Required Report: Required - Public Distribution **Date:** October 07, 2022

Report Number: JA2022-0079

Report Name: Food and Agricultural Import Regulations and Standards Country Report

Country: Japan

Post: Tokyo

Report Category: FAIRS Annual Country Report

Prepared By: FAS Japan Staff

Approved By: Mark Wallace

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.

Table of Contents

Executive Summary

Seven major laws govern food and agricultural products in Japan. These laws cover food safety and sanitation, labeling, plant health, animal health, nutrition standards, and quality assurance. Japan revised the Food Sanitation Act in 2018; several changes took 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 take effect April 1, 2023. From August 5, 2023, Japan will start enforcing stricter rules on import plant quarantine and require the attachment of phytosanitary certificates to grains and oilseeds shipments (previously that requirement had been waived). Thenceforth, shipments without required phytosanitary certificates on arrival will be subject to disposal under the Plant Protection Act.

Prior to importing food products, importers must submit the Notification Form of Importation of Foods to the MHLW quarantine stations at the port of entry. MHLW quarantine stations permit entry of products once they confirm compliance with Japanese food regulations. Quarantine officials may request additional information, such as ingredient proportions and manufacturing processes, prior to granting entry. Importers seeking preferential tariff treatment for U.S. products under the U.S.-Japan Trade Agreement must ensure they meet the applicable rules of origin. The scope of this report includes all *food* products. Import regulations and standards for *feed* are covered in JA2021-0091; *wood* products are covered in JA2019-0214; hemp and hemp-derived products are addressed in the "Hemp-Derived Products" section.

Section I. Food Laws

Seven major laws in Japan govern 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; it also prohibits the sale and import of foods and beverages containing harmful substances. The law sets the monitoring guidelines, plans, and inspection measures (including penalties for failed inspections) for domestic and imported foods and beverages, as well as tableware, kitchen utensils, and more. The law is administered by the Ministry of Health, Labor, and Welfare (MHLW), Japan's food safety authority.

3) Food Labeling Act: This law sets the Food Labeling Standards (Japanese only) (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. The Consumer Affairs Agency (CAA) administers the law.

4) Plant Protection Act: This law aims to prevent plant pests and diseases from establishing or spreading in Japan. The Ministry of Agriculture, Forestry, and Fisheries (MAFF), Japan's national plant protection authority, administers the law. 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 MAFF's list of prohibited plants organized by quarantine pests).

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 products that meet the JAS criteria for that product category. Labels are permitted for production, handling, and testing methods. Private companies may propose new JAS standards. MAFF administers the law. Additional information can be found in JA2019-0195 and on MAFF's website.

Section II. Labeling Requirements

All foods sold to consumers must comply with labeling requirements set by the Food Labeling Standards (Japanese language only) of the Food Labeling Act. Japanese importers bear sole responsibility to develop labels in Japanese compliant with specific Food Labeling Standards. U.S. labels are not acceptable. Please see the CAA's website for detailed information.

Fresh Food Labeling

The Food Labeling Standards defines fresh food 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 (Japanese only) exist for the following items:

- Rice
- Shiitake mushrooms
- Citrus, stone fruit, kiwi, banana, apple, pear, and other fruits
- Meat
- Milk
- Eggs with shell
- Beans containing cyanide
- Farmed seafood
- Frozen seafood
- Chilled seafood
  - 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
    - Allergen labeling: the ingredient list must identify products classified as significant allergens (i.e., shrimp, crab, wheat, buckwheat, egg, dairy, peanuts) by MHLW. MHLW highly recommends also listing the following additional allergens on the ingredients list: 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.
    - Labeling of certain genetically engineered (GE) ingredients as "GE" or "GE non-segregated." Further details in sections below.
  - Country of origin labeling for main ingredients: CAA requires country of origin labeling of the main ingredient, by weight, of all domestically manufactured processed products. For imported processed foods, it is not required. For additional details, please see CAA's website and JA7132.
- 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
- 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 voluntary. 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

Food additives, including post-harvest fungicides (PHFs), must be labeled. CAA requires additive labeling to contain either (i) substance name (e.g., DL-Alanine), (ii) a combination of the substance name and function (e.g., preservative (sorbic acid)), (iii) commonly known name (e.g., "Vitamin C" instead of "Sodium L-ascorbate"), or (iv) a collective name for certain approved additive categories[1] (e.g., flavoring agents, acidifiers, etc.). The JETRO guide (page 21) details Japan's specific labeling requirements. Since July 2020 CAA prohibits the use of terms, such as "artificial" and "synthetic," in food additive labeling to avoid misleading consumers (see JA2020-0084).

