Required Report: Required - Public Distribution **Date:** January 03,2020

Report Number: JA2019-0216

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

Country: Japan

Post: Tokyo

Report Category: FAIRS Annual Country Report

Prepared By: USDA Japan

Approved By: Alexander Blamberg

Report Highlights:

This report is an overview and update of Japan's food and agricultural import regulations and standards (FAIRS) for U.S. agricultural exports to Japan. For more information on Japan's certificate requirements, see the FAIRS Export Certificate Report for Japan at https://gain.fas.usda.gov/. While every possible care has been taken in preparation of this report, information provided may no longer be complete or precise as some import requirements are subject to frequent changes. U.S. exporters should ensure that all necessary custom clearance requirements have been verified with local authorities through foreign importers before the sales conditions are finalized. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

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 set to take 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 for food safety, including food additives and maximum residue limits. The Ministry of Agriculture, Forestry, and Fisheries (MAFF) oversees animal and plant health, geographical indications, and organic standards enforcement. The Consumer Affairs Agency (CAA) oversees labeling. Importers are solely responsible 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 or agricultural products, importers must submit the Notification Form of Importation of Foods to the quarantine stations at the port of entry. The product will be allowed entry once the product 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.

The scope of this report includes all edible food products. Import regulations and standards for wood products are covered in JA2019-0214.

Contents

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[1]: 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 imports of foods and beverages containing harmful substances. The law also sets the monitoring guidelines, plans, and inspection measures for both domestic and imported foods and beverages, as well as tableware, kitchen utensils, etc. and establishes penalties for failing inspections. It is administered by the Ministry of Health, Labor and Welfare (MHLW), Japan's food risk management agency,
3) Food Labeling Act: This law sets 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" that are suitable for special dietary uses for infant, children, pregnant women, sick people, etc. It is administered by MHLW.
7) Japanese Agricultural Standards (JAS) Act: This law establishes a voluntary quality assurance system for foods, beverages (excluding alcohols) 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 or on MAFF's website.

[1] The Act was revised in June 2018 and MHLW enforcement of most revisions will begin in 2020. The major revisions pertaining to imported foods that have been proposed are to require public health attestations for dairy products and some seafood (e.g., puffer fish and fresh consumption oyster) and Hazard Analysis Critical Control Point (HACCP) based sanitation management for some products such as meat (see JA8103). The revision also includes the introduction of a positive list system for food container and packaging materials (see JA8045).

Section II. Labeling Requirements

Japanese importers bear sole responsibility for the development of labels compliant with Japanese food labeling regulations. Japanese importers may request application of Japanese language labels in the United States, but it is not required by the Government of Japan.

Fresh Food Labeling

Fresh food products require the name of the product and country of origin on the label. Special additional labeling requirements for the following 13 items are described on the CAA's website (Japanese only):

1) Rice
2) Shiitake mushrooms
3) Citrus
4) Meat
5) Milk
6) Eggs with shell
7) Beans containing cyanide
8) Seafood
9) Processed seafood for raw consumption (excluding oysters and pufferfish)
10) Pufferfish for cooking
11) Pufferfish for raw consumption
12) Frozen fresh seafood
13) Oysters for raw consumption

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:

- 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;
- The 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 (see CAA's instructions);
- Storage instructions;
- Labeling of certain genetically engineered (GE) ingredients as "GE" or "GE non-segregated." Further details in sections below;
- Allergen labeling (see details).
    - Foods containing shrimp, crab, wheat, buckwheat, egg, dairy products, and peanut which are known to cause significant allergic reactions are required to be labeled. The voluntary labeling is recommended for 20 additional allergens: abalone, squid,

salmon roe, orange, cashew nut, kiwi fruit, beef, walnut, sesame, salmon, mackerel, soybean, chicken, banana, pork, matsutake mushroom, peach, yam, apple, and gelatin.

Food Additives Labeling

The labeling of food additives, including post-harvest fungicides, is mandatory in Japan and administered by CAA. Additives are required 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 (e.g., flavoring agents, acidifiers, etc.). Details on Japan's specific labeling requirements can be found on the CAA's website (in Japanese only) and on page 21 of the JETRO guide.

Country of Origin Labeling for Certain Ingredients

Country of origin labeling (COOL) is required 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, the country of origin of the finished product is required on the label.

