. exporters of meat and poultry products are advised to closely review the information provided on the USDA FSIS [Export Library for Japan](#).

## **Appendix I. Government Regulatory Key Agency Contacts**

### **Ministry of Health, Labor, and Welfare (MHLW)**

Address: 1-2-2, Kasumigaseki, Chiyoda-ku, Tokyo

#### Food Safety Standards (food additives, MRLs, etc.)

Standards and Evaluation Division, Department of Human Health and Environment, Pharmaceutical Safety and Environmental Health Bureau, MHLW

Tel: 81-3-3595-2341

#### Food Safety Monitoring (Imported Food Monitoring Policy)

Office of Import Food Safety, Department of Human Health and Environment, Pharmaceutical Safety and Environmental Health Bureau, MHLW

<https://www.mhlw.go.jp/english/topics/importedfoods/index.html>

#### Quarantine Stations

<https://www.mhlw.go.jp/english/topics/importedfoods/1-2.html>

### **Ministry of Agriculture, Forestry and Fisheries (MAFF)**

Address: 1-2-1, Kasumigaseki, Chiyoda-ku, Tokyo

#### Animal Health and Quarantine

Animal Health Division, Food Safety and Consumer Affairs Bureau, MAFF

Tel: 81-3-3502-5994

MAFF Animal Quarantine Service: <http://www.maff.go.jp/aqs/english/>

11-1, Haramachi, Isogoku, Yokohama City, Kanagawa 235-0006

#### Plant Health and Quarantine

Plant Protection Division, Food Safety and Consumer Affairs Bureau, MAFF

Tel: 81-3-3502-5976

MAFF Plant Quarantine Service: <http://www.maff.go.jp/pps/j/information/languages.html#en>

Address: Kitanakadori, Naka-ku, Yokohama City, Kanagawa 231-0003

#### State-Traded Rice, Wheat and Barley

Grain Trade and Operation Division, Crop Production Bureau, MAFF

Tel: 81-3-6744-0585

#### Organic JAS System: [https://www.maff.go.jp/e/policies/standard/specific/organic\\_JAS.html](https://www.maff.go.jp/e/policies/standard/specific/organic_JAS.html)

Standards and Conformity Assessment Policy Office, Food Manufacture Affairs Division, New Business and Food Industry Department, Minister's Secretariat, MAFF

Tel: 81-3-6744-7180

#### Fisheries Products

Fishery Products Trade Office, Japan Fisheries Agency, MAFF

Tel: 81-3-3501-1961

**Consumer Affairs Agency**

Address: 3-1-1, Kasumigaseki, Chiyoda-ku, Tokyo, 100-8958

Tel: 81-3-3507-8800

<http://www.caa.go.jp/en/index.html>

**Japan Customs**

Address: 3-1-1 Kasumigaseki, Chiyoda-ku, Tokyo

Advance Classification Ruling System (FAQ):

[http://www.customs.go.jp/english/c-answer\\_e/imtsukan/1202\\_e.htm](http://www.customs.go.jp/english/c-answer_e/imtsukan/1202_e.htm)

Customs Answer (FAQ) – Information on importation into Japan: [http://www.customs.go.jp/english/c-answer\\_e/customsanswer\\_e.htm](http://www.customs.go.jp/english/c-answer_e/customsanswer_e.htm)

**World Trade Organization (WTO) Enquiry Point**

Standards Information Service International Trade Division, Economic Affairs Bureau

Ministry of Foreign Affairs

Address: 2-2-1, Kasumigaseki, Chiyoda-ku Tokyo

Tel: (81) 3 5501 8344 (International)

Fax: (81) 3 5501 8343 (International)

Email: [enquiry@mofa.go.jp](mailto:enquiry@mofa.go.jp)

For additional assistance, please contact USDA Japan at:

**U.S. Department of Agriculture's Office of Agricultural Affairs in Tokyo, Japan**

Embassy of the United States of America

Office of Agricultural Affairs

Unit 9800 Box 475

DPO AP 96303-0475

Tel: 81-3-3224-5102

Fax: 81-3-3589-0793

E-mail: [agtokyo@fas.usda.gov](mailto:agtokyo@fas.usda.gov)

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

Twitter: @USDAJapan

**Attachments:**

No Attachments