On March 1, 2022, CAA finalized a new guideline (in Japanese) in response to the proliferation of "no food additive used" labeling on food packaging. The guideline only addresses package labeling in Japanese for all edible products. Importers and distributors are responsible for compliance. The guideline does not uniformly prohibit the "no food additive[2]" labeling or advertisement, but lists the following examples of misleading statements on food additives which are prohibited:

1. "additive-free" claim that does not specify a particular food additive compound;
2. terms such as "artificial," "synthetic," "natural" and "no chemicals" as they are not statutorily defined;
3. products for which MHLW has not approved food additives (see Japan's list of approved food additives with target foods);
4. when manufacturer utilizes food additive X for a similar purpose as food additive Y, then the food packaging must not state "no food additive Y";
5. when product contains an ingredient which serves the same function as ingredient Z, then packaging must not state "no ingredient Z";
6. package must not claim association between absence of food additives and food safety or health; all approved food additives passed Japan's food safety review;
7. quality claims (such as desirable taste or shelf life) due to the absence of food additives in the product;
8. "no food additive" claims on packages of products for which the industry standard is no food additives;

[1] Collective name labeling is not presently permitted for PHFs.
[2] The guidance also covers equivalent phrases, such as "food additive not used," "no additive" etc.

9. claims of "no additive Q" in product, when an ingredient contained additive Q so substance Q can be carried over[3] and manufacturer cannot confirm absence of the specific substance;
10. use of graphics or design to call attention and emphasize "no additive" claims.

Organic Food Labeling

The organic section of the JAS Act, enforced by MAFF, establishes Japan's requirements for food and feed to carry organic labeling (for import requirements for organic feed, see JA2021-0091). 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 may be imported and labeled as such since Japan does not currently enforce organic regulations for alcoholic beverages[4].

Genetically Engineered (GE)[5] 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 from the labeling requirement most highly refined products that have no remaining foreign DNA, such as cooking oil and sugar.

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 it is 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.

On April 1, 2023, CAA will begin to enforce new Food Labeling Standards for GE products which changed the threshold of unintentional contamination of GE products from five percent to non-detectable. For more information on these upcoming changes see JA9055 and the CAA website (Japanese only).

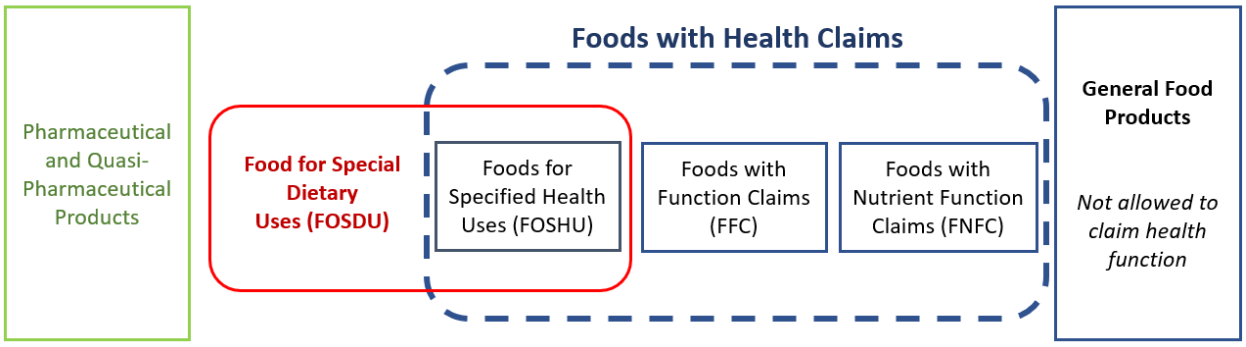
Genome Edited Product Labeling

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.

[3] Japan does not require labeling of carried over ingredients.
[4] Japan has notified to the World Trade Organization (WTO) regarding the future revision of organic JAS Act to regulate organic alcoholic beverages, but its enforcement timing is undetermined as of September 23, 2022.
[5] The Japanese Government uses "Genetically Modified" rather than "Genetically Engineered". The term in Japanese "*idenshi kumikae* (遺伝子組換え)" is used in the label.