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

Organic Food Labeling

The Organic JAS Law, enforced by MAFF, establishes Japan's requirements for food and feed to carry organic labeling. Based on the 2014 U.S.-Japan equivalency arrangement, all USDA/Agricultural Marketing Service (AMS)/National Organics Program (NOP) certified plant products within the scope of this arrangement are permitted to be labeled as organic if accompanied by a TM-11 export certificate completed by a USDA-accredited certifying agent. Additionally, Japan unilaterally permits certified organic animal feed from countries that share organic equivalency with Japan, such as the United States (see JA7059). Organic dairy, meat products, and alcoholic beverages are not included in the equivalency arrangement but may be imported and labeled as such since Japan does not currently enforce organic JAS regulations for these products.

Genetically Engineered (GE) Product Labeling

Three types of GE claims may be made on food labels in Japan: GE, non-segregated (i.e. without identity preservation), and non-GE. GE and non-segregated product labeling is mandatory. If a product is identity-preserved as GE, it must be labeled as GE. If a product for which approved GE varieties exist (e.g. grains, oilseeds) is distributed without identity preservation, it must be labeled as non-segregated (regardless of the percentage of GE or non-GE in the product). Separate guidance applies to other GE crops such as potatoes and papaya. See JA9055 for further details.

Non-GE labeling is voluntary. To make non-GE labeling claims about foods or ingredients, the commodities must be handled under an identity preservation system and segregated from other GE and non-segregated products. A non-GE product cannot contain more than five percent of GE components. If test results demonstrate more than five percent of GE components are contained therein, the product must be labeled as non-segregated.

The Food Labeling Act was revised in April 2019 to amend these labeling requirements effective April 1, 2023. For more information on these upcoming changes see JA9055 and the CAA website (Japanese only).

Genome Edited Foods Labeling

In 2019, CAA announced that genome edited foods without foreign DNA will not be subject to the Food Labeling Act and therefore do not require mandatory labeling. However, the CAA recommends labeling for genome edited products that have been 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).

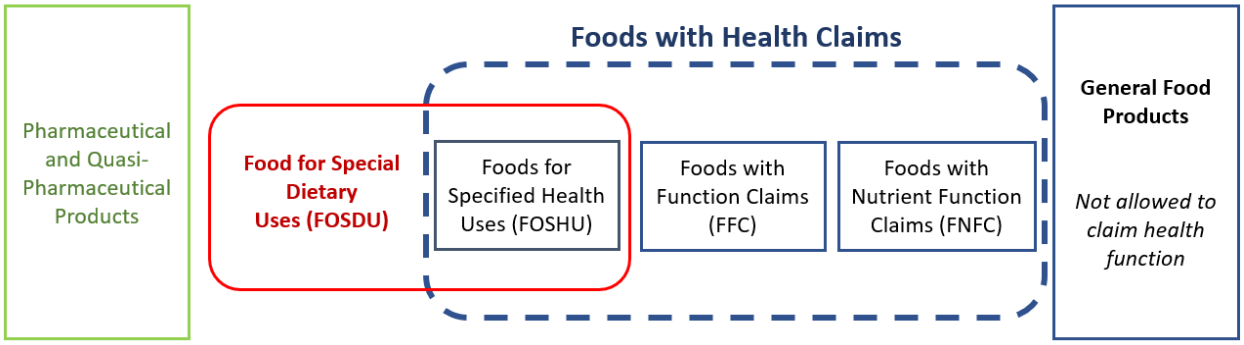
Nutritional Labeling and Nutrition Claims

Nutritional labeling requirements for processed foods will come into effect on April 1, 2020. Nutritional labeling will become 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, it is required to include the nutritional component on the label. The U.S. nutritional fact panel is not acceptable and manufacturers/importers must convert nutritional values into the Japanese format.

Manufactures/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 CAA's website (Japanese only).

Foods with Health Claims and for Special Uses

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. Advance permission from the government is not required, however 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 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 the law. For additional information, see CAA's website.

Section III. Packaging and Container Regulations

The Food Sanitation Act prohibits the sale, manufacture, or import of apparatus, containers, or 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.