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 in which the exported alcoholic products are classified. For a summary of alcoholic 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 Foods for Special Uses
Manufacturers 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).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. See JA5025, JA2020-0068 and the CAA's website (Japanese only) for more information.



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 law.

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. General names can be found in Appendix Table 4 of the Food Labeling Standards (Japanese only) or the product developer can coin 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. MAFF has approved several JAS standards for plant-based meat and dairy, including textured soy protein products (see JA2021-0149) and soymilk (see JA2022-0076). In September, JAS also set standards for labeling

processed foods suitable for vegetarians or vegans (see JA021-0089) and defined the terms "vegetarian" and "vegan." Importers and distributors are responsible for ensuring JAS-compliant use of product terms in Japanese.

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. For details, consult 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. Although MHLW has closed the official comment period on the proposed list of allowed synthetic resins (JA2022-0042), interested parties are encouraged to contact MHLW and FAS/Japan with inquiries since MHLW will only permit approved packaging materials beginning June 2025 (JA2020-0130 and JA2020-0094).

Packaging Sustainability Measures

With the aim of reducing waste and promoting reuse of containers and packaging, the Container Packaging Recycling Law requires businesses to recycle glass, plastic and paper containers and packaging, and polyethylene terephthalate bottles. The law also requires food manufacturers and retailers to label the following recycling identification logos on retail food and beverage 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.

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." MHLW's definition of "food additives" includes compounds used as processing aids (such as infiltration-supporting agents) or for antimicrobial treatments, vitamins, minerals and amino acids, post-harvest fungicides, and flavoring agents. Prior to use, MHLW requires approval of substances categorized as food additives. The full list of approved additives is available on the MHLW website. The Food Sanitation Act prohibits the sale of products containing unapproved food additives.

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. 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. For more details on 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 each chemical;
2. Names of all food additives in the 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 compliance with Japanese regulations for the specific product imported;
4. Artificial flavors identified by their chemical name as it appears on the Japanese approved additive list.

Food Additive Approval Process

Japan requires MHLW's safety review and approval of all food additives prior to commercial application. MHLW details the application procedure for approval of new food additives or new uses of approved additives in the Guidelines for Designation of Food Additives and for Revision of Standards for Use of Food Additives. 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 use limits set for approved additives. After a preliminary review, MHLW transfers 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 Food Additive Designation Consultation Center (FADCC) of Japan's National Institute of Health Science is available to assist companies with food additive applications. The FADCC provides consultations free of charge (see FADCC contact page for email address and phone number). All in-person interactions must be in Japanese so applicants who do not speak Japanese must come to FADCC with an interpreter.

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 to be blended with the additive
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 (such as 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. Japan's current MRLs can be found at the Japan Food Chemical Research Foundation website. There are 75 exempted substances that have been determined to pose no adverse health risks and therefore do not have MRLs. There are 21 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, except for antibiotics. For antibiotics without established or provisional MRLs, MHLW applies a 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. Japan does not accept Codex MRLs for imported foodstuffs unless MHLW adopts the MRLs.

MHLW tests agricultural chemical residues in processed food to determine 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 Positive List System webpage. MHLW's monitoring plan for imported foods (Japanese Fiscal Year 2022 monitoring plan), which MHLW updates annually, details commodities and compound types that are subject to import inspections.

MHLW considers foods which contains residues that exceed established MRLs as violative of the Food Sanitation Act and bars them 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 either 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 hold and test during which each shipment of the same commodity must pass inspection prior to clearance for entry. MHLW will lift the 100 percent test and hold requirement[6] 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.

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.

[6] Currently, it is possible for the industry to be subject to enhanced monitoring, even though the initial violator has met conditions to exit MHLW's inspection order.

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.

Establishment/Amendment of MRLs for Agricultural Chemicals

Japan does not require pesticide registration for use on imported foodstuffs, but MHLW must approve relevant MRLs. To establish a new MRL or to change an existing MRL, interested parties must apply 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 agricultural chemical 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 via GAIN reports about FSG's MRL proposals and comment deadlines (e.g. Japan 249th Food Safety Group).

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 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 spices, tree nuts and peanuts, including processed products with peanut or tree nut content of least 30 percent, and some grains, 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. Fish poison (e.g., poison of *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 natural cheese and unheated meat products to be consumed without further cooking;
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, except for 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 (such as meats and dairy), seafood (such as fish and shellfish), plant foods (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 2022. Schedule 1 lists items subject to irradiation inspections, as well as annual monitoring frequencies.

Section VI: Other Requirements, Regulations, and Registration Measures

Facility Registration for Animal Products
Various U.S. agencies administer facility registration according to products, such as meat, poultry, and egg products. U.S. exporters are encouraged to first check with the FSIS Export Library. U.S. establishments exporting beef, sheep (lamb), and goat meat as well as all 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).

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 products derived from unapproved biotechnology. MHLW will deny entry of any shipment found to contain an unapproved GE variety. As of September 2022, Japan has approved 331 GE events for food use; please see MHLW's website for a complete list. Additional information can be found at JA2021-0140.

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 the registration of foreign products for protection in Japan. MAFF maintains the list of approved GIs for food, agricultural, forestry, and fishery products (registered GIs and designated GIs). The National Tax Agency (NTA) establishes guidelines (available in Japanese language only), which are based on the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)) for the GI system for alcoholic beverages. 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 September 2022, there are 456 registered regional collective trademarks for agriculture, forestry, and fisheries products (including three foreign products, such as Ceylon Tea and Prosciutto di Parma). 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 (see 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, the quarantine station will permit entry into Japan once it examines the product and confirms compliance with Japan's food regulations. Unless imported products are under an inspection order, they will usually be permitted to clear customs while the laboratory testing is ongoing. Quarantine officials will apply a stamp of approval to the Notification Form prior to entry.

Required Importation Documents

The following import documents in Japanese are required for entry into Japan:

1. Import notification - two copies of the Notification Form of Importation of Foods, etc.;
2. Export certificate, if required (e.g., animal health certificates and phytosanitary certificates, 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 required).

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

MHLW does not require the Notification Form for products imported as commercial samples. However, depending on the product 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 entry without that certification, even if imported for sample purposes. U.S. exporters are advised to consult 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 here.

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, goods are considered to be originating from the United States if they are wholly obtained or produced in the United States; produced entirely from U.S.- originating materials; or the final product produced in the U.S. 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, but exporters *may* submit supplementary documents directly to Japan Customs *in coordination with the importer*. Japan Customs is unlikely to retroactively award preferential tariff for USJTA eligible items. Exporters should inform importers about relevant USJTA preferential access so that the importer can provide proper documentation to Japan Customs. Additional information on preferential rules of origin is available on the Japan Customs website and JA2020-0049. Additional information on USJTA is available is 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 should 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; and 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 issued by registered foreign official laboratories and waives chemical residue inspections during import unless (i) MHLW perceives risk of increased contamination during transit (such as bacteria and mycotoxins) or (ii) imported product is under inspection order. To be added to the list of MHLW-registered Foreign Official Laboratories, 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 does not accept electronic sanitary or phytosanitary certificates for U.S. products. Japan does not use the IPPC Global e-phyto hub.

Since 2020, in response to the COVID-19 pandemic, Japan has temporarily accepted pdf copies of sanitary and phytosanitary certificates to help clear import quarantine requirements. Details for animal products are available in JA2020-0089 and for select horticultural products in JA2020-0111.

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. Also, importers must bear test fees for products subject to MHLW inspection orders.

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 according to the 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)
Head Office: Address: 1-2-1, Kasumigaseki, Chiyoda-ku, Tokyo

Animal Health and Quarantine
Animal Health Division, Food Safety and Consumer Affairs Bureau, MAFF (Head Office)
Tel: 81-3-3502-5994
MAFF Animal Quarantine Service: http://www.maff.go.jp/aqs/english/
11-1, Haramachi, Isogo-ku, Yokohama City, Kanagawa 235-0006

Plant Health and Quarantine
Plant Protection Division, Food Safety and Consumer Affairs Bureau, MAFF (Head Office)
Tel: 81-3-3502-5976
MAFF Plant Quarantine Stations: 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 (Head Office)
Tel: 81-3-6744-0585

Organic JAS System: 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 (Head Office)
Tel: 81-3-6744-7180

Fisheries Products
Fishery Products Trade Office, Japan Fisheries Agency, MAFF (Head Office)
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
Customs Answer (FAQ) – Information on importation into Japan: 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

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

Attachments:

No Attachments