In 2018, the Food Sanitation Act was revised to introduce a positive list system for food packaging materials (for additional information, see JA8045). The positive list targets synthetic resins used in the manufacture of food containers in Japan, and the containers used for foods imports. MHLW intends to implement the new system on June 1, 2020, at which time only packaging materials registered in the list will be permitted in the Japanese market, however, the specific transition process of enforcement remains unclear.

Package Recycling

Private industry is required pay all costs associated with collecting, sorting, transporting and recycling paper and plastic packaging. Paper and plastic packaging and containers must be labeled for appropriate recycling. 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.

Container and Packaging Requirements for Stated-Traded Rice, Wheat and Barley

MAFF requires importers of the state-traded rice, wheat, or barley to provide a document verifying that the packaging materials (such as flexible container bags) were tested and meet the specifications and standards for packaging and containers as described in the Food Sanitation Act. Bags carrying state-traded rice, wheat, or barley must use the same lot of materials tested. There is no specific format for certification; however, importers generally submit test results from MHLW-registered Foreign Official Laboratories. In addition, importers must verify that shipments meet all testing requirements under the purchase contract. With the aforementioned introduction of a positive list system for food apparatus, containers and packaging in 2020, MAFF intends to revise this requirement.

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 imported 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 certain food additives as "designated additives" which are limited for use on 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 at the MHLW website listed above and the Japan Food Chemical Research Foundation's (JFCRF) Standards for Use of Food Additives website. Unapproved or excessive use of "designated 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. The three additional food additive categories are: Existing Food Additives, Substances Which are Generally Provided for Eating or Drinking as Foods and Which are Used as Food Additives, and Plant or Animal Sources of Natural Flavorings.

To facilitate MHLW's import inspections, the following information should be readily available to port inspector at the time of import:

1. The chemical names and content in parts per million (ppm) of all synthetic additives with tolerance levels set by MHLW;
2. Names of all natural food additives;
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 exported; and,
4. Artificial flavors identified by their chemical name as they appear on the Japanese approved additive list for the specific product exported.

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 completion of risk assessment by FSC, MHLW sets the specific use limitation level of 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, however all interaction must be in person and 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 to be 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 agricultural chemical residues, feed additives, and veterinary drugs (hereinafter referred to as agricultural chemicals) in food. This system establishes maximum

residue limits (MRLs) for the combination of an agricultural chemical and a product. 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 for use (i.e. zero tolerance).

For compound-commodity combinations with no official or provisional MRLs, a uniform tolerance of 0.01 parts per million (ppm) is applied as the maximum allowable limit. MHLW maintains a unique crop categorization for the designation of MRLs which may differ from U.S. crop categorizations (see MHLW Food Classifications). The Global MRL Database™ compares U.S and Japanese MRLs.

For compound-processed food combinations with no established MRLs in Japan, MHLW tests the processed food for chemical residues and determines compliance with Japanese regulation based on a calculation of the relative proportion of ingredients in the final product. Therefore, U.S. exporters may to be asked to provide recipes or the proportional content of the ingredients in question. Additional information about Japan's positive list system, including actual MRLs, can be found at the MHLW's Positive List System webpage. Each year MHLW develops a specific monitoring plan (see here for 2019), and the monitoring plan may be revised if a violation is reported.

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. 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 the violator (exporter) of that commodity, MHLW initiates a 100 percent hold and test during which each shipment of the same commodity is tested prior to entry. MHLW will lift the 100 percent hold and test requirement after 60 clean tests from the violating exporter or one year from the date of the initial violation if 60 tests have not been conducted. 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 inspection order. In this case, MHLW requires 300 clean 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 Agrochemicals

To establish a new MRL or to change existing MRLs, 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 target pesticides). 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 if the MRL for an agrochemical has not yet been finalized in the exporting country.

Additionally, MHLW periodically reviews existing and provisional MRLs, and notifies proposed MRLs to trading partners via the Food Safety Group (FSG) and World Trade Organization (WTO) notification. GAIN reports provide U.S. stakeholders with information about proposed MRL changes and comment processes, including deadlines.

Other Contaminants and Potential Factors Leading to a Violation

Officials look for the following items in foods susceptible to naturally occurring harmful substances, or that may be contaminated with harmful substances, or germs during the manufacturing process.

1. Aflatoxin in tree nuts and peanuts, as well as processed products containing tree nuts or peanuts (at the 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 meat 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;
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; and,
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 to suppress germination and must be labeled accordingly. Irradiation inspection is conducted for a wide range of foods including (but not limited to): livestock products (e.g. meats and dairy), seafood (e.g. fish and shellfish), agricultural foods (e.g. vegetables, fruits, nuts, grains, and spices) and processed foods containing livestock, seafood and agricultural products. For further details, please refer to "the section IV-vii of the 'Implementation of Imported Foods Monitoring Plan for FY 2019'". Schedule 1 lists items subject to irradiation inspections, as well as annual monitoring frequencies.

Section VI: Other Requirements, Regulations, and Registration Measures

Product Registration

Product registration is not mandatory. However, MHLW administers several voluntary product registration processes that serve to expedite the import quarantine process. These programs are listed on the MHLW's website. Please note that these processes are customarily initiated by Japanese importers rather than U.S. exporters.

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 LT30 QSA Program or 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 optional alternate certification for heat-treated liquid egg product exports must be listed on the FSIS Export Requirements for Japan (Egg Products). Processing facilities of oysters for raw consumption must be listed on the Interstate Certified Shellfish Shippers List (ICSSL).

Optional Pre-export Testing

Pre-export testing is not required, but can facilitate entry for new-to-market products. MHLW recommends that Japanese importers deliver a small sample of the product to the Japanese customs and MHLW port inspection offices with a certificate guaranteeing compliance with required product regulations. During the review process, a Japanese port official may request the importer to test the sample in a MHLW-registered domestic laboratory in Japan.

Pre-export tests may also be conducted at MHLW-registered laboratories in the United States. MHLW may waive testing upon arrival in Japan if accompanying documentation contains the necessary test results and confirmation of product specifications and compliance with Japanese regulations. 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.

Wood Products

Japan's import regulations and standards for wood products are described in a separate FAIRS report (JA2019-0214), which details phytosanitary, sustainability and other requirements for wood materials.

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 plants that have been approved include soybeans, canola,

corn, potatoes, sugar beets, cotton, alfalfa, and papaya. MHLW monitors imports for unapproved varieties of biotechnology in order to enforce its zero tolerance for varieties whose safety has not been officially confirmed by the Japanese government. Any shipment found to contain an unapproved variety may not be imported into Japan. As of November 12, 2019, Japan has approved 322 GE events for food use (see MHLW's website). Additional information can be found at JA8086.

Foods from Genome Editing Technology

Developers of products derived from genome editing are required to notify the relevant regulatory authority prior to commercialization in Japan. MHLW regulates food safety (see JA9096 and JA2019-0011). MAFF regulates policy and guidance for environmental safety (latest information available in JA2019-0196). MAFF also regulates, but has not yet finalized policy and guidance for feed safety.

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 products as intellectual property and allows for the registration of foreign products for protection in Japan. 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 alcoholic beverage GIs is available at 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 October 2019, there were 669 registered regional collective trademarks (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

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. Samples will be taken and forwarded for laboratory analysis. The product will be allowed entry into Japan once it is examined and found to be in compliance with Japanese food regulations. The Notification Form will receive a stamp of approval prior to entry. For repeated imports of the same products, submission of some documents may be waived. MHLW provides a useful flowchart on their website outlining the process.

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. Test results, if required;
4. Documents showing ingredients, additives and the manufacturing process (e.g. manufacturer's certification), when required.

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

Import Duties

Import duties can be found at Japan's Tariff Schedule. Inquires 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.

Sample Products

The Notification Form is not required for products imported as commercial samples. However, depending upon the product and/or the quarantine station, officials may require a document attesting that the product is a sample only and to 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 upon 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.

Appendix I. Government Regulatory Key Agency Contacts

Ministry of Health, Labor, and Welfare (MHLW)
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)
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: http://www.maff.go.jp/e/policies/standard/jas/specific/organic.html
  Standards and Conformity Assessment Policy Office, Food Manufacture Affairs Division, Food Industry Affairs Bureau, 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
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: 81-3-3582-6429
E-mail: agtokyo@fas.usda.gov
Website: http://www.usdajapan.org/
Twitter: @USDAJapan

Attachments:

No Attachments